Azitra, Inc. Announces Q1 2025 Results and Provides Business Updates

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BRANFORD, Conn., May 13, 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 quarter ended March 31, 2025, and provided a business update.

Q1 2025 and Recent Business Highlights

- Announced acceptance of poster detailing the Phase 1/2 clinical trial of the ATR-04 program in EGFR inhibitor ("EGFRi")-associated rash at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting
- Entered into Purchase Agreement for up to $20 Million in Partnership with institutional investor Alumni Capital LP, to fund clinical pipeline
- Announced closing of two public offerings raising a total of $2.2M

"The start of 2025 has been a vital period for Azitra as we build towards key milestones expected by mid-year for our first-in-class, precision, live biotherapeutic candidates designed for major undertreated dermatological diseases," said Francisco Salva, CEO of Azitra. "For ATR-12, our lead program targeting the rare, chronic and devastating Netherton syndrome, we expect to provide initial safety data from our Phase 1b trial in the first half of 2025 with topline results expected by year-end 2025. There are no approved treatments for Netherton syndrome, and we believe this novel approach has potential to be life-changing for these patients."

Salva continued: "Also by mid-2025, we look forward to dosing the first patient in our Phase 1/2 trial with our ATR-04 program, which contains a live biotherapeutic product candidate containing an isolated, naturally derived *S. epidermidis* strain being developed for the treatment of EGFRi-associated rash. EGFRi-associated rash is a dermatologic toxicity that often accompanies EGFRi treatments for cancer, impacting approximately 150,000 patients in the United States annually. These severe skin conditions can interfere with cancer treatment efforts, often causing significant physical and psychological discomfort for patients. Given the importance of EGFRi therapies to the cancer industry, Azitra was invited to present an update of our ATR-04 Phase 1/2 trial at ASCO 2025, which is the most prestigious cancer research conference in the world."

Salva concluded: "The remainder of 2025 is expected to be a milestone-rich period for Azitra during which we look forward to showcasing the potential of ATR-12 and ATR-04, as well as our unique, proprietary platform for delivering engineered proteins using topical live biotherapeutic products."

Pipeline and Anticipated Milestones

- 1H 2025: Initial safety data from first set of Netherton syndrome patients in the ATR-12 Phase 1b trial
- 1H 2025: First patient dosed with for EGFRi-associated rash in a Phase 1/2 trial for ATR-04
- YE 2025: Topline data of the Phase 1b trial with ATR-12 in Netherton syndrome patients

Financial Results for the Quarter Ended March 31, 2025

- **Research and Development (R&D) expenses:** R&D expenses for the quarter ended March 31, 2025, were $1.3 million compared to $1.5 million for the comparable period in 2024.
- **General and Administrative (G&A) expenses:** G&A expenses for the quarter ended March 31, 2025, were $1.9 million compared to $1.5 million for the comparable period in 2024.
- **Net Loss** was $3.1 million for the quarter ended March 31, 2025, compared to $2.9 million for the comparable period in 2024.
- **Cash and cash equivalents:** As of March 31, 2025, the Company had cash and cash equivalents of $3.2 million.

About Azitra, Inc.
Azitra, Inc. is a clinical stage biopharmaceutical company focused on developing innovative therapies for precision dermatology. The Company'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 adult Netherton syndrome patients. ATR-04, Azitra's additional advanced program, utilizes another engineered strain of S. epidermidis 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 its ATR-04 program in patients with EGFRi associated rash. 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 and (iii), the initiation of dosing in the Phase 1/2 clinical trial for our ATR-04 program, and 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 that 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, we may fail to present this abstract detailing the Phase 1/2 clinical trial or, if we are able to do so, that the abstract will be favorably received; we may experience delays in the dosing the first patient in this Phase 1/2 trial; 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 or incorporated by reference in our annual report on Form 10-K filed with the SEC 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 March 31,	
	2025	2024
Operating expenses:		
General and administrative	$ 1,850,138	$ 1,488,527
Research and development	1,250,100	1,472,970
Total operating expenses	3,100,238	2,961,497
Loss from operations	(3,100,238)	(2,961,497)
Other income (expense):		
Interest income	37,164	7,609
Interest expense	(1,293)	(915)
Change in fair value of warrants	143	28,255
Other expense	(4,121)	(6,327)
Total other income	31,893	28,622
Net loss before income taxes	(3,068,345)	(2,932,875)
Income tax expense	-	-
Net loss	$ (3,068,345)	$ (2,932,875)
Net loss attributable to common shareholders	$ (3,068,345)	(2,932,875)

Net loss per Share, basic and diluted	$ (0.23)	$ (4.32)
Weighted average common stock outstanding, basic and diluted	13,171,516	678,885

Condensed Balance Sheets
(Unaudited)

	March 31, 2025	December 31, 2024
Assets		
Current Assets:		
Cash and cash equivalents	$ 3,206,710	$ 4,554,719
Other receivables	103,046	101,896
Prepaid expenses and other current assets	561,798	571,675
Total current assets	$ 3,871,554	$ 5,228,290
Property and equipment, net	621,012	653,957
Other assets	1,415,325	1,476,555
Total assets	$ 5,907,891	$ 7,358,802
Liabilities, and stockholders' equity		
Current liabilities:		
Accounts payable	$ 558,924	$ 490,255
Current financing lease liability	16,456	16,066
Current operating lease liability	237,647	255,177
Accrued expenses	467,394	614,359
Total current liabilities	1,280,421	1,375,857
Long-term financing lease liability	5,843	10,105
Long-term operating lease liability	213,765	274,161
Warrant liability	238	381
Total liabilities	1,500,267	1,660,504
Stockholders' equity		
Common stock	1,498	763
Additional paid-in capital	65,040,296	63,263,360
Accumulated deficit	(60,634,170)	(57,565,825)
Total stockholders' equity	4,407,624	5,698,298
Total liabilities and stockholders' equity	$ 5,907,891	$ 7,358,802

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