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Azitra, Inc. (AZTR: NYSE)

AZTR: ATR-04 Trial to Dose 1st Patient Mid-2025

Azitra's valuation relies on a DCF model and a 15% discount rate applied to our cash flow estimates for commercialization of ATR-12 in Netherton syndrome. We apply a success probability of 20% to the program. The model includes contributions from the United States and the developed world.

Current Price (5/20/2025)	$0.30
Valuation	**$3.00**

OUTLOOK

Azitra is developing genetically engineered bacteria for therapeutic use in dermatology. The company possesses a microbial library of 1,500 unique bacterial strains that are candidates for a variety of indications. Azitra's lead candidate is ATR-12 for the rare disease Netherton syndrome (NS). A second candidate is ATR-04 targeting EGFRi-associated rash and a third, ATR-01, ichthyosis vulgaris. Each one is topically formulated.

Preclinical work has shown effective and safe use of ATR-12 as a potentially disease-modifying therapy able to colonize the skin and replace the missing LEKTI protein. An IND has been cleared and Azitra has started a Ph1 for NS. ATR-04 should enroll its 1st patient by June 2025.

ATR-12 provides the missing active protein segment for NS and if successful, will be a disease modifying therapy. The therapy is not a cure and patients will require ongoing treatment.

We expect clinical trials for NS will follow an expedited pathway as NS is a rare disease that affects children. Our forecasts call for Ph2 and pivotal trials producing a Biologics License Application (BLA) submission in 2028 and approval the following year. ATR-12 may also qualify for a rare pediatric disease priority review voucher.

SUMMARY DATA

52-Week High	**6.70**
52-Week Low	**0.23**
One-Year Return (%)	**-95.0**
Beta	**-1.3**
Average Daily Volume (sh)	**1,393,788**
Shares Outstanding (mil)	**16.5**
Market Capitalization ($mil)	**5.0**
Short Interest Ratio (days)	**1.0**
Institutional Ownership (%)	**5.7**
Insider Ownership (%)	**4.6**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2025 Estimate	**N/A**
P/E using 2026 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue

(In millions of USD)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2024	$0.0 A	$0.8 A	$0.0 A	$0.0 A	$0.8 A
2025	$0.0 A	$0.0 E	$0.0 E	$0.0 E	$0.0 E
2026					$0.0 E
2027					$0.0 E

Earnings per Share

	Q1	Q2	Q3	Q4	Year
2024	-$4.36 A	-$2.74 A	-$0.17 A	-$0.31 A	-$2.37 A
2025	-$0.23 A	-$0.21 E	-$0.21 E	-$0.22 E	-$0.87 E
2026					-$0.66 E
2027					-$0.64 E

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WHAT'S NEW

Azitra, Inc. (NYSE: AZTR) reported first quarter 2025 results in a May 13th press release sharing financial results and providing a business update. Year to date, the company has presented posters at multiple scientific conferences, entered into a purchase agreement to raise additional capital and is looking ahead to several clinical trial related milestones over the remainder of the year. Management reiterates its expectation that initial safety data for ATR-12 will be reported in 2Q:25 and that topline data for this Phase Ib trial will be reported by year end 2025. The ATR-04 trial is expected to dose its first patient in 2Q:25.

Operational and Financial Results

Azitra reported 1Q:25 results in a press release and Form 10-Q filing with the SEC on May 13th. For the quarter ending March 31st, 2025 and versus the prior year's comparable period, no revenues were reported. Net loss for the three-month period totaled ($3.1) million or ($0.23) per share. Operational expenses rose 5% as increases in general and administrative (G&A) expenses were partially offset by declines in research and development (R&D) expenses. Below, we detail financial results for 1Q:25, compared to the same prior year period:

- Research and development expenses totaled $1.3 million, down from $1.5 million due to lower chemistry, manufacturing and control (CMC) costs and consultant costs partially offset by higher ATR-04 and ATR-01 program expenses and lab supply costs;
- General & Administrative expenses were $1.9 million, up from $1.5 million due to greater public company costs including auditor, New York Stock Exchange (NYSE) and legal fees. Public relations expenses were also higher along with the use of business consultants and repair and maintenance cost;
- Net interest income was $36,000 compared to $7,000;
- Other expense was ($4,000) compared with $22,000;
- Net loss was ($3.1) million vs. ($2.9) million or ($0.23) and ($4.36) per share respectively;

As of March 31st, 2025, cash totaled $3.2 million. This amount compares to the $4.6 million balance in cash held at the end of 2024. No debt was held on the balance sheet. 1Q:25 cash burn was ($3.1) million - approximately the same amount presented in 1Q:24. Cash from financing was $1.7 million representing proceeds from public offerings. Following the end of the reporting period, Azitra entered into a purchase agreement with Alumni Capital. Azitra raised $400,000 from this arrangement during the second quarter.

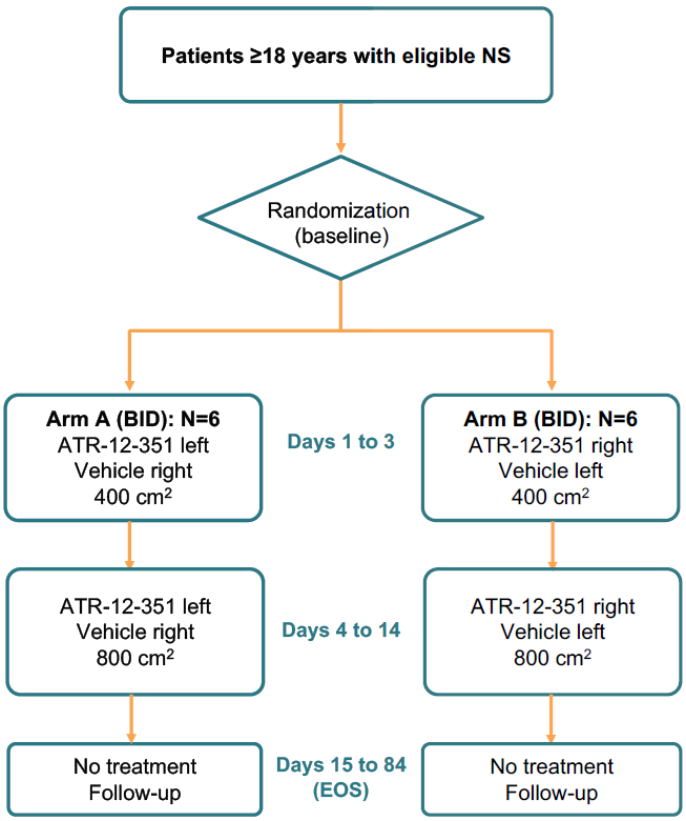
ATR-12 Clinical Trials

Azitra received investigational new drug (IND) clearance for its Netherton syndrome candidate, ATR-12, in January 2023. The company has since launched a Phase Ib clinical trial under the identifier NCT06137157 and expects to enroll 12 patients. Primary endpoints will examine safety and tolerability while secondary and exploratory endpoints will assess efficacy signals and biomarkers. ATR-12 will be topically administered twice daily. A clinical site at Yale University has been established and other sites including one at Stanford are being sought.

The study will apply ATR-12 to lesions on one side of a subject's body and apply the vehicle to the other. Application of ATR-12 and the vehicle will be performed twice daily for two weeks. Patients will be randomized to receive ATR-12 on either the right or left side. Initially, the FDA requires that patients be dosed one at a time and sequentially to provide an initial safety profile before allowing parallel enrollment. We anticipate that this will be required for the first two or three patients to provide enough data to support parallel enrollment when the FDA feels comfortable. Another hurdle to rapid enrollment has been the difficulty of scheduling families to come to the Yale site. The study requires that the young patients stay at the location for two weeks for treatment. Azitra opened another site at Stanford in Northern California which should ease the distance burden on some families' participation in the trial. One of the positive features of the Netherton community is that there are Netherton syndrome registries and constant communication among patients and their caregivers connected to the disease which should generate interest in a sufficient population to enroll 12 patients for this trial.

The primary endpoint is adverse events at 84 days as well as quantifying and qualifying incidence, severity, seriousness and relatedness. Secondary endpoints include investigators' and patients' global assessment of severity, concentration of recombinant human lymphoepithelial Kazal-type related inhibitor (rhLEKTI) in the plasma and on the skin following topical application. Biomarkers will be evaluated including KLK5, KLK7, IL-36, TARC/CCL17, trypsin-like activity and chymotrypsin-like activity.

Exhibit I – ATR-12 Trial Design



Source: Azitra SID Poster, May 2024

First Patient Screened and Dosed

Azitra screened its first patient in the ATR-12 trial in August as reported in a press release. By the end of the month, the patient had been dosed. Since then, we believe at least one more patient has been enrolled. Interim safety data are expected to be available in 2Q:25 with full results available by year-end.

ATR-04

Epidermal growth factor receptor inhibitors (EGFRi) are targeted cancer therapies that have been effective in breast, colon, lung and pancreatic cancer. EGFR is a protein found on the surface of cells, and it plays a role in cell growth and division. In some cancers, such as certain types of lung cancer and colorectal cancer, the EGFR gene is mutated or overexpressed, leading to uncontrolled cell growth. EGFR inhibitors work by blocking the activity of this protein, thereby slowing down or stopping cancer cell growth.

In the skin, EGFR regulates multiple keratinocyte functions including proliferation, adhesion and migration, survival, and differentiation. Consequently, inhibition of EGFR in the skin results in adverse skin reactions, which make it difficult for patients to continue therapy. Two of the leading EGFR inhibitors, erlotinib and gefitinib, carry FDA labels that warn of rash and skin reactions in over 20% of patients. In many cases it is severe enough for the individual to stop EGFRi therapy. The skin reaction, which is referred to as an acneiform or papulopustular rash, can vary in intensity. Mild rash is treated with topical medications and oral antibiotics; however, in severe cases a doctor may stop treatment.

The side effect is an unmet need that may be addressed using ATR-04, which is a genetically modified strain of SE. The strain demonstrated properties of inhibiting IL-36γ, *S. aureus* and related biofilms. ATR-04 has been modified to be auxotrophic for D-alanine. The product is formulated as a topical application and may also help reduce the use of antibiotics, allow for better compliance with EGFRi regimens and improve patient quality of life.

ATR-04 is a drug product derived from an *S. epidermidis* strain and is administered topically. It was sourced from a healthy volunteer and engineered to be auxotrophic to control growth. The product inhibits IL-36γ and *S. aureus* both of which can cause and exacerbate inflammatory skin conditions. ATR-04 also increases human beta defensin 2 which provides antimicrobial benefits, maintains skin barrier functions and contributes to the wound healing process by preventing infections and regulating the inflammatory response.

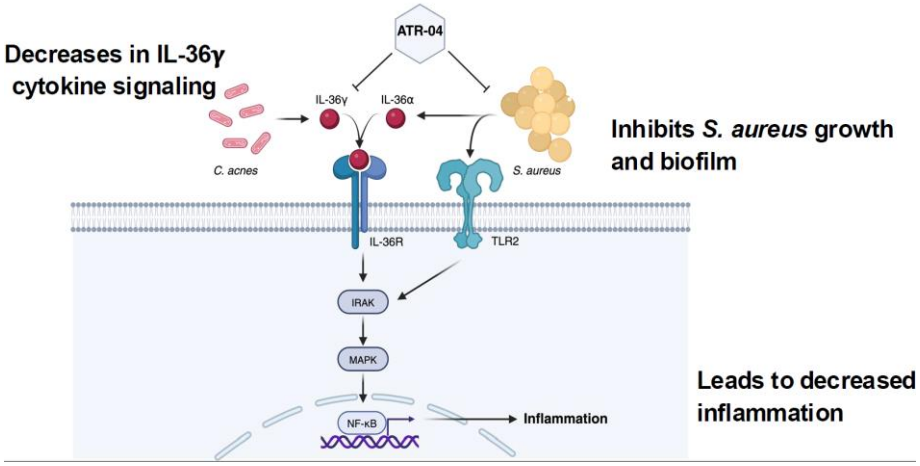
Preclinical work for ATR-04 was completed and assembled with other required data into an investigational new drug (IND) application submitted last summer to the FDA. In an August 22nd press release, Azitra announced that the IND had been cleared which allows the company to begin its Phase I/II study of ATR-04 for moderate to severe EGFRi associated dermal toxicity. In September, the FDA granted Fast Track Designation to ATR-04 for Azitra's indication.

A Phase I/II is now planned to start during 2Q:25 that will enroll eight patients in a single ascending dose Phase I study over 28 days. The Phase II portion will target 24 patients for this segment of the study. A contract research organization (CRO) is in place and four sites across the US are being identified for use. Azitra anticipates a rapid enrollment as these are high volume cancer centers with many potential candidates receiving EGFRi treatment.

ATR-04 American Society of Gene and Cell Therapy (ASGCT) Presentation

Azitra presented a poster on ATR-04 entitled A Novel Staphylococcus epidermidis Compound for the Topical Treatment Epidermal Growth Factor Receptor (EGFR) Inhibitor-Induced Dermal Toxicity at the American Society of Gene and Cell Therapy (ASGCT) meeting in New Orleans, Louisiana. The poster began with a background on toxicities from EGFR inhibitors then provided a description of the preclinical trial design and finally discussed the upcoming Phase I/II. The mechanism of action for ATR-04 was illustrated, describing how it decreases inflammation.

Exhibit II – Mechanism of Action of ATR-04



Source: ASGCT ATR-04 Poster

Conclusions from the poster asserted that EGFRi-associated dermal toxicity is associated with a significant unmet need for treatment, as it leads to EGFRi discontinuations and poor quality of life in cancer patients. ATR-04 demonstrated

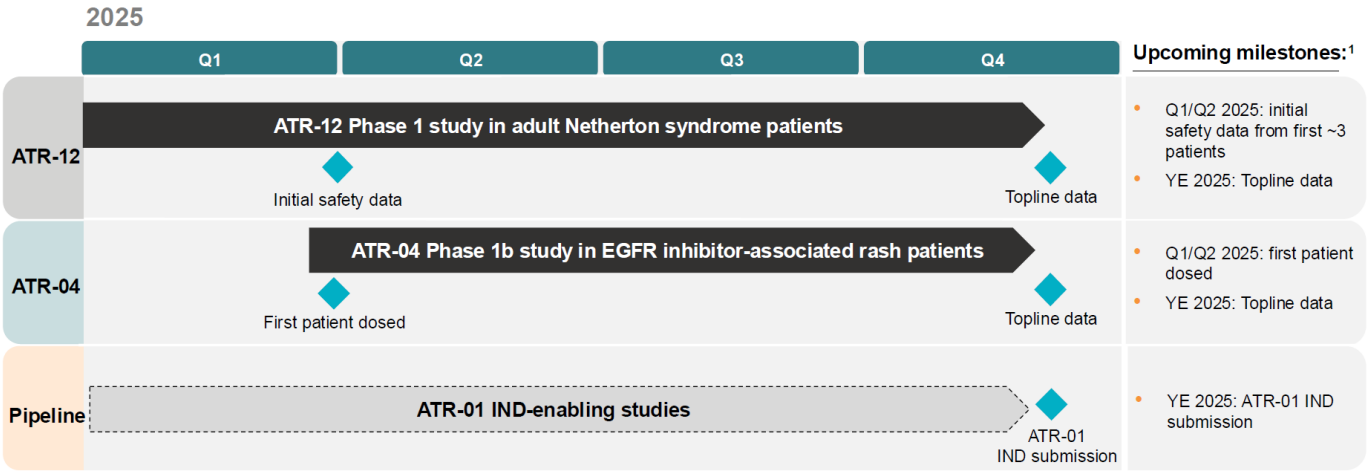
- Proof of concept in this study with auxotroph controlled by D-alanine;
- Significant reduction in IL-36γ induced by erlotinib;
- Significant reduction in *S. aureus* in multiple animal models.

The poster directed stakeholders' attention towards the upcoming Phase I/II multi-dose clinical trial for EGFRi dermal toxicity that will begin soon.

Alumni Capital Share Purchase Agreement

Azitra announced a share purchase agreement with Alumni Capital for up to $20 million to fund the clinical pipeline. Azitra controls the timing of the common stock sales and can put shares to Alumni of up to $750,000 at its own election and up to $4 million on consent of the purchaser. Shares are sold at a discount to the lowest daily volume weighted price in the five days preceding the transaction. Warrants equal to 10% of the shares issued will also be granted to Alumni with an exercise price of 130% of the price paid for the common stock shares.

Exhibit III – Timeline for Azitra Pipeline

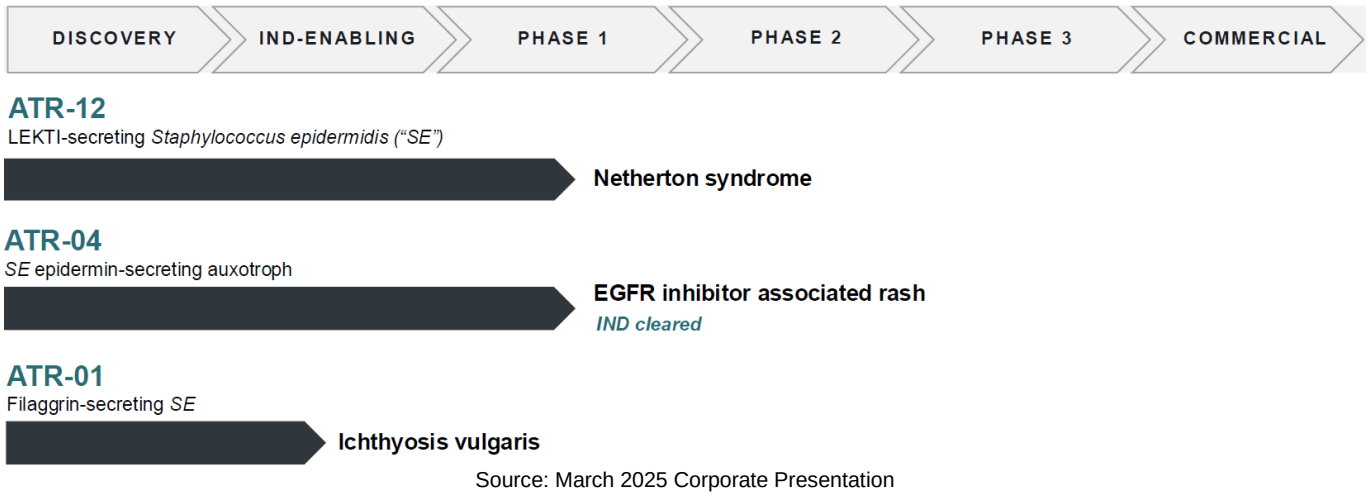


Source: March 2025 Corporate Presentation

Milestones

- Presentations at BIO CEO – 1Q:25
- Presentation at Microbiome Times Partnering Forum – March 2025
- Share purchase agreement with Alumni Capital – April 2025
- Presentation of ATR-04 data at ASCO – May 30 to June 3, 2025
- Initial safety data from Phase Ib ATR-12 – 2Q:25
- First patient dosed with ATR-04 for EGFRi rash (Phase I/II) – mid-2025
- Topline from Phase Ib ATR-12 trial – 4Q:25
- ATR-01 investigational new drug (IND) submission – 4Q:25

Exhibit IV – Azitra Pipeline



Source: March 2025 Corporate Presentation

Summary

Azitra reported first quarter 2025 results and is expecting to both report interim safety data from the Phase Ib study in ATR-12 for Netherton and dose its first patient in the EGFRi rash trial before the end of the second quarter. Since our last update the company has presented at several scientific conferences including the Microbiome Times Partnering Forum and ASGCT. Azitra will also present at ASCO in less than two weeks with a poster describing ATR-04. In addition to operational achievements, the company has also raised additional capital and signed a share repurchase agreement with Alumni Capital to fund its clinical pipeline. Nothing new was available on the Bayer relationship for the undisclosed consumer product, which is not surprising as many established pharmaceutical companies are very slow to respond unless contractually obligated. Our price target remains $3.00 per share.

PROJECTED FINANCIALS

Azitra, Inc. - Income Statement

Azitra, Inc.	2024 A	Q1 A	Q2 E	Q3 E	Q4 E	2025 E	2026 E	2027 E
Revenues	**$8**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
General & Administrative	$6,269	$1,850	$1,500	$1,450	$1,450	$6,250	$5,500	$5,750
Research & Development	$4,723	$1,250	$1,900	$2,100	$2,350	$7,600	$9,100	$10,200
Operating Income	($10,985)	($3,100)	($3,400)	($3,550)	($3,800)	($13,850)	($14,600)	($15,950)
Operating Margin								
Interest Income, net	$110	$36	$0	$0	$0	$36	$0	$0
Other Income (Loss)	$1,916	($4)	$0	$0	$0	($4)	$0	$0
Loss Before Income Taxes	($8,958)	($3,068)	($3,400)	($3,550)	($3,800)	($13,818)	($14,600)	($15,950)
Income Tax	($9)	$0	$0	$0	$0	$0	$0	$0
Net Loss	**($8,967)**	**($3,068)**	**($3,400)**	**($3,550)**	**($3,800)**	**($13,818)**	**($14,600)**	**($15,950)**
Preferred Stock Dividends	$0	$0	$0	$0	$0	$0	$0	$0
Net Loss Per Share	**($2.37)**	**($0.23)**	**($0.21)**	**($0.21)**	**($0.22)**	**($0.87)**	**($0.66)**	**($0.64)**
Weighted Average Shares	3,784	13,172	16,400	16,650	17,000	15,805	22,000	25,000

Source: Company Filing // Zacks Investment Research, Inc. Estimates

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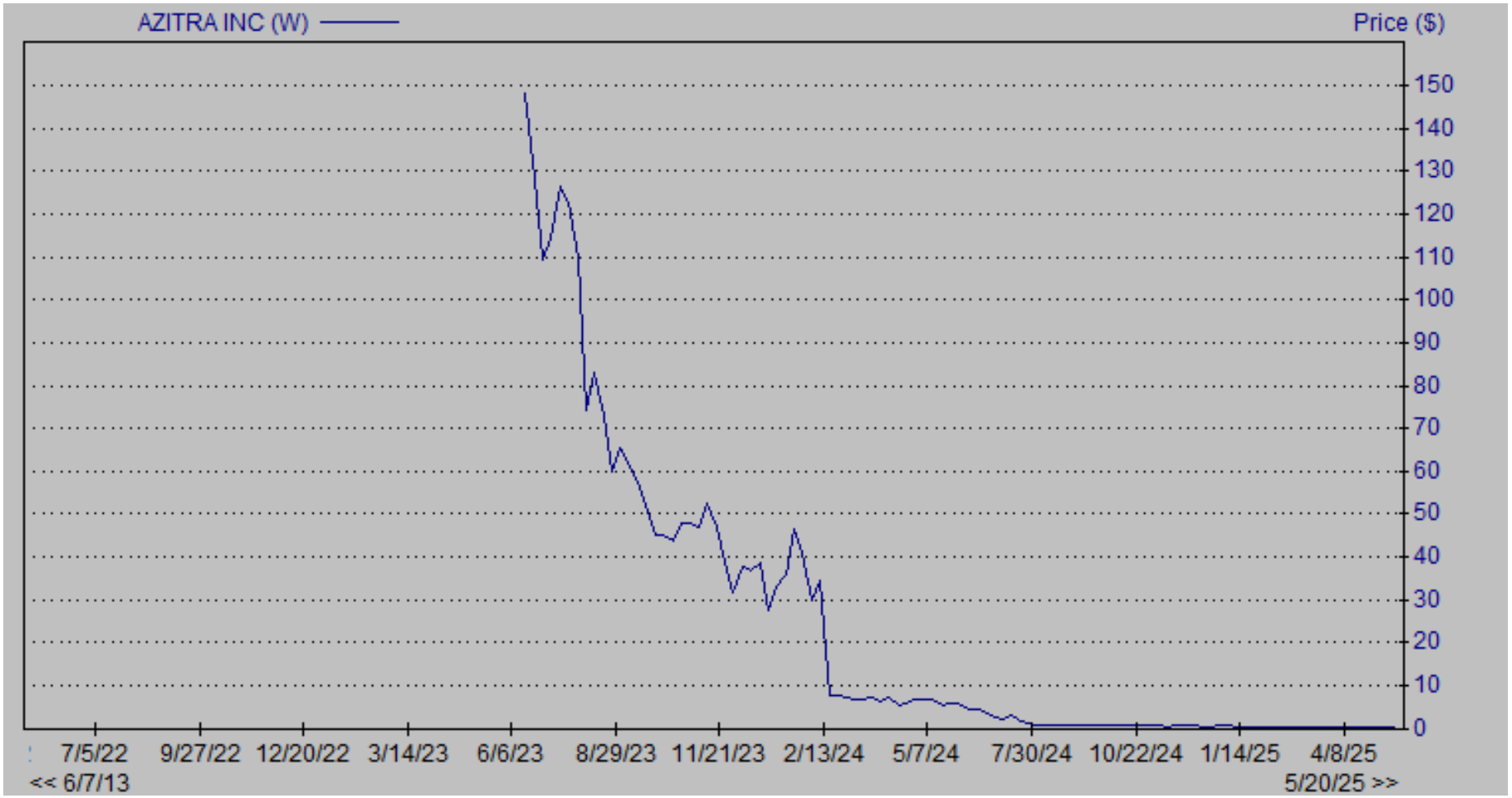
HISTORICAL STOCK PRICE

Azitra, Inc. – Share Price Chart



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