The information in this prospectus is not complete and may be change. This preliminary prospectus supplement and the accompanying prospectus are not an offer to sell these securities, nor are they soliciting offers to buy these securities in any jurisdiction where the offer or sale is not permitted.

# SUBJECT TO COMPLETION, DATED JANUARY 14, 2025

Preliminary Prospectus Supplement (To the Prospectus dated July 8, 2024)



## Shares of Common Stock Pre-Funded Warrants to Purchase Shares of Common Stock

We are offering shares of our common stock, par value \$0.0001 per share ("common stock") pursuant to this prospectus supplement and the accompanying base prospectus in a registered public offering. The purchase price for each share of common stock is \$ .

We are also offering to each purchaser whose purchase of common stock in this offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% of our outstanding common stock immediately following the consummation of this offering, pre-funded warrants to purchase up to shares of our common stock (the "Pre-Funded Warrants"). Subject to limited exceptions, a holder of Pre-Funded Warrants will not have the right to exercise any portion of its Pre-Funded Warrants if the holder, together with its affiliates, would beneficially own in excess of 4.99% (or, at the election of the holder, 9.99%) of the number of shares of common stock outstanding immediately after giving effect to such exercise. Each Pre-Funded Warrant is exercisable for one share of common stock at an exercise price of \$0.0001 per share of common stock. The purchase price of each Pre-funded Warrant is equal to the price per share, minus \$0.0001. The Pre-funded Warrants will be immediately exercisable and may be exercised at any time until all of the Pre-funded Warrants are exercised in full. The shares of common stock, the Pre-Funded Warrants, and the shares of common stock underlying the Pre-Funded Warrants are collectively referred to herein as the "Securities."

Our common stock is listed on the NYSE American stock exchange under the symbol "AZTR." On January 13, 2025, the closing price of our common stock on the NYSE American was \$0.5750 per share. There is no established trading market for the Pre-funded Warrants, and we do not intend to list the Pre-funded Warrants on any securities exchange or nationally recognized trading system.

We have retained Maxim Group LLC ("Maxim" or the "placement agent") to act as our exclusive placement agent in connection with the securities offered by this prospectus supplement and the accompanying prospectus. The placement agent has no obligation to buy any of the securities from us or to arrange for the purchase or sale of any specific number or dollar amount of securities. We have agreed to pay the placement agent the placement agent the placement agent the securities we are offering.

As of January 14, 2025, the aggregate market value of our outstanding common stock held by non-affiliates, or public float, was approximately \$4.37 million, based on 7,626,056 shares of our common stock issued and outstanding on January 14, 2025, of which approximately 24,129 shares were held by affiliates, and a price of \$0.5750 per share, which was the closing price at which our common stock was last sold on NYSE American on January 13, 2025. Pursuant to General Instruction I.B.6 of Form S-3, in no event will we sell securities registered on this registration statement in a public primary offering with a value exceeding more than one-third of our public float in any 12-month period so long as our public float remains below \$75 million. As of January 14, 2025, prior to the consummation of this offering, we have not sold any securities under the foregoing "shelf" registration statement.

Before you invest, you should carefully read this prospectus supplement, the accompanying prospectus and all information incorporated by reference therein. These documents contain information you should consider when making your investment decision.

# Investing in our securities involves a high degree of risk. See "*Risk Factors*" beginning on page S-7 of this prospectus supplement and on page 3 of the accompanying prospectus, and the documents incorporated by reference herein and therein.

Neither the Securities and Exchange Commission (the "SEC") nor any state securities commission has approved or disapproved of these securities or determined if this prospectus supplement or the accompanying prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	Per Pre-Funded		
	Per Share	Warrant	Total
Offering price	\$	\$	\$
Placement agent fees <sup>(1)</sup>	\$	\$	\$
Proceeds to us, before expenses <sup>(2)</sup>	\$	\$	\$

(1) We have agreed to pay the placement agent a cash fee of 7.0% of the gross proceeds raised in this offering.

(2) We have also agreed to reimburse the placement agent for certain of its accountable expenses relating to the offering, including, but not limited to, the placement agent's legal fees and all travel and reasonable out of pocket expenses incurred in this offering. Additionally, we have agreed to issue to the placement agent, or its designees, warrants to purchase common stock equal to 4.0% of the shares (or Pre-Funded Warrants in lieu thereof) issued in this offering. See "*Plan of Distribution*" for additional information about our compensation arrangements with the placement agent.

We expect that delivery of the shares of Common Stock being offered pursuant to this prospectus supplement and the accompanying base prospectus will be made on or about , 2025, subject to satisfaction of customary closing conditions.

# **Maxim Group LLC**

The date of this prospectus supplement is \_\_\_\_\_, 2025

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#### ABOUT THIS PROSPECTUS SUPPLEMENT

This prospectus supplement and the accompanying prospectus form part of a registration statement on Form S-3 that we filed with the Securities and Exchange Commission (the "SEC") using a "shelf" registration process. This document contains two parts. The first part consists of this prospectus supplement, which provides you with specific information about this offering. The second part, the accompanying prospectus, provides more general information, some of which may not apply to this offering. Generally, when we refer only to the "prospectus," we are referring to both parts combined. As of January 14, 2025, prior to the consummation of this offering, we have not sold any securities under the foregoing "shelf" registration statement.

This prospectus supplement, and the information incorporated herein by reference, may add, update, or change information in the accompanying prospectus and any free writing prospectuses. You should read both this prospectus supplement, the accompanying prospectus, and any free writing prospectuses together with additional information described under the heading "Where You Can Find More Information." If there is any inconsistency between the information in this prospectus supplement and the accompanying prospectus, you should rely on the information in this prospectus supplement.

You should rely only on the information contained in or incorporated by reference to this prospectus supplement, the accompanying prospectus, and any free writing prospectuses. We have not authorized any other person to provide information different from that contained in this prospectus supplement, the accompanying prospectus, the documents incorporated by reference herein and therein, and any free writing prospectuses. If anyone provides you with different or inconsistent information, you should not rely on it. You should assume that the information appearing in the accompanying prospectus and this prospectus supplement is accurate as of the dates on their respective covers, regardless of time of delivery of the prospectus and this prospectus supplement or any sale of securities. Our business, financial condition, results of operations, and prospects may have changed since those dates.

All references in this prospectus supplement to our consolidated financial statements include, unless the context indicates otherwise, the related notes.

The industry and market data and other statistical information contained in this prospectus supplement, the accompanying prospectus, and the documents we incorporate by reference are based on independent industry, government and non-government organization publications or other publicly available information, as well as other information based on our internal sources. Although we believe these sources are reliable, we have not independently verified the information. None of the independent industry publications used in this prospectus supplement, the accompanying prospectus, or the documents we incorporate by reference were prepared on our behalf or on behalf of any of our affiliates. None of the sources cited by us consented to the inclusion of any data from its reports, and we have not sought their consent.

We are not making an offer to sell the securities covered by this prospectus supplement in any jurisdiction in which an offer or solicitation is not permitted or in which the person making the offer or solicitation is not qualified to do so or to anyone to whom it is unlawful to make an offer or solicitation.

Unless the context otherwise indicates, references in this prospectus to "we," "our" and "us" refer, collectively, to Azitra, Inc., a Delaware corporation, and its subsidiaries.



#### NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains, and any accompanying prospectus supplement will contain, forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and the Private Securities Litigation Reform Act of 1993. Also, documents that we incorporate by reference into this prospectus, including documents that we subsequently file with the SEC, will contain forward-looking statements. Forward-looking statements are those that predict or describe future events or trends and that do not relate solely to historical matters. You can generally identify forward-looking statements as statements containing the words "may," "will," "could," "should," "expect," "anticipate," "intend," "estimate," "believe," "project," "plan," "assume" or other similar expressions, or negatives of those expressions, although not all forward-looking statements contain these identifying words. All statements contained or incorporated by reference in this prospectus and any prospectus supplement regarding our business strategy, future operations, projected financial position, potential strategic transactions, proposed licensing arrangements, projected sales growth, estimated future revenues, cash flows and profitability, projected costs, potential outcome of litigation, potential sources of additional capital, future prospects, future economic conditions, the future of our industry and results that might be obtained by pursuing management's current plans and objectives are forward-looking statements.

You should not place undue reliance on our forward-looking statements because the matters they describe are subject to certain risks, uncertainties and assumptions that are difficult to predict. Our forward-looking statements are based on the information currently available to us and speak only as of the date on the cover of this prospectus, the date of any prospectus supplement, or, in the case of forward-looking statements incorporated by reference, the date of the filing that includes the statement. Over time, our actual results, performance, or achievements may differ from those expressed or implied by our forward-looking statements, and such difference might be significant and materially adverse to our security holders. Except as required by law, we undertake no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

We have identified some of the important factors that could cause future events to differ from our current expectations and they are described in this prospectus and supplements to this prospectus under the caption "Risk Factors," as well as in our most recent Annual Report on Form 10-K, including under the captions "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," and in other documents that we may file with the SEC, all of which you should review carefully. Please consider our forward-looking statements in light of those risks as you read this prospectus and any prospectus supplement.

#### PROSPECTUS SUPPLEMENT SUMMARY

The information below is only a summary of more detailed information included elsewhere in or incorporated by reference in this prospectus supplement and the accompanying prospectus. This summary may not contain all the information that is important to you or that you should consider before deciding to invest in our common stock. Please read this entire prospectus supplement and the accompanying prospectus, including the risk factors, as well as the information incorporated by reference in this prospectus supplement and the accompanying prospectus, carefully.

#### **Our Company**

We are an early-stage clinical biopharmaceutical company focused on developing innovative therapies for precision dermatology using engineered proteins and topical live biotherapeutic products. We have built a proprietary platform that includes a microbial library comprised of approximately 1,500 unique bacterial strains that can be screened for unique therapeutic characteristics. The platform is augmented by an artificial intelligence and machine learning technology that analyzes, predicts and helps screen our library of strains for drug like molecules. The platform also utilizes a licensed genetic engineering technology, which can enable the transformation of previously genetically intractable strains. Our initial focus is on the development of genetically engineered strains of *Staphylococcus epidermidis, or S. epidermidis*, which we consider to be an optimal therapeutic candidate species for engineering of dermatologic therapies. The particular species demonstrates a number of well-described properties in the skin. As of the date of this prospectus, we have identified among our microbial library over 60 distinct bacterial species that we believe are capable of being engineered to create living organisms or engineered proteins with significant therapeutic effect.

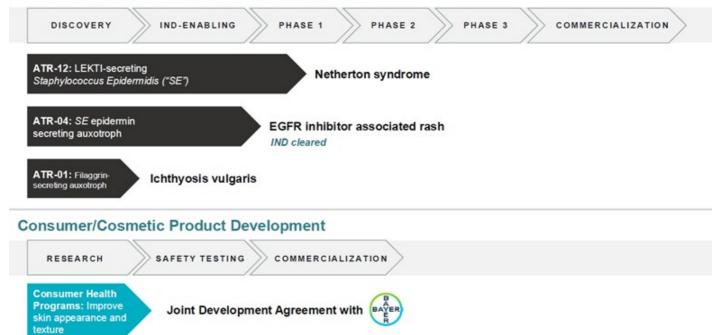
We focus on developing innovative therapies for precision dermatology using engineered proteins and topical live biotherapeutic products. We have built a proprietary platform that includes a microbial library comprised of approximately 1,500 unique bacterial strains that can be screened for unique therapeutic characteristics. The platform is augmented by an artificial intelligence and machine learning technology that analyzes, predicts and helps screen our library of strains for drug like molecules. The platform also utilizes a licensed genetic engineering technology, which can enable the transformation of previously genetically intractable strains. Our initial focus is on the development of genetically engineered strains of *Staphylococcus epidermidis, or S. epidermidis,* which we consider to be an optimal therapeutic candidate species for engineering of dermatologic therapies. The particular species demonstrates a number of well-described properties in the skin. As of the date of this report, we have identified among our microbial library over 60 distinct bacterial species that we believe are capable of being engineered to create living organisms or engineered proteins with significant therapeutic effect.

We are a pioneer in genetically engineered bacteria for therapeutic use in dermatology. Our goal is to leverage our platforms and internal microbial library bacterial strains to create new therapeutics that are either engineered living organisms or engineered proteins or peptides to treat skin diseases. Our initial focus is on the development of our current product candidates, including:

- ATR-12, a genetically modified strain of *S. epidermidis* for treating the orphan disease, Netherton syndrome, a chronic and sometimes fatal disease of the skin estimated to affect approximately one in every 100,000, but its prevalence may be underestimated due to misdiagnosis caused by similarities to other skin diseases. We received Pediatric Rare Disease Designation for ATR-12 by the United States Food and Drug Administration, or FDA, in 2019. In December 2022, we submitted an investigational new drug application, or IND, for a Phase 1b clinical trial of ATR-12 in Netherton syndrome patients, and on January 27, 2023 we received notification from the FDA that the "study may proceed" with respect to the proposed Phase 1b clinical trial. After submitting post-IND manufacturing reports, we have commenced operating activities for our Phase 1b clinical trial in December 2023, and we dosed our first patient in August 2024. We expect to report initial clinical safety results in the first half of 2025.
- ATR-04, a genetically modified strain of *S. epidermidis* for treating the papulopustular rash experienced by cancer patients undergoing epidermal growth factor receptor inhibitor, or EGFRi, targeted therapy. In August 2024, we obtained IND clearance from the FDA to commence a Phase 1/2 clinical trial in certain cancer patients undergoing EGFRi targeted therapy. In September 2024, we obtained Fast Track designation by the FDA in this indication. We expect to commence our Phase 1b clinical trial in the fourth quarter of 2024 and dose the first patient in the first half of 2025.

- ATR-01, a genetically modified strain of S. epidermidis that expresses an engineered recombinant human filaggrin protein for treating ichthyosis vulgaris, a chronic, xerotic (abnormally dry), scaly skin disease with an estimated incidence and prevalence of 1 in 250, which suggests a total patient population of 1.3 million in the United States. We are planning to perform lead optimization and IND-enabling studies in 2025 to support an IND filing targeted for early 2026.
- Two separate strains of bacterial microbes being investigated and developed by us and Bayer Consumer Care AG, the consumer products division of Bayer AG, or Bayer, the international life science company. We entered into a Joint Development Agreement, or JDA, with Bayer in December 2019. Under the terms of the JDA, we are responsible for testing our library of bacterial strains and their natural products for key preclinical properties. After screening through hundreds of strains, we and Bayer have selected two particular strains to move forward into further development. Bayer holds the exclusive option to license the patent rights to these strains. In December 2020, Bayer purchased \$8 million of our Series B preferred stock, which converted into 48,324 shares of our common stock.

# FDA-regulated candidates for drug development



We also have established partnerships with teams from Carnegie Mellon University and the Fred Hutchinson Cancer Center, or Fred Hutch, two of the premier academic centers in the United States. Our collaboration with the Carnegie Mellon based team also takes advantage of the power of whole genome sequencing. This partnership is mining our proprietary library of bacterial strains for novel, drug like peptides and proteins. The artificial intelligence/machine learning technology developed by this team predicts the molecules made by microbes from their genetic sequences. The system then compares the predictions to the products actually made through tandem mass spectroscopy and/or nuclear magnetic resonance imaging to refine future predictions. The predictions can be compared to publicly available 2D and 3D protein databases to select drug like structures.

We hold an exclusive, worldwide license from Fred Hutch regarding the use of its patented SyngenicDNA Minicircle Plasmid, or SyMPL, technologies for all fields of genetic engineering, including to discover, develop and commercialize engineered microbial therapies and microbial-derived peptides and proteins for skin diseases. We are utilizing our licensed patent rights to build plasmids in order to make genetic transformations that have never been previously achieved. To date, our team has successfully engineered our lead therapeutic candidates without the SyMPL technology. However, we believe that SyMPL will open up the ability to make genetic transformations of an expanded universe of microbial species, and we expect that some or all of our future product candidates will incorporate the SyMPL technology.

We own U.S. and foreign registered trademarks, including our company name. All other trademarks or trade names referred to in this prospectus are the property of their respective owners. Solely for convenience, the trademarks and trade names in this prospectus are referred to without the symbols  $\mathbb{R}$  and TM, but such references should not be construed as any indication that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto.

# Implications of Being an Emerging Growth Company

The Jumpstart Our Business Startups Act, or the JOBS Act, was enacted in April 2012 with the intention of encouraging capital formation in the United States and reducing the regulatory burden on newly public companies that qualify as "emerging growth companies." We are an emerging growth company within the meaning of the JOBS Act. As an emerging growth company, we may take advantage of certain exemptions from various public reporting requirements, including:

- the requirement that our internal control over financial reporting be attested to by our independent registered public accounting firm pursuant to Section 404 of the Sarbanes-Oxley Act of 2002;
- certain requirements related to the disclosure of executive compensation in this prospectus and in our periodic reports and proxy statements;
- the requirement that we hold a nonbinding advisory vote on executive compensation and any golden parachute payments; and
- the ability to delay compliance with new or revised financial accounting standards until private companies are required to comply with the new or revised financial accounting standard.

We may take advantage of the exemptions under the JOBS Act discussed above until we are no longer an emerging growth company. We will remain an emerging growth company until the earliest to occur of (1) the last day of the fiscal year in which we have \$1.235 billion or more in annual revenue; (2) the date we qualify as a "large accelerated filer," with at least \$700 million of equity securities held by non-affiliates; (3) the date on which we have issued, in any three-year period, more than \$1.0 billion in non-convertible debt securities; or (4) the last day of the fiscal year ending after the fifth anniversary of our initial public offering.

We may choose to take advantage of some, but not all, of the available benefits under the JOBS Act. We have chosen to take advantage of all of the other exemptions discussed above. Accordingly, the information contained herein and in our subsequent filing with the SEC may be different than the information you receive from other public companies in which you hold stock.

## **Implications of Being a Smaller Reporting Company**

Additionally, we are a "smaller reporting company" as defined in Rule 10(f)(1) of Regulation S-K. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited financial statements. We will remain a smaller reporting company until the last day of the fiscal year in which (1) the market value of our common stock held by non-affiliates equals or exceeds \$250 million as of the end of that year's second fiscal quarter, or (2) our annual revenues equaled or exceeded \$100 million during such completed fiscal year and the market value of our common stock held by non-affiliates equals or exceeds \$700 million as of the end of that year's second fiscal quarter.

#### **Corporate Information**

We were incorporated under the laws of the state of Delaware on January 2, 2014. Our principal executive offices are located at 21 Business Park Drive, Branford, Connecticut 06405, and our telephone number is (203) 646-6446. Our website address is www.azitrainc.com. The information contained in, or accessible through, our website is not incorporated by reference into this prospectus, and you should not consider any information contained in, or that can be accessed through, our website as part of this prospectus or in deciding whether to purchase our common stock.



# THE OFFERING

Issuer:	Azitra, Inc.
Shares offered by us:	shares of our common stock
Pre-Funded Warrants offered by us:	We are also offering to each purchaser whose purchase of common stock in this offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% of our outstanding common stock immediately following the consummation of this offering, to purchase Pre-Funded Warrants to purchase shares of our common stock. Subject to limited exceptions, a holder of Pre-Funded Warrants will not have the right to exercise any portion of its Pre-Funded Warrants if the holder, together with its affiliates, would beneficially own in excess of 4.99% (or, at the election of the holder, 9.99%) of the number of shares of common stock outstanding immediately after giving effect to such exercise.
	The purchase price of each Pre-funded Warrant is equal to the price per share of common stock being sold to the public in this offering, minus \$0.0001. The Pre-Funded Warrants are immediately exercisable and may be exercised at any time until all of the Pre-funded Warrants are exercised in full. This prospectus supplement also relates to the offering of common stock issuable upon exercise of the Pre-Funded Warrants.
Public offering price:	<pre>\$ per share of common stock; \$ per Pre-Funded Warrant.</pre>
Shares of common stock outstanding after the offering:	shares, assuming full exercise of the Pre-Funded Warrants.
Use of proceeds:	We expect the net proceeds from this offering will be approximately \$, after deducting placement agent fees and commissions and estimated offering expenses payable by us. We expect to use the net proceeds from this offering for working capital and general corporate purposes. See <i>"Use of Proceeds."</i>
NYSE American	Our common stock is listed on the NYSE American under the symbol "AZTR."
listing:	We do not intend to list the Pre-Funded Warrants on any securities exchange or nationally recognized trading system. Without an active trading market, the liquidity of the Pre-Funded Warrants will be limited.
Risk factors:	Investing in our common stock involves a high degree of risk and purchasers of our common stock may lose their entire investment. See " <i>Risk Factors</i> " and the other information included and incorporated by reference into this prospectus supplement and the accompanying prospectus for a discussion of risk factors you should carefully consider before deciding to invest in our common stock.

The number of shares of our common stock to be outstanding after this offering is based on approximately 7,626,056 shares of common stock outstanding as of January 14, 2025, and excludes:

- 41,608 shares of our common stock issuable upon exercise of outstanding options, with a weighted average exercise price of \$41.60 per share, granted pursuant to our 2016 Stock Incentive Plan (the "2016 Plan"), and our 2023 Stock Incentive Plan (the "2023 Plan");
- approximately 13,628,614 shares of our common stock issuable upon exercise of outstanding warrants, with a weighted average exercise price of \$0.85 per share; and
- 7,457 shares of our common stock reserved for future grants under our 2016 Plan and 1,209,735 shares of our common stock reserved for future grants under our 2023 Plan.

#### **RISK FACTORS**

Any investment in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below and all of the information contained or incorporated by reference into this prospectus supplement and the accompanying prospectus before deciding whether to purchase our common stock, including the risk factors contained herein and in the accompanying prospectus, as well as those in our periodic reports filed with the SEC incorporated by reference in this prospectus supplement and the accompanying prospectus, including those set forth in Item 1A to our Annual Report on Form 10-K for the fiscal year ended December 31, 2023, which is incorporated herein by reference. If any of these risks actually occurs, our business, financial condition, liquidity, and results of operations would suffer. The risks discussed below also include forward-looking statements and our actual results may differ substantially from those discussed in these forward-looking statements. See the information under the heading "Note Regarding Forward-Looking Statements" in this prospectus supplement.

## **Risks Relating to This Offering**

### As an investor, you may lose all of your investment.

Investing in our securities involves a high degree of risk. As an investor, you may never recoup all, or even part, of your investment and you may never realize any return on your investment. You must be prepared to lose all of your investment.

# We expect we will need additional financing to execute our business plan and fund operations, which additional financing may not be available on reasonable terms or at all.

As of September 30, 2024, we had total assets of \$9.8 million and working capital of \$6.3 million. We believe that net proceeds of this offering, along with our cash on hand as of the date of this prospectus supplement, will not be sufficient to cover our proposed plan of operations over, at least, the next 12 months. We intend to seek additional funds through various financing sources, including the sale of our equity, licensing fees for our technology and joint ventures with industry partners. In addition, we will consider alternatives to our current business plan that may enable to us to achieve revenue producing operations and meaningful commercial success with a smaller amount of capital. However, there can be no guarantees that such funds will be available on commercially reasonable terms, if at all. If such financing is not available on satisfactory terms, we may be unable to further pursue our business plan and we may be unable to continue operations, in which case you may lose your entire investment.

# Because we will have broad discretion and flexibility in how the net proceeds from this offering are used, we may use the net proceeds in ways in which you disagree.

We intend to use the net proceeds from this offering for working capital and general corporate purposes. See "Use of Proceeds" for additional information. Accordingly, our management will have significant discretion and flexibility in applying the net proceeds of this offering. You will be relying on the judgment of our management with regard to the use of these net proceeds, and you will not have the opportunity, as part of your investment decision, to assess whether the net proceeds are being used appropriately. It is possible that the net proceeds will be invested in a way that does not yield a favorable, or any, return for us. The failure of our management to use such funds effectively could have a material adverse effect on our business, financial condition, operating results, and cash flow.

#### The offering price will be set by our board of directors and does not necessarily indicate the actual or market value of our common stock.

Our board of directors will approve the offering price and other terms of this offering after considering, among other things: the number of shares authorized in our certificate of incorporation, as amended and restated (our "certificate of incorporation"); the current market price of our common stock; trading prices of our common stock over time; the volatility of our common stock; our current financial condition and the prospects for our future cash flows; the availability of and likely cost of capital of other potential sources of capital; the characteristics of interested investors and market and economic conditions at the time of the offering. The offering price is not intended to bear any relationship to the book value of our assets or our past operations, cash flows, losses, financial condition, net worth, or any other established criteria used to value securities. The offering price may not be indicative of the fair value of the common stock.

#### The market price of our shares may be subject to fluctuation and volatility. You could lose all or part of your investment.

The market price of our common stock is subject to wide fluctuations in response to various factors, some of which are beyond our control. Since shares of our common stock were sold in our initial public offering ("IPO") in June 2023 at a price of \$150.00 per share, the reported high and low sales prices of our common stock have ranged from \$155.40 to \$0.4920 through September 30, 2024. The market price of our shares on the NYSE American may fluctuate as a result of a number of factors, some of which are beyond our control, including, but not limited to:

- actual or anticipated variations in our and our competitors' results of operations and financial condition;
- changes in earnings estimates or recommendations by securities analysts, if our shares are covered by analysts;
- market acceptance of our product candidates;
- development of technological innovations or new competitive products by others;
- announcements of technological innovations or new products by us;
- publication of the results of preclinical or clinical trials for our product candidates;
- failure by us to achieve a publicly announced milestone;
- delays between our expenditures to develop and market new or enhanced products and the generation of sales from those products;
- developments concerning intellectual property rights, including our involvement in litigation brought by or against us;
- regulatory developments and the decisions of regulatory authorities as to the approval or rejection of new or modified products;
- changes in the amounts that we spend to develop, acquire or license new products, technologies or businesses;
- changes in our expenditures to promote our product candidates;
- our sale or proposed sale, or the sale by our significant stockholders, of our shares or other securities in the future;
- changes in key personnel;
- success or failure of our research and development projects or those of our competitors;
- the trading volume of our shares; and
- general economic and market conditions and other factors, including factors unrelated to our operating performance.

These factors and any corresponding price fluctuations may materially and adversely affect the market price of our shares and result in substantial losses being incurred by our investors. In the past, following periods of market volatility, public company stockholders have often instituted securities class action litigation. If we were involved in securities litigation, it could impose a substantial cost upon us and divert the resources and attention of our management from our business.

### This offering may cause the trading price of our shares of common stock to decrease.

The price per share, together with the number of shares of common stock that we propose to issue and ultimately will issue if this offering is completed, may result in an immediate decrease in the market price of our shares. This decrease may continue after the completion of this offering.

# Resales of our shares of common stock in the public market by our stockholders as a result of this offering may cause the market price of our shares of common stock to fall.

Sales of substantial amounts of our shares of common stock in the public market, or the perception that such sales might occur, could adversely affect the market price of our shares of common stock. The issuance of new shares of common stock could result in resales of our shares of common stock by our current shareholders concerned about the potential ownership dilution of their holdings. Furthermore, in the future, we may issue additional shares of common stock or other equity or debt securities exercisable or convertible into shares of common stock. Any such issuance could result in substantial dilution to our existing shareholders and could cause our stock price to decline.

# If you purchase our securities in this offering, you may experience future dilution as a result of future equity offerings or other equity issuances.

In order to raise additional capital, we believe that we will offer and issue additional shares of our common stock or other securities convertible into or exchangeable for our common stock in the future. We are generally not restricted from issuing additional securities, including shares of common stock, securities that are convertible into or exchangeable for, or that represent the right to receive, common stock or substantially similar securities. The issuance of securities in future offerings may cause dilution to our stockholders, including investors in this offering. We cannot assure you that we will be able to sell shares or other securities in any other offering at a price per share that is equal to or greater than the price per share paid by investors in this offering, and investors purchasing other securities convertible into or exchangeable for our common stock in future transactions may be higher or lower than the price per share in this offering. Further, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

# Purchasers who purchase our securities in this offering pursuant to a securities purchase agreement may have rights not available to purchasers that purchase without the benefit of a securities purchase agreement.

In addition to rights and remedies available to all purchasers in this offering under federal securities and state law, the purchasers that enter into a securities purchase agreement will also be able to bring claims of breach of contract against us. The ability to pursue a claim for breach of contract provides those investors with the means to enforce the covenants uniquely available to them under the securities purchase agreement including, but not limited to (i) timely delivery of securities, (ii) agreement to not issue any shares or securities convertible into shares for a period of days from closing of the offering, subject to certain exceptions and (iii) indemnification for breach of contract.

#### Our failure to meet the continued listing requirements of the NYSE American could result in a delisting of our common stock.

If we fail to satisfy the continued listing requirements of the NYSE American, such as the corporate governance requirements or the minimum closing bid price requirement, the NYSE American may take steps to delist our common stock. Such a delisting would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the NYSE American's minimum bid price requirement or prevent future non-compliance with the NYSE American's listing requirements.

#### You may experience immediate and substantial dilution in the book value per share of the common stock you purchase.

Because the public offering price per share in this offering may be substantially higher than the book value per share of our common stock, you may suffer immediate and substantial dilution in the net tangible book value of the common stock you purchase in this offering. After giving effect to the sale in this offering of our common stock at an offering price of \$ per share, and after deducting placement agent fees and estimated expenses payable by us, our as adjusted net tangible book deficit as of September 30, 2024 would have been approximately \$ , or \$ per share of our common stock. This represents an immediate increase in the net tangible book value of \$ per share to our existing stockholders and an immediate and substantial dilution in as-adjusted net tangible book value of \$ per share to new investors who purchase securities in the offering. See "*Dilution*" for a more detailed discussion of the dilution you may incur in connection with this offering.

## Future capital raises may dilute your ownership and/or have other adverse effects on our operations.

If we raise additional capital by issuing equity securities, our existing stockholders' percentage ownership will be reduced, and these stockholders may experience substantial dilution. If we raise additional funds by issuing debt securities, these debt securities would have rights senior to those of our common stock and the terms of the debt securities issued could impose significant restrictions on our operations, including liens on our assets. If we raise additional funds through collaborations and licensing arrangements, we may be required to relinquish some rights to our intellectual property or candidate products, or to grant licenses on terms that are not favorable to us.

#### We have not paid dividends on our common stock in the past and have no immediate plans to pay such dividends.

We plan to reinvest all of our earnings, to the extent we have earnings, to cover operating costs and otherwise become and remain competitive. We do not plan to pay any cash dividends with respect to our common stock in the foreseeable future. We cannot assure you that we would, at any time, generate sufficient surplus cash that would be available for distribution to the holders of our common stock as a dividend. Therefore, you should not expect to receive cash dividends on the common stock we are offering.

# If equity research analysts do not publish research or reports about our business or if they issue unfavorable commentary or downgrade our shares, the price of our shares could decline.

The trading market for our shares will rely in part on the research and reports that equity research analysts publish about us and our business, if at all. We do not have control over these analysts, and we do not have commitments from them to write research reports about us. The price of our shares could decline if no research reports are published about us or our business, or if one or more equity research analysts downgrades our shares or if those analysts issue other unfavorable commentary or cease publishing reports about us or our business.

#### There is no public market for the Pre-Funded Warrants being offered by us in this offering.

There is no established public trading market for the Pre-Funded Warrants offered in this offering, and we do not expect a market to develop. In addition, we do not intend to apply to list the Pre-Funded Warrants on any national securities exchange or other nationally recognized trading system. Without an active market, the liquidity of the pre-funded warrants will be limited.

#### The Pre-Funded Warrants are speculative in nature.

Except as otherwise provided in the Pre-Funded Warrants, until holders of Pre-Funded Warrants acquire our common stock upon exercise of the Pre-Funded Warrants, holders of Pre-Funded Warrants will have no rights with respect to our common stock underlying such Pre-Funded Warrants. Upon exercise of the Pre-Funded Warrants, the holders will be entitled to exercise the rights of a stockholder of our common stock only as to matters for which the record date occurs after the exercise date.

Moreover, following this offering, the market value of the Pre-Funded Warrants is uncertain. There can be no assurance that the market price of our common stock will ever equal or exceed the price of the Pre-Funded Warrants, and, consequently, whether it will ever be profitable for investors to exercise their Pre-Funded Warrants.

# We will not receive any meaningful amount of additional funds upon the exercise of the Pre-Funded Warrants.

Each Pre-Funded Warrant will be exercisable until it is fully exercised and by means of payment of the nominal cash purchase price upon exercise, or \$ cash purchase price upon exercise, respectively, or through a "cashless exercise" procedure. Accordingly, we will not, in case of the Pre-Funded Warrants, receive any meaningful additional funds upon the exercise of the Pre-Funded Warrants.



#### **USE OF PROCEEDS**

We estimate the net proceeds from this offering will be approximately \$, based on the offering price of \$ per share, after deducting placement agent fees and commissions and estimated offering expenses payable by us. We expect to use the net proceeds from this offering for working capital and general corporate purposes.

Our management will have broad discretion to allocate the net proceeds to us from this offering, and investors will be relying on the judgment of our management regarding the application of the proceeds from this offering. We reserve the right to change the use of these proceeds as a result of certain contingencies such as competitive developments, the results of our marketing efforts, and other factors. An investor will not have the opportunity to evaluate the economic, financial, or other information on which we base our decisions on how to use the proceeds.

# CAPITALIZATION

The following table sets forth our cash and capitalization as of September 30, 2024:

- on an actual basis; and
- on an adjusted basis, after giving effect to the sale of the shares in this offering at a public offering price of \$ per share, after placement agent fees
  and commissions and estimated offering expenses.

The information in this table is illustrative only, and our capitalization following the closing of the offering will be adjusted based upon the actual public offering price and other terms of this offering determined at pricing.

	As of September 30, 2024			, 2024
	Unaudited,			Unaudited,
(in thousands, except share and per share values)		Actual		As Adjusted
Cash and cash equivalents	\$	7,260	\$	
Stockholders' Equity:				
Common stock, par value \$0.0001 per share; 100,000,000 shares authorized, actual, and as				
adjusted; 7,626,056 shares issued and outstanding actual; shares issued and outstanding				
actual, as adjusted				
Additional paid-in capital	\$	63,230		
Accumulated deficit	\$	(55,173)		
Total Stockholders' Equity	\$	8,058	\$	
Total Capitalization	\$	8,058	\$	-

The above discussion and table are based on approximately 7,626,056 shares of common stock outstanding as of September 30, 2024, and excludes:

- 41,608 shares of our common stock issuable upon exercise of outstanding options, with a weighted average exercise price of \$41.60 per share, granted pursuant to our 2016 Stock Incentive Plan (the "2016 Plan"), and our 2023 Stock Incentive Plan (the "2023 Plan");
- Approximately 13,628,614 shares of our common stock issuable upon exercise of outstanding warrants, with a weighted average exercise price of \$0.85 per share; and
- 7,457 shares of our common stock reserved for future grants under our 2016 Plan and 1,209,735 shares of our common stock reserved for future grants under our 2023 Plan.

## DILUTION

If you purchase Securities in this offering, your interest will be immediately and substantially diluted to the extent of the difference between the public offering price per share of our common stock (or Pre-Funded Warrants) and the as adjusted net tangible book value per share of our common stock after giving effect to this offering.

Our net tangible book value as of September 30, 2024, was approximately \$7.2 million, or approximately \$0.95 per share. Net tangible book value is determined by subtracting our total liabilities from our total tangible assets, and net tangible book value per share is determined by dividing our net tangible book value by the number of outstanding shares of our common stock. After giving effect to the sale of shares of our common stock in this offering at the public offering price of \$ per share and Pre-Funded Warrants exercisable for shares of common stock at an offering price of \$ per Pre-Funded Warrant, and after deducting the placement agent fees and commissions, and estimated offering expenses payable by us and assuming the exercise of all Pre-Funded Warrants, our adjusted net tangible book value as of September 30, 2024, would have been approximately \$ , or approximately \$ per share. This represents an immediate increase in net tangible book value of approximately \$ per share to investors participating in this offering. The following table illustrates this calculation on a per share basis:

Public offering price per share of common stock or Pre-Funded Warrant	\$
Net tangible book value per share as of September 30, 2024	\$ 0.95
Increase in net tangible book value per share attributable to this offering	\$
Adjusted net tangible book value per share after this offering	\$
Amount of dilution in net tangible book value per share to new investors in this offering	\$

The above discussion and table are based on approximately 7,626,056 shares of common stock outstanding as of September 30, 2024, and excludes:

- 41,608 shares of our common stock issuable upon exercise of outstanding options, with a weighted average exercise price of \$41.60 per share, granted pursuant to our 2016 Stock Incentive Plan (the "2016 Plan"), and our 2023 Stock Incentive Plan (the "2023 Plan");
- approximately 13,628,614 shares of our common stock issuable upon exercise of outstanding warrants, with a weighted average exercise price of \$0.85 per share; and
- 7,457 shares of our common stock reserved for future grants under our 2016 Plan and 1,209,735 shares of our common stock reserved for future grants under our 2023 Plan.

#### **DESCRIPTION OF SECURITIES**

The following description of our Securities is only a summary. This description is subject to, and qualified in its entirety by reference to, our certificate of incorporation and bylaws, as amended and restated (the "bylaws"), each of which has previously been filed with the SEC, and the Delaware General Corporation Law ("DGCL").

### **Common Stock**

Our authorized capital stock includes 100,000,000 shares of common stock, par value \$0.0001 per share. As of December 31, 2024, there were 7,626,056 shares of common stock issued and outstanding and no shares of common stock held in the treasury. The following description of the rights of the common stock.

Subject to preferences that may apply to preferred shares outstanding at the time, the holders of outstanding common stock are entitled to receive dividends out of assets legally available therefor at such times and in such amounts as our board of directors may from time to time determine. Each stockholder is entitled to one vote for each share of common stock held on all matters submitted to a vote of stockholders. Directors are elected by plurality vote. Therefore, the holders of a majority of the common stock votes can elect all of the directors then standing for election. The common stock is not entitled to preemptive rights and are not subject to conversion. If we are liquidated or dissolved or our business is otherwise wound up, the holders of common stock would be entitled to share ratably in the distribution of all of our assets remaining available for distribution after satisfaction of all our liabilities and the payment of the liquidation preference of any outstanding preferred shares. Each outstanding share of common stock is, and all shares of common stock to be outstanding upon completion of this offering, will be, fully paid and non-assessable.

#### Authorized but Unissued Common Stock

The DGCL does not require stockholder approval for any issuance of authorized shares, except in certain limited circumstances. However, the listing requirements of the NYSE American, which would apply for so long as our common stock is listed on the NYSE American, require stockholder approval of certain issuances (other than a public offering) equal to or exceeding 20% of the then outstanding voting power or then outstanding number of shares of common stock, as well as for certain issuances of stock in compensatory transactions. These additional shares may be used for a variety of corporate purposes, including future public offerings, to raise additional capital or to facilitate acquisitions. One of the effects of the existence of unissued and unreserved shares of common stock may be to enable our Board of Directors to sell shares to persons friendly to current management, for such consideration, in form and amount, as is acceptable to the Board, which issuance could render more difficult or discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise, and thereby protect the continuity of our management and possibly deprive stockholders of opportunities to sell their common stock at prices higher than prevailing market prices.

#### Dividends

We have not declared or paid any cash dividends on our common stock, and we do not anticipate declaring or paying cash dividends for the foreseeable future. We are not subject to any legal restrictions respecting the payment of dividends, except that we may not pay dividends if the payment would render us insolvent. Any future determination as to the payment of cash dividends on our common stock will be at our board of directors' discretion and will depend on our financial condition, operating results, capital requirements and other factors that our board of directors considers to be relevant. Currently, the board of directors does not intend to pay any cash dividends but retain all funds for working capital.

#### **Transfer Agent and Registrar**

The transfer agent and registrar for our common stock is VStock Transfer, LLC. The transfer agent and registrar's address is 18 Lafayette Place, Woodmere, New York 11598.

#### **Pre-Funded Warrants**

The following summary of certain terms and provisions of the Pre-Funded Warrants that are being offered hereby is not complete and is subject to, and qualified in its entirety by, the provisions of the Pre-Funded Warrant, the form of which will be filed as an exhibit to a Current Report on Form 8-K in connection with this offering and incorporated by reference into the registration statement of which this prospectus supplement forms a part. Prospective investors should carefully review the terms and provisions of the form of Pre-Funded Warrant for a complete description of the terms and conditions of the Pre-Funded Warrants.

Pre-Funded Warrants will be issued in certificated form only.

## Duration and Exercise Price

Each Pre-Funded Warrant offered hereby has an initial exercise price per share equal to \$0.0001. The Pre-Funded Warrants are immediately exercisable and have an indefinite term. The exercise price and number of shares of common stock issuable upon exercise is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock and the exercise price.

#### Exercisability

The Pre-Funded Warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). A holder (together with its affiliates) may not exercise any portion of such holder's Pre-Funded Warrants to the extent that the holder would own more than 9.99% (or, at the election of the purchaser, 4.99%) of the outstanding shares of common stock immediately after exercise, except that upon prior notice from the holder to us, the holder may increase the amount of ownership of outstanding shares of common stock after exercise, as such percentage ownership is determined in accordance with the terms of the Pre-Funded Warrants. No fractional shares of common stock will be issued in connection with the exercise of a Pre-Funded Warrant. In lieu of fractional shares, we will either pay the holder an amount in cash equal to the fractional amount multiplied by the exercise price or round up to the next whole share.

#### Cashless Exercise

The Pre-Funded Warrants may be exercised, in whole or in part, by means of cashless exercise. In lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the Pre-Funded Warrants.

#### Fundamental Transaction

In the event of any fundamental transaction, as described in the Pre-Funded Warrants and generally including any merger with or into another entity, sale of all or substantially all of our assets, tender offer or exchange offer, or reclassification of our shares of common stock, upon any subsequent exercise of a Pre-Funded Warrant, the holder will have the right to receive as alternative consideration, for each share of common stock that would have been issuable upon such exercise immediately prior to the occurrence of such fundamental transaction, the number of shares of common stock of the successor or acquiring corporation of our company, if it is the surviving corporation, and any additional consideration receivable upon or as a result of such transaction by a holder of the number of shares of common stock for which the Pre-Funded Warrant is exercisable immediately prior to such event.

#### Transferability

Subject to applicable laws, a Pre-Funded Warrant or the rights thereunder may be transferred or assigned, in whole or in part. The ownership of the Pre-Funded Warrants and any transfers of the Pre-Funded Warrants will be registered in a warrant register maintained by the warrant agent. We will initially act as warrant agent.

# Exchange Listing

There is no trading market available for the Pre-Funded Warrants on any securities exchange or nationally recognized trading system. We do not intend to list the Pre-Funded Warrants on any securities exchange or nationally recognized trading system.

#### Right as a stockholder

Except as otherwise provided in the Pre-Funded Warrants or by virtue of such holder's ownership of shares of our common stock, the holders of the Pre-Funded Warrants do not have the rights or privileges of holders of our common stock, including any voting rights, until they exercise their Pre-Funded Warrants.

#### PLAN OF DISTRIBUTION

Investors purchasing securities offered hereby will have the option to execute a securities purchase agreement with us. In addition to the rights and remedies available to all investors in this offering under federal and state securities laws, the investors which enter into a securities purchase agreement will also be able to bring claims of breach of contract against us. Investors who do not enter into a securities purchase agreement shall rely solely on this prospectus in connection with the purchase of our securities in this offering.

Maxim Group LLC has agreed to act as the exclusive placement agent in connection with this offering. The placement agent is not purchasing or selling any of the shares of our common stock offered by this prospectus supplement but will use their best efforts to arrange for the sale of the Securities offered by this prospectus supplement.

# Fees and Expenses

We have agreed to pay the placement agent an aggregate placement agent fee of up to \$, which represents 7.0% of the aggregate purchase price of the shares of our common stock sold in this offering. The following table shows the per share and total cash placement agent fees we will pay to the placement agent in connection with the sale of the shares of our common stock offered pursuant to this prospectus supplement and the accompanying prospectus.

	Per Pre-Funded		
	Per Share	Warrant	Total
Offering price	\$	\$	\$
Placement agent fees <sup>(1)</sup>	\$	\$	\$
Proceeds to us, before expenses	\$	\$	\$

(1) In addition, subject to compliance with FINRA Rule 5110(f)(2)(D), we have agreed to reimburse the placement agent for all reasonable travel and other necessary out-of-pocket expenses of third parties incurred directly in connection with the placement agency agreement, including the placement agent's legal fees in an amount equal to \$60,000.

#### **Placement Agent Warrants**

We have agreed to issue to the placement agent, or its designees, warrants to purchase shares of our common stock in an amount equal to 4.0% of the aggregate number of shares of common stock (or Pre-Funded Warrants in lieu thereof) sold in this offering (the "Placement Agent's Warrants"). The Placement Agent's Warrants will be exercisable at a per share exercise price of \$ , equal to 125% of the public offering price per share in this offering. The Placement Agent's Warrants are exercisable at any time, from time to time, in whole or in part, during the four and one half year period commencing 180 days from the commencement of sales of the securities in this offering.

The Placement Agent's Warrants and the shares of common stock underlying the Placement Agent's Warrants have been deemed compensation by the Financial Industry Regulatory Authority ("FINRA") and are, therefore, subject to a 180-day lock-up pursuant to FINRA Rule 5110(e)(1) except as permitted under FINRA Rule 5110(e)(2). The Placement Agent's Warrants and the securities underlying the Placement Agent's Warrants may not be sold, transferred, assigned, pledged, or hypothecated, nor may they be the subject of any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of the Placement Agent's Warrants or the underlying shares of common stock for a period of 180 days from the commencement of sales in this offering. The Placement Agent's Warrants will provide for cashless exercise and for registration rights (including a one-time demand registration right and unlimited piggyback rights) consistent with FINRA Rule 5110(g)(8). The Placement Agent's Warrants will also provide for customary anti-dilution provisions (for stock dividends and splits and recapitalizations) consistent with FINRA Rule 5110.

#### **Determination of Offering Price**

The public offering price of the shares of common stock we are offering was negotiated between us and the investors, in consultation with the placement agent based on the trading of our common stock prior to the offering, among other things. Other factors considered in determining the public offering price of our common stock we are offering include the history and prospects of the Company, the stage of development of our business, our business plans for the future and the extent to which they have been implemented, an assessment of our management, general conditions of the securities markets at the time of the offering and such other factors as were deemed relevant.

#### Indemnification

We have agreed to indemnify the placement agent against certain liabilities, including liabilities under the Securities Act, and to contribute to payments that the placement agent may be required to make in respect of those liabilities.

The placement agent may be deemed to be an underwriter within the meaning of Section 2(a)(11) of the Securities Act, and any commissions received by it and any profit realized on the resale of the shares sold by it while acting as principal might be deemed to be underwriting discounts or commissions under the Securities Act. As an underwriter, the placement agent would be required to comply with the requirements of the Securities Act and the Exchange Act of 1934 (the "Exchange Act"), including, without limitation, Rule 415(a)(4) under the Securities Act and Rule 10b-5 and Regulation M under the Exchange Act. These rules and regulations may limit the timing of purchases and sales of shares by the placement agent acting as principal. Under these rules and regulations, the placement agent may not engage in any stabilization activity in connection with our securities; and may not bid for or purchase any of our securities or attempt to induce any person to purchase any of our securities, other than as permitted under the Exchange Act, until it has completed its participation in the distribution.

#### Lock-up Agreements

We have agreed to a lock-up that, subject to certain exceptions, prevents us from entering into any agreement to issue or announce the issuance or proposed issuance of any shares of common stock or securities convertible into, exchangeable for, exercisable for, or repayable with common stock or file any registration statement or amendment or supplement thereto for a period of days (the "lock-up period") after the closing date of this offering. In addition, subject to certain exceptions, we have agreed, for a period of days following the closing date of the offering, not to issue any securities that are subject to a price reset based on the trading price of our common stock or upon a specified or contingent event in the future, or enter into any agreement to issue securities at a future determined price, except that, following the expiration of the lock-up period, the forgoing limitation will not apply to an "at-the-market" offering facility.

The lock-up may be waived by the written consent of the Company, the placement agent, and a majority of the purchasers that execute a securities purchase agreement (representing at least 50.1% in interest of the shares of common stock (including shares underlying the Pre-Funded Warrants) based on the initial subscription amounts thereunder).

#### **Tail Financing Payments**

We have also agreed to pay the placement agent a tail fee equal to the compensation as disclosed herein on any proceeds received by us from any investor who was contacted by the placement agent during the term of its engagement, if such investor provides us with capital in any public or private offering or other financing or capital raising transaction for a period of six months after expiration or termination of the engagement with the placement agent.

#### **Regulation M**

The placement agent may be deemed to be an underwriter within the meaning of Section 2(a)(11) of the Securities Act, and any commissions received by it and any profit realized on the resale of the securities sold by it while acting as principal might be deemed to be underwriting discounts or commissions under the Securities Act. As an underwriter, the placement agent would be required to comply with the requirements of the Securities Act and the Exchange Act, including, without limitation, Rule 415(a)(4) under the Securities Act and Rule 10b-5 and Regulation M under the Exchange Act. These rules and regulations may limit the timing of purchases and sales of shares of common stock and warrants by the placement agent acting as principal. Under these rules and regulations, the placement agent:

- may not engage in any stabilization activity in connection with our securities; and
- may not bid for or purchase any of our securities or attempt to induce any person to purchase any of our securities, other than as permitted under the Exchange Act, until it has completed its participation in the distribution.

From time to time, Maxim may provide in the future various advisory, investment and commercial banking and other services to us in the ordinary course of business, for which they have received and may continue to receive customary fees and commissions. However, except as disclosed in this prospectus supplement, we have no present arrangements with Maxim for any further services.

#### **Electronic Distribution**

A prospectus supplement in electronic format may be made available on a website maintained by the placement agent. In connection with the offering, the placement agent or selected dealers may distribute prospectuses electronically. No forms of electronic prospectus supplements other than prospectuses supplements that are printable as Adobe® PDF will be used in connection with this offering.

Other than the prospectus supplement in electronic format, the information on each of the placement agent's websites and any information contained in any other website maintained by the placement agent is not part of the prospectus supplement or the registration statement of which this prospectus supplement forms a part, has not been approved and/or endorsed by us or either placement agent in its capacity as placement agent and should not be relied upon by investors.

#### **Certain Relationships**

The placement agent and its affiliates have and may in the future provide, from time to time, investment banking and financial advisory services to us in the ordinary course of business, for which they may receive customary fees and commissions.

#### Listing

Our Common Stock is listed for trading on the NYSE American under the symbol "AZTR."

#### **Selling Restrictions**

*Canada*. The securities may be sold in Canada only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the securities must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus supplement (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the placement agents are not required to comply with the disclosure requirements of NI 33-105 regarding placement agents conflicts of interest in connection with this offering.

*European Economic Area*. In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (each, a "Relevant Member State") an offer to the public of any securities may not be made in that Relevant Member State, except that an offer to the public in that Relevant Member State of any securities may be made at any time under the following exemptions under the Prospectus Directive, if they have been implemented in that Relevant Member State:

- to any legal entity which is a qualified investor as defined in the Prospectus Directive;
- to fewer than 100 or, if the Relevant Member State has implemented the relevant provision of the 2010 PD Amending Directive, 150, natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the representatives for any such offer; or
- in any other circumstances falling within Article 3(2) of the Prospectus Directive, provided that no such offer of securities shall result in a requirement for the publication by us or any placement agents of a prospectus pursuant to Article 3 of the Prospectus Directive.

For the purposes of this provision, the expression an "offer to the public" in relation to any securities in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and any securities to be offered so as to enable an investor to decide to purchase any securities, as the same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State, the expression "Prospectus Directive" means Directive 2003/71/EC (and amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member State), and includes any relevant implementing measure in the Relevant Member State, and the expression "2010 PD Amending Directive" means Directive 2010/73/EU.

*Israel.* This document does not constitute a prospectus under the Israeli Securities Law, 5728-1968, or the Securities Law, and has not been filed with or approved by the Israel Securities Authority. In the State of Israel, this document is being distributed only to, and is directed only at, and any offer of the shares is directed only at, investors listed in the first addendum, or the Addendum, to the Israeli Securities Law, consisting primarily of joint investment in trust funds, provident funds, insurance companies, banks, portfolio managers, investment advisors, members of the Tel Aviv Stock Exchange, placement agents, venture capital funds, entities with equity in excess of NIS 50 million and "qualified individuals", each as defined in the Addendum (as it may be amended from time to time), collectively referred to as qualified investors (in each case purchasing for their own account or, where permitted under the Addendum, for the accounts of their clients who are investors listed in the Addendum). Qualified investors will be required to submit written confirmation that they fall within the scope of the Addendum, are aware of the meaning of same and agree to it.

United Kingdom. Each placement agent has represented and agreed that:

- it has only communicated or caused to be communicated and will only communicate or cause to be communicated an invitation or inducement to engage in investment activity (within the meaning of Section 21 of the Financial Services and Markets Act 2000 (the FSMA) received by it in connection with the issue or sale of the securities in circumstances in which Section 21(1) of the FSMA does not apply to us; and
- it has complied and will comply with all applicable provisions of the FSMA with respect to anything done by it in relation to the securities in, from or otherwise involving the United Kingdom.

*Switzerland*. The securities may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange (the SIX) or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the securities or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, or the securities have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of securities will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA, and the offer of securities has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes (CISA). Accordingly, no public distribution, offering or advertising, as defined in CISA, its implementing ordinances and notices, and no distribution to any non-qualified investor, as defined in CISA, its implementing ordinances, shall be undertaken in or from Switzerland, and the investor protection afforded to acquirers of interests in collective investment schemes under CISA does not extend to acquirers of securities.

Australia. No placement document, prospectus, product disclosure statement or other disclosure document has been lodged with the Australian Securities and Investments Commission (ASIC), in relation to the offering.

This prospectus does not constitute a prospectus, product disclosure statement or other disclosure document under the Corporations Act 2001 (the Corporations Act) and does not purport to include the information required for a prospectus, product disclosure statement or other disclosure document under the Corporations Act.

Any offer in Australia of the securities may only be made to persons (the Exempt Investors) who are "sophisticated investors" (within the meaning of section 708(8) of the Corporations Act), "professional investors" (within the meaning of section 708(11) of the Corporations Act) or otherwise pursuant to one or more exemptions contained in section 708 of the Corporations Act so that it is lawful to offer the securities without disclosure to investors under Chapter 6D of the Corporations Act.

The securities applied for by Exempt Investors in Australia must not be offered for sale in Australia in the period of 12 months after the date of allotment under the offering, except in circumstances where disclosure to investors under Chapter 6D of the Corporations Act would not be required pursuant to an exemption under section 708 of the Corporations Act or otherwise or where the offer is pursuant to a disclosure document which complies with Chapter 6D of the Corporations Act. Any person acquiring securities must observe such Australian on-sale restrictions.

This prospectus contains general information only and does not take account of the investment objectives, financial situation, or particular needs of any particular person. It does not contain any securities recommendations or financial product advice. Before making an investment decision, investors need to consider whether the information in this prospectus is appropriate to their needs, objectives and circumstances, and, if necessary, seek expert advice on those matters.

*Notice to Prospective Investors in the Cayman Islands*. No invitation, whether directly or indirectly, may be made to the public in the Cayman Islands to subscribe for our securities.

*Taiwan*. The securities have not been and will not be registered with the Financial Supervisory Commission of Taiwan pursuant to relevant securities laws and regulations and may not be sold, issued or offered within Taiwan through a public offering or in circumstances which constitutes an offer within the meaning of the Securities and Exchange Act of Taiwan that requires a registration or approval of the Financial Supervisory Commission of Taiwan. No person or entity in Taiwan has been authorized to offer, sell, give advice regarding or otherwise intermediate the offering and sale of the securities in Taiwan.

*Notice to Prospective Investors in Hong Kong*. The contents of this prospectus have not been reviewed by any regulatory authority in Hong Kong. You are advised to exercise caution in relation to the offer. If you are in any doubt about any of the contents of this prospectus, you should obtain independent professional advice. Please note that (i) our shares may not be offered or sold in Hong Kong, by means of this prospectus or any document other than to "professional investors" within the meaning of Part I of Schedule 1 of the Securities and Futures Ordinance (Cap.571, Laws of Hong Kong) (SFO) and any rules made thereunder, or in other circumstances which do not result in the document being a "prospectus" within the meaning of the Companies Ordinance (Cap.32, Laws of Hong Kong) (CO) or which do not constitute an offer or invitation to the public for the purpose of the CO or the SFO, and (ii) no advertisement, invitation or document relating to our shares may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere) which is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to the shares which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" within the meaning of the SFO and any rules made thereunder.

Notice to Prospective Investors in the People's Republic of China. This prospectus may not be circulated or distributed in the PRC and the shares may not be offered or sold and will not offer or sell to any person for re-offering or resale directly or indirectly to any resident of the PRC except pursuant to applicable laws, rules and regulations of the PRC. For the purpose of this paragraph only, the PRC does not include Taiwan and the special administrative regions of Hong Kong and Macau.

#### LEGAL MATTERS

The validity of the securities offered by this prospectus supplement will be passed upon for us by Thompson Hine LLP, New York, New York. Ellenoff Grossman & Schole LLP, New York, New York is acting as counsel for the placement agent in connection with this offering.

# EXPERTS

The financial statements as of and for the fiscal years ended December 31, 2023, and 2022, incorporated by reference in this prospectus supplement have been so included in reliance on the report of Grassi & Co., CPAs, P.C., an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

## INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

The SEC permits us to "incorporate by reference" the information and reports we file with it. This means that we can disclose important information to you by referring to another document. The information that we incorporate by reference is considered to be part of this prospectus, and later information that we file with the SEC automatically updates and supersedes this information. We incorporate by reference the documents listed below, except to the extent information in those documents is different from the information contained in this prospectus, and all future documents filed with the SEC under Sections 13(a), 13(c), 14, or 15(d) of the Exchange Act (other than current reports furnished under Item 2.02 or Item 7.01 of Form 8-K and exhibits filed on such form that are related to such items unless such Form 8-K expressly provides to the contrary) until we terminate the offering of these securities:

- Our Annual Report on Form 10-K for the fiscal year ended December 31, 2023 filed with the SEC on March 15, 2024;
- Our Amendment No. 1 to our Annual Report on Form 10-K for the fiscal year ended December 31, 2023 filed with the SEC on April 29, 2024;
- Our Quarterly Reports on Form 10-Q for the fiscal quarter ended <u>March 31, 2024</u>, filed with the SEC on May 9, 2024, for the fiscal quarter ended <u>June 30, 2024</u>, filed with the SEC on <u>August 12, 2024</u>, and for the fiscal quarter ended September 30, 2024, filed with the SEC on November 12, 2024;
- Our Current Reports on Form 8-K filed with the SEC on February 14, 2024, July 3, 2024, July 26, 2024, and November 26, 2024; and
- The description of our common stock set forth in our registration statement on Form 8-A12B filed with the SEC on May 16, 2023.

To the extent that any statement in this prospectus is inconsistent with any statement that is incorporated by reference and that was made on or before the date of this prospectus, the statement in this prospectus shall supersede such incorporated statement and the incorporated statement shall not be deemed, except as modified or superseded, to constitute a part of this prospectus or the registration statement. Statements contained in this prospectus as to the contents of any contract or other document are not necessarily complete and, in each instance, we refer you to the copy of each contract or document filed as an exhibit to our various filings made with the SEC.

You may request a copy of these filings, at no cost, by writing or telephoning us at the following address or telephone number:

Azitra, Inc. 21 Business Park Drive, Branford, Connecticut 06405 Attention: Corporate Secretary Telephone: (203) 646-6446

#### WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly, and periodic reports, proxy statements, and other information with the SEC using the SEC's Electronic Data Gathering, Analysis, and Retrieval ("EDGAR") system. The SEC maintains a web site that contains reports, proxy and information statements, and other information about issuers, such as us, who file electronically with the SEC. The address of that website is www.sec.gov.

These filings are also available free of charge to the public on, or accessible through, our corporate website at www.azitrainc.com. Our website and the information contained on, or that can be accessed through, our website is not deemed to be incorporated by reference in, and is not considered part of, this prospectus. You should not rely on any such information in making your decision whether to purchase our common stock.

We have not authorized anyone to give you any information or to make any representations about us or the transactions we discuss in this prospectus other than those contained in this prospectus supplement. If you are given any information or representations about these matters that is not discussed in this prospectus supplement, you must not rely on that information. This prospectus supplement is not an offer to sell or a solicitation of an offer to buy securities anywhere or to anyone where or to whom we are not permitted to offer or sell securities under applicable law.

The information in this prospectus is not complete and may be changed without notice. We may not sell these securities until the registration statement relating to these securities has been declared effective by the Securities and Exchange Commission. This prospectus is neither an offer to sell nor a solicitation of an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

**SUBJECT TO COMPLETION, DATED JULY 1, 2024** 

# PROSPECTUS

# \$50,000,000

Azitra, Inc. Common Stock Preferred Stock Debt Securities Warrants Subscription Rights Units

#### 217,082 Shares of Common Stock Offered by Selling Stockholders

We may issue securities from time to time in one or more offerings of up to \$50,000,000 in aggregate offering price. This prospectus describes the general terms of these securities and the general manner in which these securities will be offered. We will provide the specific terms of these securities in supplements to this prospectus. The prospectus supplements will also describe the specific manner in which these securities will be offered and may also supplement, update or amend information contained in this document. You should read this prospectus and any applicable prospectus supplement before you invest. We may offer these securities in amounts, at prices and on terms determined at the time of offering. The securities may be sold directly to you, through agents, or through underwriters and dealers. If agents, underwriters or dealers are used to sell the securities, we will name them and describe their compensation in a prospectus supplement.

As of July 1, 2024, the aggregate market value of our outstanding common stock held by non-affiliates, or public float, was approximately \$2.38 million, based on approximately 960,154 shares of our common stock, of which approximately 255,599 shares were held by affiliates, and a price of \$3.38 per share, which was the price at which our common stock was last sold on the NYSE American on July 1, 2024. We have not offered or sold any shares of our common stock pursuant to General Instruction I.B.6 of Form S-3 during the prior 12-calendar-month period that ends on and includes the date of this prospectus. Pursuant to General Instruction I.B.6 of Form S-3, in no event will we sell securities registered on this registration statement in a public primary offering with a value exceeding more than one-third of our public float in any 12-month period so long as our public float remains below \$75 million.

In addition, this prospectus relates to the resale by the selling stockholders identified in this prospectus of up to an aggregate of 217,082 shares of common stock, par value \$0.0001 per share, of Azitra, Inc., consisting of (i) 211,470 shares of our common stock and (ii) 5,612 shares of our common stock issuable upon exercise of warrants issued in connection with our 2018 placement of our unsecured convertible promissory notes and our 2019 placement of Series A-1 convertible preferred shares. The selling stockholders or any of their pledges, donees, transferees or other successors-in-interests may offer to sell, from time to time, in amounts at prices and on terms determined at the time of the offering, up to 217,082 shares of our common stock under this prospectus. These sales may occur through ordinary brokerage transactions, directly to market makers of our shares or through any other means described in the section of this prospectus entitled "Plan of Distribution" beginning on page 16 or by any applicable prospectus supplement. We will not receive any proceeds from the sale of common stock by the selling stockholders, but we will incur expenses in connection with the sale of those shares. We and the selling stockholders may offer securities at the same time or in separate transactions.

Our common stock is listed on the NYSE American under the symbol "AZTR". On July 1, 2024, the last reported sale price of our common stock on the NYSE American was \$3.38 per share.

On July 1, 2024, we effected a reverse stock split at a ratio of 1-for-30. All share and share price information in this prospectus have been adjusted to give effect to the reverse stock split.

Investing in these securities involves significant risks. See "Risk Factors" included in any accompanying prospectus supplement and in the documents incorporated by reference in this prospectus for a discussion of the factors you should carefully consider before deciding to purchase these securities.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus is \_\_\_\_\_, 2024

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#### **ABOUT THIS PROSPECTUS**

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission, which we refer to as the "SEC," utilizing a "shelf" registration process. Under this shelf registration process, we may from time to time sell any combination of the securities described in this prospectus in one or more offerings for an aggregate initial offering price of up to \$50,000,000.

This prospectus provides you with a general description of the securities we may offer. From time to time, we may provide one or more prospectus supplements that will contain specific information about the terms of the offering. The prospectus supplement may also add, update or change information contained in this prospectus. You should read both this prospectus and any accompanying prospectus supplement together with the additional information described under the heading "Where You Can Find More Information" beginning on page 18 of this prospectus.

The selling stockholders also may use the shelf registration statement to sell an aggregate amount of 217,082 shares of our common stock from time to time in the public market. We will not receive any proceeds from the sale of common stock by the selling stockholders. The selling stockholders will deliver a supplement with this prospectus, if required, to update the information contained in this prospectus. Each selling stockholders may sell its shares of common stock through any means described in the section entitled "Plan of Distribution" or in an accompanying prospectus supplement. As used herein, the term "selling stockholder" includes the selling stockholder and its pledges, donees, transferees or other successors-in-interest.

We and the selling stockholders have not authorized anyone to provide you with information different from that contained in or incorporated by reference in this prospectus, any accompanying prospectus supplement or in any related free writing prospectus filed by us with the SEC. We do not take any responsibility for, and cannot provide any assurance as to the reliability of, any information other than the information contained or incorporated by reference in this prospectus, any accompanying prospectus supplement or in any related free writing prospectus filed by us with the SEC. Neither this prospectus nor any accompanying prospectus supplement or in any related free writing prospectus filed by us with the SEC. Neither this securities described in the accompanying prospectus supplement or an offer to sell or the solicitation of an offer to buy such securities in any circumstances in which such offer or solicitation is unlawful. You should assume that the information appearing in this prospectus, any prospectus supplement, the documents incorporated by reference and any related free writing prospectus is accurate only as of their respective dates. Our business, financial condition, results of operations and prospects may have changed materially since those dates.

Unless the context otherwise indicates, references in this prospectus to "we," "our" and "us" refer, collectively, to Azitra, Inc., a Delaware corporation, and its subsidiaries.

#### ABOUT AZITRA, INC.

We are an early-stage clinical biopharmaceutical company focused on developing innovative therapies for precision dermatology using engineered proteins and topical live biotherapeutic products. We have built a proprietary platform that includes a microbial library comprised of approximately 1,500 unique bacterial strains that can be screened for unique therapeutic characteristics. The platform is augmented by an artificial intelligence and machine learning technology that analyzes, predicts and helps screen our library of strains for drug like molecules. The platform also utilizes a licensed genetic engineering technology, which can enable the transformation of previously genetically intractable strains. Our initial focus is on the development of genetically engineered strains of *Staphylococcus epidermidis, or S. epidermidis*, which we consider to be an optimal therapeutic candidate species for engineering of dermatologic therapies. The particular species demonstrates a number of well-described properties in the skin. As of the date of this prospectus, we have identified among our microbial library over 60 distinct bacterial species that we believe are capable of being engineered to create living organisms or engineered proteins with significant therapeutic effect.

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We were incorporated under the laws of the state of Delaware on January 2, 2014. Our principal executive offices are located at 21 Business Park Drive, Branford, Connecticut 06405, and our telephone number is (203) 646-6446. Our website address is www.azitrainc.com. The information contained in, or accessible through, our website is not incorporated by reference into this prospectus, and you should not consider any information contained in, or that can be accessed through, our website as part of this prospectus or in deciding whether to purchase our common stock.

We own U.S. and foreign registered trademarks, including our company name. All other trademarks or trade names referred to in this prospectus are the property of their respective owners. Solely for convenience, the trademarks and trade names in this prospectus are referred to without the symbols  $\mathbb{R}$  and  $^{TM}$ , but such references should not be construed as any indication that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto.

On July 1, 2024, we effected a reverse stock split at a ratio of 1-for-30. All share and share price information in this prospectus have been adjusted to give effect to the reverse stock split.

### THE OFFERING

We may offer and sell, from time to time, in one or more offerings, any combination of debt and equity securities that we describe in this prospectus having a total initial offering price not exceeding \$50,000,000 at prices and on terms to be determined by market conditions at the time of any offering. This prospectus provides you with a general description of the securities we may offer. Each time we offer a type or series of securities under this prospectus, we will provide a prospectus supplement that will describe the specific amounts, prices and other important terms of the securities.

In addition, the selling stockholder or their donees, pledges, transferees or other successors-in-interests may offer to sell an aggregate of 217,082 shares of our common stock from time to time in the public market under this prospectus. We will not receive any proceeds from the sale of shares of common stock by the selling stockholders. Each selling stockholder will deliver a supplement with this prospectus, if required, to update the information contained in this prospectus. Each selling stockholder may sell its shares of common stock through any means described in the section entitled "Plan of Distribution" or in an accompanying prospectus supplement. See "Selling Stockholders" on page 4 for more information on the selling stockholders.

The prospectus supplement also may add, update or change information contained in this prospectus or in documents we have incorporated by reference into this prospectus. However, no prospectus supplement will fundamentally change the terms that are set forth in this prospectus or offer a security that is not registered and described in this prospectus at the time of its effectiveness.

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#### **RISK FACTORS**

Investing in our securities involves significant risks. You should carefully consider the risks and uncertainties described in this prospectus and any accompanying prospectus supplement, including the risk factors in our most recent Annual Report on Form 10-K, any subsequently filed Quarterly Report on Form 10-Q or Current Report on Form 8-K, together with all of the other information appearing in or incorporated by reference into this prospectus and any applicable prospectus supplement, before making an investment decision pursuant to this prospectus and any accompanying prospectus supplement relating to a specific offering.

Our business, financial condition and results of operations could be materially and adversely affected by any or all of these risks or by additional risks and uncertainties not presently known to us or that we currently deem immaterial that may adversely affect us in the future.

# NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains, and any accompanying prospectus supplement will contain, forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and the Private Securities Litigation Reform Act of 1993. Also, documents that we incorporate by reference into this prospectus, including documents that we subsequently file with the SEC, will contain forward-looking statements. Forward-looking statements are those that predict or describe future events or trends and that do not relate solely to historical matters. You can generally identify forward-looking statements as statements containing the words "may," "will," "could," "should," "expect," "anticipate," "intend," "estimate," "believe," "project," "plan," "assume" or other similar expressions, or negatives of those expressions, although not all forward-looking statements contain these identifying words. All statements contained or incorporated by reference in this prospectus and any prospectus supplement regarding our business strategy, future operations, projected financial position, potential strategic transactions, proposed licensing arrangements, projected sales growth, estimated future revenues, cash flows and profitability, projected costs, potential outcome of litigation, potential sources of additional capital, future prospects, future economic conditions, the future of our industry and results that might be obtained by pursuing management's current plans and objectives are forward-looking statements.

You should not place undue reliance on our forward-looking statements because the matters they describe are subject to certain risks, uncertainties and assumptions that are difficult to predict. Our forward-looking statements are based on the information currently available to us and speak only as of the date on the cover of this prospectus, the date of any prospectus supplement, or, in the case of forward-looking statements incorporated by reference, the date of the filing that includes the statement. Over time, our actual results, performance or achievements may differ from those expressed or implied by our forward-looking statements, and such difference might be significant and materially adverse to our security holders. Except as required by law, we undertake no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

We have identified some of the important factors that could cause future events to differ from our current expectations and they are described in this prospectus and supplements to this prospectus under the caption "Risk Factors," as well as in our most recent Annual Report on Form 10-K, including under the captions "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," and in other documents that we may file with the SEC, all of which you should review carefully. Please consider our forward-looking statements in light of those risks as you read this prospectus and any prospectus supplement.

#### **USE OF PROCEEDS**

Unless otherwise specified in the applicable prospectus supplement, we intend to use the net proceeds from the sale of the securities described in this prospectus for general corporate and operations purposes and to fund our anticipated growth. The applicable prospectus supplement will provide more details on the use of proceeds of any specific offering. We will not receive any proceeds from the sale of common stock by the selling stockholders.

## SELLING STOCKHOLDERS

The selling stockholders listed in the table below may from time to time offer and sell pursuant to this prospectus any or all of the shares of our common stock that they respectively beneficially own as set forth below. When we refer to "selling stockholders" in this prospectus, we mean the persons and entities listed in the table below, and their pledgees, donees, permitted transferees, assignees, successors and others who later come to hold any of the selling stockholders' interests in shares of our common stock other than through a public sale.

The SEC has defined "beneficial ownership" to mean more than ownership in the usual sense. For example, a person has beneficial ownership of a share not only if he owns it, but also if he has the power (solely or shared) to vote, sell or otherwise dispose of the share. Beneficial ownership also includes the number of shares that a person has the right to acquire within 60 days of the date of this prospectus, pursuant to the exercise of options or warrants or the conversion of notes, debentures or other indebtedness. Two or more persons might count as beneficial owners of the same share.

Certain of the selling stockholders may be deemed to be underwriters as defined in the Securities Act. Any profits realized by the selling stockholders may be deemed to be underwriting commissions.

The following table sets forth, as of the date of this prospectus, the name of each selling stockholder for whom we are registering shares for resale to the public, and the number of shares that each selling stockholder may offer pursuant to this prospectus. The shares offered by the selling stockholders were originally issued and sold by us in connection with our convertible preferred stock and convertible note financings pursuant to exemptions from the registration requirements of the Securities Act, all of which converted to shares of our common stock upon the closing of our June 2023 initial public offering, or IPO.

We have been advised that none of the selling stockholders are broker-dealers or affiliates of broker-dealers. None of the selling stockholders have, or have had during the past three years, any position, office or other material relationship with us or any of our affiliates, except as follows. In connection the Bios entities' investment in our Company, we granted the Bios entities certain board appointment rights pursuant to which they appointed to our Board a representative who served on our Board from April 2016 to a date immediately preceding our June 2023 IPO. In addition, Travis Whitfill, our chief operating officer and a member of our Board, was a partner of Bios Equity Partners, LP, the general partner of the Bios entities until June 2023, however we are advised that Mr. Whitfill had no voting or investment power over the shares they are offering for resale. Finally, the managing partner of KdT Ventures LP, Andrew McClary, M.D., has served on our Board since March 2019.

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Based on information provided to us by the selling stockholders and as of the date the same was provided to us, assuming that the selling stockholders sell all the shares of our common stock beneficially owned by them that have been registered by us and do not acquire any additional shares during the offering, the selling stockholders will not own any shares other than those appearing in the column entitled "Number of Shares Owned After the Offering." We cannot advise as to whether the selling stockholders will in fact sell any or all of such shares. In addition, the selling stockholders may have sold, transferred or otherwise disposed of, or may sell, transfer or otherwise dispose of, at any time and from time to time, the shares in transactions exempt from the registration requirements of the Securities Act after the date on which they provided the information set forth on the table below.

Name of Beneficial Owner	Shares Beneficially Owned Before the Offering		Maximum Number of Shares Offered	Shares Benet Owned After the Offe	I
	Number	%		Number	%
			(2)		
Bios Azitra Co-Invest I, LP	15,864	1.6%	15,864(3)	-0-	—
Bios Fund I QP, LP	15,587	1.6%	15,587(2)	-0-	—
Bios Fund I, LP	26,648	2.8%	26,648(2)	-0-	—
Bios Fund II NT, LP	4,897	*	(2) 4,897(4) (2)	-0-	_
Bios Fund II QP, LP	36,588	3.8%	36,588(5)	-0-	
			(2)		
Bios Fund II, LP	11,198	1.2%	11,198(6)	-0-	
Bios Fund III NT, LP	11,774	1.2%	11,774(2)	-0-	
Bios Fund III QP, LP	72,909	7.6%	72,909(2)	-0-	_
Bios Fund III, LP	31,162	3.2%	11,162(2)	20,000	2.1%
KdT Ventures LP	10,455	*	10,455(7)	-0-	

#### • Less than one percent

(1) Assumes that all securities offered are sold.

(2) Aaron Fletcher and Leslie Kreis, Jr. have voting and investment power over the shares.

(3) Includes 1,325 shares of our common stock issuable upon exercise of presently exercisable warrants.

(4) Includes 331 shares of our common stock issuable upon exercise of presently exercisable warrants.

(5) Includes 2,474 shares of our common stock issuable upon exercise of presently exercisable warrants.

(6) Includes 757 shares of our common stock issuable upon exercise of presently exercisable warrants.

(7) Includes 725 shares of our common stock issuable upon exercise of presently exercisable warrants. Andrew McClary, a member of our Board of Directors, has voting and investment power over the shares.

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#### THE SECURITIES WE MAY OFFER

We may offer and sell, from time to time in one or more offerings, any combination of common stock, preferred stock, debt securities, warrants, subscription rights and units having an aggregate initial offering price not exceeding \$50,000,000. In this prospectus, we refer to the common stock, preferred stock, debt securities, warrants, subscription rights and units that we may offer collectively as "securities."

### **Common Stock**

We are authorized to issue 100,000,000 shares of \$0.0001 par value common stock. Holders of shares of common stock are entitled to one vote per share on all matters to be voted upon by the stockholders generally. Stockholders are entitled to receive such dividends as may be declared from time to time by the board of directors out of funds legally available therefor, and in the event of liquidation, dissolution or winding up of the company to share ratably in all assets remaining after payment of liabilities. The holders of shares of common stock have no preemptive, conversion, subscription or cumulative voting rights.

This prospectus provides a general description of the securities we may offer other than our common stock. Each time we sell any of our securities under this prospectus, we will, to the extent required by law, provide a prospectus supplement that will contain specific information about the terms of the offering. The prospectus supplement may also add, update or change information in this prospectus. For more information, see "About this Prospectus."

### **Preferred Stock**

We are authorized to issue up to 10,000,000 shares of preferred stock, par value \$0.0001 per share. Pursuant to our certificate of incorporation, our board of directors has the authority, without further action by the stockholders (unless such stockholder action is required by applicable law or the rules of the NYSE American), to designate and issue up to 10,000,000 shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the designations, powers, preferences and rights of the shares of each wholly unissued series, and any qualifications, limitations or restrictions thereon, and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding. Shares of our preferred stock, if issued, will be fully paid and non-assessable.

We will fix the designations, powers, preferences and rights of the preferred stock of each series, as well as the qualifications, limitations or restrictions thereon, in the certificate of designation relating to that series. We will file as an exhibit to the registration statement of which this prospectus is a part, or will incorporate by reference from reports that we file with the SEC, the form of any certificate of designation that describes the terms of the series of preferred stock we are offering before the issuance of that series of preferred stock. This description will include:

- the title and stated value;
- the number of shares we are offering;
- the liquidation preference per share;
- the purchase price;
- the dividend rate, period and payment date and method of calculation for dividends;
- whether dividends will be cumulative or non-cumulative and, if cumulative, the date from which dividends will accumulate;
- the procedures for any auction and remarketing, if any;
- the provisions for a sinking fund, if any;
- the provisions for redemption or repurchase, if applicable, and any restrictions on our ability to exercise those redemption and repurchase rights;
- any listing of the preferred stock on any securities exchange or market;
- whether the preferred stock will be convertible into our common stock, and, if applicable, the conversion price, or how it will be calculated, and the conversion period;
- whether the preferred stock will be exchangeable into debt securities, and, if applicable, the exchange price, or how it will be calculated, and the exchange period;
- voting rights, if any, of the preferred stock;
- preemptive rights, if any;
- restrictions on transfer, sale or other assignment, if any;
- whether interests in the preferred stock will be represented by depositary shares;
- a discussion of any material United States federal income tax considerations applicable to the preferred stock;
- the relative ranking and preferences of the preferred stock as to dividend rights and rights if we liquidate, dissolve or wind up our affairs;
- any limitations on the issuance of any class or series of preferred stock ranking senior to or on a parity with the series of preferred stock as to dividend rights and rights if we liquidate, dissolve or wind up our affairs; and

• any other specific terms, preferences, rights or limitations of, or restrictions on, the preferred stock.

The General Corporation Law of the State of Delaware, or DGCL, the state of our incorporation, provides that the holders of preferred stock will have the right to vote separately as a class (or, in some cases, as a series) on an amendment to our certificate of incorporation if the amendment would change the par value or, unless the certificate of incorporation provided otherwise, the number of authorized shares of the class or change the powers, preferences or special rights of the class or series so as to adversely affect the class or series, as the case may be. This right is in addition to any voting rights that may be provided for in the applicable certificate of designation.

Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of our common stock. Preferred stock could be issued quickly with terms designed to delay or prevent a change in control of our company or make removal of management more difficult. Additionally, the issuance of preferred stock may have the effect of decreasing the market price of our common stock.

#### **Description of Debt Securities**

We may offer debt securities which may be senior or subordinated. We refer to the senior debt securities and the subordinated debt securities collectively as debt securities. The following description summarizes the general terms and provisions of the debt securities. We will describe the specific terms of the debt securities and the extent, if any, to which the general provisions summarized below apply to any series of debt securities in the prospectus supplement relating to the series and any applicable free writing prospectus that we authorize to be delivered.

We may issue senior debt securities from time to time, in one or more series, which may be issued under a senior indenture to be entered into between us and a senior trustee to be named in a prospectus supplement, which we refer to as the senior trustee. We may issue subordinated debt securities from time to time, in one or more series, which may be issued under a subordinated indenture to be entered into between us and a subordinated trustee to be named in a prospectus supplement, which we refer to as the subordinated indenture to be entered into between us and a subordinated trustee to be named in a prospectus supplement, which we refer to as the subordinated trustee. While it is highly likely that any debt securities we issue will be issued under an indenture, we reserve the right to issue debt securities other than under an indenture pursuant to an exemption from the indenture requirement under the Trust Indenture Act of 1939. Any debt securities issued by us other than pursuant to an indenture will subject the purchasers of such debt securities to certain unique risks arising from the lack of a trustee charged with the responsibility of monitoring the debt securities and enforcing the rights of the holders of such debt securities, which will be set forth in a prospectus supplement filed with regard to such unindentured debt securities.

The forms of senior indenture and subordinated indenture are filed as exhibits to the registration statement of which this prospectus forms a part. Together, the senior indenture and the subordinated indenture are referred to as the indentures and, together, the senior trustee and the subordinated trustee are referred to as the trustees. This prospectus briefly outlines some of the provisions of the indentures. The following summary of the material provisions of the indentures is qualified in its entirety by the provisions of the indentures, including definitions of certain terms used in the indentures. Wherever we refer to particular sections or defined terms of the indentures, those sections or defined terms are incorporated by reference in this prospectus forms a part for additional information.

If we issue debt securities other than under an indenture, we will likely be limited to issuing a maximum of \$50 million of such debt securities and it is also likely that such debt securities will be unsecured and subordinated. Any indenture regarding debt securities issued by us will not limit the amount of debt securities that we may issue. The debt securities or applicable indenture, if any, will provide that debt securities may be issued up to an aggregate principal amount authorized from time to time by us and may be payable in any currency or currency unit designated by us or in amounts determined by reference to an index.

#### General

The following is a summary of the general terms of the debt securities we may issue under an indenture or otherwise, except as otherwise described in a prospectus supplement.

The senior debt securities will constitute our unsubordinated general obligations and will rank pari passu with our other unsubordinated obligations. The subordinated debt securities will constitute our subordinated general obligations and will be junior in right of payment to our senior indebtedness (including senior debt securities).

The debt securities will be our unsecured obligations unless otherwise specified in the applicable prospectus supplement. Any secured debt or other secured obligations will be effectively senior to the debt securities to the extent of the value of the assets securing such debt or other obligations.

The applicable prospectus supplement and any free writing prospectus will include any additional or different terms of the debt securities or any series being offered, including the following terms:

- the title and type of the debt securities;
- whether the debt securities will be issued under an indenture;
- whether the debt securities will be senior or subordinated debt securities, and, with respect to subordinated debt securities, the terms on which they are subordinated;
- the aggregate principal amount of the debt securities;
- the price or prices at which we will sell the debt securities;
- the maturity date or dates of the debt securities and the right, if any, to extend such date or dates;
- the rate or rates, if any, per year, at which the debt securities will bear interest, or the method of determining such rate or rates;
- the date or dates from which such interest will accrue, the interest payment dates on which such interest will be payable or the manner of determination of such interest payment dates and the related record dates;
- the right, if any, to extend the interest payment periods and the duration of that extension;
- the manner of paying principal and interest and the place or places where principal and interest will be payable;
- provisions for a sinking fund, purchase fund or other analogous fund, if any;
- any redemption dates, prices, obligations and restrictions on the debt securities;
- the currency, currencies or currency units in which the debt securities will be denominated and the currency, currencies or currency units in which principal and interest, if any, on the debt securities may be payable;

• any conversion or exchange features of the debt securities;

- whether and upon what terms the debt securities may be defeased;
- any events of default or covenants in addition to or in lieu of those set forth in any indenture;
- whether the debt securities will be issued in definitive or global form or in definitive form only upon satisfaction of certain conditions;
- whether the debt securities will be guaranteed as to payment or performance;
- if the debt securities of the series will be secured by any collateral and, if so, a general description of the collateral and the terms and provisions of such collateral security, pledge or other agreements; and
- any other material terms of the debt securities.

The applicable prospectus supplement will also describe any applicable material U.S. federal income tax consequences. When we refer to "principal" in this section with reference to the debt securities, we are also referring to "premium, if any."

We may from time to time, without notice to or the consent of the holders of any series of debt securities, create and issue further debt securities of any such series ranking equally with the debt securities of such series in all respects (or in all respects other than (1) the payment of interest accruing prior to the issue date of such further debt securities or (2) the first payment of interest following the issue date of such further debt securities). Such further debt securities may be consolidated and form a single series with the debt securities of such series and have the same terms as to status, redemption or otherwise as the debt securities of such series.

You may present debt securities for exchange and you may present debt securities for transfer in the manner, at the places and subject to the restrictions set forth in the debt securities and the applicable prospectus supplement. We will provide you those services without charge, although you may have to pay any tax or other governmental charge payable in connection with any exchange or transfer, as set forth in the debt securities or any indenture.

Debt securities may bear interest at a fixed rate or a floating rate. Debt securities bearing no interest or interest at a rate that at the time of issuance is below the prevailing market rate (original issue discount securities) may be sold at a discount below their stated principal amount.

We may issue debt securities with the principal amount payable on any principal payment date, or the amount of interest payable on any interest payment date, to be determined by reference to one or more currency exchange rates, securities or baskets of securities, commodity prices or indices. You may receive a payment of principal on any principal payment date, or a payment of interest on any interest payment date, that is greater than or less than the amount of principal or interest otherwise payable on such dates, depending on the value on such dates of the applicable currency, security or basket of securities, commodity or index. Information as to the methods for determining the amount of principal or interest payable on any date, the currencies, securities or baskets of securities, commodities or indices to which the amount payable on such date will be set forth in the applicable prospectus supplement.

## Certain Terms of the Senior Debt Securities

The following is a summary of the general terms of the senior debt securities we may issue under a senior indenture, except as otherwise described in a prospectus supplement.

*Covenants.* Unless we indicate otherwise in a prospectus supplement, the senior debt securities will not contain any financial or restrictive covenants, including covenants restricting either us or any of our subsidiaries from incurring, issuing, assuming or guaranteeing any indebtedness secured by a lien on any of our or our subsidiaries' property or capital stock, or restricting either us or any of our subsidiaries from entering into sale and leaseback transactions.

Consolidation, Merger and Sale of Assets. Unless we indicate otherwise in a prospectus supplement, we may not consolidate with or merge into any other person, in a transaction in which we are not the surviving corporation, or convey, transfer or lease our properties and assets substantially as an entirety to any person, in either case, unless:

- the successor entity, if any, is a U.S. corporation, limited liability company, partnership or trust (subject to certain exceptions provided for in the senior indenture);
- the successor entity assumes our obligations on the senior debt securities and under the senior indenture;
- immediately after giving effect to the transaction, no default or event of default shall have occurred and be continuing; and
- certain other conditions are met.

*No Protection in the Event of a Change in Control.* Unless we indicate otherwise in a prospectus supplement with respect to a particular series of senior debt securities, the senior debt securities will not contain any provisions that may afford holders of the senior debt securities protection in the event we have a change in control or in the event of a highly leveraged transaction (whether or not such transaction results in a change in control).

*Events of Default*. Unless we indicate otherwise in a prospectus supplement with respect to a particular series of senior debt securities, the following are events of default under the senior indenture for any series of senior debt securities:

- failure to pay interest on any senior debt securities of such series when due and payable, if that default continues for a period of 90 days (or such other period as may be specified for such series);
- failure to pay principal on the senior debt securities of such series when due and payable whether at maturity, upon redemption, by declaration or otherwise (and, if specified for such series, the continuance of such failure for a specified period);
- default in the performance of or breach of any of our covenants or agreements in the senior indenture applicable to senior debt securities of such series, other than a covenant breach which is specifically dealt with elsewhere in the senior indenture, and that default or breach continues for a period of 90 days after we receive written notice from the trustee or from the holders of 25% or more in aggregate principal amount of the senior debt securities of such series;
- certain events of bankruptcy or insolvency, whether or not voluntary; and
- any other event of default provided for in such series of senior debt securities as may be specified in the applicable prospectus supplement.

Unless we indicate otherwise in a prospectus supplement, the default by us under any other debt, including any other series of debt securities, is not a default under the senior indenture.

If an event of default other than an event of default specified in the fourth bullet point above occurs with respect to a series of senior debt securities and is continuing under the senior indenture, then, and in each such case, either the trustee or the holders of not less than 25% in aggregate principal amount of such series then outstanding under the senior indenture (each such series voting as a separate class) by written notice to us and to the trustee, if such notice is given by the holders, may, and the trustee at the request of such holders shall, declare the principal amount of and accrued interest on such series of senior debt securities to be immediately due and payable, and upon this declaration, the same shall become immediately due and payable.



If an event of default specified in the fourth bullet point above occurs with respect to us and is continuing, the entire principal amount of and accrued interest, if any, on each series of senior debt securities then outstanding shall become immediately due and payable.

Unless otherwise specified in the prospectus supplement relating to a series of senior debt securities originally issued at a discount, the amount due upon acceleration shall include only the original issue price of the senior debt securities, the amount of original issue discount accrued to the date of acceleration and accrued interest, if any.

Upon certain conditions, declarations of acceleration may be rescinded and annulled and past defaults may be waived by the holders of a majority in aggregate principal amount of all the senior debt securities of such series affected by the default, each series voting as a separate class. Furthermore, prior to a declaration of acceleration and subject to various provisions in the senior indenture, the holders of a majority in aggregate principal amount of a series of senior debt securities, by notice to the trustee, may waive an existing default or event of default with respect to such senior debt securities and its consequences, except a default in the payment of principal of or interest on such senior debt securities or in respect of a covenant or provision of the senior indenture which cannot be modified or amended without the consent of the holders of each such senior debt security. Upon any such waiver, such default shall cease to exist, and any event of default with respect to such senior debt securities shall be deemed to have been cured, for every purpose of the senior indenture; but no such waiver shall extend to any subsequent or other default or event of default or impair any right consequent thereto. For information as to the waiver of defaults, see "—Modification and Waiver."

The holders of a majority in aggregate principal amount of a series of senior debt securities may direct the time, method and place of conducting any proceeding for any remedy available to the trustee or exercising any trust or power conferred on the trustee with respect to such senior debt securities. However, the trustee may refuse to follow any direction that conflicts with law or the senior indenture, that may involve the trustee in personal liability or that the trustee determines in good faith may be unduly prejudicial to the rights of holders of such series of senior debt securities not joining in the giving of such direction and may take any other action it deems proper that is not inconsistent with any such direction received from holders of such series of senior debt securities unless:

- the holder gives the trustee written notice of a continuing event of default;
- the holders of at least 25% in aggregate principal amount of such series of senior debt securities make a written request to the trustee to pursue the remedy in respect of such event of default;
- the requesting holder or holders offer the trustee indemnity satisfactory to the trustee against any costs, liability or expense;
- the trustee does not comply with the request within 60 days after receipt of the request and the offer of indemnity; and
- during such 60-day period, the holders of a majority in aggregate principal amount of such series of senior debt securities do not give the trustee a direction that is inconsistent with the request.

These limitations, however, do not apply to the right of any holder of a senior debt security to receive payment of the principal of and interest, if any, on such senior debt security in accordance with the terms of such debt security, or to bring suit for the enforcement of any such payment in accordance with the terms of such debt securities, which right shall not be impaired or affected without the consent of the holder.

The senior indenture requires certain of our officers to certify, on or before a fixed date in each year in which any senior debt security is outstanding, as to their knowledge of our compliance with all covenants, agreements and conditions under the senior indenture.

Satisfaction and Discharge. We can satisfy and discharge our obligations to holders of any series of senior debt securities if:

- we pay or cause to be paid, as and when due and payable, the principal of and any interest on all senior debt securities of such series outstanding under the senior indenture; or
- all senior debt securities of such series have become due and payable or will become due and payable within one year (or are to be called for
  redemption within one year) and we deposit in trust a combination of cash and U.S. government or U.S. government agency obligations that
  will generate enough cash to make interest, principal and any other payments on the debt securities of that series on their various due dates.

Under current U.S. federal income tax law, the deposit and our legal release from the senior debt securities would be treated as a taxable event, and beneficial owners of such debt securities would generally recognize any gain or loss on such senior debt securities. Purchasers of the senior debt securities should consult their own advisers with respect to the tax consequences to them of such deposit and discharge, including the applicability and effect of tax laws other than the U.S. federal income tax law.

*Defeasance.* Unless the applicable prospectus supplement provides otherwise, the following discussion of legal defeasance and discharge and covenant defeasance will apply to any senior series of senior debt securities issued under the indentures.

Legal Defeasance. We can legally release ourselves from any payment or other obligations on the senior debt securities of any series (called "legal defeasance") if certain conditions are met, including the following:

- We deposit in trust for your benefit and the benefit of all other direct holders of the senior debt securities of the same series a combination of cash and U.S. government or U.S. government agency obligations that will generate enough cash to make interest, principal and any other payments on the senior debt securities of that series on their various due dates.
- There is a change in current U.S. federal income tax law or an IRS ruling that lets us make the above deposit without causing you to be taxed on the senior debt securities any differently than if we did not make the deposit and instead repaid the senior debt securities ourselves when due.
- We deliver to the trustee a legal opinion of our counsel confirming the tax law change or ruling described above.

If we ever did accomplish legal defeasance, as described above, you would have to rely solely on the trust deposit for repayment of the debt securities. You could not look to us for repayment in the event of any shortfall.

*Covenant Defeasance.* Without any change of current U.S. federal tax law, we can make the same type of deposit described above and be released from some of the covenants in the senior debt securities (called "covenant defeasance"). In that event, you would lose the protection of those covenants but would gain the protection of having money and securities set aside in trust to repay the senior debt securities. In order to achieve covenant defeasance, we must do the following (among other things):

• We must deposit in trust for your benefit and the benefit of all other direct holders of the senior debt securities of the same series a combination of cash and U.S. government or U.S. government agency obligations that will generate enough cash to make interest, principal and any other payments on the senior debt securities of that series on their various due dates.

• We must deliver to the trustee a legal opinion of our counsel confirming that under current U.S. federal income tax law we may make the above deposit without causing you to be taxed on the senior debt securities any differently than if we did not make the deposit and instead repaid the senior debt securities ourselves when due.

If we accomplish covenant defeasance, you can still look to us for repayment of the senior debt securities if there were a shortfall in the trust deposit. In fact, if one of the events of default occurred (such as our bankruptcy) and the debt securities become immediately due and payable, there may be such a shortfall. Depending on the events causing the default, you may not be able to obtain payment of the shortfall.

Modification and Waiver. We and the trustee may amend or supplement the senior indenture or the senior debt securities without the consent of any holder:

- to comply with the requirements of the SEC in order to effect or maintain the qualification of the indenture under the Trust Indenture Act of 1939, as amended, or the Trust Indenture Act;
- to convey, transfer, assign, mortgage or pledge any assets as security for the senior debt securities of one or more series;
- to evidence the succession of a corporation, limited liability company, partnership or trust to us, and the assumption by such successor of our covenants, agreements and obligations under the senior indenture;
- to add to our covenants such new covenants, restrictions, conditions or provisions for the protection of the holders, and to make the occurrence, or the occurrence and continuance, of a default in any such additional covenants, restrictions, conditions or provisions an event of default;
- to cure any ambiguity, defect or inconsistency in the senior indenture or in any supplemental indenture or to conform the senior indenture or the senior debt securities to the description of senior debt securities of such series set forth in this prospectus or any applicable prospectus supplement;
- to provide for or add guarantors with respect to the senior debt securities of any series;
- to establish the form or forms or terms of the senior debt securities as permitted by the senior indenture;
- to evidence and provide for the acceptance of appointment under the senior indenture by a successor trustee, or to make such changes as shall be necessary to provide for or facilitate the administration of the trusts in the senior indenture by more than one trustee;
- to add to, delete from or revise the conditions, limitations and restrictions on the authorized amount, terms, purposes of issue, authentication
  and delivery of any series of senior debt securities;
- to make any change to the senior debt securities of any series so long as no senior debt securities of such series are outstanding; or
- to make any change that does not adversely affect the rights of any holder in any material respect.

Other amendments and modifications of the senior indenture or the senior debt securities issued may be made, and our compliance with any provision of the senior indenture with respect to any series of senior debt securities may be waived, with the consent of the holders of a majority of the aggregate principal amount of the outstanding senior debt securities of all series affected by the amendment or modification (voting together as a single class); provided, however, that each affected holder must consent to any modification, amendment or waiver that:

• extends the final maturity of any senior debt securities of such series;

- reduces the principal amount of any senior debt securities of such series;
- reduces the rate or extends the time of payment of interest on any senior debt securities of such series;
- reduces the amount payable upon the redemption of any senior debt securities of such series;
- changes the currency of payment of principal of or interest on any senior debt securities of such series;
- reduces the principal amount of original issue discount securities payable upon acceleration of maturity or the amount provable in bankruptcy;
- waives a default in the payment of principal of or interest on the senior debt securities;
- changes the provisions relating to the waiver of past defaults or changes or impairs the right of holders to receive payment or to institute suit for the enforcement of any payment or conversion of any senior debt securities of such series on or after the due date therefor;
- modifies any of the provisions of these restrictions on amendments and modifications, except to increase any required percentage or to provide that certain other provisions cannot be modified or waived without the consent of the holder of each senior debt security of such series affected by the modification; or
- reduces the above-stated percentage of outstanding senior debt securities of such series whose holders must consent to a supplemental indenture or to modify or amend or to waive certain provisions of or defaults under the senior indenture.

It shall not be necessary for the holders to approve the particular form of any proposed amendment, supplement or waiver, but it shall be sufficient if the holders' consent approves the substance thereof. After an amendment, supplement or waiver of the senior indenture in accordance with the provisions described in this section becomes effective, the trustee must give to the holders affected thereby certain notice briefly describing the amendment, supplement or waiver. Any failure by the trustee to give such notice, or any defect therein, shall not, however, in any way impair or affect the validity of any such amendment, supplemental indenture or waiver.

No Personal Liability of Incorporators, Stockholders, Officers, Directors. The senior indenture provides that no recourse shall be had under any obligation, covenant or agreement of ours in the senior indenture or any supplemental indenture, or in any of the senior debt securities or because of the creation of any indebtedness represented thereby, against any of our incorporators, stockholders, officers or directors, past, present or future, or of any predecessor or successor entity thereof under any law, statute or constitutional provision or by the enforcement of any assessment or by any legal or equitable proceeding or otherwise. Each holder, by accepting the senior debt securities, waives and releases all such liability.

*Concerning the Trustee.* The senior indenture provides that, except during the continuance of an event of default, the trustee will not be liable except for the performance of such duties as are specifically set forth in the senior indenture. If an event of default has occurred and is continuing, the trustee will exercise such rights and powers vested in it under the senior indenture and will use the same degree of care and skill in its exercise as a prudent person would exercise under the circumstances in the conduct of such person's own affairs.

The senior indenture and the provisions of the Trust Indenture Act incorporated by reference therein contain limitations on the rights of the trustee thereunder, should it become a creditor of ours or any of our subsidiaries, to obtain payment of claims in certain cases or to realize on certain property received by it in respect of any such claims, as security or otherwise. The trustee is permitted to engage in other transactions, provided that if it acquires any conflicting interest (as defined in the Trust Indenture Act), it must eliminate such conflict or resign.

We may have normal banking relationships with the senior trustee in the ordinary course of business.

Unclaimed Funds. All funds deposited with the trustee or any paying agent for the payment of principal, premium, interest or additional amounts in respect of the senior debt securities that remain unclaimed for two years after the date upon which such principal, premium or interest became due and payable will be repaid to us. Thereafter, any right of any holder of senior debt securities to such funds shall be enforceable only against us, and the trustee and paying agents will have no liability therefor.

Governing Law. The senior indenture and the senior debt securities will be governed by, and construed in accordance with, the internal laws of the State of New York.

# Certain Terms of the Subordinated Debt Securities

The following is a summary of the general terms of the subordinated debt securities we may issue under a subordinated indenture, except as otherwise described in a prospectus supplement.

Other than the terms of the subordinated indenture and subordinated debt securities relating to subordinated indenture as described in the prospectus supplement relating to a particular series of subordinated debt securities, the terms of the subordinated indenture and subordinated debt securities are identical in all material respects to the terms of the senior indenture and senior debt securities.

Additional or different subordination terms may be specified in the prospectus supplement applicable to a particular series.

Subordination. The indebtedness evidenced by the subordinated debt securities is subordinate to the prior payment in full of all of our senior indebtedness, as defined in the subordinated indenture. During the continuance beyond any applicable grace period of any default in the payment of principal, premium, interest or any other payment due on any of our senior indebtedness, we may not make any payment of principal of or interest on the subordinated debt securities (except for certain sinking fund payments). In addition, upon any payment or distribution of our assets upon any dissolution, winding-up, liquidation or reorganization, the payment of the principal of and interest on the subordinated debt securities will be subordinated to the extent provided in the subordinated indenture in right of payment to the prior payment in full of all our senior indebtedness. Because of this subordination, if we dissolve or otherwise liquidate, holders of our subordinated debt securities may receive less, ratably, than holders of our senior indebtedness. The subordination provisions do not prevent the occurrence of an event of default under the subordinated indenture.

The term "senior indebtedness" of a person means with respect to such person the principal of, premium, if any, interest on, and any other payment due pursuant to any of the following, whether outstanding on the date of the subordinated indenture or incurred by that person in the future:

- all of the indebtedness of that person for money borrowed;
- all of the indebtedness of that person evidenced by notes, debentures, bonds or other securities sold by that person for money;
- all of the lease obligations that are capitalized on the books of that person in accordance with generally accepted accounting principles;
- all indebtedness of others of the kinds described in the first two bullet points above and all lease obligations of others of the kind described in the third bullet point above that the person, in any manner, assumes or guarantees or that the person in effect guarantees through an agreement to purchase, whether that agreement is contingent or otherwise; and

all renewals, extensions or refundings of indebtedness of the kinds described in the first, second or fourth bullet point above and all renewals
or extensions of leases of the kinds described in the third or fourth bullet point above;

unless, in the case of any particular indebtedness, renewal, extension or refunding, the instrument creating or evidencing it or the assumption or guarantee relating to it expressly provides that such indebtedness, renewal, extension or refunding is not superior in right of payment to the subordinated debt securities. Our senior debt securities constitute senior indebtedness for purposes of the subordinated debt indenture.

#### **Description of Warrants**

We may issue warrants for the purchase of shares of common stock, preferred stock, debt securities, and/or units from time to time. We may issue warrants independently or together with common stock, preferred stock and/or debt securities, and the warrants may be attached to or separate from those securities. If we issue warrants, they will be evidenced by warrant agreements or warrant certificates issued under one or more warrant agreements, which will be contracts between us and the holders of the warrants or an agent for the holders of the warrants. We encourage you to read the prospectus supplement that relates to any warrants we may offer, as well as the complete warrant agreement or warrant certificate that contain the terms of the warrants. If we issue warrants, the forms of warrant agreements and warrant certificates, as applicable, relating to the warrants will be filed as exhibits to the registration statement that includes this prospectus, or as an exhibit to a filing with the SEC that is incorporated by reference into this prospectus.

#### **Description of Subscription Rights**

We may issue rights to purchase our securities. The rights may or may not be transferable by the persons purchasing or receiving the rights. In connection with any rights offering, we may enter into a standby underwriting, standby purchase or other arrangement with one or more underwriters or other persons pursuant to which such underwriters or other persons would purchase any offered securities remaining unsubscribed for after such rights offering. In connection with a rights offering to holders of our capital stock a prospectus supplement will be distributed to such holders on or after the record date for receiving rights in the rights offering set by us.

We will file as exhibits to the registration statement of which this prospectus is a part, or will incorporate by reference from a current report on Form 8-K that we file with the SEC, forms of the subscription rights, standby underwriting agreement or other agreements, if any. The prospectus supplement relating to any rights that we offer will include specific terms relating to the offering, including, among other matters:

- the date of determining the security holders entitled to the rights distribution;
- the aggregate number of rights issued and the aggregate amount of securities purchasable upon exercise of the rights;
- the exercise price;
- the conditions to completion of the rights offering;
- the date on which the right to exercise the rights will commence and the date on which the rights will expire; and
- any applicable federal income tax considerations.

Each right would entitle the holder of the rights to purchase the principal amount of securities at the exercise price set forth in the applicable prospectus supplement. Rights may be exercised at any time up to the close of business on the expiration date for the rights provided in the applicable prospectus supplement. After the close of business on the expiration date, all unexercised rights will become void.

Holders may exercise rights as described in the applicable prospectus supplement. Upon receipt of payment and the rights certificate properly completed and duly executed at the corporate trust office of the rights agent, if any, or any other office indicated in the prospectus supplement, we will, as soon as practicable, forward the securities purchasable upon exercise of the rights. If less than all of the rights issued in any rights offering are exercised, we may offer any unsubscribed securities directly to persons other than stockholders, to or through agents, underwriters or dealers or through a combination of such methods, including pursuant to standby underwriting or purchase arrangements, as described in the applicable prospectus supplement.

# **Description of Units**

We may issue units comprised of one or more of the other securities described in this prospectus in any combination from time to time. Each unit will be issued so that the holder of the unit is also the holder of each security included in the unit. Thus, the holder of a unit will have the rights and obligations of a holder of each included security. If we issue units, they will be evidenced by unit agreements or unit certificates issued under one or more unit agreements, which will be contracts between us and the holders of the units or an agent for the holders of the units. The unit agreement under which a unit is issued may provide that the securities included in the unit may not be held or transferred separately, at any time or at any time before a specified date. We encourage you to read the prospectus supplement that relates to any units we may offer, as well as the complete unit agreement or unit certificate that contain the terms of the units. If we issue units, the forms of unit agreements and unit certificates, as applicable, relating to the units will be filed as exhibits to the registration statement that includes this prospectus, or as an exhibit to a filing with the SEC that is incorporated by reference into this prospectus.



### PLAN OF DISTRIBUTION

We and the selling stockholders may sell our securities from time to time in any manner permitted by the Securities Act, including any one or more of the following ways:

- through agents;
- to or through underwriters;
- to or through broker-dealers (acting as agent or principal);
- in "at the market" offerings, within the meaning of Rule 415(a)(4) of the Securities Act, to or through a market maker or into an existing trading market, on an exchange or otherwise; and/or
- directly to purchasers, through a specific bidding or auction process or otherwise.

The securities may be sold at a fixed price or prices, which may be changed, at market prices prevailing at the time of sale, at prices relating to the prevailing market prices or at negotiated prices.

Offers to purchase offered securities may be solicited by agents designated by us from time to time. Any agent involved in the offer or sale of the offered securities in respect of which this prospectus is delivered will be named, and any commissions payable by us will be set forth, in the applicable prospectus supplement. Unless otherwise set forth in the applicable prospectus supplement, any agent will be acting on a reasonable best efforts basis for the period of its appointment. Any agent may be deemed to be an underwriter, as that term is defined in the Securities Act, of the offered securities so offered and sold.

We and the selling stockholders will set forth in a prospectus supplement the terms of the offering of our securities, including:

- the name or names of any agents, underwriters or dealers;
- the purchase price of our securities being offered and the proceeds we will receive from the sale;
- any over-allotment options under which underwriters may purchase additional securities from us;
- any agency fees or underwriting discounts and commissions and other items constituting agents' or underwriters' compensation;
- the public offering price;
- any discounts or concessions allowed or reallowed or paid to dealers; and
- any securities exchanges on which such securities may be listed.

If we or any selling stockholder offer securities to be sold to the public by means of an underwritten offering, either through underwriting syndicates represented by managing underwriters or directly by the managing underwriters, we or the selling stockholder will execute an underwriting agreement with an underwriter or underwriters, and the names of the specific managing underwriter or underwriters, as well as any other underwriters, will be set forth in the applicable prospectus supplement. In addition, the terms of the transaction, including commissions, discounts and any other compensation of the underwriters and dealers, if any, will be set forth in the applicable prospectus supplement will be used by the underwriters to make resales of the offered securities. If underwriters are utilized in the sale of the offered securities, the offered securities will be acquired by the underwriters for their own account and may be resold from time to time in one or more transactions, including:

• transactions on the NYSE American or any other organized market where the securities may be traded;



- in the over-the-counter market;
- in negotiated transactions; or
- under delayed delivery contracts or other contractual commitments.

We or the selling stockholders may grant to the underwriters options to purchase additional offered securities to cover over-allotments, if any, at the public offering price with additional underwriting discounts or commissions, as may be set forth in the applicable prospectus supplement. If we or the selling stockholder grant any over-allotment option, the terms of the over-allotment option will be set forth in the applicable prospectus supplement.

We or the selling stockholders may authorize agents or underwriters to solicit offers by certain types of institutional investors to purchase securities from us at the public offering price set forth in the prospectus supplement pursuant to delayed delivery contracts providing for payment and delivery on a specified date in the future. The conditions to these contracts and the commissions to be paid for solicitation of these contracts will be described in the prospectus supplement.

We or the selling stockholders may indemnify agents, underwriters and dealers against specified liabilities, including liabilities incurred under the Securities Act, or to contribution by us to payments they may be required to make in respect of such liabilities. Agents, underwriters or dealers, or their respective affiliates, may be customers of, engage in transactions with or perform services for us, the selling stockholder or our respective affiliates, in the ordinary course of business.

Unless otherwise specified in the applicable prospectus supplement, each class or series of securities will be a new issue with no established trading market, other than our common stock, which is traded on the NYSE American. We may elect to list any other class or series of securities on any exchange and, in the case of our common stock, on any additional exchange. However, unless otherwise specified in the applicable prospectus supplement, we will not be obligated to do so. It is possible that one or more underwriters may make a market in a class or series of securities, but the underwriters will not be obligated to do so and may discontinue any market making at any time without notice. We cannot give any assurance as to the liquidity of the trading market for any of the offered securities.

Any underwriter may engage in over-allotment, stabilizing transactions, short-covering transactions and penalty bids in accordance with Regulation M under the Exchange Act. Over-allotment involves sales in excess of the offering size, which create a short position. Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum price. Syndicate-covering or other short-covering transactions involve purchases of the securities, either through exercise of the over-allotment option or in the open market after the distribution is completed, to cover short positions. Penalty bids permit the underwriters to reclaim a selling concession from a dealer when the securities originally sold by the dealer are purchased in a stabilizing or covering transaction to cover short positions. Those activities may cause the price of the securities to be higher than it would otherwise be. If commenced, the underwriters may discontinue any of the activities at any time.

We have advised the selling stockholder that the anti-manipulation rules of Regulation M may apply to sales of shares in the market and to the activities of the selling stockholder its affiliates. This regulation may limit the timing of purchases and sales of any of the shares of common stock offered in this prospectus by the selling stockholder. The anti-manipulation rules under the Exchange Act may apply to sales of shares in the market and to the activities of the selling stockholder and its affiliates.

To comply with the securities laws of certain states, if applicable, the securities offered by this prospectus will be offered and sold in those states only through registered or licensed brokers or dealers.



#### LEGAL MATTERS

The validity of the issuance of the securities offered by this prospectus has been passed upon for us by Greenberg Traurig, LLP, Irvine, California.

### EXPERTS

The consolidated financial statements of Azitra, Inc., as of December 31, 2023 and 2022 and for each of the two years in the period ended December 31, 2023, incorporated by reference into this prospectus from the Company's Annual Report on Form 10-K for the year ended December 31, 2023, have been audited by Grassi & Co., CPAs, P.C., Independent Registered Public Accounting Firm, an independent registered public accounting firm, as stated in their report (which contains an explanatory paragraph expressing substantial doubt about the Company's ability to continue as a going concern) which is incorporated by reference herein, and has been so incorporated in reliance upon such report and upon the authority of such firm as experts in accounting and auditing.

# WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-3 under the Securities Act that registers the securities to be sold in this offering. In addition, we file annual, quarterly and current reports and proxy statements and other information with the SEC. Our SEC filings are and will become available to the public over the Internet at the SEC's website at www.sec.gov. You may also read and copy any document we file with the SEC at its public reference facilities at 100 F Street N.E., Washington, D.C. 20549. You can also obtain copies of the documents upon the payment of a duplicating fee to the SEC. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference facilities. Copies of certain information filed by us with the SEC are also available on our website at <u>https://ir.tffpharma.com/financial-information/sec-filings</u>. We have not incorporated by reference into this prospectus the information on our website and it is not a part of this document.

This prospectus does not contain all of the information set forth in the registration statement and the exhibits and schedules thereto. Some items are omitted in accordance with the rules and regulations of the SEC. You should review the information and exhibits included in the registration statement for further information about us and the securities we are offering. Statements in this prospectus concerning any document we filed as an exhibit to the registration statement or that we otherwise filed with the SEC are not intended to be comprehensive and are qualified by reference to these filings. You should review the complete document to evaluate these statements.

#### INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

The SEC permits us to "incorporate by reference" the information and reports we file with it. This means that we can disclose important information to you by referring to another document. The information that we incorporate by reference is considered to be part of this prospectus, and later information that we file with the SEC automatically updates and supersedes this information. We incorporate by reference the documents listed below, except to the extent information in those documents is different from the information contained in this prospectus, and all future documents filed with the SEC under Sections 13(a), 13(c), 14, or 15(d) of the Exchange Act (other than current reports furnished under Item 2.02 or Item 7.01 of Form 8-K and exhibits filed on such form that are related to such items unless such Form 8-K expressly provides to the contrary) until we terminate the offering of these securities:

- Our Annual Report on Form 10-K for the fiscal year ended December 31, 2023 filed with the SEC on March 15, 2024;
- Our Amendment No. 1 to our Annual Report on Form 10-K for the fiscal year ended December 31, 2023 filed with the SEC on April 29, 2024;
- Our Quarterly Report on Form 10-Q for the three months ended March 31, 2024 filed with the SEC on May 9, 2024;
- Our Current Report on Form 8-K filed with the SEC on February 14, 2024; and
- The description of our common stock set forth in our registration statement on Form 8-A12B filed with the SEC on May 16, 2023.

To the extent that any statement in this prospectus is inconsistent with any statement that is incorporated by reference and that was made on or before the date of this prospectus, the statement in this prospectus shall supersede such incorporated statement and the incorporated statement shall not be deemed, except as modified or superseded, to constitute a part of this prospectus or the registration statement. Statements contained in this prospectus as to the contents of any contract or other document are not necessarily complete and, in each instance, we refer you to the copy of each contract or document filed as an exhibit to our various filings made with the SEC.

You may request a copy of these filings, at no cost, by writing or telephoning us at the following address or telephone number:

Azitra, Inc. 21 Business Park Drive, Branford, Connecticut 06405 Attention: Corporate Secretary Telephone: (203) 646-6446

You should rely only on information contained in, or incorporated by reference into, this prospectus. We have not authorized anyone to provide you with information different from that contained in this prospectus or incorporated by reference into this prospectus. We are not making offers to sell the securities in any jurisdiction in which such an offer or solicitation is not authorized or in which the person making such offer or solicitation is not qualified to do so or to anyone to whom it is unlawful to make such offer or solicitation.

#### INDEMNIFICATION OF DIRECTORS AND OFFICERS

The Delaware General Corporation Law provides that corporations may include a provision in their certificate of incorporation relieving directors of monetary liability for breach of their fiduciary duty as directors, provided that such provision shall not eliminate or limit the liability of a director (i) for any breach of the director's duty of loyalty to the corporation or its stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) for unlawful payment of a dividend or unlawful stock purchase or redemption, or (iv) for any transaction from which the director derived an improper personal benefit. Our amended and restated certificate of incorporation provides that directors are not liable to us or our stockholders for monetary damages for breach of their fiduciary duty as directors to the fullest extent permitted by Delaware law. In addition to the foregoing, our amended and restated certificate of incorporation provides that we shall indemnify directors and officers to the fullest extent permitted by law and we have entered into indemnification agreements with each of our directors and executive officers.

The above provisions in our amended and restated certificate of incorporation may have the effect of reducing the likelihood of derivative litigation against directors and may discourage or deter stockholders or management from bringing a lawsuit against directors for breach of their fiduciary duty, even though such an action, if successful, might otherwise have benefited us and our stockholders. However, we believe that the foregoing provisions are necessary to attract and retain qualified persons as directors.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to our directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable.



\_\_\_\_Shares of Common Stock \_\_\_Pre-Funded Warrants to Purchase \_\_\_\_Shares of Common Stock

PROSPECTUS SUPPLEMENT

Maxim Group LLC

January, 2025