Azitra, Inc. Announces Q1 2024 Financial Results and Provides Business Updates

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BRANFORD, Conn.--(BUSINESS WIRE)--May 9, 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 March 31, 2024, and provided a business update.

Q1 2024 and Recent Business Highlights

- Advanced ATR-12's Phase 1b trial, activating sites, advancing central IRB approval, and identifying initial subjects with Netherton syndrome for dosing; primary endpoints are safety and tolerability, with efficacy endpoints also being evaluated
- Successfully completed a pre-IND meeting with the FDA for ATR-04, a novel treatment for EGFR inhibitor-induced rash, a common and debilitating side effect in cancer patients; on track for IND submission mid-2024
- Announced new preclinical data at ASGCT related to ATR-12
  - Topical application of ATR-12 to *ex vivo* human skin demonstrates the potential for superior LEKTI delivery compared to topical LEKTI application
  - Preclinical data suggests ATR-12 can significantly reduce IL-36γ, a pro-inflammatory cytokine that drives Netherton syndrome
  - Full data to be presented on May 10th at ASGCT
- Advanced Bayer Joint Development Agreement and discussions with Bayer for a license agreement
- Strengthened IP portfolio with U.S. patent issuance from the USPTO for treating skin diseases with recombinant microorganisms, including ichthyosis vulgaris, a condition affecting about 1.3 million Americans
- Completed a follow-on public offering in February 2024, raising $5.0 million in gross proceeds

Francisco Salva, CEO of Azitra, commented:

"Azitra has made significant progress in 2024, advancing towards crucial milestones and potentially transformative catalysts, including key data readouts. Our lead program, ATR-12, has secured clinical sites and identified Netherton syndrome patients for enrollment in our 12-patient, Phase 1b clinical trial, which will assess safety, tolerability, and efficacy endpoints. We expect to announce initial safety data before year end.

We also announced novel preclinical findings at ASGCT related to ATR-12, showcasing its potential for superior LEKTI delivery compared to topical LEKTI application when administered to ex vivo human skin. Moreover, preclinical evidence suggests that ATR-12 can markedly reduce IL-36g, a pro-inflammatory cytokine implicated in Netherton syndrome, further validating the potential of our approach.

In addition, we made notable progress with ATR-04, targeting EGFRi-associated rash in cancer patients. Following a successful pre-IND meeting with the FDA, we plan to submit an IND for a Phase 1b trial by mid-2024. Subject to FDA clearance, we aim to initiate the trial before year-end in patients undergoing a rash due to EGFR inhibitors.

In February 2024, we completed a follow-on public offering, garnering $5.0 million in gross proceeds, which will support the advancement of our clinical programs. Additionally, we bolstered our IP portfolio with the issuance of a U.S. patent from the USPTO for treating skin diseases, including ichthyosis vulgaris, a condition affecting roughly 1.3 million Americans, using recombinant microorganisms.

Furthermore, we are encouraged by the recent advancements in our Joint Development Agreement with Bayer and their renewed commitment to executing a license agreement.

With a robust pipeline, strong partnerships, and upcoming value-driving milestone announcements, we believe Azitra is poised to revolutionize the treatment landscape for severe skin conditions and deliver significant shareholder value in the near future."

Pipeline and Upcoming Milestones

- **ATR-12 - Netherton syndrome** *(Rare skin disease with no FDA approved treatment options)*. Global Prevalence: 20K+ patients. Estimated Peak Sales Opportunity: ~$250 million.
  - Clinical Status: Phase 1b
  - Upcoming milestones:
    - Publication of preclinical data at the ASGCT (American Society for Gene and Cell Therapy) Annual Meeting on May 10, 2024 and at the SID (Society for Investigative Dermatology) Annual Meeting on May 17, 2024
    - First patient dosed in 12-patient clinical trial
    - Initial clinical safety data in late 2024
- **ATR-04 - EGFRi-associated rash** *(Chemotherapy agents such as EGFR inhibitors and immunotherapies such as early BTK inhibitors lead to an aggressive and debilitating rash on many patients)*. US Prevalence: ~150K patients. Estimated Peak Sales Opportunity: >$1B.
  - Clinical Status: Pre-IND
  - Upcoming milestones:
    - Publication of preclinical data at the ASCO (American Society of Clinical Oncology) Annual Meeting on May 23, 2024
    - IND submission in mid-2024
    - First patient dosed in first-in-human clinical trial in late 2024 or early 2025
- **Bayer Joint Development Agreement** (Joint development on *S. epidermidis* strains and products for eczema-prone skin.) Global Prevalence: 230 million. Annual economic burden in Europe: $30B.
  - Status: Azitra is responsible for early research, and Bayer is responsible for clinical development and commercialization
  - Upcoming milestones:
    - Execution of a licensing agreement with upfront payment

Financial Results for the Quarter Ended March 31, 2024

- **Service Revenue – Related Party**: The Company generated $0 service revenue during the quarter ended March 31, 2024, compared to $113,300 for the comparable period in 2023.
- **Research and Development (R&D) expenses**: R&D expenses for the quarter ended March 31, 2024, were $1.5 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 March 31, 2024, were $1.5 million compared to $0.8 million for the comparable period in 2023.
- **Net Loss** was $2.9 million for the quarter ended March 31, 2024, compared to $2.5 million for the comparable period in 2023.
- **Cash and cash equivalents**: As of March 31, 2024, the Company had cash and cash equivalents of $3.0 million.

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 annual report on Form 10-K filed with the SEC. Azitra explicitly disclaims any obligation to update any forward-looking statements except to the extent required by law.

Condensed Consolidated Statement of Operations
(Unaudited)

	Three Months Ended March 31,	
	2024	2023
Service revenue – related party	$ -	$ 113,300

Total revenue	-	113,300
Operating expenses:		
General and administrative	1,488,527	843,012
Research and development	1,472,970	829,035
Total operating expenses	2,961,497	1,672,047
Loss from operations	(2,961,497)	(1,558,747)
Other income (expense):		
Interest income	7,609	285
Interest expense	(915)	(89,832)
Change in fair value of convertible note	-	(800,000)
Change in fair value of warrants	28,255	5,621
Other expense	(6,327)	(4,792)
Total other income (expense)	28,622	(888,718)
Net loss before income taxes	(2,932,875)	(2,447,465)
Income tax expense	-	(9,715)
Net loss	$ (2,932,875)	(2,457,180)
Dividends on preferred stock	-	(712,080)
Net loss attributable to common shareholders	$ (2,932,875)	(3,169,260)
Net loss per Share, basic and diluted	$ (0.15)	$ (3.00)
Weighted average common stock outstanding, basic and diluted	20,182,346	1,055,455

Condensed Consolidated Balance Sheets
(Unaudited)

	March 31, 2024	December 31, 2023
Assets		
Current Assets:		
Cash and cash equivalents	$ 3,001,158	$ 1,795,989
Other receivables	141,608	223,474
Prepaid expenses and other current assets	383,131	516,116
Total current assets	$ 3,525,897	$ 2,535,579
Property and equipment, net	676,383	710,075
Other assets	1,865,713	1,869,832
Total assets	$ 6,067,993	$ 5,115,486
Liabilities, preferred stock, and stockholders' equity		
Current liabilities:		
Accounts payable	$ 583,055	$ 897,272
Current financing lease liability	14,954	14,600
Current operating lease liability	310,929	307,655
Accrued expenses	348,930	383,668
Total current liabilities	1,257,868	1,603,195
Long-term financing lease liability	22,296	26,169
Long-term operating lease liability	465,315	537,523
Warrant liability	7,298	35,453
Total liabilities	1,743,777	2,202,340
Stockholders' equity		
Common stock	2,880	1,210
Additional paid-in capital	55,852,544	51,510,269
Accumulated deficit	(51,531,208)	(48,598,333)
Total stockholders' equity	4,324,126	2,913,146
Total liabilities and stockholders' equity	$ 6,067,993	$ 5,115,486

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