UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 OR 15(d) of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 14, 2023

AZITRA, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-41705**	**46-4478536**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

21 Business Park Drive
Branford, CT 06405
(Address of principal executive offices)(Zip Code)

(203) 646-6446
(Registrant's telephone number, including area code)

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligations of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock: Par value $0.0001	AZTR	NYSE American

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On November 14, 2023, Azitra, Inc. (the "Company") issued a press release announcing its financial results for the fiscal quarter ended September 30, 2023. A copy of the press release is attached as Exhibit 99.1 to this Current Report and is incorporated herein by reference.

The information in this Item 2.02, including the press release attached as Exhibit 99.1 hereto, is furnished pursuant to Item 2.02 but shall not be deemed "filed" for any purpose, including for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section, nor shall it be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits		**Method Filing**
The following exhibit is furnished with this report:		
Exhibit 99.1	Press release dated November 14, 2023 regarding the Registrant's financial results for the fiscal quarter ended September 30, 2023.	Filed Electronically herewith
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)	

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

AZITRA, INC.

Dated: November 14, 2023

/s/ Francisco D. Salva

Francisco D. Salva
Chief Executive Officer

Exhibit 99.1

Azitra, Inc. Announces Third Quarter 2023 Financial Results and Business Updates

BRANFORD, Conn. — Azitra, Inc. (NYSE American: AZTR), a clinical-stage biopharmaceutical company focused on developing innovative therapies for precision dermatology, today reported financial results for the third quarter ended September 30, 2023.

Q3 and Recent Business Highlights

- **Advanced its pipeline programs including ATR-12 (Netherton syndrome), ATR-4 (EGFRi-associated rash) and its Joint Development Agreement with Bayer**
- **Completed and filed post-IND, FDA commitments for characterization of drug product for ATR-12**
- **Selected and hired clinical research organization for ATR-12 clinical trial. Selected initial sites for activation**

Francisco Salva, Chief Executive Officer of Azitra commented:

“During the third quarter, we made important progress towards reaching multiple significant near-term milestones. Firstly, for our lead program ATR-12 for Netherton syndrome, we’ve selected and hired our clinical research organization for the Netherton syndrome clinical trial. Additionally, we are in discussion with our lead sites to get the program activated and start recruiting an initial ~12 patients. We’re now poised for key catalysts, including first patient enrolled, followed by initial clinical data in 2024.”

“Next, for our ATR-04 program targeting EGFRi-associated rash, we’ve been advancing towards our IND (Investigational New Drug) filing to enable clinical development. We are moving through the necessary preclinical and manufacturing activities. We are now building towards several pivotal events over the next 12 to 18 months, starting with IND submission, followed by enrolling ~15 patients, and then announcing data.”

“Additionally, regarding our Joint Development Agreement with Bayer, we are very pleased with the recent progress of our collaboration.”

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 IND cleared
    - Upcoming milestones:
        - First patient enrolled (FPI)
        - Initial clinical data
- **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: 200K+ patients. Estimated Peak Sales Opportunity: >$1B.
    - Clinical Status: Pre-IND
    - Upcoming milestones:
        - Preclinical animal data
        - IND submission
- **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 royalty-bearing licensing agreement

Financial Results for the Three Months Ended September 30, 2023

- **Cash and cash equivalents**: As of September 30, 2023, the Company had cash and cash equivalents of $4.4 million.
- **Service Revenue – Related Party**: The Company generated $310,700 of service revenue during the three months ended September 30, 2023 compared to $48,500 for the comparable period in 2022.
- **Research and Development (R&D) expenses**: R&D expenses for the three months ended September 30, 2023 were $548,524 compared to $1.4 million from the prior year period.
- **General and Administrative (G&A) expenses**: G&A expenses for the three months ended September 30, 2023 were $1.8 million compared to $1.1 million from the prior year period.
- **Net Loss** was $1.9 million for the three months ended September 30 2023, compared to $2.4 million for the same period in 2022.

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.

Company Contact

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Condensed Consolidated Statement of Operations
(Unaudited)

	Three months Ended September 30,	
	2023	**2022**
Service revenue – related party	$ 310,700	$ 48,500
Total revenue	310,700	48,500
Operating expenses:		
General and administrative	1,755,908	1,054,570
Research and development	548,524	1,364,380
Total operating expenses	2,304,432	2,418,950
Loss from operations	(1,993,732)	(2,370,450)
Other income (expense):		
Interest income	634	3,201
Interest expense	(710)	(31,333)
Other expense	50,519	(19,038)
Total other income (expense)	50,443	(47,170)
Net loss before income taxes	(1,943,289)	(2,417,620)
Income tax benefit (expense)	-	
Net loss	$ (1,943,289)	(2,417,620)
Dividends on preferred stock	-	(692,246)
Net loss attributable to common shareholders	$ (1,943,289)	(3,109,866)
Net loss per Share, basic and diluted	(.16)	(2.95)
Weighted average common stock outstanding, basic and diluted	$ 12,097,643	$ 1,055,455

Condensed Consolidated Balance Sheets
(Unaudited)

	September 30, 2023	December 31, 2022
Assets		
Current Assets:		
Cash and cash equivalents	$ 4,400,327	$ 3,492,656
Other receivables	54,247	266,208
Prepaid expenses and other current assets	409,170	377,019
Total current assets	$ 4,863,744	$ 4,135,883
Property and equipment, net	736,423	846,958
Other assets	1,890,077	2,184,602
Total assets	$ 7,490,244	$ 7,167,443
Liabilities, preferred stock, and stockholders' equity		
Current liabilities:		
Accounts payable	$ 417,928	$ 784,687
Current financing lease liability	14,254	-
Current operating lease liability	301,423	287,384
Accrued expenses	720,095	993,961
Contract liabilities	-	156,000
Total current liabilities	1,453,700	2,222,032
Long-term financing lease liability	29,952	-
Long-term operating lease liability	613,572	840,896
Warrant liability	60,933	70,283
Convertible notes payable, net	0	6,600,000
Total liabilities	2,158,157	9,733,211
Stockholders' equity (deficit)		
Preferred stock	0	33,694,542
Common stock	1,210	104
Additional paid-in capital	51,475,425	1,054,138
Accumulated deficit	(46,144,548)	(37,314,552)
Total stockholders' equity (deficit)	5,332,087	(36,260,310)
Total liabilities, preferred stock and stockholders' equity (deficit)	$ 7,490,244	$ 7,167,443