Azitra, Inc. Announces Q1 2026 Results and Provides Business Updates

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BRANFORD, Conn., May 13, 2026 /PRNewswire/ -- Azitra, Inc. ("Azitra" or the "Company") (NYSE American: AZTR), a clinical stage biopharmaceutical company focused on developing innovative therapies for precision dermatology, today reported financial results for the quarter ended March 31, 2026, and provided a business update.

Q1 2026 and Recent Business Highlights

- Announced the addition of MD Anderson Cancer Center as a clinical site for Phase 1/2 trial of ATR-04 targeting EGFRi-associated skin rash.
- Launched innovative protein and peptide programs for the cosmetic and cosmeceutical markets leveraging proprietary filaggrin technologies.
- Secured new U.S. patent covering ATR-12, the Company's lead product candidate being developed for Netherton syndrome.
- Announced poster presentation at American Society of Gene and Cell Therapy Annual Meeting (ASGCT) 2026 highlighting ATR-01 preclinical data and the broader potential of Azitra's engineered live biotherapeutic platform.
- Priced private placement financing of up to approximately $10.5 million, with up to an additional approximately $20.9 million upon exercise of warrants.

"The first quarter of 2026 marked a period of meaningful execution across our clinical and strategic priorities as we continue to advance Azitra's leadership in precision dermatology," said Francisco Salva, CEO of Azitra. "Notably, we significantly grew the clinical footprint for our Phase 1/2 Trial of ATR-04 targeting EGFRi-associated skin rash by adding the world-renowned MD Anderson Cancer Center, which is one of the world's premier oncology institutions. We believe the addition of MD Anderson will serve to enhance patient access and support efficient trial execution in EGFR inhibitor-associated rash—a condition impacting the majority of patients receiving these therapies."

Mr. Salva continued: "In parallel, we expanded our strategic footprint with the launch of our cosmeceutical initiative, leveraging our proprietary filaggrin protein and peptide technologies to potentially address large and growing consumer markets. Based on our preliminary research, we are confident that our technologies and expertise can offer an exciting new way to address the appearance of fine lines and wrinkles as well as dry sensitive skin and eczema-like rashes. As such, this program represents a compelling opportunity to extend our platform beyond therapeutics and create additional avenues for value creation."

Mr. Salva added: "We are also highlighting our platform this week at ASGCT 2026, where we are presenting ATR-01 preclinical data that underscores the potential of our engineered live biotherapeutics. With this scientific visibility occurring alongside our quarterly update, we believe it reinforces the continued progress and relevance of our platform within the broader gene and cell therapy landscape."

Mr. Salva concluded: "We are also excited to report the recent issuance of a new U.S. patent providing broad protection for our lead product, ATR-12, which we are advancing in a Phase 1b clinical trial for Netherton syndrome. With a strengthened balance sheet, expanding clinical execution, and multiple near-term catalysts, we believe Azitra is well positioned to drive continued progress across both our therapeutic pipeline and emerging cosmeceutical platform."

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, expected mid-2026.
- Human cosmetic application study planned for Q3 2026.

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

- In June 2025, Azitra reported promising safety data with 50% of patients enrolled.
- ATR12-351, a live biotherapeutic product candidate has been generally safe and well-tolerated with occasional, transient, mild to moderate symptoms at application site to date.
- Topline data from the Phase 1b trial is anticipated H2 2026.

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

- Dosed first patient in Phase 1/2 Trial for ATR-04 program targeting oncology patients with EGFRi-associated rash in Q3 2025.
- Topline data from first cohort of Phase 1/2 trial expected in H2-2026.

ATR-01 – Targeting Ichthyosis Vulgaris Which Impacts 1.3 million in the United States

- Announced positive preclinical data for ATR-01 program in Q3 2025, demonstrating delivery of active, functional filaggrin through human stratum corneum and repair of damaged model skin.
- IND-enabling studies continue in 2026.

Financial Results for the Quarter Ended March 31, 2026

- **Research and Development (R&D) expenses:** R&D expenses for the quarter ended March 31, 2026, were $1.6 million compared to $1.3 million for the comparable period in 2025.
- **General and Administrative (G&A) expenses:** G&A expenses for the quarter ended March 31, 2026, were $2.4 million compared to $1.9 million for the comparable period in 2025.
- **Net Loss** was $3.9 million for the quarter ended March 31, 2026, compared to $3.1 million for the comparable period in 2025.
- **Cash and cash equivalents:** As of March 31, 2026, Azitra had cash and cash equivalents of $10.1 million.

About Azitra, Inc.

Azitra, Inc. is a clinical stage biopharmaceutical company focused on developing innovative therapies for precision dermatology. The Company's lead program, ATR-12, uses an engineered strain of *S. epidermidis* designed to treat Netherton syndrome, a rare, chronic skin disease with no approved treatment options. Netherton syndrome may be fatal in infancy with those living beyond a year having profound lifelong challenges. The ATR-12 program includes a Phase 1b clinical trial in adult Netherton syndrome patients. ATR-04, Azitra's additional advanced program, utilizes another engineered strain of S. epidermidis for the treatment of EGFR inhibitor ("EGFRi") associated rash. Azitra has received Fast Track designation from the FDA for EGFRi associated rash, which impacts approximately 150,000 people in the U.S. Azitra has an open IND for its ATR-04 program in patients with EGFRi associated rash. The ATR-12 and ATR-04 programs were developed from Azitra's proprietary platform of engineered proteins and topical live biotherapeutic products that includes a microbial library comprised of approximately 1,500 bacterial strains. The platform is augmented by artificial intelligence and machine learning technology that analyzes, predicts, and helps screen the library of strains for drug like molecules. Azitra is also developing its proprietary filaggrin protein and peptide technologies for the consumer, cosmeceutical market. The new initiative is the first amongst others, which aims to leverage Azitra's microbial genetic engineering platform to manufacture innovative proteins and peptides for the cosmetic and research 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 provision 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, and (iv) statements about our clinical and preclinical programs, and corporate and clinical/preclinical strategies, including our cosmeceutical strategy.

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-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 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 March 31,	
	2026	2025
Operating expenses:		
General and administrative	$ 2,373,359	$ 1,850,138
Research and development	1,560,565	1,250,100
Total operating expenses	3,933,924	3,100,238
Loss from operations	(3,933,924)	(3,100,238)
Other income (expense):		
Interest income	14,719	37,164
Interest expense	(3,411)	(1,293)
Change in fair value of warrants	—	143
Other income	(4,624)	(4,121)
Total other income	6,684	31,893
Loss before income taxes	(3,927,240)	(3,068,345)
Income tax expense	—	—
Net loss	$ (3,927,240)	$ (3,068,345)
Net loss per Share, basic and diluted	$ (0.25)	$ (1.55)
Weighted average common stock outstanding, basic and diluted	15,517,992	1,977,670

Condensed Balance Sheets
Unaudited

	March 31, 2026	December 31, 2025
Assets		
Current Assets:		
Cash and cash equivalents	$ 10,051,003	$ 2,068,083
Other receivables	154,492	141,295
Prepaid expenses and other current assets	554,646	809,949
Total current assets	10,760,141	3,019,327
Property and equipment, net	530,438	548,591
Other assets	836,225	1,457,468
Total assets	$ 12,126,804	$ 5,025,386
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 932,217	$ 399,356
Current financing lease liability	5,850	10,111
Current operating lease liability	240,740	255,776
Insurance premium financing liability	100,463	198,983
Accrued expenses	270,511	203,740
Total current liabilities	1,549,781	1,067,966
Long-term financing lease liability	—	—
Long-term operating lease liability	96,740	156,190
Warrant liability	—	—
Total liabilities	1,646,521	1,224,156
Stockholders' equity		
Common stock	1,619	1,074
Additional paid-in capital	82,927,100	72,321,352
Accumulated deficit	(72,448,436)	(68,521,196)
Total stockholders' equity	10,480,283	3,801,230
Total liabilities and stockholders' equity	$ 12,126,804	$ 5,025,386

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