Azitra, Inc. Announces Q3 2024 Financial Results and Provides Business Updates

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BRANFORD, Conn., Nov. 12, 2024 /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 three months ended September 30, 2024 and provided a business update.

Q3 2024 and Recent Business Highlights:

- Completed a follow-on offering of $10 million in gross proceeds
- Dosed first Netherton syndrome patient with ATR-12
- Submitted an IND to the FDA and received IND clearance for ATR-04 to treat skin rash from EGFR inhibitors
- Received Fast Track designation from the FDA for ATR-04
- Presented positive preclinical data and the clinical plan of a Phase 1/2 clinical study of ATR-04 in a late-breaking presentation at the European Academy of Dermatology and Venereology (EADV) Congress
- Strengthened intellectual property (IP) portfolio with newly granted and allowed patents

Francisco Salva, CEO of Azitra commented:

"Azitra achieved a number of significant milestones in the third quarter of 2024 to propel our pipeline forward, highlighted by the dosing of the first patient with ATR-12 in our ongoing Netherton syndrome trial. Additionally during the quarter, we completed a follow-on offering of $10 million in gross proceeds, submitted an IND for ATR-04 for skin rash from epidermal growth factor receptor inhibitors (EGFRis), obtained IND clearance and Fast Track designation for ATR-04, and strengthened our IP portfolio.

"With a clear roadmap, strong execution on two programs, and a dedicated team, Azitra is well-positioned to execute these milestones, deliver transformative therapies to patients in need, and ultimately maximize shareholder value."

Pipeline and Anticipated Milestones

- **Q1 2025:** Initial safety data from first set of Netherton syndrome patients in the Phase 1b trial
- **Q1 2025:** First patient dosed with ATR-04 for EGFRi rash in a Phase 1/2 trial
- **YE 2025:** Topline data of the Phase 1b trial with ATR-12 in Netherton syndrome patients expected

Financial Results for the Three Months Ended September 30, 2024

- **Service Revenue – Related Party**: The Company generated $0 service revenue during the quarter ended September 30, 2024, compared to $310,700 for the comparable period in 2023.
- **Research and Development (R&D) expenses**: R&D expenses for the quarter ended September 30, 2024, were $1.0 million compared to $0.5 million for the comparable period in 2023.
- **General and Administrative (G&A) expenses**: G&A expenses for the quarter ended September 30, 2024, were $1.9 million compared to $1.8 million for the comparable period in 2023.
- **Net Loss** was $1.0 million for the quarter ended September 30, 2024, compared to $1.9 million for the comparable period in 2023.
- **Cash and cash equivalents**: As of September 30, 2024, the Company had cash and cash equivalents of $7.3 million.

About ATR-12

ATR-12 (also known as ATR12-351) is an engineered strain of *S. epidermidis* that expresses a fragment of human lympho-epithelial Kazal-type-related inhibitor (LEKTI) protein, which is missing in patients with Netherton syndrome, a chronic and sometimes fatal disease of the skin estimated to affect approximately 20,000 patients globally. ATR-12 has been engineered to deliver missing LEKTI protein when applied topically to Netherton syndrome patients. Azitra has an open Phase 1b clinical trial that is actively recruiting adult Netherton syndrome patients (NCT06137157). Azitra has identified Netherton syndrome patients for enrollment in its 12-patient, Phase 1b clinical trial, which will assess safety, tolerability, and efficacy endpoints.

About ATR-04

ATR-04 is a live biotherapeutic product candidate including an isolated, naturally derived *S. epidermidis* strain that was engineered to be safer by deleting an antibiotic resistance gene and engineering auxotrophy to control the growth of ATR-04. ATR-04 is in development for EGFR inhibitor ("EGFRi") associated rash, which is caused by the suppression of skin immunity by EGFRis and subsequent inflammation and often elevated levels of IL-36γ and *S. aureus*. There are approximately 150,000 patients suffering from EGFRi rash in the United States. Azitra has received Fast Track designation from the FDA for EGFRi associated rash and plans to initiate a Phase 1/2 clinical study in patients undergoing EGFRi rash in early 2025.

About Azitra, Inc.

Azitra, Inc. is an early-stage clinical biopharmaceutical company focused on developing innovative therapies for precision dermatology using engineered proteins and topical live biotherapeutic products. The Company has built a proprietary platform that includes a microbial library comprised of approximately 1,500 unique bacterial strains that can be screened for unique therapeutic characteristics. The platform is augmented by artificial intelligence and machine learning technology that analyzes, predicts, and helps screen the Company's library of strains for drug like molecules. The Company's initial focus is on the development of genetically engineered strains of Staphylococcus epidermidis, or *S. epidermidis*, which the Company considers to be an optimal therapeutic candidate species for engineering of dermatologic therapies. 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 filing of an IND application, and the presentation of data from our Phase 1b for ATR-04, the IND filing for ATR-01, the timing of having a signed license agreement with Bayer, and 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 fail to successfully complete our Phase 1b trial for ATR-12, we may experience delays in the initiation of our Phase 1/2 trial fpr 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 or incorporated by reference in our prospectus dated July 23, 2024 filed with the SEC on July 25, 2024 in our most recent quarterly report on Form 10-Q filed with the SEC on November 12, 2024. 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,	
	2024	2023
Service revenue – related party	$ -	$ 310,700
Total revenue	-	310,700
Operating expenses:		
General and administrative	1,913,400	1,755,908
Research and development	1,015,807	548,524
Total operating expenses	2,929,207	2,304,432
Loss from operations	(2,929,207)	(1,993,732)
Other income (expense):		

Interest income	47,389	634
Interest expense	(3,851)	(710)
Change in fair value of warrants	4,001,469	98,061
Loss on issuance of common stock	(2,132,800)	-
Other income (expense)	7,509	(47,542)
Total other income (expense)	1,919,716	50,443
Net loss before income taxes	(1,009,491)	(1,943,289)
Income tax expense	-	-
Net loss	$ (1,009,491)	(1,943,289)
Dividends on preferred stock	-	-
Net loss attributable to common shareholders	$ (1,009,491)	(1,943,289)
Net loss per Share, basic and diluted	$ (.17)	$ (4.82)
Weighted average common stock outstanding, basic and diluted	5,814,350	403,255

Condensed Balance Sheets
(Unaudited)

	September 30, 2024	December 31, 2023
Assets		
Current Assets:		
Cash and cash equivalents	$ 7,260,234	$ 1,795,989
Other receivables	9,923	223,474
Prepaid expenses and other current assets	364,673	516,116
Total current assets	$ 7,634,830	$ 2,535,579
Property and equipment, net	638,107	710,075
Other assets	1,504,562	1,869,832
Total assets	$ 9,777,499	$ 5,115,486
Liabilities, and stockholders' equity		
Current liabilities:		
Accounts payable	$ 588,460	$ 897,272
Current financing lease liability	15,687	14,600
Current operating lease liability	276,839	307,655
Accrued expenses	486,981	383,668
Total current liabilities	1,367,967	1,603,195
Long-term financing lease liability	14,266	26,169
Long-term operating lease liability	336,556	537,523
Warrant liability	457	35,453
Total liabilities	1,719,246	2,202,340
Stockholders' equity		
Common stock	763	40
Additional paid-in capital	63,230,182	51,510,269
Accumulated deficit	(55,172,692)	(48,597,163)
Total stockholders' equity	8,058,253	2,913,146
Total liabilities and stockholders' equity	$ 9,777,499	$ 5,115,486

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