Azitra, Inc. Announces Full Year 2023 Financial Results and Provides Business Updates

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BRANFORD, Conn.--(BUSINESS WIRE)--Mar. 15, 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 full year ended December 31, 2023, and provided a business update.

FY 2023 and Recent Business Highlights

- Completed an initial public offering, raising $7.5 million in gross proceeds.
- Obtained IND clearance of ATR-12 for a Phase 1b clinical trial in Netherton syndrome.
- Completed and filed post-IND, FDA commitments for characterization of drug substance and drug product for ATR-12.
- Selected and hired clinical research organization for ATR-12 clinical trial and selected initial clinical sites for activation.
- Advanced ATR-04 into IND-enabling studies.
- 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.
- Named Travis Whitfill COO and added Barbara Ryan and John Schroer to board of directors.
- Successfully completed a follow-on public offering in February 2024, raising $5.0 million in gross proceeds.

"Throughout 2023 and now into 2024, Azitra's unwavering commitment to combatting multiple serious skin conditions and diseases has propelled the company towards fundamental near-term catalysts," said Francisco Salva, CEO of Azitra. "For our leading program, ATR-12 targeting Netherton's syndrome, we've transitioned into the operational phase for our Phase 1b clinical trial. With a CRO onboard and discussions finalized with lead sites to activate the program and recruit ~12 patients, we're poised to execute on a series of potentially high-impact catalysts. Moving forward, we're focused on executing on key value-driving milestones, including getting the first patient enrolled, and a release of initial clinical data."

"Next, for our ATR-04 program targeting EGFRi-associated rash, we intend to submit an IND for a Phase 1b clinical trial in cancer patients undergoing EGFRi targeted therapy in mid-2024. Subject to FDA clearance of our IND, we plan to initiate a Phase 1b clinical trial by year end.

"Additionally, regarding our Joint Development Agreement with Bayer, we are pleased with the recent progress of our collaboration and Bayer's re-affirmed commitment to an execution of a license agreement."

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:
    - First patient dosed in 12-patient clinical trial
    - Publication of preclinical data at major medical meetings in Q2 2024
    - 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 major medical meetings in Q2 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 Year Ended December 31, 2023

- **Service Revenue – Related Party**: The Company generated $0.7 million of service revenue during the year ended December 31, 2023, compared to $0.3 million for the comparable period in 2022.
- **Research and Development (R&D) expenses**: R&D expenses for the year ended December 31, 2023, were $3.8 million compared to $6.1 million for the comparable period in 2022.
- **General and Administrative (G&A) expenses**: G&A expenses for the year ended December 31, 2023, were $4.5 million compared to $3.6 million for the comparable period in 2022.
- **Net Loss** was $11.3 million for the year ended December 31, 2023, compared to $10.7 million for the comparable period in 2022.
- **Cash and cash equivalents**: As of December 31, 2023, the Company had cash and cash equivalents of $1.8 million, which does not include net proceeds of approximately $4.4 million from a February 15, 2024, follow-on offering.

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 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 Consolidated Statement of Operations
Audited

	2023	2022
Service revenue – related party	$ 686,000	$ 284,000
Total revenue	686,000	284,000
Operating expenses:		
General and administrative	4,493,332	3,639,666
Research and development	3,809,063	6,097,938
Total operating expenses	8,302,395	9,737,604
Loss from operations	(7,616,395)	(9,453,604)
Non- operating income (expense):		
Interest income	1,577	4,818
Interest expense	(167,726)	(251,891)
Employee retention credit	-	229,813
Other income	-	65,849
Forgiveness of accounts payable	56,285	-
Change in fair value of convertible note	(3,630,100)	(1,250,000)

Other income (expense)	89,886	(25,351)
Total non-operating expenses	(3,650,078)	(1,226,762)
Loss before income taxes	(11,266,473)	(10,680,366)
Income tax benefit (expense)	(17,308)	-
Net loss	$ (11,283,781)	(10,680,366)
Dividends on preferred stock	(1,355,347)	(2,768,984)
Net loss attributable to common shareholders	$ (12,639,128)	(13,449,350)
Net loss per Share, basic and diluted	(1.83)	(12.74)
Weighted average common stock outstanding, basic and diluted	$ 6,924,453	$ 1,055,399

Condensed Consolidated Balance Sheets
Audited

	December 31, 2023	December 31, 2022
Assets		
Current Assets:		
Cash and cash equivalents	$ 1,795,989	$ 3,492,656
Other receivables	223,474	266,208
Prepaid expenses and other current assets	516,116	377,019
Total current assets	$ 2,535,579	$ 4,135,883
Property and equipment, net	710,075	846,958
Other assets	1,869,832	2,184,602
Total assets	$ 5,115,486	$ 7,167,443
Liabilities, preferred stock, and stockholders' equity		
Current liabilities:		
Accounts payable	$ 897,272	$ 784,687
Current financing lease liability	14,600	-
Current operating lease liability	307,655	287,384
Accrued expenses	383,668	993,961
Contract liabilities	-	156,000
Total current liabilities	1,603,195	2,222,032
Long-term financing lease liability	26,169	-
Long-term operating lease liability	537,523	840,896
Warrant liability	35,453	70,283
Convertible notes payable, net	0	6,600,000
Total liabilities	2,202,340	9,733,211
Stockholders' equity (deficit)		
Preferred stock	0	33,694,542
Common stock	1,210	104
Additional paid-in capital	51,510,269	1,054,138
Accumulated deficit	(48,598,333)	(37,314,552)
Total stockholders' equity (deficit)	2,913,146	(36,260,310)
Total liabilities, preferred stock and stockholders' equity (deficit)	$ 5,115,486	$ 7,167,443

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