

**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): August 14, 2023

AZITRA, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-41705
(Commission
File Number)

46-4478536
(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 August 14, 2023, Azitra, Inc. (the “Company”) issued a press release announcing its financial results for the fiscal quarter ended June 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 August 14, 2023 regarding the Registrant’s financial results for the fiscal quarter ended June 30, 2023.](#)

Filed Electronically herewith

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: August 14, 2023

/s/ Francisco D. Salva

Francisco D. Salva
Chief Executive Officer



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

BRANFORD, Conn., August 14, 2023 - Azitra, Inc. (NYSE American: AZTR), a clinical-stage biopharmaceutical company focused on developing innovative therapies for precision dermatology, today reported financial results for the second quarter ended June 30, 2023.

Francisco Salva, Chief Executive Officer of Azitra, commented, "We are extremely pleased with the exciting recent progress at Azitra, and we are thrilled to have closed on our initial public offering in June. This year, we have demonstrated the potential of our regulatory, manufacturing, and clinical capabilities that resulted in a new IND for ATR-12 for a Phase 1b clinical trial in Netherton syndrome. Additionally, we are very pleased with the recent progress of our platform and collaboration with Bayer.

Recent Business Highlights

- **Completed an initial public offering:** In June, the Company raised \$7.5 million in gross proceeds in an initial public offering before deducting underwriting discounts and offering expenses.
- **Announced key appointments to executive team and board of directors:** The Company made several key appointments during recent months, including Travis Whitfill as chief operating officer and Barbara Ryan and John Schroer to its board of directors.
- **Obtained IND clearance of ATR-12 for a Phase 1b clinical trial in Netherton syndrome**

Financial Results for the Three Months Ended June 30, 2023

- **Cash and cash equivalents:** As of June 30, 2023, the Company had cash and cash equivalents of \$6.3 million, which includes the proceeds from an initial public offering in June 2023.
 - **Service Revenue – Related Party:** The Company generated \$172,000 of service revenue during the three months ended June 30, 2023 compared to service revenue of \$85,000 for the comparable period in 2022. The increase of \$87,000 in service revenue is attributable to an increase in the amount of reimbursable development costs incurred in 2023.
 - **Research and Development (R&D) expenses:** R&D expenses for the three months ended June 30, 2023 were \$812,836 compared to \$1.5 million from the prior year period. The decrease was primarily related to a decrease of \$575,000 in research and development related costs attributable to our efforts in moving our Netherton syndrome program forward and a net decrease in payroll and related costs of \$120,000 attributable to a reduction in staff offset by a net increase in other costs of \$2,389. There was no government and nonprofit grant revenue received by us during the second quarter of fiscal 2023 or 2022.
 - **General and Administrative (G&A) expenses:** G&A expenses for the three months ended June 30, 2023 were \$844,640 compared to \$667,940 from the prior year period. The increase was primarily related to an increase of \$259,000 in accounting, legal, hiring, and insurance costs offset by a decrease of \$80,000 in payroll and related costs attributable to the discontinuation of separation benefits paid to our former chief operating officer, and \$2,300 net decrease of other overhead expenses.
 - **Net Loss** was \$4.4 million for the three months ended June 30 2023, compared to \$1.9 million for the same period in 2022.
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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

Norman Staskey
Chief Financial Officer
staskey@azitra.com

Condensed Consolidated Statement of Operations
(Unaudited)

	Three months Ended June 30,	
	2023	2022
Service revenue – related party	\$ 172,000	\$ 85,000
Total revenue	172,000	85,000
Operating expenses:		
General and administrative	844,640	667,940
Research and development	812,836	1,505,447
Total operating expenses	1,657,476	2,173,387
Loss from operations	(1,485,476)	(2,088,387)
Other income (expense):		
Interest income	265	335
Interest expense	(76,187)	(17,811)
Employee retention credit	-	229,813
Other income	1,600	-
Forgiveness of accounts payable	56,285	-
Change in fair value of convertible note	(2,830,100)	-
Other expense	(95,915)	(14,103)
Total other income (expense)	(2,944,052)	198,234
Net loss before income taxes	(4,429,528)	(1,890,153)
Income tax benefit (expense)	-	-
Net loss	\$ (4,429,528)	(1,890,153)
Dividends on preferred stock	(643,267)	(692,246)
Net loss attributable to common shareholders	\$ (5,072,795)	(2,582,399)
Net loss per Share, basic and diluted	(2.36)	(2.45)
Weighted average common stock outstanding, basic and diluted	\$ 2,147,526	\$ 1,055,454

Condensed Consolidated Balance Sheets
(Unaudited)

	<u>June 30,</u> <u>2023</u>	<u>December 31,</u> <u>2022</u>
Assets		
Current Assets:		
Cash and cash equivalents	\$ 6,290,355	\$ 3,492,656
Other receivables	501,288	266,208
Prepaid expenses and other current assets	48,523	377,019
Total current assets	<u>\$ 6,840,166</u>	<u>\$ 4,135,883</u>
Property and equipment, net	803,107	846,958
Other assets	2,186,284	2,184,602
Total assets	<u>\$ 9,829,557</u>	<u>\$ 7,167,443</u>
Liabilities, preferred stock, and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 364,183	\$ 784,687
Current operating lease liability	298,047	287,384
Accrued expenses	767,721	993,961
Contract liabilities	310,700	156,000
Total current liabilities	<u>1,740,651</u>	<u>2,222,032</u>
Long-term operating lease liability	693,609	840,896
Warrant liability	158,994	70,283
Convertible notes payable, net	0	6,600,000
Total liabilities	<u>2,593,254</u>	<u>9,733,211</u>
Stockholders' equity (deficit)		
Preferred stock	0	33,694,542
Common stock	1,210	104
Additional paid-in capital	51,436,352	1,054,138
Accumulated deficit	<u>(44,201,259)</u>	<u>(37,314,552)</u>
Total stockholders' equity (deficit)	7,236,303	(36,260,310)
Total liabilities, preferred stock and stockholders' equity (deficit)	<u>\$ 9,829,557</u>	<u>\$ 7,167,443</u>