Azitra, Inc. Announces Q2 2024 Financial Results and Provides Business Updates

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BRANFORD, Conn.--(BUSINESS WIRE)--Aug. 12, 2024-- 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 June 30, 2024, and provided a business update.

Q2 2024 and Recent Business Highlights

- Completed a follow-on offering of $10 million in gross proceeds expected to provide cash runway into 2025. With the recent financing, the company anticipates announcing multiple clinical milestones
- Strengthened global intellectual property portfolio with newly granted and allowed patents
- Exhibited positive preclinical data from ATR-04 at the Society of Investigative Dermatology Annual Meeting
- Presented positive preclinical data of ATR-12 and clinical design in Netherton Syndrome at the ASGCT Annual Meeting
- Opened a Phase 1b clinical trial for ATR-12 for recruitment

Francisco Salva, CEO of Azitra commented:

"Azitra is poised to achieve significant milestones in the second half of 2024 and beyond, propelling our pipeline forward. In Q3 2024, we expect to dose the first Netherton syndrome patient with ATR-12. Additionally, we anticipate filing and clearing an Investigational New Drug (IND) application for ATR-04, targeting epidermal growth factor receptor inhibitor (EGFRi) rash, a condition with high unmet need. This milestone will expand our clinical pipeline to two clinical-stage programs.

Approximately year-end 2024, we anticipate reporting initial safety data from the ATR-12 Phase 1b trial in Netherton syndrome patients and providing an update on our Bayer license agreement. We expect to initiate a first-in-human clinical trial with ATR-04 for EGFRi rash this fall.

Looking ahead to mid-2025, we eagerly anticipate reporting topline data from the ATR-12 Phase 1b trial, a defining moment as we aim to demonstrate biological proof of concept of our innovative approach in addressing this severe, rare skin disorder.

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

Pipeline and Upcoming Milestones

- **Q3 2024:** First Netherton syndrome patient dosed with ATR-12
- **Q3 2024:** New investigational new drug (IND) application filed and cleared with the FDA for a Phase 1/2 clinical study of ATR-04 in patients with dermal toxicity undergoing treatment with EGFR inhibitors ("EGFRi rash")
- **YE 2024:** Initial safety data from first set of Netherton syndrome patients in the Phase 1b trial
- **YE 2024:** First patient dosed with ATR-04 for EGFRi rash by year end 2024
- **YE 2024:** Bayer collaboration continues with update on license agreement expected by year end
- **Mid 2025:** Topline data of the Phase 1b trial with ATR-12 in Netherton syndrome patients expected

Financial Results for the Three Months Ended June 30, 2024

- **Service Revenue – Related Party**: The Company generated $7,500 service revenue during the quarter ended June 30, 2024, compared to $172,000 for the comparable period in 2023.
- **Research and Development (R&D) expenses**: R&D expenses for the quarter ended June 30, 2024, were $1.1 million compared to $0.8 million for the comparable period in 2023.
- **General and Administrative (G&A) expenses**: G&A expenses for the quarter ended June 30, 2024, were $1.5 million compared to $0.8 million for the comparable period in 2023.
- **Net Loss** was $2.6 million for the quarter ended June 30, 2024, compared to $5.1 million for the comparable period in 2023.
- **Cash and cash equivalents**: As of June 30, 2024, the Company had cash and cash equivalents of $0.8 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 IND for a 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 plans to initiate a Phase 1/2 clinical study in patients undergoing EGFRi rash by year end 2024.

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 and pre-clinical studies of other product candidates and obtain required approval before commercialization; 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 in its registration statement on Form S-1, which is on file with the SEC, and in its most recent quarterly report on Form 10-Q to be filed with the SEC. Azitra explicitly disclaims any obligation to update any forward-looking statements except to the extent required by law.

Condensed Statement of Operations
(Unaudited)

	Three months Ended June 30,	
	2024	2023
Service revenue – related party	$ 7,500	$ 172,000
Total revenue	7,500	172,000
Operating expenses:		
General and administrative	1,549,228	844,639
Research and development	1,118,552	754,951
Total operating expenses	2,667,780	1,599,590
Loss from operations	(2,660,280)	(1,427,590)
Other income (expense):		
Interest income	16,268	264
Interest expense	(1,782)	(76,187)
Change in fair value of convertible note	-	(2,830,100)
Change in fair value of warrants	4,272	(94,232)
Other income (expense)	9,529	(1,683)
Total other income (expense)	28,287	(3,001,938)
Net loss before income taxes	(2,631,993)	(4,429,528)
Income tax expense	-	-
Net loss	$ (2,631,993)	(4,429,528)
Dividends on preferred stock	-	(643,267)
Net loss attributable to common shareholders	$ (2,631,993)	(5,072,795)
Net loss per Share, basic and diluted	$ (2.74)	$ (70.83)
Weighted average common stock outstanding, basic and diluted	960,146	71,622

Condensed Balance Sheets
(Unaudited)

	June 30, 2024	December 31, 2023
Assets		
Current Assets:		
Cash and cash equivalents	$ 803,082	$ 1,795,989
Other receivables	111,895	223,474
Prepaid expenses and other current assets	420,828	516,116
Total current assets	$ 1,335,805	$ 2,535,579
Property and equipment, net	658,731	710,075
Other assets	1,888,018	1,869,832
Total assets	$ 3,882,554	$ 5,115,486
Liabilities, and stockholders' equity		
Current liabilities:		
Accounts payable	$ 996,700	$ 897,272
Current financing lease liability	15,317	14,600
Current operating lease liability	293,026	307,655
Accrued expenses	434,103	383,668
Total current liabilities	1,739,146	1,603,195
Long-term financing lease liability	18,329	26,169
Long-term operating lease liability	395,987	537,523
Warrant liability	2,926	35,453
Total liabilities	2,156,388	2,202,340
Stockholders' equity		
Common stock	96	40
Additional paid-in capital	55,889,271	51,510,269
Accumulated deficit	(54,163,201)	(48,597,163)
Total stockholders' equity	1,726,166	2,913,146
Total liabilities and stockholders' equity	$ 3,882,554	$ 5,115,486

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