

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 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 12, 2026

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

Delaware
(State or other jurisdiction of
incorporation or organization)

001-41705
(Commission File Number)

46-4478536
(I.R.S. Employer Identification Number)

21 Business Park Drive
Branford CT06405
(Address of principal executive offices and 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 obligation 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:

<u>Title of each class</u>	<u>Trading Symbol</u>	<u>Name of each exchange on which registered</u>
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 (Section 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (Section 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 12, 2026, Azitra, Inc. (the “Company”) issued a press release announcing its financial results as of and for the quarter ended June 30, 2026. 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 and 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): The following exhibits are being filed electronically herewith:

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release dated August 12, 2026 regarding the Registrant's financial results for the fiscal quarter ended June 30, 2026.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

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 on **August 12, 2026**.

AZITRA, INC.

By: /s/ Francisco D. Salva
Name: Francisco D. Salva
Title: Chief Executive Officer



Azitra, Inc. Announces Q2 2026 Results and Provides Business Updates

BRANFORD, Conn. – August 12, 2026 — Azitra, Inc. (“Azitra” or the “Company”) (NYSE American: AZTR), a clinical stage biopharmaceutical company focused on developing innovative therapies for precision dermatology and high value cosmetic proteins and peptides, today reported financial results for the quarter ended June 30, 2026, and provided a business update.

Q2 2026 and Recent Business Highlights

- Reported the first preclinical data from ATR-COSF demonstrating breakthrough repeat-dose distribution, controlled delivery into targeted skin layers and anti-wrinkle activity in *ex vivo* human skin, supporting advancement toward a planned proof-of-concept clinical study.
- Continued enrollment of the first cohort in the Phase 1/2 clinical trial evaluating ATR-04 for EGFR inhibitor-associated rash.
- Continued advancement of recombinant protein initiatives, including Tobacco Etch Virus (TEV) Protease and T7 RNA Polymerase, expanding the Company's platform into biotechnology research and manufacturing applications.
- Issued CEO Letter to Shareholders detailing Azitra's expanded strategy to leverage its proprietary microbial genetic engineering platform across therapeutics, cosmetic ingredients and biotechnology products.

“The second quarter has marked an exciting evolution for Azitra with the first data from our ATR-COSF program, which provided validation of our strategy to leverage our microbial genetic engineering platform beyond traditional therapeutics,” said Francisco Salva, Chief Executive Officer of Azitra. “Combined with the continued advancement of ATR-04 and our recombinant protein initiatives, these accomplishments reflect the breadth of opportunities we are creating in multiple billion dollar markets, including therapeutics, cosmetic ingredients and biotechnology applications.”

Salva continued: “Our ATR-COSF program continues to excite our team, as it represents one of the first to demonstrate the wrinkle reducing potential of recombinant filaggrin ingredient in *ex vivo* human skin. It shows Azitra’s ability to translate our cutting edge science into observable benefits for consumers. The ATR-COSF program represents our first step in unlocking meaningful value for shareholders while positioning Azitra at the intersection of synthetic biology, artificial intelligence and next-generation biological manufacturing.

“During the quarter, we also continued enrollment of the first cohort in our Phase 1/2 clinical trial evaluating ATR-04 for EGFR inhibitor-associated rash. With six active clinical sites, including MD Anderson Cancer Center, we remain on track to report topline data from the first cohort around year end. Additionally, we are in the process to open eligibility criteria to other cancer treatment related rashes driven by inhibitors along the same EGFR/KRAS/MEK/ERK pathway. EGFR inhibitor-associated rash remains a significant unmet medical need, affecting an estimated 50% to 90% of patients receiving EGFR-targeted cancer therapies and frequently leading to dose reductions, treatment interruptions or discontinuation.”

Salva concluded: "Looking ahead, we remain focused on implementing the strategy outlined in our recent shareholder letter. That includes advancing ATR-COSF toward a planned proof-of-concept clinical study, continuing development of our recombinant protein portfolio, including TEV Protease and T7 RNA Polymerase, and progressing ATR-04 as our lead clinical therapeutic program. We believe these initiatives position Azitra to unlock the full potential of our platform while creating multiple avenues for long-term growth and shareholder value."

Pipeline Achievements and Upcoming Milestones

ATR-COSF - New Consumer Initiative to Improve the Appearance of Fine Lines and Wrinkles

- Results from synthesized filaggrin ingredients, repeat application study on explanted cosmetic surgery skin.
- Announced positive preclinical data demonstrating breakthrough repeat-dose delivery and distribution together with anti-wrinkle activity in *ex vivo* human skin, supporting advancement toward a planned proof-of-concept cosmetic study evaluating the safety and efficacy of ATR-COSF.
- Human cosmetic application study planned to start in Q3 2026.

ATR-04 – Addressing an Unmet Need for Cancer Patients in a Billion Dollar Market Opportunity

- Continued enrollment of the first cohort of the ongoing Phase 1/2 clinical trial evaluating ATR-04 for the treatment of EGFRi-associated rash.
- Topline data from first cohort of Phase 1/2 trial expected in Q4-2026.

Recombinant Protein Platform

- Announced plans to advance development of its recombinant protein portfolio, including TEV Protease and T7 RNA Polymerase.
- Platform provides opportunity to develop high-quality recombinant proteins for biotechnology research and manufacturing applications, representing potential opportunities to leverage its microbial genetic engineering expertise while broadening its long-term commercial potential.

ATR-12 - Advancing Phase 1b Clinical Trial in Netherton Syndrome

- Consistent with the priorities outlined in the Company's recent shareholder letter, Azitra plans to strategically pause further enrollment in the ongoing Phase 1b study evaluating ATR-12 for Netherton syndrome.
- This decision reflects the Company's disciplined approach to capital allocation and its focus on advancing programs with the greatest near-term opportunities for clinical, commercial and shareholder value creation.

Financial Results for the Quarter Ended June 30, 2026

- **Research and Development (R&D) expenses:** R&D expenses for the quarter ended June 30, 2026, were \$1.4 million compared to \$1.4 million for the comparable period in 2025.
- **General and Administrative (G&A) expenses:** G&A expenses for the quarter ended June 30, 2026, were \$2.1 million compared to \$1.5 million for the comparable period in 2025.
- **Net Loss** was \$3.3 million for the quarter ended June 30, 2026, compared to \$2.9 million for the comparable period in 2025.
- **Cash and cash equivalents:** As of June 30, 2026, Azitra had cash and cash equivalents of \$6.7 million.

About Azitra, Inc.

Azitra, Inc. is a clinical-stage biopharmaceutical company focused on developing innovative therapies for precision dermatology and novel products across therapeutics, cosmeceuticals and biotechnology applications. The Company's portfolio is highlighted by ATR-COSF, a recombinant protein technology designed for cosmetic and skincare applications, and ATR-04, an investigational live biotherapeutic for EGFR inhibitor ("EGFRi") associated rash. Azitra has received Fast Track designation from the FDA for EGFR inhibitor-associated rash, which impacts approximately 150,000 people in the U.S. Azitra is also advancing additional recombinant protein initiatives designed to support biotechnology research and manufacturing applications. Azitra's technology platforms combine engineered proteins, topical live biotherapeutics, artificial intelligence, and a proprietary microbial library to develop differentiated products for consumer, research and healthcare markets. 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 (i) our potential resumption and expected timing of initial safety data and topline results for the Phase 1b trial for our ATR-12, (ii) the abstract detailing the Phase 1/2 clinical trial for our ATR-04 program, (iii) our provision of initial safety data and topline results for the Phase 1/2 clinical trial for our ATR-04 program, (iv) statements about our clinical and preclinical programs, and corporate and clinical/preclinical strategies, including our cosmeceutical strategy and our recombinant protein platform, (v) the expected timing of our planned human cosmetic application study for ATR-COSF, and (vi) statements regarding our strategy plans and priorities, including those outlined in our recent shareholder letter.

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: the timing of clinical trials and their results; we may experience delays in the provision of initial safety data and topline results for ATR-COSF, our recombinant protein platform, ATR-12 and ATR-04 and, if we do, such data and results may not be favorably received; the safety and efficacy of our product candidates; possible 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 or incorporated by reference in our annual report on Form 10-K filed with the United States Securities and Exchange Commission (the “SEC”) on February 27, 2026 and our quarterly report on Form 10-Q filed on May 13, 2026 and August 12, 2026 with the SEC. Azitra explicitly disclaims any obligation to update any forward-looking statements except to the extent required by law.

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Condensed Statement of Operations
(Unaudited)

Three Months Ended June 30,

	2026	2025
Operating expenses:		
General and administrative	\$ 2,067,639	\$ 1,469,513
Research and development	1,351,529	1,401,839
Total operating expenses	<u>3,419,168</u>	<u>2,871,352</u>
Loss from operations	3,419,168	2,871,352
Other income (expense):		
Interest income	74,661	15,461
Interest expense	(1,365)	(468)
Change in fair value of warrants	—	54
Other income	(1,788)	(32,688)
Total other income (expense)	<u>71,508</u>	<u>(17,641)</u>
Loss before income taxes	3,347,660	2,888,993
Income tax expense	<u>—</u>	<u>—</u>
Net loss	\$ 3,347,660	\$ 2,888,993
Net loss per Share, basic and diluted	\$ (0.17)	\$ (1.18)
Weighted average common stock outstanding, basic and diluted	<u>19,300,704</u>	<u>2,444,340</u>

Condensed Balance Sheets
Unaudited

	June 30, 2026	December 31, 2025
Assets		
Current Assets:		
Cash and cash equivalents	\$ 6,727,810	\$ 2,068,083
Other receivables	144,730	141,295
Prepaid expenses and other current assets	571,282	809,949
Total current assets	7,443,822	3,019,327
Property and equipment, net	536,422	548,591
Other assets	935,802	1,457,468
Total assets	\$ 8,916,046	\$ 5,025,386
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 497,985	\$ 399,356
Current financing lease liability	1,486	10,111
Current operating lease liability	357,569	255,776
Insurance premium financing liability	—	198,983
Accrued expenses	673,669	203,740
Total current liabilities	1,530,709	1,067,966
Long-term operating lease liability	50,998	156,190
Total liabilities	1,581,707	1,224,156
Stockholders' equity		
Common stock	6,060	1,074
Additional paid-in capital	83,124,375	72,321,352
Accumulated deficit	(75,796,096)	(68,521,196)
Total stockholders' equity	7,334,339	3,801,230
Total liabilities and stockholders' equity	\$ 8,916,046	\$ 5,025,386