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Zacks Small-Cap Research (NOTE)

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Azitra, Inc. (AZTR: NYSE)

AZTR: Historical and Financial Review

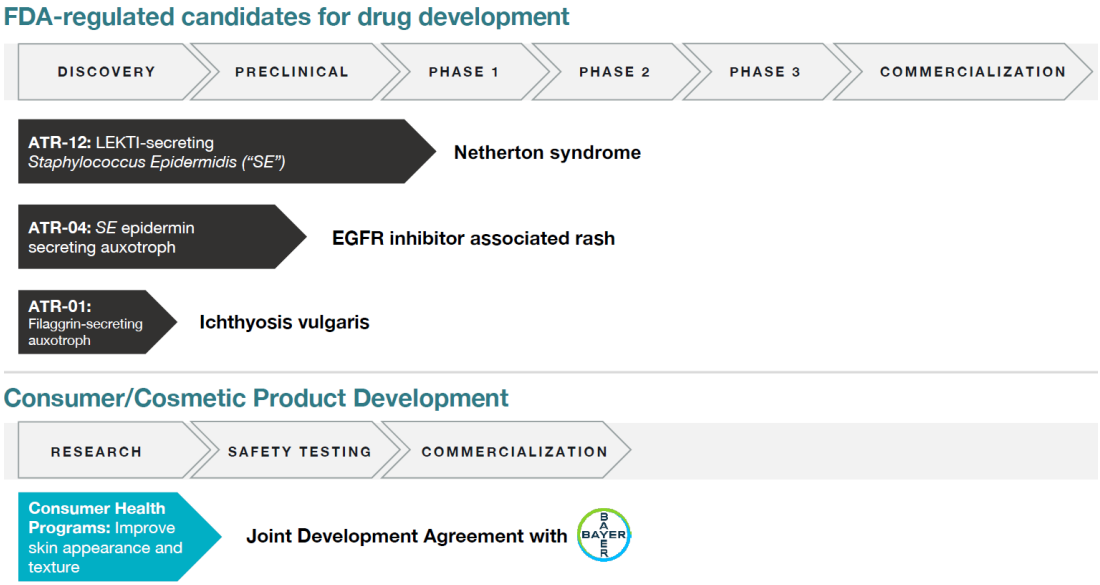
Research Note

Azitra, Inc. (NYSE: AZTR) is a clinical stage precision dermatology company developing candidates for a variety of rare and serious skin diseases. It is developing genetically engineered bacteria for therapeutic use in dermatology leveraging 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 Netherton Syndrome (NS), a rare disease. A second candidate is ATR-04 targeting epidermal growth factor receptor inhibitor (EGFRi)-associated rash and a third, ATR-01, ichthyosis vulgaris. All are 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 a missing protein. An IND has been cleared for ATR-12 and a Phase I study has started. An IND is expected for ATR-04 by year end 2024. Outside of its pipeline, the company has signed a Joint Development Agreement with Bayer Consumer Care AG for consumer health candidates.

We have developed this note to provide background on Azitra, its history since inception and a review of recent financial performance and status. We have published previous notes in the last few weeks and encourage readers and investors to review them. They include A Brief Introduction to Precision Dermatology and S. Epidermidis, Netherton Syndrome Review and ATR-12 Clinical Trial and Pipeline Review.

Exhibit I – Pipeline



Source: Azitra Corporate Presentation

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Historical Review, Financial & Operational Results

Milestones

- Azitra founded – January 2014
- Pediatric Rare Disease Designation Granted – May 2020
- CEO Francisco Salva appointed as CEO – May 2021
- Investigational New Drug (IND) application filed for ATR-12 – December - 2022
- IND clearance – January 2023
- Closing of IPO – June 2023
- Filaggrin patent granted (#11,850,267) – January 2024
- $5 million public offering – February 2024
- ATR-12 presentation at ASGCT meeting – May 2024
- Preclinical data from ATR-04 presented at the Society of Investigative Dermatology – May 2024
- Corporate update presentation at BIO International Convention – May 2024

Background

Co-founded by Chief Operating Officer Travis Whitfill and former CEO Azim Munivar, Azitra was formed as a corporation in January 2014 with resources from both Yale University and the Jackson Laboratory. During its early years, the company built out its microbial library which now boasts approximately 1,500 unique bacterial strains with a variety of therapeutic characteristics. The company began work early in its life on the ATR-12 program and was able to secure a Pediatric Rare Disease Designation from the FDA in 2019. Despite slow progress during the pandemic, Azitra compiled an investigational new drug (IND) application during this period which was submitted to the FDA in December 2022.

After the mid-2023 IPO, the company expanded its management ranks, elevating co-founder Travis Whitfill to COO and adding two new board members. Communication with investors increased with attendance at several conferences including those hosted by HC Wainwright, ThinkEquity and Biotech Showcase. Attendance at scientific conferences moved to the forefront in May 2024, as the company announced planned attendance at three conferences including the American Society of Gene and Cell Therapy (ASGCT), Society of Investigative Dermatology (SID) and American Society of Clinical Oncology (ASCO). The company also provided updates on the company's progress to stakeholders at the BIO International Convention in San Diego at the end of May.

The spotlight is on the ATR-12 program which has received a cleared IND and is expected to dose its first patient soon. Initial data from the trial is expected to be available in late 2024. The ATR-04 program is also advancing with IND submission expected mid-2024 and preclinical data to be presented at scientific conferences. We are also interested in the next steps related to the Bayer JDA which could produce a licensing agreement and upfront payments sometime this year.

Recent History

In December 2022 Azitra submitted its IND for ATR-12 to the FDA. The FDA cleared the request in January 2023, opening the starting gates for the Phase Ib trial in Netherton syndrome. An IPO in June provided funding to secure a contract research organization (CRO), identify trial sites and prepare for patient identification and screening. Other preparatory work includes approval by the Institutional Review Board (IRB) and identifying initial subjects for dosing. Work on ATR-04 has also progressed and an IND application is expected later this year. Azitra is also active with its large pharma collaborator and has proposed two strains of its bacteria to Bayer for consumer health use. It is waiting to see if the multinational pharmaceutical and life sciences company will license the candidates. As Azitra moved into 2024, it was granted a new patent protecting a filaggrin-secreting strain of *Staphylococcus epidermidis* for the treatment of ichthyosis vulgaris and conducted another public offering, ultimately raising gross proceeds of $5 million. The company had a busy May, participating in three scientific conferences including the American Society of Gene and Cell Therapy (ASGCT) in Baltimore, Maryland, Society of Investigative Dermatology (SID) in Dallas, Texas and the American Society of Clinical Oncology (ASCO) in Chicago, Illinois.

1Q:24 Operational and Financial Results

Azitra reported 1Q:24 results in a press release and Form 10-Q filing with the SEC on May 9th. For the first quarter of 2024 ending March 31, 2024 and versus the prior year's first quarter, no revenues were reported compared with $113,000 in the prior year related to the Bayer JDA. Net loss for the first quarter totaled ($2.9) million or ($0.15) per share. Operational expenses rose 77% 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 March 31, 2024, compared to the same prior year period:

- Revenues were $0 down from $113,000;
- Research and development expenses totaled $1.5 million, up 77% from $0.8 million with the increase attributable to moving ATR-12 into the clinic, advancing other programs and a rise in miscellaneous costs;
- General & Administrative expenses were $1.5 million, up 77% from $0.8 million on account of the addition of new personnel, legal fees, listing fees, premiums for directors' and officers' insurance, investor and public relations costs, conference costs and an increase in other overhead expenses;
- Net interest income was $7,000 compared to net interest expense of ($90,000);
- Other income was $22,000 vs. ($799,000) with the variation due to prior year changes in valuation for convertible notes;
- Net loss was ($2.9) million vs. ($2.5) million or ($0.15) and ($3.00) per share, respectively with the variation in per share loss due to a greater share balance.

As of March 31, 2024, cash totaled $3.0 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 three months of the year, cash used in operations was ($3.1) million in 1Q:24 versus ($1.3) million for the same period in 2023. Net proceeds from the $5 million raise in February were $4.3 million.

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