Zacks Small-Cap Research
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Azitra, Inc. (AZTR: NYSE)

AZTR: Planning 2nd Site for ATR-12 Trial

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 (11/15/2024)	$0.45
Valuation	**$4.00**

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. An IND is expected for ATR-04 by year end 2024.

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 BLA submission in 2028 and approval the following year. ATR-12 may also qualify for a rare pediatric disease priority review voucher which may hold substantial value if sold.

SUMMARY DATA

52-Week High	**6.70**
52-Week Low	**0.58**
One-Year Return (%)	**-99**
Beta	**1.2**
Average Daily Volume (sh)	**577,732**
Shares Outstanding (mil)	**7.6**
Market Capitalization ($mil)	**3.4**
Short Interest Ratio (days)	**0.8**
Institutional Ownership (%)	**9.5**
Insider Ownership (%)	**10.7**
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 2024 Estimate	**N/A**
P/E using 2025 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)
2023	$0.1 A	$0.2 A	$0.3 A	$0.1 A	$0.7 A
2024	$0.0 A	$0.8 A	$0.0 A	$0.0 E	$0.8 E
2025					$0.0 E
2026					$0.0 E

Earnings per Share

	Q1	Q2	Q3	Q4	Year
2023					-$54.76 A
2024	-$4.36 A	-$2.74 A	-$0.17 E	-$0.51 E	-$2.78 E
2025					-$0.95 E
2026					-$0.66 E

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WHAT'S NEW

Azitra, Inc. (NYSE: AZTR) reported third quarter results in mid-November highlighting its $10 million raise back in July, dosing of the first patient in the Netherton syndrome trial, investigational new drug (IND) clearance from the FDA for ATR-04 and the issuance of new patents during the reporting period. Other updates since our last report include Azitra management participating in several investor and industry conferences and the FDA's grant of fast-track designation for skin rash from EGFR inhibitors.

Operational and Financial Results

Azitra reported 3Q:24 results in a press release and Form 10-Q filing with the SEC on November 12th. For the third quarter of 2024 ending September 30, 2024 and versus the prior year's comparable period, revenues of $0 were reported compared with $311,000 in the prior year. Net loss for the quarter totaled ($1.0) million or ($0.17) per share. Operational expenses rose 47% as increases in both research and development (R&D) expenses and general and administrative (G&A) expenses were recognized. Below, we summarize financial results for the three-month period ended September 30, 2024, compared to the same prior year period:

- Revenues were $0, compared to $311,000 with amounts in the prior periods related to the Bayer joint development agreement (JDA);
- Research and development expenses totaled $1.0 million, up from $0.5 million with the increase attributable to moving ATR-12 into the clinic and the use of clinical consultants in the most recent period. Greater spending was also due to moving the ATR-04 program forward and higher salaries and benefits partially offset by lower other costs;
- General & Administrative expenses were $1.9 million, up from $1.8 million due to greater public company costs, salaries and benefits in part related to the hiring of the Chief Financial Officer, public relations costs partially offset by lower financing costs and legal expenses;
- Net interest income was $44,000 compared to net interest expense of ($76,000);
- Other income was $1.9 million due to an increase in fair value of warrants related to a stock price decline partially offset by a loss on issuance of common stock;
- Net loss was ($1.0) million vs. ($1.9) million or ($0.17) and ($4.82) per share respectively;

As of September 30, 2024, cash totaled $7.6 million. This amount compares to the $1.8 million balance in cash held at the end of 2023. No debt was held on the balance sheet. For the first nine months of the year, cash burn was ($7.9) million versus ($5.1) million for the same nine-month period in 2023. Cash from financing was $13.3 million representing the gross $5 million raise in February and the gross $10 million raise in July.

ATR-12 Clinical Trials

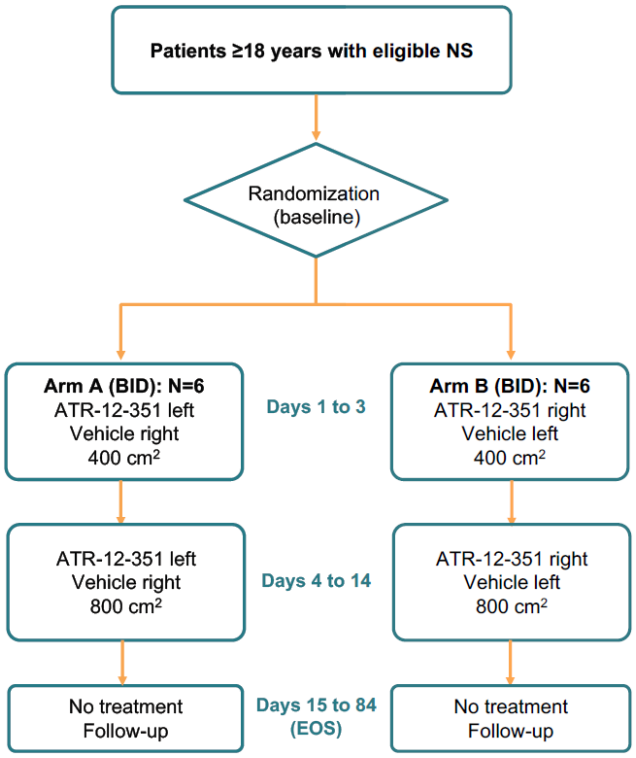
Azitra received investigational new drug (IND) clearance for its treatment of Netherton Syndrome, ATR-12 in January 2023. The company has since launched a Phase Ib clinical trial under the identifier NCT06137157 and expects to enroll 12 patients. Primary endpoints will examine safety and tolerability while secondary and exploratory endpoints will assess efficacy signals and biomarkers. ATR-12 will be topically administered using twice-daily treatment. 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 for two weeks with the young patients for treatment. Azitra is planning to open another site at Stanford which should help overcome this hurdle. One of the positive features of the Netherton community is that there are patient registries and constant communication among patients and their caregivers which should engender interest in a sufficient population to easily enroll 12 patients for this trial.

The primary endpoint is adverse events at 84 days as well as quantifying or 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.

The ongoing Phase I study for ATR-12 may evolve into a proof-of-concept trial that could enroll up to 20 patients including those in the Phase I portion. If supportive, the Phase II could lead to a larger pivotal trial acceptable to the FDA for BLA submission and approval.

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 early 2025 with full results available in 2H:25.

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, which was submitted earlier this summer to the FDA. In an August 22nd press release, Azitra announced that 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 in late 1Q: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. Azitra anticipates a rapid enrollment as these are high volume cancer centers with many potential candidates receiving EGFRi treatment.

Capital Raise

On July 25th, Azitra announced that it had closed a $10 million public offering which allowed the company to begin screening and enrolling patients in its Phase Ib Netherton Syndrome trial. The company issued 6.665 million units that consist of one underlying share and two warrants at an offering price of $1.50. The warrants have an exercise price of $1.50 and a duration of five years.

Patents

Azitra gained several new patent grants earlier this year strengthening its intellectual property portfolio in the areas of using its proprietary bacterial strains in atopic dermatitis and other skin diseases. The patents were granted in the U.S., China and Canada. Patents were issued with the following titles:

- Methods and Compositions for Treating Inflammatory Skin Disease with Recombinant Microorganisms
  - U.S. Patent Application No. 16/121,903
  - Covers the composition of filaggrin-secreting strains of Staphylococcus epidermidis
- Methods and Compositions for Treating Atopic Dermatitis with Recombinant Microorganisms
  - Canadian Patent Application No. 2979079
  - Covers the use of filaggrin-secreting strains of Staphylococcus epidermidis for atopic dermatitis and other skin diseases
- Methods and Compositions for Treating Inflammatory Skin Disease with Recombinant Microorganisms
  - Chinese Patent Application No. 201880071303.9
  - Covers the composition of filaggrin-secreting strains of Staphylococcus epidermidis

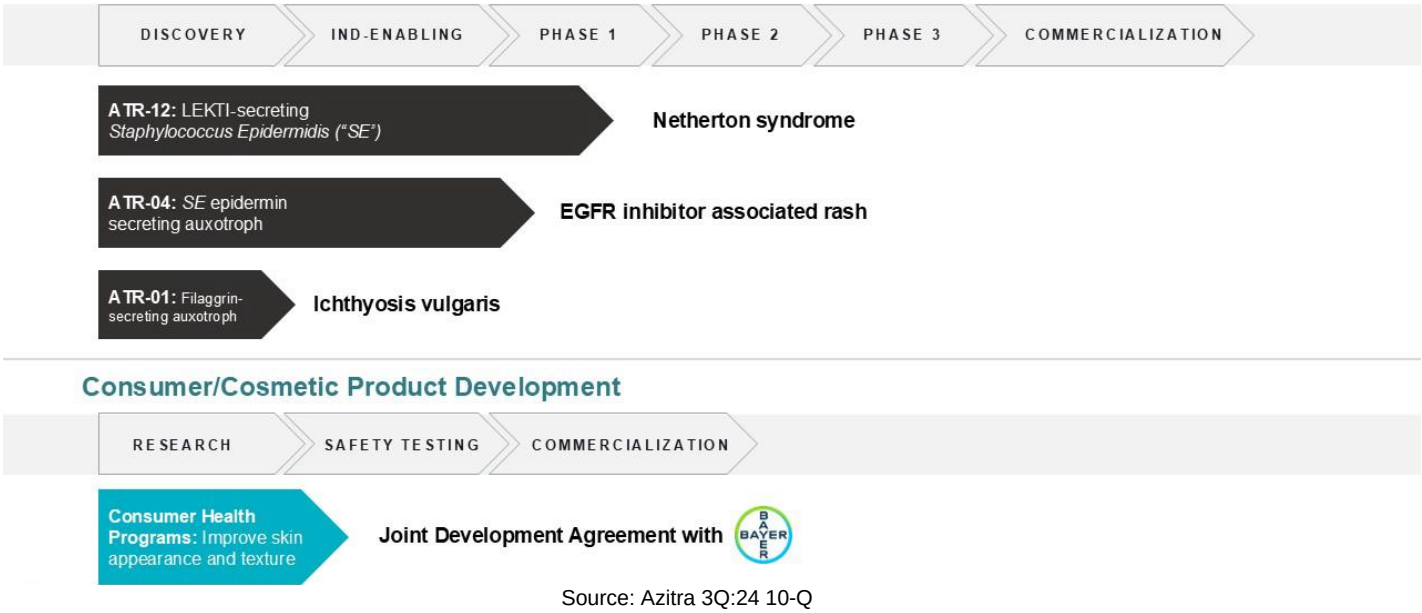
Following these issuances, Azitra will hold four granted U.S. patents, 14 granted international patents, nine pending U.S. patent applications and 44 pending international patent applications.

Milestones

- Filaggrin patent granted (#11,850,267) – January 2024
- ATR-12 presentation at ASGCT meeting – May 2024
- Presentation at the BIO International Convention – June 2024
- 1:30 reverse stock split – July 2024
- Closing of $10 million public offering – July 2024
- Dosing of first patient for ATR-12 – August 2024
- IND clearance by FDA for ATR-04 – August 2024

- H.C. Wainwright Global Investment Conference – September 2024
- Presentation at European Academy of Dermatology & Venereology Congress – September 2024
- Maxim Healthcare Virtual Summit – October 2024
- BIO-Europe (Stockholm) – November 2024
- Initial safety data from Phase Ib ATR-12 trial – 1Q:25
- First patient dosed with ATR-04 for EGFRi rash (Phase I/II) – 1Q:25
- Topline from Phase Ib ATR-12 trial – 4Q:25

Exhibit II – Azitra Pipeline



Source: Azitra 3Q:24 10-Q

Summary

Azitra reported third quarter results in mid-November bringing investors up to date on the status of the ATR-012 and ATR-04 programs. Progress has been made on both fronts with the first patient enrolled for the Netherton syndrome program and a grant of Fast Track status by the FDA for the EGFRi rash program. We expect to see a site in California added for the ATR-012 trial and an acceleration of enrollment as early safety is confirmed. The ATR-04 trial is slated to begin in 1Q:25 as a Phase I/II study that should enroll at four sites around the US. No update was provided 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. An additional $10 million was raised during the third quarter which extends the runway and will allow continued progress on the clinical trials. We maintain our price target of $4.00 per share.

PROJECTED FINANCIALS

Azitra, Inc. - Income Statement

Azitra, Inc.	2023 A	Q1 A	Q2 A	Q3 A	Q4 E	2024 E	2025 E	2026 E
Revenues	**$686**	**$0**	**$8**	**$0**	**$0**	**$8**	**$0**	**$0**
General & Administrative	$4,493	$1,489	$1,549	$1,913	$1,132	$6,083	$5,200	$5,500
Research & Development	$3,809	$1,473	$1,119	$1,016	$2,820	$6,427	$9,000	$9,100
Operating Income	($7,616)	($2,961)	($2,660)	($2,929)	($3,952)	($12,503)	($14,200)	($14,600)
Operating Margin								
Interest Expense, net	($166)	$7	($2)	($4)	$0	$1	$0	$0
Other Income (Loss)	($3,484)	$22	$30	$1,924	$0	$1,976	$0	$0
Loss Before Income Taxes	($11,266)	($2,933)	($2,632)	($1,009)	($3,952)	($10,526)	($14,200)	($14,600)
Income Tax	($17)	$0	$0		$0	$0	$0	$0
Net Loss	**($11,284)**	**($2,933)**	**($2,632)**	**($1,009)**	**($3,952)**	**($10,526)**	**($14,200)**	**($14,600)**
Preferred Stock Dividends	($1,355)	$0	$0	$0	$0	$0	$0	$0
Net Loss Per Share	**($54.76)**	**($4.36)**	**($2.74)**	**($0.17)**	**($0.51)**	**($2.78)**	**($0.95)**	**($0.66)**
Weighted Average Shares	231	673	960	5,814	7,700	3,787	15,000	22,000

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

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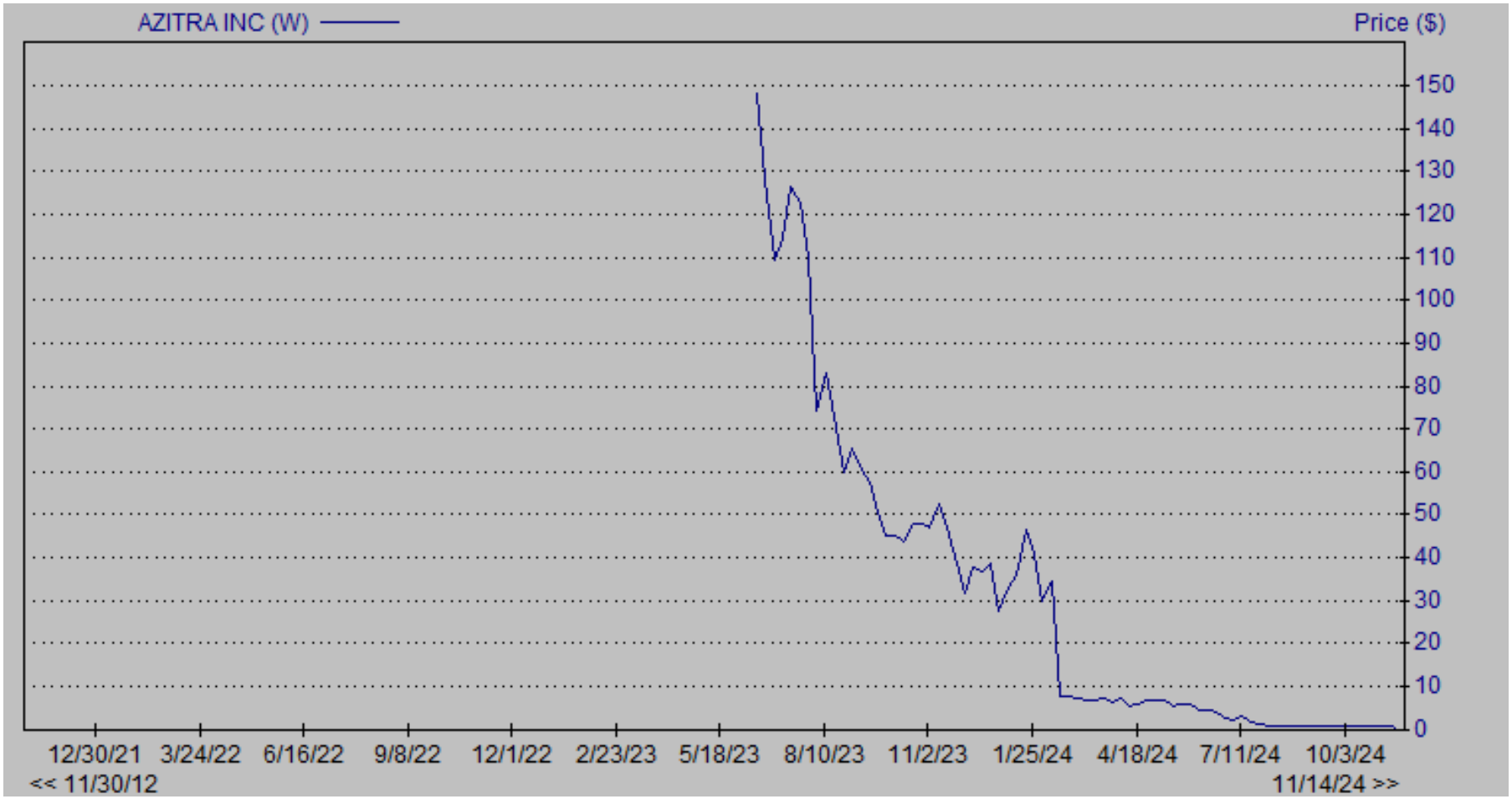
HISTORICAL STOCK PRICE

Azitra, Inc. – Share Price Chart



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