As filed with the U.S. Securities and Exchange Commission on April 10, 2023

Registration No. 333-269876

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

AMENDMENT NO. 2
TO
FORM S-1
REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

AZITRA INC
(Exact name of registrant as specified in its charter)

Delaware	**2834**	**46-4478536**
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

21 Business Park Drive
Branford, CT 06405
(203) 646-6446
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Francisco D. Salva
21 Business Park Drive
Branford, CT 06405
(203) 646-6446
(Name, address, including zip code, and telephone number, including area code, of agent for service)

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Approximate date of commencement of proposed sale to the public: As soon as practicable after this Registration Statement becomes effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box. ☐

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act:

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☒	Smaller reporting company ☒ Emerging Growth Company☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided to Section 7(a)(2)(B) of the Securities Act. ☐

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

The information contained in this preliminary prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

PRELIMINARY PROSPECTUS **SUBJECT TO COMPLETION** **DATED APRIL 10, 2023**

2,400,000 Shares
Common Stock

Azitra Inc

This is a firm commitment initial public offering of shares of common stock of Azitra Inc. Prior to this offering, there has been no public market for our common stock. We anticipate that the initial public offering price of our shares will be between $4.50 and $5.50.

We have applied to have our common stock listed on the NYSE American, under the symbol "AZTR" and this offering is contingent on the listing of our common stock on the NYSE American.

We are an "emerging growth company" under the federal securities laws and have elected to comply with certain reduced public company reporting requirements.

Investing in our common stock involves a high degree of risk. See the section titled "*Risk Factors*" beginning on page 11. Neither the Securities and Exchange Commission, or the SEC, nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	Per Share	Total
Initial public offering price	$	$
Underwriting discounts and commissions(1)	$	$
Proceeds to us, before expenses	$	$

(1) Underwriting discounts and commissions do not include a non-accountable expense allowance equal to 1.0% of the initial public offering price payable to the underwriters. We refer you to "*Underwriting*" beginning on page 105 for additional information regarding underwriters' compensation.

We have granted a 45-day option to the representative of the underwriters to purchase up to 360,000 additional shares of common stock solely to cover over-allotments, if any.

The underwriters expect to deliver the shares to purchasers on or about, 2023.

ThinkEquity

The date of this prospectus is , 2023

azitra

Precision dermatology powered by synthetic biology.

Netherton Syndrome: ATR-12 Summary

- Netherton syndrome is a rare, orphan autosomal recessive disease with no currently FDA-approved treatment option

- Characterized by severe inflammation, pruritus, scaling, red, and dehydrated skin
  - Caused by mutations in the *SPINK5* gene, which encodes the serine protease inhibitor, LEKTI
  - Results in overactive proteases causing desquamation, skin barrier defects, and activation of inflammation
  - High mortality and morbidity

- Mechanism of action: topical protein replacement strategy
  - Auxotrophic ATR-12 inhibits the overactive proteases through LEKTI secretion

ATR-12 Key Facts

Primary Mechanism: Kallikrein Inhibition

Clinical Status: Phase 1b IND Filed in 4Q22

Global Prevalence: ~20K+ Patients

Pipeline

FDA Regulated Drug Development Clinical Trials

Discovery | Pre-clinical | Phase 1 | Phase 2 | Phase 3 | Commercialization

ATR-12: LEKTI-secreting *Staphylococcus Epidermidis ("SE")* — **Netherton syndrome**

ATR-04: *SE* epidermin secreting auxotroph — **EGFR inhibitor associated rash**

ATR-01: Filaggrin protein — **Ichthyosis vulgaris**

Consumer/Cosmetic Product Development

Research | Safety Testing | Commercialization

Consumer Health Programs: Improve skin appearance and texture — **Joint Development Agreement with** BAYER

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You should rely only on the information contained in this prospectus. We have not authorized any other person to provide you with information different from or in addition to that contained in this prospectus, and we take no responsibility for any other information others may give you. If anyone provides you with different or inconsistent information, you should not rely on it. We are not making an offer to sell these securities in any jurisdiction where an offer or sale is not permitted. You should assume that the information appearing in this prospectus is accurate only as of the date on the front cover of this prospectus. Our business, financial condition, results of operations and prospects may have changed since that date.

No action is being taken in any jurisdiction outside the United States to permit a public offering of our common stock or possession or distribution of this prospectus in that jurisdiction. Persons who come into possession of this prospectus in jurisdictions outside the United States are required to inform themselves about and to observe any restrictions as to this offering and the distribution of this prospectus applicable to that jurisdiction.

As used in this prospectus, unless the context indicates or otherwise requires, "the Company," "our Company," "we," "us," and "our" refer to Azitra Inc, a Delaware corporation.

INDUSTRY AND MARKET DATA

This prospectus, particularly the section "Business," contains observations, statistical data, estimates, and forecasts that 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 that the third-party sources referred to in this prospectus are reliable, estimates as they relate to projections involve numerous assumptions, are subject to risks and uncertainties, and are subject to change based on various factors, including those discussed under the section titled "*Risk Factors*" and elsewhere in this prospectus. These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us.

Certain information in the text of this prospectus is contained in independent industry government and non-governmental organizational publications. The sources of these publications are provided below:

- Stacy and Belkaid Study*, Apollo Stacy and Yasmine* Belkaid, Microbial Guardians of Skin Health. Science, 2019 Jan 18;363(6424):227-228. Doi: 10.1126/science.aat4326. PMID: 30655428
- Oh Study, Zhou W, Spoto M, Hardy R, Guan C, Fleming E, Larson PJ, Brown JS, Oh J. Host-Specific Evolutionary and Transmission Dynamics Shape the Functional Diversification of Staphylococcus epidermidis in Human Skin. Cell. 2020 Feb 6;180(3):454-470.e18. doi: 10.1016/j.cell.2020.01.006. Epub 2020 Jan 30. PMID: 32004459; PMCID
- Satoh Study, Satoh TK, Mellett M, Meier-Schiesser B, Fenini G, Otsuka A, Beer HD, Rordorf T, Maul JT, Hafner J, Navarini AA, Contassot E, French LE. IL-36γ drives skin toxicity induced by EGFR/MEK inhibition and commensal Cutibacterium acnes. J Clin Invest. 2020 Mar 2;130(3):1417-1430. doi: 10.1172/JCI128678. PMID: 31805013; PMCID: PMC7269569
- Barbati Study, Netherton Syndrome in Children: Management and Future Perspectives, Federica Barbati, Mattia Giovannini Teresa Oranges, Lorenzo Lodi, Simona Barni, Elio Novembre, Ermanno Baldo, Mario Cristofolini, Stefano Stagi, Silvia Ricci, Francesca Mori, Cesare Filippeschi, Chiara Azzari and Giuseppe Indol; Frontiers in Pediatrics, May 2021
- Sun Study, Netherton syndrome: A case report and review of the literature, Joannie D. Sun, MD, and Kenneth G. Linden, PhD, MD, International Journal of Dermatology 2006
- Orphanet, Netherton Syndrome, Orphanet: Netherton syndrome

PROSPECTUS SUMMARY

This summary highlights certain information appearing elsewhere in this prospectus. Investing in our common stock involves a high degree of risk. Because it is only a summary, it does not contain all of the information that you should consider before investing in our common stock and it is qualified in its entirety by, and should be read in conjunction with, the more detailed information appearing elsewhere in this prospectus. Before you decide to invest in our common stock, you should read the entire prospectus carefully, including "Risk Factors" beginning on page 11 and the financial statements and related notes included in this prospectus.

Upon the effectiveness of the registration statement of which this prospectus forms a part, we will effect a forward stock split at a ratio of 7.1-for-1. Except for the audited financial statements included elsewhere in this prospectus, and as otherwise provided herein, all share and share price information in this prospectus have been adjusted to give effect to the forward stock split.

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.

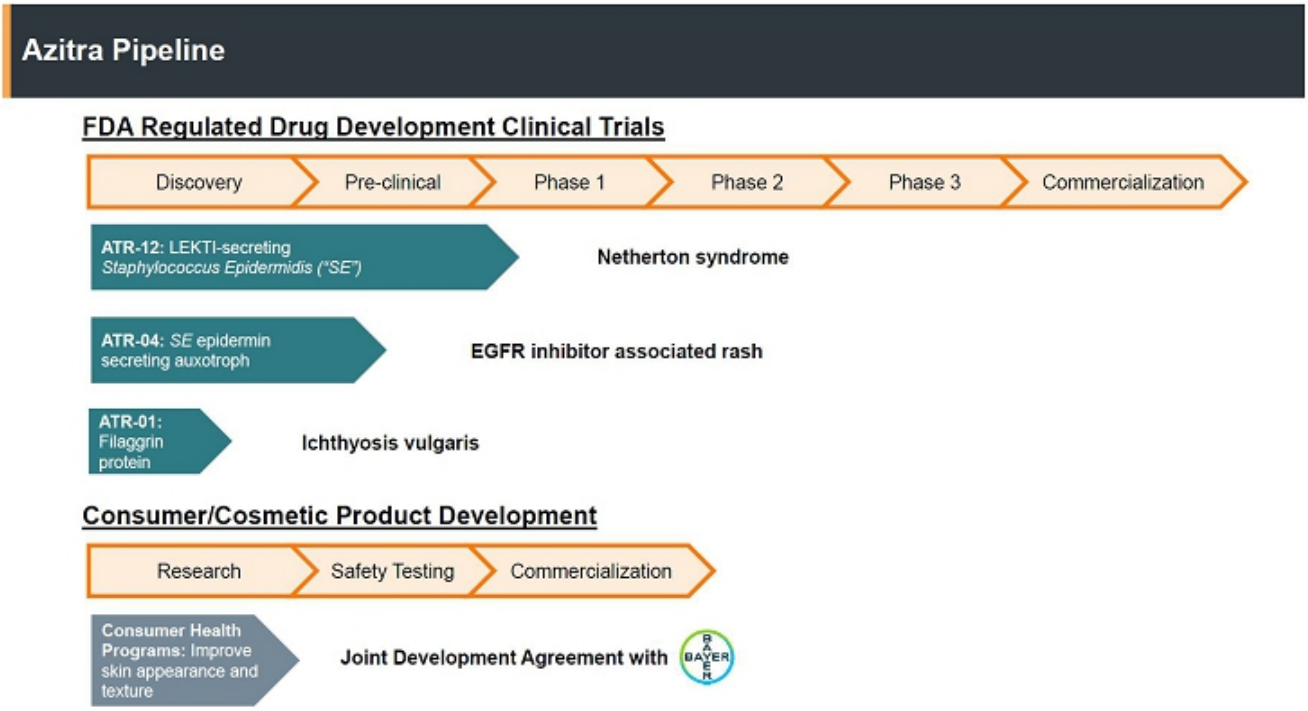
We are a pioneer in genetically engineered bacteria for therapeutic use in dermatology. Our goal is to leverage our platforms and internal microbial library bacterial strains to create new therapeutics that are either engineered living organisms or engineered proteins or peptides to treat skin diseases. 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. We expect to commence our Phase 1b clinical trial in the first half of 2023 and report initial results in the first half of 2024.

- **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. We intend to submit an IND for a Phase 1b clinical trial in certain cancer patients undergoing EGFRi targeted therapy by the end of 2023. Subject to FDA approval of our IND, we expect to commence our Phase 1b clinical trial in the first-half of 2024 with initial results expected as early as late 2024.

- **ATR-01**, 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 complete lead optimization and IND-enabling studies in 2023 to support an IND filing in late 2024.

- 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. 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.



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. Our collaboration with Fred Hutch is led by Dr. Christopher Johnston, an expert in microbial engineering, and the innovator behind the SyMPL technology.

Bayer Partnership

In December 2019, we entered into a Joint Development Agreement, or JDA, with Bayer pursuant to which we agreed to the joint development of certain strains selected from our proprietary microbial library. We and Bayer have agreed to cooperate in the identification and *in vitro* and *ex vivo* characterization of microbial strains for topical formulations, which we intend to develop as potential over-the-counter cosmetic products. Bayer paid us a one-time payment upon execution of the JDA and has agreed to reimburse us for our development costs. In October 2021, Bayer expanded the option agreement and paid us a second fee for additional characterization work. We have granted Bayer an option to acquire an exclusive royalty bearing license for up to six strains subject to development activities under the JDA, including an exclusive royalty bearing license to any related patent rights. Bayer has an option to acquire the exclusive license rights for a period of six months following our delivery of the results of the JDA development activities to Bayer. After screening through hundreds of strains, we and Bayer have selected two particular strains to move forward with in vitro and ex vivo characterization.

In September 2020, Bayer's venture capital group, LEAPS by Bayer, purchased $8 million of our Series B preferred stock.

Our Strategy

Beyond our three lead product candidates and collaboration with Bayer, our goal is to develop a broad portfolio of product candidates focused on expanding the application of our platforms for precision dermatology. We believe that we have established a unique position in advancing the development of biologics for precision dermatology.

We intend to create a broad portfolio of product candidates for precision dermatology through our development of genetically engineered proteins selected from our proprietary microbial library of approximately 1,500 unique bacterial strains. Our strategy is as follows:

- ***Build a sustainable precision dermatology company.*** Our goal is to build a leading precision dermatology company with a sustainable

pipeline of product candidates. To that end, we are focused on rapidly advancing our current pipeline of live biotherapeutic candidates while actively developing additional product candidates. Each of our current product candidates are proprietary and subject to pending patent applications. We expect that most, if not all, genetically engineered product candidates we develop will be eligible for patent protection.

- ***Advance our lead product candidates, ATR-12 and ATR-04, through clinical trials.*** In Netherton syndrome patients in 2022, we obtained pre-IND correspondence with the FDA for purposes of discussing our proposed regulatory pathway for ATR-12 and obtaining guidance from the FDA on the pre-clinical plan leading to the filing and acceptance of an IND for ATR-12. In December 2022, we filed an IND for a first-in-human trial of ATR-12 in Netherton syndrome patients. Our IND proposes a Phase 1b clinical study of ATR-12 in patients with Netherton syndrome. On January 27, 2023, we received notification from the FDA that the "study may proceed" with respect to the proposed Phase 1b clinical trial, and we expect to commence our Phase 1b clinical trial in the first half of 2023, with initial results expected in the first half of 2024. We also plan to conduct a Phase 1b trial of our ATR-04 in certain cancer patients undergoing EGFRi therapy, and expect to file an IND for ATR-04 by the end of 2023.

- ***Broaden our platform by selectively exploring strategic partnerships that maximize the potential of our precision dermatology programs.*** We intend to maintain significant rights to all of our core technologies and product candidates. However, we will continue to evaluate partnering opportunities in which a strategic partner could help us to accelerate development of our technologies and product candidates, provide access to synergistic combinations, or provide expertise that could allow us to expand into the treatment of different types of skin diseases. We may also broaden the reach of our platform by selectively in-licensing technologies or product candidates. In addition, we will consider potentially out-licensing certain of our proprietary technologies for indications and industries that we are not ourselves pursuing. We believe our genetic engineering techniques and technologies have applicability outside of the field of medicine, including cosmetics and in the generation of clean fuels and bioremediation.

- ***Leverage our academic partnerships.*** We currently have partnerships with investigators at the Fred Hutchinson Cancer Center, Yale University, Jackson Laboratory for Genomic Medicine, and Carnegie Mellon University. We expect to leverage these partnerships and potentially expand them or form other academic partnerships to bolster our engineering platforms and expand our research and development pipeline.

- ***Expand on our other potential product candidates.*** Beyond our three lead product candidates, our goal is to develop a broad portfolio of product candidates focused on expanding the application of our platforms for precision dermatology. We have a proprietary platform for discovering and developing therapeutic products for precision dermatology. Our platform is built around a microbial library comprised of approximately 1,500 unique bacterial strains to allow screening for unique therapeutic characteristics and utilizes a microbial genetic technology that analyzes, predicts and engineers the proteins, peptides and molecules made by skin microbes. Our ability to genetically engineer intractable microbial species is uniquely leveraged by our exclusive license to the SyMPL technology.

Our Intellectual Property

As of the date of this prospectus, we own or exclusively license two issued U.S. patents, four pending U.S. patent applications, one pending PCT application and 38 other foreign national-stage applications, including three European regional-phase applications that are important to the development of our business.

Our Leadership Team

We are led by Francisco D. Salva, our chief executive officer, and Travis Whitfill, our co-founder, who have more than 35 years of combined experience in the management of biotechnology companies and healthcare investing. Mr. Salva was previously a co-founder of Acerta Pharma, which was sold to AstraZeneca for approximately $6.3 billion in a staged acquisition beginning in 2016. He also worked on the turnaround of Pharmacyclics, which subsequently sold to Abbvie for approximately $21 billion in 2015. Before that, Mr. Salva spent almost a decade in life sciences venture capital. Mr. Whitfill served as associate research scientist and assistant professor adjunct at Yale University with appointments in the Departments of Pediatrics and Emergency Medicine. He has led numerous grant-funded projects, holds nearly a dozen patents and has co-authored over 50 publications.

Our Competitive Strengths

Azitra is a pioneer in genetically engineering bacteria for therapeutic use in dermatology clinical trials. We have built a proprietary platform that includes a microbial library comprised of approximately 1,500 unique bacterial strains that are screened for therapeutic characteristics as well as lead drug candidates. Furthermore, we have exclusively licensed a novel technology, which potentially enables the genetic transformation of previously intractable bacterial microbes. The history of recombinant protein engineering in biotech has traditionally been limited to less than 20 species. Our licensed technology opens up the potential to genetically engineer thousands of microbial species to build proteins and peptides that have never been previously built. Our management team has significant experience in discovering, developing, manufacturing and commercializing therapeutics. The members of our leadership team have specialized expertise developed at companies including Pharmacyclics, Acerta Pharma, Botanix Pharmaceuticals, and Realm Therapeutics.

Our Market Opportunity

We believe there are significant market opportunities to capture in each of our addressable markets. The dermatology market itself has shown considerable growth over the last decade and is predicted to continue to grow. According to Vision Research Reports, the dermatology drug market surpassed $17 billion in 2021 and is expected to grow at a compound annual growth rate of 8.8% through 2030. Our first product candidate to emerge from our platform focuses on the orphan indication of Netherton syndrome. Based on the Barbati and Sun Studies, we believe that this product candidate represents a potential $250 million global sales opportunity by the mid-2030's. The diseases we intend to target are well characterized, often by a monogenic genetic mutation. Additionally, the era of genomic sequencing has ushered in unprecedented progress in genetic testing. The defined molecular pathophysiology of over 100 rare skin diseases has now been defined.

Our 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.

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 ® and ™, 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.

Private Placements of our Convertible Securities

To date, we have capitalized our operations through a series of private placements of our convertible preferred stock and convertible promissory notes, all of which will convert into shares of our common stock upon the consummation of this offering, including:

- The March 2017 placement of 205,385 shares of our Series A convertible preferred stock, at a price of $16.25 per share, which will convert into 1,458,234 shares of our common stock upon the consummation of this offering;
- The February 2019 placement of 380,657 shares of our Series A-1 convertible preferred stock, at a price of $37.50 per share, which will convert into 2,958,120 shares of our common stock upon the consummation of this offering;
- The September 2020 placement of 392,000 shares of our Series B convertible preferred stock, at a price of $43.45 per share, which will convert into 3,277,083 shares of our common stock upon the consummation of this offering;
- The January 2021 placement of a $1 million unsecured convertible promissory note, the principal amount of which, along with all accrued and unpaid interest thereunder, converted into 23,432 shares of our Series B convertible preferred stock in January 2023; and
- The September 2022 placement of $4.35 million of our unsecured convertible promissory notes, the principal amount of which, along with all accrued and unpaid interest thereunder, is convertible into shares of our common at the per share conversion price equal to the lower of (i) $30 million divided the number of our shares of common stock issued and outstanding, on a fully diluted basis, immediately prior to the close of this offering or (ii) 50% of the price per share in this offering.

Except as otherwise indicated, all information in this prospectus concerning our outstanding shares of common stock assumes the automatic conversion of the above-described shares of convertible preferred stock and convertible notes into a total of approximately 9,513,143 shares of our common stock upon the consummation of this offering, assuming an initial public offering price of $5.00 per share (which is the midpoint of the price range set forth on the cover page of this prospectus).

Changes to our Capitalization

Upon the effectiveness of the registration statement of which this prospectus forms a part, we plan to amend and restate our certificate of incorporation to (i) increase our authorized common stock from 1,950,000 shares to 100,000,000 shares, (ii) authorize 10,000,000 shares of "blank check" preferred stock and (iii) change the par value of our capital stock from $0.01 to $0.0001. At that time, we also plan to complete a 7.1-for-1 forward stock split of our outstanding common stock, or the Stock Split. As a result of the Stock Split, and after giving effect to the conversion of all outstanding shares of convertible preferred stock and convertible notes discussed immediately above, we will have 10,557,134 shares of common stock issued and outstanding immediately prior to the close of this offering, assuming an initial public offering price of $5.00 per share (which is the midpoint of the price range set forth on the cover page of this prospectus).

Except for the audited financial statements included elsewhere in this prospectus, and as otherwise indicated herein, all share and share price information in this prospectus have been adjusted to give effect to the Stock Split. In addition, except for the audited financial statements included elsewhere in this prospectus, and as otherwise indicated herein, all information in this prospectus concerning our outstanding shares of common stock assumes the automatic conversion of the above-described shares of convertible preferred stock and convertible notes upon the consummation of this offering.

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 $1.07 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 are choosing 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.

For certain risks related to our status as an emerging growth company, see the disclosure elsewhere in this prospectus under "*Risk Factors—Risks Related to this Offering and Owning Our Common Stock - we are an 'emerging growth company' under the JOBS Act and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our common stock less attractive to investors*."

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.

THE OFFERING

Issuer	Azitra Inc
Common stock offered	2,400,000 shares
Common stock to be outstanding after this offering	12,957,134 shares (or 13,317,134 shares if the underwriters' option to purchase additional shares is exercised in full) of common stock.
Over-allotment option	We have granted the underwriters the option to purchase up to an additional 360,000 shares of our common stock at the initial public offering price, less the underwriting discount, within 45 days of the date of this prospectus, to cover over-allotments, if any.
Use of proceeds	We estimate that we will receive net proceeds of approximately $9.9 million from our sale of common stock in this offering, or approximately $11.6 million if the underwriters exercise their over-allotment option in full, based on an initial public offering price of $5.00 per share (which is the midpoint of the price range set forth on the cover page of this prospectus). We intend to use the net proceeds from this offering, along with our existing cash and cash equivalents, for clinical trials and product development, research and development, clinical manufacturing as well as for working capital and other general corporate purposes. See the section titled "*Use of Proceeds*" in this prospectus for a more complete description of the intended use of processed from this offering.
Proposed trading market and symbol	We have applied to list our common stock for trading on the NYSE American under the symbol "AZTR"
Risk factors	Investing in our common stock involves a high degree of risk. See the section titled "*Risk Factors*" beginning on page 11 and the other information in this prospectus for a discussion of the factors you should consider carefully before you decide to invest in our common stock.
Lock-Up	We, each of our directors, officers and any stockholder that owns 0.5% or more common stock have agreed, subject to certain exceptions, not to sell, offer, agree to sell, contract to sell, hypothecate, pledge, grant any option to purchase, make any short sale of, or otherwise dispose of or hedge, directly or indirectly, any shares of our capital stock or any securities convertible into or exercisable or exchangeable for shares of capital stock, for a period of six (6) months or twelve (12) months, as applicable, after the date of this prospectus, without the prior written consent of the representative. Following the expiration of the applicable lock-up period, all of the issued and outstanding shares of our common stock will be eligible for future sale, subject to the applicable volume, manner of sale, holding period, and other limitations of Rule 144. See the section of this prospectus entitled "*Underwriting*" for additional information.

The number of shares of our common stock to be outstanding after this offering is based on 10,557,134 shares of our common stock outstanding as of March 17, 2023 (after giving effect to the Stock Split and the conversion of our shares of convertible preferred stock and convertible promissory notes described above), and excludes:

- 1,290,319 shares of our common stock issuable upon exercise of outstanding options, with a weighted average exercise price of $1.33 per share, granted pursuant to our 2016 Stock Incentive Plan, or the 2016 Plan;
- approximately 275,210 shares of our common stock issuable upon exercise of outstanding warrants, with a weighted average exercise price of $4.23 per share
- up to 360,000 shares issuable pursuant to the underwriters' over-allotment option;
- 96,000 shares issuable upon exercise of a warrant to be issued to the underwriter as part of its compensation in connection with this offering (up to 110,400 shares if the over-allotment option is exercised in full) at an exercise price of $6.25 per share; and
- 157,989 shares of our common stock reserved for future grants under our 2016 Plan and 2,000,000 shares of our common stock reserved for future grants under our 2023 Stock Incentive Plan, or the 2023 Plan.

Unless we indicate otherwise or unless the context otherwise requires, all information in this prospectus assumes the following:

- the automatic conversion of all outstanding shares of our convertible preferred stock and all of our convertible promissory notes upon the close of this offering;
- no exercise of outstanding warrants or options described above; and
- no exercise of the underwriters' over-allotment option.

SUMMARY RISK FACTORS

Our business is subject to numerous risks, including risks that may prevent us from achieving our business objectives or adversely affect our business, results of operations, cash flows, and prospects, to consider before investing in our common stock. These risks are further discussed in the section "*Risk Factors*" immediately following this prospectus summary. Some of those risks include:

- we are an early-stage clinical biopharmaceutical company with limited operating history;
- we have a history of significant operating losses and anticipate continued operating losses for the foreseeable future;
- 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;
- the clinical and commercial utility of our microbial library and genetic engineering platform is uncertain and may never be realized;
- our product candidates are in early stages of development, and therefore they will require extensive additional preclinical and clinical testing;
- the ongoing COVID-19 pandemic could adversely impact our business, including our clinical trials, supply chain and business development activities;
- we will need to grow the size of our organization, and we may experience difficulties in managing this growth;
- we currently have no sales and marketing organization;
- we will be completely dependent for the foreseeable future on third parties to manufacture our product candidates for commercial sale;
- our business model includes the potential out-licensing of strains from our proprietary microbial library or our product candidates to other pharmaceutical companies, however technology licensing in the pharmaceutical industry is a lengthy process and subject to several risks and factors outside of our control;
- our business may suffer with the loss of key personnel;
- if product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates;
- our business operations could suffer in the event of information technology systems' failures or security breaches;
- we face significant competition from other biotechnology and pharmaceutical companies targeting medical dermatological indications;
- our success is entirely dependent on our ability to obtain the marketing approval for our product candidates by the FDA and the regulatory authorities in foreign jurisdictions in which we intend to market our product candidates, of which there can be no assurance;
- our clinical trials may fail to demonstrate substantial evidence of the safety and efficacy of our product candidates or any future product candidates;
- results of preclinical studies of our product candidates may not be predictive of the results of future preclinical studies or clinical trials;
- even if we receive regulatory approval for any of our product candidates, we may not be able to successfully commercialize the product and the revenue that we generate from its sales, if any, may be limited;
- current and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain;
- it is difficult and costly to protect our intellectual property rights, and we cannot ensure the protection of these rights;
- our product candidates may infringe the intellectual property rights of others, which could increase our costs and delay or prevent our development and commercialization efforts;
- an active, liquid and orderly trading market for our shares may not develop;
- future capital raises may dilute your ownership and have other adverse effects on our operations;
- the market price of our shares may be subject to fluctuation and volatility;
- if we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud;
- we ratified certain corporate actions pursuant to Section 204 of the Delaware General Corporate Law, or DGCL, however there can be no assurance that claims will not be made to challenge the validity of the ratification or the related corporate actions; and
- our charter documents and Delaware law may inhibit a takeover that stockholders consider favorable.

SUMMARY FINANCIAL DATA

The following tables summarize our financial data. You should read this summary financial data together with the section entitled "*Management's Discussion and Analysis of Financial Condition and Results of Operations*" and our financial statements and related notes that are included elsewhere in this prospectus. The financial information as of and for the fiscal years ended December 31, 2022 and 2021 is derived from the audited financial statements that are included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that may be expected in the future.

(in thousands, except share amounts)	Years Ended December 31, 2022	2021
Revenues	$ 284	$ 110
Net loss	$ (10,680)	$ (8,940)
Net loss per share, basic and diluted[(1)]	$ (90.47)	$ (79.49)
Net loss – pro forma and pro forma as adjusted[(2)(3)]	$ (14,014)	$ (8,940)
Loss per share, basic and diluted – pro forma[(2)]	$ (1.32)	$ (0.85)
Loss per share, basic and diluted – pro forma as adjusted[(3)]	$ (1.08)	$ (0.69)

(in thousands)	December 31, 2022 Actual (unaudited)	Pro Forma[(2)] (unaudited)	Pro Forma as Adjusted[(3)] (unaudited)
Balance Sheet Data:			
Cash and cash equivalents	$ 3,493	$ 3,493	$ 13,655
Working capital	$ 1,914	$ 1,914	$ 12,076
Total assets	$ 7,167	$ 7,167	$ 17,329
Convertible notes payable[(4)]	$ 6,600	$ -	$ -
Convertible preferred stock	$ (33,695)	$ -	$ -
Total common stock	$ 1	$ 106	$ 1
Additional paid-in capital	$ 1,053	$ 45,870	$ 55,598
Total stockholders' equity (deficit)	$ (36,260)	$ 5,327	$ 14,951

(1) Does not give effect to the Stock Split to take place upon the effectiveness of the registration statement of which this prospectus forms a part at a ratio of 7.1-for-1.

(2) The pro forma loss per share includes a $3.5 million loss upon conversion of our convertible promissory notes, and the pro forma column reflects the (i) Stock Split, (ii) automatic conversion of all of our outstanding shares of convertible preferred stock at the close of this offering into 7,693,436 shares of our common stock and reclassification into common stock, and (iii) automatic conversion of all principal and accrued and unpaid interest under our outstanding convertible promissory notes at the close of this offering into approximately 1,819,706 shares of our common stock and additional paid-in capital, assuming an initial public offering price of $5.00 per share (which is the midpoint of the price range set forth on the cover page of this prospectus).

(3) The pro forma as adjusted column reflects all adjustments included in the pro forma column and gives effect to the sale by us of 2,400,000 shares of common stock offered by this prospectus, assuming an initial public offering price of $5.00 per share (which is the midpoint of the price range set forth on the cover page of this prospectus), after deducting underwriting discounts and commissions and estimated offering costs payable by us.

(4) Represents the fair value of the convertible note as we have elected to account for the instrument at its fair value

RISK FACTORS

Any investment in our common stock involves a high degree of risk. You should carefully consider the risks described below, which we believe represent certain of the material risks to our business, together with the information contained elsewhere in this prospectus, before you make a decision to invest in our common stock. Please note that the risks highlighted here are not the only ones that we may face. For example, additional risks presently unknown to us or that we currently consider immaterial or unlikely to occur could also impair our operations. If any of the following events occur or any additional risks presently unknown to us actually occur, our business, financial condition and operating results may be materially adversely affected. In that event, the trading price of our common stock could decline and you could lose all or part of your investment.

Risks Relating to Our Business

We are an early-stage clinical biopharmaceutical company with limited operating history.

We are an early-stage clinical biopharmaceutical company, incorporated on January 2, 2014, and have limited operating history. We have not commenced revenue-producing operations apart from limited grant and service revenue. To date, our operations have consisted of the development of our proprietary microbial library, the identification, characterization, genetic engineering and testing of certain bacterial species to provide therapeutic effect and the development of our initial product candidates. Our limited operating history makes it difficult for potential investors to evaluate our technology or prospective operations. As an early-stage clinical biopharmaceutical company, we are subject to all the risks inherent in the organization, financing, expenditures, complications and delays involved with a new business. Accordingly, you should consider our prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by companies in the early stages of development, especially early-stage clinical-stage biopharmaceutical companies such as ours. Potential investors should carefully consider the risks and uncertainties that a company with a limited operating history will face. In particular, potential investors should consider that we may be unable to:

- successfully implement or execute our business plan, or that our business plan is sound;
- successfully complete pre-clinical and clinical trials and obtain regulatory approval for the marketing of our product candidates;
- successfully demonstrate a favorable differentiation between our precision dermatological product candidates and the current products on the market;
- successfully contract for the manufacture of our clinical drug products and establish a commercial drug supply;
- secure market exclusivity or adequate intellectual property protection for our product candidates;
- attract and retain an experienced management and advisory team; and
- raise sufficient funds in the capital markets to effectuate our business plan, including product and clinical development, regulatory approval and commercialization for our product candidates.

Investors should evaluate an investment in us in light of the uncertainties encountered by developing companies in a competitive environment. There can be no assurance that our efforts will be successful or that we will ultimately be able to attain profitability. If we cannot successfully execute any one of the foregoing, our business may not succeed and your investment will be adversely affected. You must be prepared to lose all of your investment.

We have a history of significant operating losses and anticipate continued operating losses for the foreseeable future.

For the fiscal years ended December 31, 2022 and 2021, we incurred a net loss of $10.7 million and $8.9 million, respectively. As of December 31, 2022, we had an accumulated deficit of $37.3 million. Following completion of this offering, we expect to continue to incur substantial expenses without any meaningful revenues unless and until we are able to obtain regulatory approval and successfully commercialize at least one of our product candidates. We also believe that, at a minimum, it will take us four to six years from the closing of the offering for us to obtain regulatory approval of our first drug candidates, assuming we are able to get regulatory approval at all. Even if we are able to commercialize our product candidates, there can be no assurance that we will generate significant revenues or ever achieve profitability.

We expect to have significant research, regulatory and development expenses as we advance our product candidates towards commercialization. As a result, we expect to incur substantial losses for the foreseeable future, and these losses will be increasing. We are uncertain when or if we will be able to achieve or sustain profitability. If we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Failure to become and remain profitable may impair our ability to sustain operations and adversely affect our business and our ability to raise capital. If we are unable to generate positive cash flow within a reasonable period of time, we may be unable to further pursue our business plan or continue operations, in which case you may lose your entire investment.

The report of our independent registered public accounting firm for the year ended December 31, 2022 states that due to our accumulated deficit, recurring and negative cash flow from operations there is substantial doubt about our ability to continue as a going concern.

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 December 31, 2022, we had total assets of $7.2 million and working capital of $1.9 million. We believe that net proceeds of this offering, along with our cash on hand as of the date of this prospectus, will be sufficient to cover our proposed plan of operations over, at least, the next 12 months, including dosing in the proposed Phase 1b clinical trial for ATR-12 and the initial enrollment in the proposed Phase 1b clinical trial for ATR-04. However, as of the date of this prospectus, we believe that we will need additional capital beyond the next 12 months, and there can be no assurance we will not need additional capital sooner. In addition, we believe that we will need additional capital to obtain marketing approval for ATR-12 and ATR-04, assuming such approval can be obtained at all. We intend to seek additional funds through various financing sources, including the sale of our equity and debt securities, 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.

The clinical and commercial utility of our microbial library and genetic engineering platform is uncertain and may never be realized.

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 artificial intelligence, machine learning and genetic engineering technologies. To date, our focus is on the development of genetically engineered strains of *S. epidermidis,* which we consider to be an optimal therapeutic candidate species for engineering of dermatologic therapies. However, we believe that the genetic engineering of *S. epidermidis* is a novel and unproven mode of therapy. As of the date of this prospectus, we have tested and evaluated our proprietary strains of *S. epidermidis* in pre-clinical studies and have not conducted any clinical trials designed to evaluate safety, tolerability or efficacy. We currently intend to commence a Phase 1b clinical trial for our ATR-12 in the first half of 2023 and a Phase 1b clinical trial for our ATR-04 product candidate in the first half of 2024. However, success in early clinical trials does not ensure that large-scale clinical trials will be successful, nor does it predict final results. Even after the completion of our proposed Phase 1b clinical trials, our initial product candidates will have only been tested in a small number of patients. Results from these clinical trials may not necessarily be indicative of the safety and tolerability or efficacy of our product candidates or our as we expand into larger clinical trials. Until such time, if ever, as we are able to provide the FDA with substantial clinical evidence to support a claim of safety, efficacy, purity and potency sufficient to enable the FDA to approve our proprietary product candidates for any indication, our proprietary microbial library and genetic engineering platform will remain unproven.

Our product candidates are in early stages of development, and therefore they will require extensive additional preclinical and clinical testing. Success in preclinical studies or early-stage clinical trials may not be indicative of results in future clinical trials and we cannot assure you that any ongoing, planned or future clinical trials will lead to results sufficient for the necessary regulatory approvals.

Because our product candidates are in early stages of development, they will require extensive preclinical and clinical testing. ATR-12 and ATR-04 are our only product candidates for which we have conducted meaningful pre-clinical studies. Following this offering we expect to commence a Phase 1b clinical trial for ATR-12 in the first half of 2023 and file an IND for a Phase 1b clinical trial of ATR-04 by the end of 2023. Success in preclinical testing and early-stage clinical trials does not ensure that later clinical trials will generate the same results or otherwise provide adequate data to demonstrate the efficacy and safety of a product candidate. Preclinical studies and Phase 1b clinical trials are primarily designed to test safety, to study pharmacokinetics and pharmacodynamics and to understand the side effects of product candidates at various doses and schedules. Phase 1b clinical trials also test how well a certain disease responds to a new treatment. Success in preclinical studies and earlier clinical trials does not ensure that later efficacy trials will be successful, nor does it predict final results. Our product candidates may fail to show the desired safety and efficacy in clinical development despite positive results in preclinical studies or even if they successfully advance through earlier clinical trials.

In addition, the design of a clinical trial can determine whether its results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. As an organization, we have limited experience designing clinical trials and may be unable to design and execute a clinical trial to support regulatory approval. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks, including failure in late-stage clinical trials even after achieving promising results in preclinical testing and earlier clinical trials. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval.

Further, we cannot predict with any certainty if or when we might submit a Biologics License Application, or BLA, for regulatory approval for any of our product candidates or whether any such BLA will be accepted for review by the FDA, or whether any BLA will be approved upon review. Even if our clinical trials are completed as planned, we cannot be certain that their results will support our proposed indications. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical trials will replicate the results of prior clinical trials and preclinical testing. The clinical trial process may fail to demonstrate that our product candidates are safe and effective for their proposed uses. This failure could cause us to abandon a product candidate and may delay development of other product candidates. Any delay in, or termination of, our clinical trials will delay and possibly preclude the filing of any BLAs with the FDA and, ultimately, our ability to commercialize our product candidates and generate product revenues.

The ongoing COVID-19 pandemic could adversely impact our business, including our clinical trials, supply chain and business development activities.

In connection with the ongoing COVID-19 pandemic, governments have implemented significant measures, including closures of businesses, quarantines, travel restrictions and other social distancing directives, intended to control the spread of the virus. While the disease and countermeasures have abated to some degree in recent months, the impact of this pandemic will likely continue to be extensive in many aspects of society and will likely continue to result in significant disruptions to the global economy, as well as businesses and capital markets around the world. Many pharmaceutical companies have experienced delays and suspensions of their clinical trials due to the ongoing COVID-19 pandemic, including:

- delays or difficulties in enrolling and maintaining patients in their clinical trials;
- delays or difficulties in shipping and delivering in a timely manner supplies, samples or products required for their clinical trials due to the impact of the ongoing COVID-19 pandemic on government and commercial shipping organizations;

- delays or difficulties in clinical site initiation, including difficulties completing any required contracts, successfully completing IRB review in a timely manner, or in recruiting clinical site investigators and clinical site staff;
- disruptions in supply chains that result in shortages of required raw materials, manufacturing devices, active pharmaceutical ingredients, and finished product for our preclinical research and clinical trials; and
- changes in local regulations as part of a response to the ongoing COVID-19 outbreak which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or cause us to discontinue the clinical trials altogether.

These and other disruptions in our operations and the global economy could negatively impact our business, operating results and financial condition.

We will need to grow the size of our organization, and we may experience difficulties in managing this growth. As our development and commercialization plans and strategies develop, we will need to expand the size of our employee and consultant/contractor base. Future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, motivate and integrate additional employees. In addition, our management may have to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. Our future financial performance and our ability to commercialize our product candidates and any other future product candidates and our ability to compete effectively will depend, in part, on our ability to effectively manage our future growth.

If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy. In addition, the loss of the services of our senior management would adversely impact our business prospects. Our management team has expertise in many different aspects of drug development and commercialization. However, our ability to compete in the highly competitive pharmaceuticals industry depends in large part upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We will need to hire additional personnel as we further develop our product candidates. Competition for skilled personnel in our market is intense and competition for experienced scientists may limit our ability to hire and retain highly qualified personnel on acceptable terms. Despite our efforts to retain valuable employees, members of our management, scientific and medical teams may terminate their employment with us on short notice. The loss of the services of any of our executive officers or other key employees, or our inability to hire targeted executives, could potentially harm our business, operating results or financial condition. In particular, we believe that the loss of the services of our chief executive officer would have a material adverse effect on our business.

Other biopharmaceutical companies with which we compete for qualified personnel have greater financial and other resources, different risk profiles, and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate and success at which we can develop and commercialize product candidates would be limited.

We currently have no sales and marketing organization. If we are unable to establish satisfactory sales and marketing capabilities or secure a third-party sales and marketing relationship, we may not be able to successfully commercialize any of our product candidates. At present, we have no sales or marketing personnel. Upon and subject to initial receipt of the requisite regulatory approvals for one or more of our drug products, we plan to build focused capabilities in the United States to commercialize our development programs focused on live biotherapeutic products and recombinant proteins for the treatment of skin diseases, where we believe the patient populations and medical specialists for the indications we are targeting are sufficiently concentrated to allow us to effectively promote our products with a targeted sales team. In other markets for which commercialization may be less capital efficient for us, we may selectively pursue strategic collaborations with third parties in order to maximize the commercial potential of our product candidates. In some cases, we may pursue the licensing of our microbial library or patent rights or enter into a joint development arrangement. If we are not successful in recruiting sales and marketing personnel and building a sales and marketing infrastructure or entering into appropriate collaboration arrangements with third parties, we will have difficulty successfully commercializing our product candidates, which would adversely affect our business, operating results and financial condition.

Even if we enter into third-party marketing and distribution arrangements, we may have limited or no control over the sales, marketing and distribution activities of these third parties. Our future revenues may depend heavily on the success of the efforts of these third parties. In terms of establishing a sales and marketing infrastructure, we will have to compete with established and well-funded pharmaceutical and biotechnology companies to recruit, hire, train and retain sales and marketing personnel. Factors that may inhibit our efforts to build an internal sales organization or enter into collaboration arrangements with third parties include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe any of our product candidates;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an internal sales and marketing organization.

We will be completely dependent for the foreseeable future on third parties to manufacture our product candidates for commercial sale, and the commercialization of our product candidates could be halted, delayed or made less profitable if those third parties fail to obtain manufacturing approval from the FDA or comparable foreign regulatory authorities, fail to provide us with sufficient quantities of our product candidates or fail to do so at acceptable quality levels or prices.

We do not own or operate manufacturing facilities for the commercial production of our current product candidates. We currently rely on third-party contract manufacturers for all of our required raw materials, manufacturing devices, and active pharmaceutical ingredients for our preclinical research and clinical trials. Although we are able to manufacture finished product in our Groton Connecticut facility for our clinical trials, we will rely on third parties for the manufacture of our finished product for commercial sale. We do not have long-term agreements with any of these third parties. We also do not have any current contractual relationship for commercial supplies. We intend to enter into agreements with third-party contract manufacturers and one or more backup manufacturers for future production. We are analyzing the feasibility of building manufacturing capabilities for future development and commercial quantities of any products that we develop. Such products will need to be manufactured in facilities, and by processes, that comply with the requirements of the FDA and the regulatory agencies of other jurisdictions in which we are seeking approval. In the meantime, we will be obligated to rely on contract manufacturers for our preclinical research and clinical trials and commercial production, if and when any of our product candidates are approved for commercialization.

The facilities used by us or any contract manufacturer to manufacture our raw materials, manufacturing devices, active pharmaceutical ingredients and finished products must be approved by the FDA or comparable foreign regulatory authorities. Such approvals are subject to inspections that will be conducted after we submit a BLA to the FDA or their equivalents to other relevant regulatory authorities. Until such time, if ever, as we establish our own manufacturing facilities, we will not control the manufacturing process of our product candidates, and will be completely dependent on our contract manufacturing partners for compliance with Current Good Manufacturing Practices, or cGMPs, for manufacture of our raw materials, manufacturing devices, active pharmaceutical ingredients and finished products. These cGMP regulations cover all aspects of the manufacturing, testing, quality control, storage, distribution and record keeping relating to our product candidates. If our contract manufacturers do not successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, we will not be able to secure or maintain regulatory approval for product made at their manufacturing facilities. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which could significantly delay our clinical trials and impact our ability to develop, manufacture, obtain regulatory approval for or market our product candidates, if approved. Likewise, we could be negatively impacted if any of our contract manufacturers elect to discontinue their business relationship with us.

Our contract manufacturers will be subject to ongoing periodic unannounced inspections by the FDA and corresponding state and foreign agencies for compliance with cGMPs and similar regulatory requirements. We will not have control over our contract manufacturers' compliance with these regulations and standards. Failure by any of our contract manufacturers to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure to grant approval to market any of our product candidates, delays, suspensions or withdrawals of approvals, inability to supply product, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business. In addition, we will not have control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. Failure by our contract manufacturers to comply with or maintain any of these standards could adversely affect our ability to develop, manufacture, obtain regulatory approval for or market any of our product candidates, if approved.

If, for any reason, these third parties are unable or unwilling to perform we may not be able to locate alternative manufacturers or formulators or enter into favorable agreements with them and we cannot be certain that any such third parties will have the manufacturing capacity to meet future requirements. If these manufacturers or any alternate manufacturer of finished drug product experiences any significant difficulties in its respective manufacturing processes for our required raw materials, manufacturing devices, active pharmaceutical ingredients or finished product or should cease doing business with us for any reason, we could experience significant delays in our clinical trials and significant interruptions in the supply of any of our product candidates or may not be able to create a supply of our product candidates at all.

Any manufacturing problem or the loss of a contract manufacturer could be disruptive to our operations and result in development and clinical trial delays and lost sales. Additionally, we will rely on third parties to supply the raw materials needed to manufacture our product candidates. Any such reliance on suppliers may involve several risks, including a potential inability to obtain critical materials and reduced control over production costs, delivery schedules, reliability and quality. Any unanticipated disruption to the operation of one of our contract manufacturers caused by problems with suppliers could delay our shipment of any of our product candidates, increase our cost of goods sold and result in delays in clinical trials or lost sales.

Our business model includes the potential out-licensing of strains from our proprietary microbial library or our product candidates to other biopharmaceutical companies, however technology licensing in the biopharmaceutical industry is a lengthy process and subject to several risks and factors outside of our control, and we cannot forecast our ability to successfully out-license our technology or the length of time it takes to establish a new licensing relationship.

Our business model includes the potential out-licensing or joint development of strains from our proprietary microbial library or our product candidates to other biopharmaceutical companies. Any such arrangement would typically begin with preliminary feasibility testing and evaluation by our potential partner or licensee. Assuming the feasibility testing is successful, our ability to convert the successful test into a commercial license or joint development agreement is dependent on a number of risks and factors, many of which are outside our control, including:

- the rate of adoption and incorporation of new technologies, by members of the pharmaceutical industry generally;
- our potential licensee's internal evaluation of the economic benefits of marketing a dermatological product that may be competitive with other products currently in development or commercial sale by our potential partner or licensee regardless of the perceived benefits or advantages of our technology or product;
- our potential partner's/licensee's internal budgetary and product development issues, including their ability to commit the capital and human resources towards the development and commercialization of our technology or product; and
- our potential partner's/licensee's willingness to accept our requirements for upfront fees and ongoing royalties.

In addition, we believe that in many cases our potential partners or licensee may engage with us in the early-stage feasibility testing as part of their evaluation of multiple drug and drug delivery options and prior to making any decision or commitment to the development of a new drug product. Consequently, even if our platform is successful in early feasibility studies, our potential partner/licensee may decide, for reasons unrelated to the performance of our technology, not to enter into a license agreement with us. Therefore, we are unable to predict the degree to which our proposed licensing model will be successful.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

We will face a potential risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk of such liability if we commercialize any of our product candidates. For example, we may be sued if any product we develop, including any of our product candidates, or any materials that we use in our product candidates allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and a breach of warranties. In the U.S., claims could also be asserted against us under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense of these claims would require us to employ significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for any of our product candidates or any future products that we may develop;
- injury to our reputation;
- failure to obtain regulatory approval for our product candidates;
- withdrawal of participants in our clinical trials;
- costs associated with our defense of the related litigation;
- a diversion of our management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- the inability to commercialize some or all of our product candidates; and
- a decline in the value of our stock.

As of the date of this prospectus, we carry product liability insurance that we consider adequate for our current level of clinical testing and development. However, we will need additional product liability coverage at the time we commence commercial sale of our initial product. Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop. Although we will endeavor to obtain and maintain such insurance in coverage amounts we deem adequate, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies would also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. As a result, we may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

Our business operations could suffer in the event of information technology systems' failures or security breaches.

While we believe that we have implemented adequate security measures within our internal information technology and networking systems, our information technology systems may be subject to security breaches, damages from computer viruses, natural disasters, terrorism, and telecommunication failures. Any system failure or security breach could cause interruptions in our operations in addition to the possibility of losing proprietary information and trade secrets. To the extent that any disruption or security breach results in inappropriate disclosure of our confidential information, our competitive position may be adversely affected and we may incur liability or additional costs to remedy the damages caused by these disruptions or security breaches.

We face significant competition from other biotechnology and pharmaceutical companies targeting medical dermatological indications, and our operating results will suffer if we fail to compete effectively.

The dermatological therapies market is highly competitive and led by significant technologic developments. We anticipate that, if we are successful in obtaining regulatory approval of our candidates, we will face significant competition from other approved therapies or drugs that will become available in our industry. Even if another branded, generic, or OTC product is less effective, it may be quickly adopted by physicians and patients than our product based upon cost or convenience.

Risks Related to Product Regulation

Our success is entirely dependent on our ability to obtain the marketing approval for our product candidates by the FDA and the regulatory authorities in foreign jurisdictions in which we intend to market our product candidates, of which there can be no assurance.

We are not permitted to market our product candidates as prescription pharmaceutical products in the United States until we receive approval of a BLA from the FDA, or in any foreign countries until we receive the requisite approval from such countries. In the United States, the FDA generally requires the completion of clinical trials of each biologic to establish its safety and efficacy and extensive pharmaceutical development to ensure its quality before a BLA is approved. Of the large number of biologics in development, only a small percentage result in the submission of a BLA to the FDA and even fewer are eventually approved for commercialization. As of the date of this prospectus, we have not submitted a BLA to the FDA or comparable applications to other regulatory authorities for any of our product candidates.

Our success depends on our receipt of the regulatory approvals described above, and the issuance of such regulatory approvals is uncertain and subject to a number of risks, including the following:

- such authorities may disagree with the number, design, size, conduct or implementation of our clinical trials or any of our collaborators' clinical trials;
- such authorities may disagree with our interpretation of data from preclinical studies or clinical trials or the use of results from studies that served as precursors to our current or future product candidates;
- the results of toxicology studies may not support the filing of an Investigational New Drug Application, or IND, or a BLA for our product candidates;
- the FDA or comparable foreign regulatory authorities or Institutional Review Boards, or IRBs, may disagree with the design or implementation of our clinical trials;
- we may not be able to provide acceptable evidence of our product candidates' safety and efficacy;
- the results of our clinical trials may not be satisfactory or may not meet the level of statistical or clinical significance required by the FDA, European Medicines Agency, or EMA, or other regulatory agencies for us to receive marketing approval for any of our product candidates;
- the dosing of our product candidates in a particular clinical trial may not be at an optimal level;
- patients in our clinical trials may suffer adverse effects for reasons that may or may not be related to our product candidates;
- the data collected from clinical trials may not be sufficient to support the submission of a BLA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA may require development of a Risk Evaluation and Mitigation Strategy, or REMS, as a condition of approval;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval of our product candidates.

The process of obtaining regulatory approvals is expensive, often takes many years, if approval is obtained at all, and can vary substantially based upon, among other things, the type, complexity and novelty of the product candidates involved, the jurisdiction in which regulatory approval is sought and the substantial discretion of the regulatory authorities. Changes in regulatory approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for a submitted product application may cause delays in the approval or rejection of an application. Regulatory approval obtained in one jurisdiction does not necessarily mean that a product candidate will receive regulatory approval in all jurisdictions in which we may seek approval, but the failure to obtain approval in one jurisdiction may negatively impact our ability to seek approval in a different jurisdiction. Failure to obtain regulatory approval for our product candidates for the foregoing, or any other reasons, will prevent us from commercializing our product candidates, and our ability to generate revenue will be materially impaired.

In addition, the FDA, EMA or other regulatory agencies may also approve a product candidate for fewer or more limited indications than we request, may impose significant limitations related to use restrictions for certain age groups, warnings, precautions or contraindications or may grant approval contingent on the performance of costly post-marketing clinical trials or risk mitigation requirements. The FDA, EMA or other regulatory agencies may also not accept the labeling claims that we believe would be necessary or desirable for the successful commercialization of our product candidates.

In December 2022, the U.S. Congress enacted a new law, the Modernization of Cosmetics Regulation Act of 2022, or MOCRA. MOCRA will require a cosmetic manufacturer or importer to: ensure that it has on hand substantiation of the safety of its products and ingredients; meet increased registration, record-keeping and reporting requirements; include fragrance and allergen information on its labeling; and be prepared to meet FDA's to be promulgated good manufacturing practices requirements. These additional requirements may impact budgets and timelines.

Our clinical trials may fail to demonstrate substantial evidence of the safety and efficacy of our product candidates or any future product candidates, which would prevent or delay or limit the scope of regulatory approval and commercialization.

Our business model depends entirely on the successful development, regulatory approval and commercialization of our product candidates, which may never occur. Our product candidates are in the early stages of development and as of the date of this prospectus we have not progressed any of our product candidates beyond performance characterization, animal testing and limited in-human testing of ATR-04 as a consumer health product. In December 2022, we submitted an IND for a Phase 1b clinical trial for our ATR-12, which is the means by which drug companies obtain approval to initiate clinical trials in humans in the United States, and on January 27, 2023 we received notification from the FDA that the "study may proceed" with respect to the proposed clinical trial. Other than ATR-12, we do not have an active IND with the FDA, nor an application to any comparable foreign regulatory authority, for any other of our product candidates. As of the date of this prospectus, we plan on submitting our IND for ATR-04 by the end of 2023; however, there can be no assurance we will be able to submit the IND in such timeframe. We may not be successful in obtaining approval from the FDA or comparable foreign regulatory authorities to start clinical trials for any of our product candidates. If we do not obtain such approvals as presently planned, the time in which we expect to commence clinical programs for any product candidate will be extended and such extension will increase our expenses, delay our potential receipt of any revenues and increase our need for additional capital. Moreover, there is no guarantee that we will receive approval to commence human clinical trials or, if we do receive approval, that our clinical trials will be successful or that we will continue clinical development in support of an approval from the FDA or comparable foreign regulatory authorities for any indication. We note that most product candidates never reach the clinical development stage and even those that do commence clinical development have only a small chance of successfully completing clinical development and gaining regulatory approval. Success in early phases of pre-clinical and clinical trials does not ensure that later clinical trials will be successful, and interim results of a clinical trial do not necessarily predict final results. A failure of one or more of our clinical trials can occur at any stage of testing. We may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent our ability to receive regulatory approval or commercialize our product candidates. Therefore, our business currently depends entirely on the successful development, regulatory approval and commercialization of our product candidates, which may never occur.

Results of preclinical studies of our product candidates may not be predictive of the results of future preclinical studies or clinical trials.

To obtain the requisite regulatory approvals to market and sell any of our product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our product candidates are safe, pure, and potent in humans. Before an IND can be submitted to the FDA and become effective, which is a prerequisite for conducting clinical trials on human subjects in the United States, a product candidate must successfully progress through extensive preclinical studies, which include preclinical laboratory testing, animal studies, and formulation studies in accordance with Good Laboratory Practices. Success in preclinical studies does not ensure that later preclinical studies or clinical trials will be successful. A number of companies in the biotechnology and pharmaceutical industries have suffered significant setbacks in clinical trials, even after positive results in earlier preclinical studies. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway and safety or efficacy observations made in clinical trials, including previously unreported adverse events. The design of a clinical trial can determine whether its results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. Further, we or our investigators may have little control over whether subjects comply with important aspects of clinical trial protocols In addition, preclinical and clinical data are often susceptible to varying interpretations and analyses. Notwithstanding any potential promising results in earlier studies, we cannot be certain that we will not face similar setbacks. In addition, the results of our preclinical animal studies, may not be predictive of the results of outcomes in subsequent clinical trials on human subjects. Product candidates in clinical trials may fail to show the desired pharmacological properties or safety and efficacy traits despite having progressed through preclinical studies.

If we fail to receive positive results in preclinical studies or clinical trials of our product candidates, the development timeline and regulatory approval and commercialization prospects for our most advanced product candidates, and, correspondingly, our business and financial prospects would be negatively impacted.

Any termination or suspension of, or delays in the commencement or completion of, any necessary studies of any of our product candidates for any indications could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.

The commencement and completion of clinical studies can be delayed for a number of reasons, including delays related to:

- the FDA or a comparable foreign regulatory authority failing to grant permission to proceed and placing the clinical study on hold;
- subjects for clinical testing failing to enroll or remain enrolled in our trials at the rate we expect;
- a facility manufacturing any of our product candidates being ordered by the FDA or other government or regulatory authorities to temporarily or permanently shut down due to violations of cGMP requirements or other applicable requirements, or cross-contaminations of product candidates in the manufacturing process;
- any changes to our manufacturing process that may be necessary or desired;
- subjects choosing an alternative treatment for the indications for which we are developing our product candidates, or participating in competing clinical studies;
- subjects experiencing severe or unexpected drug-related adverse effects;
- reports from clinical testing on similar technologies and products raising safety and/or efficacy concerns;
- third-party clinical investigators losing their license or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or employing methods consistent with the clinical trial protocol, cGMP requirements, or other third parties not performing data collection and analysis in a timely or accurate manner;
- inspections of clinical study sites by the FDA, comparable foreign regulatory authorities, or IRBs finding regulatory violations that require us to undertake corrective action, result in suspension or termination of one or more sites or the imposition of a clinical hold on the entire study, or that prohibit us from using some or all of the data in support of our marketing applications;
- third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or any of the data produced by such contractors in support of our marketing applications;
- one or more IRBs refusing to approve, suspending or terminating the study at an investigational site, precluding enrollment of additional subjects, or withdrawing its approval of the trial; reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- deviations of the clinical sites from trial protocols or dropping out of a trial;
- adding new clinical trial sites;
- the inability of the CRO to execute any clinical trials for any reason; and
- government or regulatory delays or “clinical holds” requiring suspension or termination of a trial.

Product development costs for any of our product candidates will increase if we have delays in testing or approval or if we need to perform more or larger clinical studies than planned. Additionally, changes in regulatory requirements and policies may occur and we may need to amend study protocols to reflect these changes. Amendments may require us to resubmit our study protocols to the FDA, comparable foreign regulatory authorities, and IRBs for reexamination, which may impact the costs, timing or successful completion of that study. If we experience delays in completion of, or if we, the FDA or other regulatory authorities, the IRB, or other reviewing entities, or any of our clinical study sites suspend or terminate any of our clinical studies of any of our product candidates, its commercial prospects may be materially harmed and our ability to generate product revenues will be delayed. Any delays in completing our clinical trials will increase our costs, slow down our development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, termination or suspension of, or a delay in the commencement or completion of, clinical studies may also ultimately lead to the denial of regulatory approval of our product candidates. In addition, if one or more clinical studies are delayed, our competitors may be able to bring competing products to market before we do, and the commercial viability of any of our affected product candidates could be significantly reduced.

Even if we receive regulatory approval for any of our product candidates, we may not be able to successfully commercialize the product and the revenue that we generate from its sales, if any, may be limited.

If approved for marketing, the commercial success of our product candidates will depend upon each product's acceptance by the medical community, including physicians, patients and health care payors. The degree of market acceptance for any of our product candidates will depend on a number of factors, including:

- demonstration of clinical safety and efficacy;
- relative convenience, dosing burden and ease of administration;
- the prevalence and severity of any adverse effects;
- the willingness of physicians to prescribe our product candidates, and the target patient population to try new therapies;
- efficacy of our product candidates compared to competing products;
- the introduction of any new products that may in the future become available targeting indications for which our product candidates may be approved;
- new procedures or therapies that may reduce the incidences of any of the indications in which our product candidates may show utility;
- pricing and cost-effectiveness;
- the inclusion or omission of our product candidates in applicable therapeutic and vaccine guidelines;
- the effectiveness of our own or any future collaborators' sales and marketing strategies;
- limitations or warnings contained in approved labeling from regulatory authorities;
- our ability to obtain and maintain sufficient third-party coverage or reimbursement from government health care programs, including Medicare and Medicaid, private health insurers and other third-party payors or to receive the necessary pricing approvals from government bodies regulating the pricing and usage of therapeutics; and
- the willingness of patients to pay out-of-pocket in the absence of third-party coverage or reimbursement or government pricing approvals.

If any of our product candidates are approved, but do not achieve an adequate level of acceptance by physicians, health care payors, and patients, we may not generate sufficient revenue and we may not be able to achieve or sustain profitability. Our efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may never be successful.

In addition, even if we obtain regulatory approvals, the timing or scope of any approvals may prohibit or reduce our ability to commercialize our product candidates successfully. For example, if the approval process takes too long, we may miss market opportunities and give other companies the ability to develop competing products or establish market dominance. Any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render our product candidates not commercially viable. For example, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for any of our product candidates, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve any of our product candidates with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that indication. Further, the FDA or comparable foreign regulatory authorities may place conditions on approvals or require risk management plans or a Risk Evaluation and Mitigation Strategy, or REMS, to assure the safe use of the drug. Moreover, product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following the initial marketing of the product. Any of the foregoing scenarios could materially harm the commercial success of our product candidates.

Even if we obtain marketing approval for any of our product candidates, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates could be subject to labeling and other restrictions and withdrawal from the market and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our product candidates.

Even if we obtain regulatory approval for any of our product candidates for an indication, the FDA or foreign equivalent may still impose significant restrictions on their indicated uses or marketing or the conditions of approval, or impose ongoing requirements for potentially costly and time-consuming post-approval studies, including Phase 4 clinical trials, and post-market surveillance to monitor safety and efficacy. Our product candidates will also be subject to ongoing regulatory requirements governing the manufacturing, labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, recordkeeping and reporting of adverse events and other post-market information. These requirements include registration with the FDA, as well as continued compliance with current Good Clinical Practices regulations, or cGCPs, for any clinical trials that we conduct post-approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current cGMPs, requirements relating to quality control, quality assurance and corresponding maintenance of records and documents.

The FDA has the authority to require a REMS as part of an BLA or after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug, such as limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria or requiring patient testing, monitoring and/or enrollment in a registry.

With respect to sales and marketing activities related to our product candidates, advertising and promotional materials must comply with FDA rules in addition to other applicable federal, state and local laws in the United States and similar legal requirements in other countries. In the United States, the distribution of product samples to physicians must comply with the requirements of the U.S. Prescription Drug Marketing Act. Application holders must obtain FDA approval for product and manufacturing changes, depending on the nature of the change. We may also be subject, directly or indirectly through our customers and partners, to various fraud and abuse laws, including, without limitation, the U.S. Anti-Kickback Statute, U.S. False Claims Act, and similar state laws, which impact, among other things, our proposed sales, marketing, and scientific/educational grant programs. If we participate in the U.S. Medicaid Drug Rebate Program, the Federal Supply Schedule of the U.S. Department of Veterans Affairs, or other government drug programs, we will be subject to complex laws and regulations regarding reporting and payment obligations. All of these activities are also potentially subject to U.S. federal and state consumer protection and unfair competition laws. Similar requirements exist in many of these areas in other countries.

In addition, if any of our product candidates are approved for a particular indication, our product labeling, advertising and promotion would be subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates the promotional claims that may be made about prescription products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. If we receive marketing approval for our product candidates, physicians may nevertheless legally prescribe our products to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability and government fines. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant sanctions. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees of permanent injunctions under which specified promotional conduct is changed or curtailed.

If we or a regulatory agency discover previously unknown problems with a product candidate, such as adverse events of unanticipated severity or frequency, problems with the facility where the product is manufactured, or we or our manufacturers fail to comply with applicable regulatory requirements, we may be subject to the following administrative or judicial sanctions:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- issuance of warning letters or untitled letters;
- clinical holds;
- injunctions or the imposition of civil or criminal penalties or monetary fines;
- suspension or withdrawal of regulatory approval;
- suspension of any ongoing clinical trials;
- refusal to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product license approvals;
- suspension or imposition of restrictions on operations, including costly new manufacturing requirements; or
- product seizure or detention or refusal to permit the import or export of product.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue. Adverse regulatory action, whether pre- or post-approval, can also potentially lead to product liability claims and increase our product liability exposure.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad, and compliance with such regulation may be expensive and consume substantial financial and management resources. If we or any future marketing collaborators or contract manufacturers are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies or are not able to maintain regulatory compliance, it could delay or prevent the promotion, marketing or sale of our products, which would adversely affect our business and results of operations

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, but a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional preclinical studies or clinical trials, as clinical studies conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our product candidates in certain countries. If we fail to comply with the regulatory requirements in international markets and/ or to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

Even though we may apply for orphan drug designation for a product candidate, we may not be able to obtain orphan drug marketing exclusivity.

We believe that in some cases our products candidates may qualify for the FDA's orphan drug status. There is no guarantee that the FDA will grant any future application for orphan drug designation for any of our product candidates, which would make us ineligible for the additional exclusivity and other benefits of orphan drug designation.

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making a drug available in the United States for this type of disease or condition will be recovered from sales of the product. Orphan drug designation must be requested before submitting an BLA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan product designation does not convey any advantage in or shorten the duration of regulatory review and approval process. In addition to the potential period of exclusivity, orphan designation makes a company eligible for grant funding of up to $400,000 per year for four years to defray costs of clinical trial expenses, tax credits for clinical research expenses and potential exemption from the FDA application user fee.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other applications to market the same drug for the same indication for seven years, except in limited circumstances, such as (i) the drug's orphan designation is revoked; (ii) its marketing approval is withdrawn; (iii) the orphan exclusivity holder consents to the approval of another applicant's product; (iv) the orphan exclusivity holder is unable to assure the availability of a sufficient quantity of drug; or (v) a showing of clinical superiority to the product with orphan exclusivity by a competitor product. If a drug designated as an orphan product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan drug exclusivity. There can be no assurance that we will receive orphan drug designation for any of our product candidates in the indications for which we think they might qualify, if we elect to seek such applications.

Current and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval for our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell our product candidates. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We do not know whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

In the United States, the Medicare Modernization Act, or MMA, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for drugs. In addition, this legislation authorized Medicare Part D prescription drug plans to use formularies where they can limit the number of drugs that will be covered in any therapeutic class. As a result of this legislation and the expansion of federal coverage of drug products, we expect that there will be additional pressure to contain and reduce costs. These cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for our product candidates and could seriously harm our business. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, and any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010 or, collectively, the ACA, is a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. The ACA revised the definition of "average manufacturer price" for reporting purposes, which could increase the amount of Medicaid drug rebates to states. Further, the law imposed a significant annual fee on companies that manufacture or import branded prescription drug products.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In 2011, the U.S. Congress enacted the Budget Control Act of 2011, or the Budget Control Act, which included provisions intended to reduce the federal deficit. The Budget Control Act resulted in the imposition of 2% reductions in Medicare payments to providers beginning in 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2027 absent additional congressional action. However, pursuant to the CARES Act, and subsequent legislation, these reductions are suspended from May 1, 2020 through March 31, 2022 due to the COVID-19 pandemic. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our drugs, if approved, and accordingly, our financial operations. If government spending is further reduced, anticipated budgetary shortfalls may also impact the ability of relevant agencies, such as the FDA, to continue to function at current levels, which may impact the ability of relevant agencies to timely review and approve research and development, manufacturing and marketing activities, which may delay our ability to develop, market and sell any product candidates we may develop. In addition, any significant spending reductions affecting Medicare, Medicaid or other publicly funded or subsidized health programs that may be implemented, or any significant taxes or fees that may be imposed on us, as part of any broader deficit reduction effort or legislative replacement to the Budget Control Act, could have an adverse impact on our anticipated product revenues.

Moreover, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their commercial products. There have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare, and reform government program reimbursement methodologies for drugs. On September 24, 2020, the FDA released a final rule providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, the U.S. Department of Health and Human Services, or HHS, finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. On August 16, 2022, Congress enacted the Inflation Reduction Act of 2022 which contains several provisions relating to prescription drug costs, including requirements for federal government price negotiations, rebate requirements, and caps on out-of-pocket spending for Medicare Part D enrollees. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

On November 20, 2020, the HHS Office of Inspector General finalized further modifications to the federal Anti-Kickback Statute. Under the final rules, the HHS Office of Inspector General added safe harbor protections under the Anti-Kickback Statute for certain coordinated care and value-based arrangements among clinicians, providers, and others, yet removed safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. This rule (with exceptions) became effective January 19, 2021. We continue to evaluate what effect, if any, these rules will have on our business. CMS issued a final rule, effective on July 9, 2019, that requires direct-to-consumer advertisements of prescription drugs and biological products, for which payment is available through or under Medicare or Medicaid, to include in the advertisement the Wholesale Acquisition Cost, or list price, of that drug or biological product if it is equal to or greater than $35 for a monthly supply or usual course of treatment. Prescription drugs and biological products that are in violation of these requirements will be included on a public list. Any adopted health reform measure could reduce the ultimate demand for our products, if approved, or put pressure on our product pricing. Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. We expect that additional state and federal healthcare reform measures will be adopted in the future.

The delivery of healthcare in the EU, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than EU, law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most EU member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing EU and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to commercialize any products for which we obtain marketing approval. Both in the United States and in the EU, legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We do not know whether additional legislative changes will be enacted, or whether the regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be.

Third-party coverage and reimbursement and health care cost containment initiatives and treatment guidelines may constrain our future revenues.

Our ability to successfully market our product candidates will depend in part on the level of reimbursement that government health administration authorities, private health coverage insurers and other organizations provide for the cost of our product candidates and related treatments. Countries in which any of our product candidates are sold through reimbursement schemes under national health insurance programs frequently require that manufacturers and sellers of pharmaceutical products obtain governmental approval of initial prices and any subsequent price increases. In certain countries, including the United States, government-funded and private medical care plans can exert significant indirect pressure on prices. We may not be able to sell our product candidates profitably if adequate prices are not approved or coverage and reimbursement is unavailable or limited in scope. Increasingly, third-party payors attempt to contain health care costs in ways that are likely to impact our development of products including:

- failing to approve or challenging the prices charged for health care products;
- introducing reimportation schemes from lower priced jurisdictions;
- limiting both coverage and the amount of reimbursement for new therapeutic products;
- denying or limiting coverage for products that are approved by the regulatory agencies but are considered to be experimental or investigational by third-party payors; and
- refusing to provide coverage when an approved product is used in a way that has not received regulatory marketing approval.

Our relationships with customers and payors are subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which, if violated, could expose us to criminal sanctions, civil penalties, exclusion from government healthcare programs, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and others will play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, primarily in the United States, that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our products for which we obtain marketing approval. Restrictions under applicable healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute prohibits, among other things, the knowing and willful offer, payment, solicitation or receipt of any form of remuneration in return for, or to induce, (i) the referral of a person, (ii) the furnishing or arranging for the furnishing of items or services reimbursable under the Medicare, Medicaid or other governmental programs, or (iii) the purchase, lease or order or arranging or recommending purchasing, leasing or ordering of any item or service reimbursable under the Medicare, Medicaid or other governmental programs. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- the federal False Claims Act imposes civil penalties, and provides for civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- HIPAA imposes criminal and civil liability for executing a scheme to defraud any health care benefit program or making false statements relating to health care matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for health care benefits, items or services;
- the Physician Payments Sunshine Act, created under the ACA, and its implementing regulations, which requires specified manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to CMS information related to payments or other "transfers of value" made to physicians. All such reported information is publicly available;
- analogous state and non-U.S. laws and regulations, such as certain state anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts; and
- regulation by CMS and enforcement by the HHS Office of Inspector General or the U.S. Department of Justice.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our future business activities could be subject to challenge under one or more of such laws.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from U.S. government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business with are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Risks Relating to Our Intellectual Property Rights

It is difficult and costly to protect our intellectual property rights, and we cannot ensure the protection of these rights.

Our commercial success will depend, in part, on our ability to prosecute and defend, if necessary, our patent rights against third-party challenges and successfully enforcing these patent rights against third party competitors. The patent positions of pharmaceutical companies can be highly uncertain and involve complex legal, scientific and factual questions for which important legal principles remain unresolved. Changes in either the patent laws or in interpretations of patent laws may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowable or enforceable in any patent applications filed by us or our licensors of patent rights. The patents and patent applications held by or licensed to us relating to our microbial platform and related technologies may be challenged, invalidated or circumvented by third parties and might not protect us against competitors with similar products or technologies.

The degree of future protection afforded by the patent rights held by or licensed to us is uncertain, because legal means afford only limited protection and may not adequately protect our rights, permit us to gain or keep our competitive advantage, or provide us with any competitive advantage at all. We cannot be certain that any patent application owned by a third party will not have priority over patent applications filed by us or in which we hold license rights or that we will not be involved in interference, opposition or invalidity proceedings before United States or foreign patent offices.

Additionally, if we were to initiate legal proceedings against a third party to enforce a patent covering any of our product candidates, the defendant could counterclaim that such patent is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include alleged failures to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for unenforceability assertions include allegations that someone connected with prosecution of the patent withheld relevant information from the United States Patent and Trademark Office, or the USPTO, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review and equivalent proceedings in foreign jurisdictions, e.g., opposition proceedings. Such proceedings could result in revocation or amendment of patents held by or licensed to us in such a way that they no longer cover our product candidates or competitive products. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to validity, for example, we cannot be certain that there is no invalidating prior art, of which, we, any licensor of our patent rights or the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on any of our product candidates. Such a loss of patent protection would have a material adverse impact on our business.

We rely on know-how and trade secrets to protect technology, especially in cases where we believe patent protection is not appropriate or obtainable. However, know-how and trade secrets are difficult to protect. While we require employees, academic collaborators, consultants and other contractors to enter into confidentiality agreements, we may not be able to adequately protect our trade secrets or other proprietary or licensed information. Typically, research collaborators and scientific advisors have rights to publish data and information in which we may have rights. Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts are sometimes less willing to protect trade secrets than patents. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

If we fail to obtain or maintain patent protection or trade secret protection for our product candidates or our technologies, third parties could use our proprietary information, which could impair our ability to compete in the market and adversely affect our ability to generate revenues and attain profitability.

Our product candidates may infringe the intellectual property rights of others, which could increase our costs and delay or prevent our development and commercialization efforts.

Our success depends in part on avoiding infringement of the proprietary technologies of others. The pharmaceutical industry has been characterized by frequent litigation regarding patent and other intellectual property rights. Identification of third-party patent rights that may be relevant to our proprietary technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. Additionally, because patent applications are maintained in secrecy until the application is published, we may be unaware of third-party patents that may be infringed by commercialization of any of our product candidates or any future product candidate. There may be certain issued patents and patent applications claiming subject matter that we may be required to license in order to research, develop or commercialize any of our product candidates, and we do not know if such patents and patent applications would be available to license on commercially reasonable terms, or at all. Any claims of patent infringement asserted by third parties would be time-consuming and may:

- result in costly litigation;
- divert the time and attention of our technical personnel and management;
- prevent us from commercializing a product until the asserted patent expires or is held finally invalid or not infringed in a court of law;
- require us to cease or modify our use of the technology and/or develop non-infringing technology; or
- require us to enter into royalty or licensing agreements.

Third parties may hold proprietary rights that could prevent any of our product candidates from being marketed. Any patent-related legal action against us claiming damages and seeking to enjoin commercial activities relating to any of our product candidates or our processes could subject us to potential liability for damages and require us to obtain a license to continue to manufacture or market any of our product candidates or any future product candidates. We cannot predict whether we would prevail in any such actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. In addition, we cannot be sure that we could redesign our product candidates or any future product candidates or processes to avoid infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing and commercializing any of our product candidates or a future product candidate, which could harm our business, financial condition and operating results.

We expect that there are other companies, including major biopharmaceutical companies, working in the areas competitive to our proposed product candidates which either has resulted, or may result, in the filing of patent applications that may be deemed related to our activities. If we were to challenge the validity of these or any issued United States patent in court, we would need to overcome a statutory presumption of validity that attaches to every issued United States patent. This means that, in order to prevail, we would have to present clear and convincing evidence as to the invalidity of the patent's claims. If we were to challenge the validity of these or any issued United States patent in an administrative trial before the Patent Trial and Appeal Board in the USPTO, we would have to prove that the claims are unpatentable by a preponderance of the evidence. There is no assurance that a jury and/or court would find in our favor on questions of infringement, validity or enforceability. Even if we are successful, litigation could result in substantial costs and be a distraction to management.

We may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers.

As is commonplace in our industry, we will employ individuals who were previously employed at other biopharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject in the future to claims that our employees or prospective employees are subject to a continuing obligation to their former employers (such as non-competition or non-solicitation obligations) or claims that our employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Risks Related to this Offering and Owning Our Common Stock

An active, liquid and orderly trading market for our shares may not develop, which may inhibit the ability of our stockholders to sell shares following this offering.

The offering under this prospectus is an initial public offering of our common shares. Prior to this offering there has been no public market for our shares. Upon completion of this offering, our common stock will commence trading on the NYSE American under the symbol "AZTR." However, an active, liquid or orderly trading market in our shares may not develop upon completion of this offering, or if it does develop, it may not be sustained. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. The lack of an active market may also reduce the fair market value of your shares. An inactive market may also impair our ability to raise capital by selling shares and may impair our ability to acquire other companies by using our shares as consideration.

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

If, after listing, 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.

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.

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

The initial public offering price for the shares will be determined by negotiations between us and the representative of the underwriters and may not be indicative of prices that will prevail in the trading market. The price of our shares may decline following this offering. The stock market in general, and early-stage public companies in particular, has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of such companies. These broad market factors may seriously harm the market price of our common stock, regardless of our actual or expected operating performance and financial condition or prospects, which may make it difficult for investors to assess the rapidly changing value of our common stock. In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been instituted. A class action suit against us could result in significant liabilities and, regardless of the outcome, could result in substantial costs and the diversion of our management's resources and attention 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;
- market acceptance of our product candidates;

- changes in earnings estimates or recommendations by securities analysts, if our shares are covered by analysts;
- 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.

We are an "emerging growth company" under the JOBS Act and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act and we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including, but not limited to:

- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act;
- reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements;
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments; and
- extended transition periods available for complying with new or revised accounting standards.

We have chosen to take advantage of all of the benefits available under the JOBS Act, including the exemptions discussed above. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

We will remain an "emerging growth company" for up to five years, although we will lose that status sooner if our revenues exceed $1.07 billion, if we issue more than $1 billion in non-convertible debt in a three-year period, or if the market value of our common stock that is held by non-affiliates exceeds $700 million as of June 30 in any future year.

Our status as an "emerging growth company" under the JOBS Act may make it more difficult to raise capital as and when we need it.

Because of the exemptions from various reporting requirements provided to us as an "emerging growth company," we may be less attractive to investors and it may be difficult for us to raise additional capital as and when we need it. Investors may be unable to compare our business with other companies in our industry if they believe that our reporting is not as transparent as other companies in our industry. If we are unable to raise additional capital as and when we need it, our financial condition and results of operations may be materially and adversely affected.

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.

Assuming a market for our common stock develops, shares eligible for future sale may adversely affect the market for our common stock.

Substantially all of our common shares outstanding prior to this offering, including the common shares issuable upon conversion of our convertible preferred stock and convertible promissory notes, are subject to lock-up agreements whereby the holder has agreed not to sell, transfer or pledge, or offering to do any of the same, directly or indirectly, any of our securities for a period of 180 days following the close of this offering, except in the case of our officers and directors who have agreed not to sell for one year following the close of this offering. Subject to the lock-up agreements, we have granted demand and piggyback registration rights to the holders of our convertible preferred stock and convertible promissory notes pursuant to which they may request the registration for resale of up to 9,513,143 shares of common stock commencing 180 days following the close of this offering. Furthermore, commencing on the 90th day following the close of this offering, our stockholders may be eligible to sell all or some of their shares of common stock by means of ordinary brokerage transactions in the open market pursuant to Rule 144, promulgated under the Securities Act, subject to certain limitations under Rule 144 and the lock-up agreements. In general, pursuant to Rule 144, non-affiliate stockholders may sell freely after six months subject only to the current public information requirement (which disappears after one year).

Any substantial sale of our common stock pursuant to Rule 144 or pursuant to any resale prospectus (including sales by investors of securities acquired in connection with this offering) may have a material adverse effect on the market price of our common stock.

You will experience immediate dilution in the book value per share of the common stock you purchase.

Because the price per share of our common stock being offered is substantially higher than the book value per share of our common stock, you will experience substantial dilution in the net tangible book value of the common stock you purchase in this offering. Based on the initial public offering price of $5.00 per share (which is the midpoint of the price range set forth on the cover page of this prospectus), if you purchase shares of common stock in this offering, you will experience immediate and substantial dilution of $3.86 per share in the net tangible book value of the common stock at December 31, 2022.

We may be at an increased risk of securities class action litigation.

Historically, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and pharmaceutical companies have experienced significant stock price volatility in recent years. If we were to be sued, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business. We maintain director and officer insurance that we regard as reasonably adequate to protect us from potential claims; however, we are responsible for meeting certain deductibles under the policies and, in any event, we cannot assure you that the insurance coverage will adequately protect us from claims made. Further, the costs of insurance may increase and the availability of coverage may decrease. As a result, we may not be able to maintain our current levels of insurance at a reasonable cost, or at all.

We have broad discretion in how we use the proceeds of this offering and may not use these proceeds effectively, which could affect our results of operations and cause our stock price to decline.

We may invest or spend these proceeds in ways with which you do not agree and in ways that may not yield a return on your investment. Our management will have considerable discretion in the application of the net proceeds of this offering, including for any purpose described in the section of this prospectus entitled *"Use of Proceeds"*. However, our needs may change as our business and industry evolve and, as a result, the proceeds we receive from this offering may be used in a manner substantially different from our current expectations. We may use the net proceeds for purposes that do not yield a significant return or any return at all for our stockholders. In addition, pending their use, we may invest the net proceeds from this offering in a manner that does not produce income or that loses value. The failure by our management to apply these funds effectively could result in financial losses that could harm our business, cause the price of our common stock to decline and delay the development of our product candidates. You will not have the opportunity as part of your investment decision to assess whether the net proceeds are being used appropriately and, as a result, you will be relying on our management's judgment.

We ratified certain corporate actions pursuant to Section 204 of the DGCL, however there can be no assurance that claims will not be made to challenge the validity of the ratification or the related corporate actions.

As part of our preparation for this offering, in February 2023, our Board and stockholders ratified certain actions pursuant to Section 204 of the DGCL, which allows a Delaware corporation to ratify a defective corporate act with effectiveness that is retroactive to the date the corporate act was originally taken. The Section 204 ratification, or the Ratification, was undertaken as a purely remedial matter in respect of certain failures of authorization and thereby remove any uncertainty and ensure the validity of certain security issuances, Board appointments and other corporate acts. To effect the Ratification, our Board identified and our Board and stockholders then ratified: (i) the adoption of the corporation's bylaws; (ii) the fixing and changing the size and composition of the Board; (iii) the issuance of certain shares, stock options, warrants, and convertible notes; and (iv) the issuance of shares pursuant to a dividend. The Ratification also had the effect of removing uncertainty and ensuring the validity of actions whose validity has been called into question as a result of the preceding uncertainty and consequent uncertainty in respect of the authority of the directors and stockholders who authorized such actions (collectively with the acts ratified by the Ratification, the "Corporate Acts") Thereafter, in accordance with Section 204, we gave prompt written notice of the Ratification to all holders of putative and valid stock (as such terms are used in Section 204) as of the date of the Corporate Acts and as of the date of the Ratification in accordance with Section 204.

Under Section 205 of the DGCL, any claim that any Corporate Act ratified under the Ratification is void or voidable due to a failure of authorization (as defined in Section 204), or that the Delaware Court of Chancery should declare in its discretion that the ratification thereof in accordance with Section 204 not be effective or be effective only on certain conditions, must be brought within 120 days from the Ratification effective time, which in this case is June 2023. The Board and the holders of approximately % of our outstanding voting securities (valid and putative) consented to the Ratification and the effectiveness of the Corporate Acts. We believe that it is unlikely that any stockholder who did not consent to the Ratification will be able to show any injury sufficient to challenge the Ratification under Section 205 of the DGCL. While we believe that there is a low risk of challenge to the Ratification, and that it would be difficult for a challenger to establish a legal or equitable basis to invalidate or limit the Ratification or the Corporate Acts, there is a possibility that a court could uphold a challenge to the Ratification or to the Corporate Acts and, if it did, it could adversely affect the management and governance of our corporation.

Our charter documents and Delaware law may inhibit a takeover that stockholders consider favorable.

Upon the closing of this offering, we intend to adopt an amended and restated certificate of incorporation and amended and restated bylaws. Provisions of our amended and restated certificate of incorporation and amended and restated bylaws and applicable provisions of Delaware law may delay or discourage transactions involving an actual or potential change in control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares, or transactions that our stockholders might otherwise deem to be in their best interests. The provisions in our amended and restated certificate of incorporation and amended and restated bylaws:

- limit who may call stockholder meetings;
- restrict our stockholders from bringing matters before our annual meeting of stockholders or from making nominations for directors at our annual meeting of stockholders if the proper procedures are not followed;
- do not provide for stockholder action by written consent;
- do not provide for cumulative voting rights; and
- provide that all board vacancies may be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum.

In addition, once we become a publicly traded corporation, Section 203 of the DGCL may limit our ability to engage in any business combination with a person who beneficially owns 15% or more of our outstanding voting stock unless certain conditions are satisfied. This restriction lasts for a period of three years following the share acquisition. These provisions may have the effect of entrenching our management team and may deprive you of the opportunity to sell your shares to potential acquirers at a premium over prevailing prices. This potential inability to obtain a control premium could reduce the price of our common stock.

General Risk Factors

Changes in accounting standards and subjective assumptions, estimates and judgments by management related to complex accounting matters may materially impact reporting of our financial condition and results of operations.

Accounting principles generally accepted in the United States and related accounting pronouncements, implementation guidelines, and interpretations we apply to a wide range of matters that are relevant to our business, such as accounting for long-lived asset impairment and share-based compensation, are complex and involve subjective assumptions, estimates and judgments by our management. Changes in these rules or their interpretation or changes in underlying assumptions, estimates or judgments by our management could significantly change or add significant volatility to our reported or expected financial performance.

A potential failure to maintain effective internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act could have a material adverse effect on our business, financial condition, and results of operations.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with U.S. generally accepted accounting principles, or GAAP. Under standards established by the Public Company Accounting Oversight Board, or PCAOB, a deficiency in internal control over financial reporting exists when the design or operation of a control does not allow management or personnel, in the normal course of performing their assigned functions, to prevent or detect misstatements on a timely basis. The PCAOB defines a material weakness as a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented, or detected and corrected, on a timely basis.

We will be required, pursuant to Section 404 of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting for our second annual report on Form 10-K filed with the SEC and in each year thereafter. Our auditors will also need to attest to the effectiveness of our internal control over financial reporting at such time as we are an accelerated filed or large accelerated filer and no longer an emerging growth company or smaller reporting company. If we are unable to assert that our internal control over financial reporting is effective, or when required in the future, if our independent registered public accounting firm is unable to express an unqualified opinion as to the effectiveness of our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could be adversely affected, and we could become subject to litigation or investigations by the stock exchange on which our common stock are listed, the SEC or other regulatory authorities, which could require additional financial and management resources and could have a material adverse effect on our business, financial condition, and results of operations.

The limited amount of public company experience of our management team could adversely impact our ability to comply with the reporting requirements of U.S. securities laws, which could have a materially adverse effect on our business.

Our officers have limited public company experience, which could impair our ability to comply with legal and regulatory requirements such as those imposed by Sarbanes-Oxley Act. Such responsibilities include complying with federal securities laws and making required disclosures on a timely basis. Any such deficiencies, weaknesses or lack of compliance could have a materially adverse effect on our ability to comply with the reporting requirements of the Securities Exchange Act of 1934, or the Exchange Act, which is necessary to maintain our public company status. If we were to fail to fulfill those obligations, our ability to continue as a U.S. public company would be in jeopardy in which event you could lose your entire investment in our Company.

We identified material weaknesses in our internal control over financial reporting, and we may identify additional material weaknesses in the future that may cause us to fail to meet our reporting obligations or result in material misstatements of our financial statements. If we fail to remediate any material weaknesses or if we otherwise fail to establish and maintain effective control over financial reporting, our ability to accurately and timely report our financial results could be adversely affected.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act, or the subsequent testing by our independent registered public accounting firm when required, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retrospective changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common shares. There is also a risk that neither we nor our independent registered public accounting firm (when applicable in the future) will be able to conclude within the prescribed timeframe that internal controls over financial reporting is effective as required by Section 404. As a result, investors could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

During the preparation of our financial statements for the years ended December 31, 2022 and 2021, we and our independent registered public accounting firm identified a material weakness as it relates to a lack of adequate segregation of accounting functions and the appropriate accounting for certain warrants in 2021 that were issued in connection with our previously issued but no longer outstanding debt instruments. We are in the process of implementing measures designed to improve our internal control over financial reporting and remediate this material weakness. We intend to increase staffing within our accounting infrastructure sufficient to facilitate proper segregation of accounting functions and to enable appropriate review of our internally prepared financial statements.

We may identify future material weaknesses in our internal controls over financial reporting or fail to meet the demands that will be placed upon us as a public company, including the requirements of the Sarbanes-Oxley, and we may be unable to accurately report our financial results, or report them within the timeframes required by law or stock exchange regulations. We cannot assure that our existing material weakness will be remediated or that additional material weaknesses will not exist or otherwise be discovered, any of which could adversely affect our reputation, financial condition and results of operations.

We will incur significant increased costs as a result of becoming a public company that reports to the SEC and our management will be required to devote substantial time to meet compliance obligations.

As a public company reporting to the SEC after this offering, we will incur significant legal, accounting and other expenses that we did not incur as a private company. We will be subject to reporting requirements of the Exchange Act and the reporting and governance provisions of the Sarbanes-Oxley Act and the Dodd-Frank Wall Street Reform and Protection Act, as well as rules subsequently implemented by the SEC, that impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. There are significant corporate governance and reporting provisions in these laws that will increase our legal and financial compliance costs, make some activities more difficult, time-consuming or costly and may also place undue strain on our personnel, systems and resources. Our management and other personnel will need to devote a substantial amount of time to these regulations. In addition, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified people to serve on our Board our Board committees or as executive officers.

We are currently operating in a period of economic uncertainty and capital markets disruption, which has been significantly impacted by geopolitical instability due to the ongoing military conflict between Russia and Ukraine.

U.S. and global markets are experiencing volatility and disruption following the escalation of geopolitical tensions and the start of the military conflict between Russia and Ukraine. In February 2022, Russia launched a full-scale military invasion of Ukraine. Although the length and impact of the ongoing military conflict is highly unpredictable, the conflict in Ukraine could lead to market disruptions, including significant volatility in commodity prices, credit and capital markets. Additionally, Russia's prior annexation of Crimea, recent recognition of two separatist republics in the Donetsk and Luhansk regions of Ukraine and subsequent military interventions in Ukraine have led to sanctions and other penalties being levied by the United States, European Union and other countries against Russia, Belarus, the Crimea Region of Ukraine, the so-called Donetsk People's Republic, and the so-called Luhansk People's Republic, including agreement to remove certain Russian financial institutions from the Society for Worldwide Interbank Financial Telecommunication (SWIFT) payment system. Additional potential sanctions and penalties have also been proposed and/or threatened. Russian military actions and the resulting sanctions could adversely affect the global economy and financial markets and lead to instability and lack of liquidity in capital markets, potentially making it more difficult for us to obtain additional funds. Any of the abovementioned factors could affect our business, prospects, financial condition, and operating results. The extent and duration of the military action, sanctions and resulting market disruptions are impossible to predict, but could be substantial. Any such disruptions may also magnify the impact of other risks described in this prospectus.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, including the sections entitled "*Prospectus Summary*," "*Risk Factors,*" "*Use of Proceeds,*" "*Management's Discussion and Analysis of Financial Condition and Results of Operations*," and "*Business*," contains forward-looking statements. The words "believe," "may," "will," "potentially," "estimate," "continue," "anticipate," "intend," "could," "would," "project," "plan," "expect" and similar expressions that convey uncertainty of future events or outcomes are intended to identify forward-looking statements. These forward-looking statements include, but are not limited to, statements concerning the following:

- our future financial and operating results;
- our intentions, expectations and beliefs regarding anticipated growth, market penetration and trends in our business;
- the timing and success of our plan of commercialization;
- our ability to successfully develop and clinically test our product candidates;
- our ability to obtain FDA approval for any of our product candidates;
- our ability to comply with all U.S. and foreign regulations concerning the development, manufacture and sale of our product candidates;
- our reliance on third parties to manufacture our product candidates;
- the adequacy of the net proceeds of this offering;
- the effects of market conditions on our stock price and operating results;
- our ability to maintain, protect and enhance our intellectual property;
- the effects of increased competition in our market and our ability to compete effectively;
- our plans to use the proceeds from this offering;
- costs associated with initiating and defending intellectual property infringement and other claims;
- the attraction and retention of qualified employees and key personnel;
- future acquisitions of or investments in complementary companies or technologies; and
- our ability to comply with evolving legal standards and regulations, particularly concerning requirements for being a public company.

These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in "*Risk Factors*" and elsewhere in this prospectus. Moreover, we operate in a very competitive and rapidly changing environment, and new risks emerge from time to time. It is not possible for us to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this prospectus may not occur and actual results could differ materially and adversely from those anticipated or implied in our forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in our forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances described in the forward-looking statements will be achieved or occur. Moreover, neither we nor any other person assumes responsibility for the accuracy and completeness of the forward-looking statements. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this prospectus to conform these statements to actual results or to changes in our expectations, except as required by law.

You should read this prospectus and the documents that we reference in this prospectus and have filed with the SEC as exhibits to the registration statement of which this prospectus is a part with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect.

TRADEMARKS, SERVICE MARKS AND TRADE NAMES

We own or have rights to use a number of registered and common law trademarks, service marks and/or trade names in connection with our business in the United States and/or in certain foreign jurisdictions.

Solely for convenience, the trademarks, service marks, logos and trade names referred to in this prospectus are without the ® and ™ symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensors to these trademarks, service marks and trade names. This prospectus contains additional trademarks, service marks and trade names of others, which are the property of their respective owners. All trademarks, service marks and trade names appearing in this prospectus are, to our knowledge, the property of their respective owners. We do not intend our use or display of other companies' trademarks, service marks, copyrights or trade names to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

USE OF PROCEEDS

We estimate that the net proceeds from our issuance and sale of 2,400,000 shares of our common stock in this offering, at an assumed initial public offering price of $5.00 per share (which is the midpoint of the price range set forth on the cover page of this prospectus), will be approximately $9.9 million (or $11.6 million if the underwriters exercise in full their option to purchase additional shares), and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

We intend to use the net proceeds from this offering, along with our existing cash and cash equivalents, as follows:

- approximately $5 million to fund clinical trials and product development, including $2.5 million for the ATR-12 Netherton syndrome program, which is expected to provide funding for dosing in the proposed Phase 1b clinical trial, and $1.5 million for the ATR-04 EGFR inhibitor associated rash program, which is expected to provide funding through the initial enrollment for the proposed Phase 1b clinical trial;
- approximately $3 million for research and development, including approximately $1.5 million on ATR-12 biomarker development, $0.5 million on ATR-04 biomarker development and $1 million on new product development;
- approximately $1 million for clinical manufacturing; and
- the balance for other general corporate purposes, including in-licensing and partnering activities, laboratory facility improvements, general and administrative expenses and working capital.

Our expected use of net proceeds from this offering represents our current intentions based upon our present plans and business condition. As of the date of this prospectus, we cannot predict with complete certainty all of the particular uses for the net proceeds to be received upon the completion of this offering or the actual amounts that we will spend on the uses set forth above. We believe opportunities may exist from time to time to expand our current business through the acquisition or in-license of complementary product candidates. While we have no current agreements or plans for any specific acquisitions or in-licenses at this time, we may use a portion of the net proceeds for these purposes.

The amounts and timing of our actual expenditures will depend on numerous factors, including the progress of our clinical trials and other development and commercialization efforts for our initial product candidates, as well as the amount of cash used in our operations. However, we cannot estimate with certainty the amount of net proceeds to be used for the purposes described above. We may find it necessary or advisable to use the net proceeds for other purposes, and we will have broad discretion in the application of the net proceeds. Pending the uses described above, we plan to invest the net proceeds from this offering in short-and intermediate-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the government.

DIVIDEND POLICY

We have never declared or paid any cash dividends on our common stock and we do not anticipate paying any cash dividends on our common stock in the foreseeable future. Investors should not purchase our common stock with the expectation of receiving cash dividends. The payment of dividends on our common stock, if any, in the future is within the discretion of our Board and will depend on our earnings, capital requirements and financial condition and other relevant facts. We currently intend to retain all future earnings, if any, to finance the development and growth of our business.

CAPITALIZATION

The following table sets forth our cash and capitalization as of December 31, 2022:

- on an actual basis;
- on a pro forma basis to give effect to (i) a forward stock split, or the Stock Split, to be effected upon the effectiveness of the registration statement of which this prospectus forms at a ratio of 7.1-for-1, (ii) the automatic conversion of all outstanding convertible preferred stock into an aggregate of 7,693,436 shares of common stock upon the closing of this offering, and (iii) the automatic conversion of all convertible promissory notes into an aggregate of 1,819,706 shares of common stock, upon the closing of this offering, based on an initial public offering price of $5.00 per share (which is the midpoint of the price range set forth on the cover page of this prospectus); and
- on a pro forma as adjusted basis to reflect, in addition, our sale of 2,400,000 shares of common stock in this offering at the assumed initial public offering price of $5.00 per share (which is the midpoint of the price range set forth on the cover page of this prospectus), after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

The historical audited financial statements included elsewhere in this prospectus have not been adjusted for the abovementioned Stock Split. Unless otherwise indicated, all other share and share price information in this prospectus have been adjusted to reflect the Stock Split.

You should read the information in this table together with our financial statements and related notes and "*Management's Discussion and Analysis of Financial Condition and Results of Operations*" appearing elsewhere in this prospectus.

	As of December 31, 2022		
(in thousands, except share amounts)	**Actual**	**Pro Forma**	**Pro Forma As Adjusted**
Cash and cash equivalents	$ 3,493	$ 3,493	$ 13,655
Convertible notes payable	$ 6,600		
Series A convertible preferred stock; $0.0001 par value, 205,385 shares authorized, issued and outstanding, actual; no shares issued and outstanding, pro forma and pro forma as adjusted	3,273	—	—
Series A-1 convertible preferred stock; $0.0001 par value, 380,657 shares authorized, issued and outstanding, actual; no shares issued and outstanding, pro forma and pro forma as adjusted	14,101	—	—
Series B convertible preferred stock; $0.0001 par value, 851,108 shares authorized, 391,303 issued and outstanding, actual; no shares issued and outstanding, pro forma and pro forma as adjusted	16,321	—	—
Common stock, $0.01 par value, 1,950,000 shares authorized, 147,041 shares issued and outstanding, actual; 10,557,134 shares issued and outstanding, pro forma; 12,957,134 shares issued and outstanding, pro forma as adjusted	1	106	1
Additional paid-in capital	1,053	45,870	55,598
Accumulated deficit	(37,315)	(40,649)	(40,649)
Total stockholders' equity (deficit)	(36,260)	5,327	14,951
Total capitalization	$ 4,034	$ 5,327	$ 14,951

DILUTION

If you invest in our common stock in this offering, your interest will be diluted to the extent of the difference between the amount per share paid by purchasers of shares of common stock in this offering and the pro forma as adjusted net tangible book value per share of common stock immediately after the completion of this offering.

As of December 31, 2022, our pro forma net tangible book value was approximately $5.0 million, or $0.48 per share of common stock. Our pro forma net tangible book value per share represents the amount of our total tangible assets reduced by the amount of our total liabilities and divided by the total number of shares of our common stock outstanding as of December 31, 2022, after giving effect to (i) a forward stock split, or the Stock Split, to be effected upon the effectiveness of the registration statement of which this prospectus forms a part at a ratio of 7.1-for-1; and (ii) the automatic conversion of all outstanding shares of our preferred stock and convertible notes as of December 31, 2022 into shares of common stock upon the closing of this offering, based on the initial public offering price of $5.00 per share (which is the midpoint of the price range set forth on the cover page of this prospectus).

After giving effect to our sale in this offering of 2,400,000 shares of our common stock, at the assumed initial public offering price of $5.00 per share (which is the midpoint of the price range set forth on the cover page of this prospectus), after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of December 31, 2022 would have been approximately $14.7 million, or $1.14 per share of our common stock. This represents an immediate increase in pro forma as adjusted net tangible book value of $0.65 per share to our existing stockholders and an immediate dilution of $3.81 per share to investors purchasing shares in this offering.

The following table illustrates this dilution:

Assumed initial public offering price per share			$	5.00
Pro forma net tangible book value per share as of December 31, 2022, before giving effect to this offering	$	5,108,000		
Increase in pro forma net tangible book value per share attributable to new investors purchasing shares in this offering	$	0.65		
Pro forma as adjusted net tangible book value per share, after giving effect to this offering			$	1.14
Dilution per share to new investors purchasing shares in this offering			$	3.86

Each $1.00 increase or decrease in the assumed initial public offering price of $5.00 per share (which is the midpoint of the price range set forth on the cover page of this prospectus), would increase or decrease, as applicable, our pro forma as adjusted net tangible book value per share to new investors by $0.20, and would increase or decrease, as applicable, dilution per share to new investors in this offering by $0.78, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions. In addition, to the extent any outstanding options or warrants are exercised, new investors would experience further dilution. If the underwriters exercise their over-allotment option in full, the pro forma as adjusted net tangible book value per share would be $1.11 per share, and the dilution in pro forma net tangible book value per share to new investors in this offering would be $3.89 per share.

The following table summarizes, on a pro forma as adjusted basis as described above, the difference between existing stockholders (after giving effect to (i) the Stock Split and (ii) the automatic conversion of all outstanding shares of our preferred stock and outstanding convertible notes into shares of common stock upon the closing of this offering) and new investors with respect to the number of shares of common stock purchased from us, the total consideration paid to us and the assumed initial public offering price of $5.00 per share (which is the midpoint of the price range set forth on the cover page of this prospectus), before deducting underwriting discounts and commissions and estimated offering expenses:

	Shares Purchased		Total Consideration		Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders	10,557,134	82%	$ 40,182,897	77%	$ 3.81
New public investors	2,400,000	18%	$ 12,000,000	23%	$ 5.00
Total	12,957,134	100.0%	$ 52,182,933	100.0%	

Except as otherwise indicated, the foregoing tables and calculations are based on the number of shares of our common stock outstanding as of December 31, 2022, after giving effect to (i) the Stock Split; and (ii) the automatic conversion of all outstanding shares of our preferred stock and convertible promissory notes into shares of common stock upon the closing of this offering, and excludes:

- 1,290,319 shares of our common stock issuable upon exercise of outstanding options, with a weighted average exercise price of $1.33 per share, granted pursuant to our 2016 Stock Incentive Plan, or the 2016 Plan;
- approximately 275,210 shares of our common stock issuable upon exercise of outstanding warrants, with a weighted average exercise price of $4.23 per share
- up to 360,000 shares issuable pursuant to the underwriters' over-allotment option;
- 96,000 shares issuable upon exercise of a warrant to be issued to the underwriter as part of its compensation in connection with this offering (up to 456,000 shares if the over-allotment option is exercised) at an exercise price of $6.25 per share; and
- 157,989 shares of our common stock reserved for future grants under our 2016 Plan and 2,000,000 shares of our common stock reserved for future grants under our 2023 Stock Incentive Plan, or the 2023 Plan.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion together with our financial statements and the related notes included elsewhere in this prospectus. This discussion contains forward-looking statements that are based on our current expectations, estimates and projections about our business and operations. Our actual results may differ materially from those currently anticipated and expressed in such forward-looking statements as a result of a number of factors, including those which we discuss under "Risk Factors" and elsewhere in this prospectus. See the section titled "Cautionary Note Regarding Forward-Looking Statements."

Overview

We were formed in January 2014 as a biopharmaceutical company focused on developing innovative therapies for precision dermatology using engineered proteins and 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 a genetic engineering technology, which can enable the transformation of previously genetically intractable strains. We are an early-stage clinical biopharmaceutical company and have not commenced commercial operations.

To date, we have capitalized our operations primarily through a series of private placements of our convertible preferred stock and convertible promissory notes, all of which will convert into shares of our common stock upon the consummation of this offering, including:

- The March 2017 placement of 205,385 shares of our Series A convertible preferred stock, at a price of $16.25 per share, which will convert into 1,458,234 shares of our common stock upon the consummation of this offering;
- The February 2019 placement of 380,657 shares of our Series A-1 convertible preferred stock, at a price of $37.50 per share, which will convert into 2,958,120 shares of our common stock upon the consummation of this offering;
- The September 2020 placement of 392,000 shares of our Series B convertible preferred stock, at a price of $43.45 per share, which will convert into 3,277,083 shares of our common stock upon the consummation of this offering;
- The January 2021 placement of a $1 million unsecured convertible promissory note, the principal amount of which, along with all accrued and unpaid interest thereunder, converted into 23,432 shares of our Series B convertible preferred stock in January 2023; and
- The September 2022 placement of $4.35 million of our unsecured convertible promissory notes, the principal amount of which, along with all accrued and unpaid interest thereunder, is convertible into shares of our common at the per share conversion price equal to the lower of (i) $30 million divided the number of our shares of common stock issued and outstanding, on a fully diluted basis, immediately prior to the close of this offering or (ii) 50% of the price per share in this offering.

Except as otherwise indicated, all information in this prospectus concerning our outstanding share of common stock assumes (i) after giving effect to a forward stock split to be effected upon the effectiveness of the registration statement of which this prospectus forms a part at a ratio of 7.1-for-1, (ii) the automatic conversion of the above-described shares of convertible preferred stock and convertible promissory notes, based on the initial public offering price of $5.00 per share (which is the midpoint of the price range set forth on the cover page of this prospectus), into a total of approximately 9,513,143 shares of our common stock upon the consummation of this offering.

The historical audited financial statements included elsewhere in this prospectus have not been adjusted for a forward stock split to be effected upon the effectiveness of the registration statement of which this prospectus forms a part at a ratio of 7.1-for-1. Unless otherwise indicated, all other share and share price information in this prospectus have been adjusted to reflect the forward stock split.

Results of Operations

We are an early-stage clinical biopharmaceutical company, formed in January 2014, and have limited operating history. We have not commenced revenue-producing operations apart from limited service revenue derived through our JDA with Bayer. Under the terms of the JDA, we are responsible for testing our library of microbial strains and their natural products for key preclinical properties and Bayer reimburses us for our development costs. To date, our operations have consisted of the development of our proprietary microbial library, the identification, characterization and testing of certain bacterial species from our microbial library that we believe are capable of being engineered to provide significant therapeutic effect and the development of our initial product candidates.

Year Ended December 31, 2022 Compared to Year Ended December 31, 2021

	Years ended December 31,			
	2022	**2021**	**$ Change**	**% Change**
Service revenue – related party	**$ 284,000**	$ 110,000	$ 174,000	158%
Total revenue	**284,000**	110,000	174,000	158%
Operating expenses:				
General and administrative	**3,639,666**	3,951,352	(311,686)	(8)%
Research and development	**6,097,938**	5,380,102	717,836	13%
Total operating expenses	**9,737,604**	9,331,454	406,150	5%
Loss from operations	**(9,453,604)**	(9,221,454)	(232,150)	3%
Other income (expense):				
Interest income	**4,818**	8,759	(3,941)	(45)%
Interest expense	**(251,891)**	(66,968)	(184,923)	276%
Other income	**65,849**	112,141	(46,292)	(41)%
Employee retention credit	**229,813**	-	229,813	100%
Forgiveness of Payroll Protection Program loan	**-**	232,506	(232,506)	(100)%
Change in fair value of convertible note	**(1,250,000)**	-	(1,250,000)	100%
Other expense	**(25,351)**	(4,659)	(20,692)	444%
Total other income (expense)	**(1,226,762)**	281,779	(1,508,541)	734%
Net loss before income taxes	**(10,680,366)**	(8,939,675)	(1,740,691)	19%
Income tax benefit (expense)	**-**	-		
Net loss	**$ (10,680,366)**	$ (8,939,675)	(1,740,691)	19%

Service Revenue - Related Party

We generated $284,000 of service revenue under the Bayer JDA during fiscal 2022 compared to service revenue of $110,000 under the JDA in fiscal 2021. The increase of $174,000 in service revenue is attributable to an increased amount of reimbursable development costs in 2022.

General and Administrative

General and administrative costs during fiscal 2022 decreased by $311,686, or 8%, to $3,639,666 from the prior year period. The decrease was primarily related to a decrease of $961,000 in payroll and related costs attributable to the discontinuation of separation benefits paid to our former chief executive officer and chief operating officer and the reduction in recruiting expenses for our new chief executive officer, offset by an increase of $607,000 in accounting and legal fees, and $43,000 net increase of other overhead expenses.

Research and Development

Research and development expenses include salaries and benefits of all research personnel, payments to contract research organizations, payments to research consultants, and the purchase of lab supplies. These expenses are offset by income earned from government grant payments. We generate grant revenue on contracts with various federal agencies and nonprofit research institutions for general research conducted by us. These grant arrangements also do not meet the criteria for revenue recognition and amounts earned under these grant contracts are recorded as a negative research and development expense.

During fiscal 2022, research and development expenses increased by $717,836, or 13%, to $6,097,938 from the prior year period. The increase was primarily related to an increase of $808,000 in research and development related costs attributable to our efforts in moving our Netherton program forward offset by a net decrease in payroll and related costs of $85,738 attributable to a reduction in staff. Research and development expenses in fiscal 2022 and 2021 were offset by $4,426 and $202,509, respectively, of government and nonprofit grant revenue received by us.

We expect our research and development expenses to significantly increase in the future due primarily to our planned clinical trial activity and continued development of product candidates.

Other Income (Expense)

Our other income (expense) consists of refundable research and development credits, employee retention credit, forgiveness of the payroll protection loan, valuation of warrants, amortization of debt issuance costs, change in fair value of the convertible note and interest expense on the placement of the $1 million unsecured promissory note in January 2021. During fiscal 2022, other income (expense) increased by $1,508,541, or 734%, compared to fiscal 2021. The increase was primarily related to an increase of $1,250,000 attributable to the change in fair value of the convertible note, an increase of $229,813 attributable to the employee retention credit, an increase of $184,923 attributable to interest expense offset by a net decrease of $156,195 of other income and expenses.

Liquidity and Financial Condition

Overview

As of December 31, 2022, we had total assets of 7.2 million and working capital of $1.9 million. As of December 31, 2022, our liquidity included $3.5 million of cash and cash equivalents, which gives effect to our receipt of $4.35 million of proceeds from our placement of unsecured convertible promissory notes in September 2022. As of the date of this prospectus, our projected working capital needs consist of funds with which to further clinical trials and product development, research and development, clinical manufacturing as well as for other general corporate purposes, including general and administrative expenses. See the section titled "*Use of Proceeds.*"

Funding Requirements

We believe that net proceeds of this offering, along with our cash on hand as of the date of this prospectus, will be sufficient to cover our proposed plan of operations over, at least, the 12 months following this offering, including dosing in the proposed Phase 1b clinical trial for ATR-12 and the initial enrollment in the proposed Phase 1b clinical trial for ATR-04. However, as of the date of this prospectus, we believe that we will need additional capital beyond the next 12 months, and there can be no assurance we will not need additional capital sooner. In addition, we believe that we will need additional capital to obtain marketing approval for ATR-12 and ATR-04, assuming such approval can be obtained at all. We intend to seek additional funds through various financing sources, including the sale of our equity and debt securities, 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.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, limit, reduce or terminate our research, product development or future commercialization efforts, or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

The report of our independent registered public accounting firm for the year ended December 31, 2022 states that due to our accumulated deficit, recurring and negative cash flow from operations there is substantial doubt about our ability to continue as a going concern. Our financial statements, in Note 1, include disclosure with respect to a substantial doubt about our ability to continue as a going concern and the report of our independent auditor incudes an explanatory paragraph with respect to that substantial doubt.

Contractual Obligations

Material contractual obligations arising in the normal course of business primarily consist of operating leases. See Note 15 to our audited financial statements for future minimum payments under non-cancelable operating leases with initial or remaining terms in excess of one year during over the next five years.

Cash Flows

The following table shows a summary of our cash flows for the periods indicated:

Year Ended December 31, 2022 Compared to Year Ended December 31, 2021

	Years Ended December 31,	
	2022	**2021**
Cash Used in Operating Activities	$ (8,349,469)	$ (8,067,359)
Cash Used in Investing Activities	$ (336,761)	$ (652,275)
Cash provided by Financing Activities	$ 4,134,624	$ 992,862
Net Decrease in Cash and Cash Equivalents	$ (4,551,606)	$ (7,726,772)

Operating Activities. During the year ended December 31, 2022, operating activities used $8.3 million of cash primarily driven by our net loss of $10.7 million offset by non-cash items of $2.4 million. During the year ended December 31, 2021, operating activities used $8.1 million of cash primarily driven by our net loss of $8.9 million offset by non-cash items of $0.8 million.

Investing Activities. During the year ended December 31, 2022, investing activities used $0.336 million of cash primarily driven by $0.308 million of trademark and patent costs and $0.028 million for the purchase of furniture and equipment. During the year ended December 31, 2021, investing activities used $0.652 million of cash primarily driven by $0.206 million of trademark and patent costs and $0.446 million for the purchase of furniture and equipment.

Financing Activities. During the year ended December 31, 2022, financing activities provided $4.1 million in cash primarily driven by the issuance of a $4.4 million convertible promissory note offset by $.3 million of deferred offering costs. During the year ended December 31, 2021, financing activities provided $.993 million in cash primarily driven by the issuance of a $1 million convertible promissory note.

Critical Accounting Policies

This management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to prepaid/accrued research and development expenses, share-based compensation and fair value of convertible promissory notes. We base our estimates on historical experience, known trends and events, and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 2 to our audited financial statements included elsewhere in this prospectus, we believe the following accounting policies are the most critical to the judgments and estimates used in the preparation of our financial statements.

Internal Control Over Financial Reporting

Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with U.S. GAAP. Under standards established by the Public Company Accounting Oversight Board, or PCAOB, a deficiency in internal control over financial reporting exists when the design or operation of a control does not allow management or personnel, in the normal course of performing their assigned functions, to prevent or detect misstatements on a timely basis. The PCAOB defines a material weakness as a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented, or detected and corrected, on a timely basis.

During the preparation of our financial statements for the years ended December 31, 2022 and 2021, we and our independent registered public accounting firm identified a material weakness as it relates to a lack of adequate segregation of accounting functions and the appropriate accounting for certain warrants in 2021 that were issued in connection with our previously issued but no longer outstanding debt instruments. We are in the process of implementing measures designed to improve our internal control over financial reporting and remediate this material weakness. We intend to increase staffing within our accounting infrastructure sufficient to facilitate proper segregation of accounting functions and to enable appropriate review of our internally prepared financial statements.

Revenue Recognition

As discussed in Note 2 to our audited financial statements included elsewhere in this registration statement, under Accounting Standards Codification, or ASC, 606, Revenue from Contracts with Customers, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services.

To determine the appropriate amount of revenue to be recognized for arrangements determined to be within the scope of ASC 606, we perform the following five steps: (i) identification of the contract(s) with the customer, (ii) identification of the promised goods or services in the contract and determination of whether the promised goods or services are performance obligations, (iii) measurement of the transaction price, (iv) allocation of the transaction price to the performance obligations, and (v) recognition of revenue when (or as) we satisfy each performance obligation. We only apply the five-step model to contracts when it is probable that the entity will collect consideration it is entitled to in exchange for the goods or services it transfers to the customer.

When optional goods or services are offered, we assess the options to determine whether the options grant the customer a material right. This determination includes whether the option is priced at an amount that the customer would not have received without entering into the contract. If we conclude the option conveys a material right, it is accounted for as a separate performance obligation. In identifying performance obligations in a contract, we identify those promises that are distinct. Promised goods or services are considered distinct when the customer can benefit from the goods or services on their own, or together with readily available resources, and the goods or services are separately identifiable from other promises in the contract. If a promise is not distinct, it is combined with other promises in the contract until the combined group of promises is capable of being distinct.

We estimate the transaction price based on the amount of consideration we expect to receive for transferring the promised goods or services in the contract. The consideration may include both fixed consideration and variable consideration. At the inception of each arrangement that includes variable consideration, we evaluate the amount of the potential payments and the likelihood that the payments will be received. If it is probable that a significant revenue reversal would not occur, the variable consideration is included in the transaction price. For contracts that include sales-based royalties for licensed compounds, we recognize revenue at the date when the related sales occur. Finally, we determine whether the contract contains a significant financing component by analyzing the promised consideration relative to the standalone selling price of the promised goods and services and the timing of payment relative to the transfer of the promised goods and services. At each reporting date, we reassess the transaction price and probability of achievement of the performance obligations and the associated constraints on transaction price. If necessary, we adjust the transaction price, recording a cumulative catch-up based on progress for the amount that was previously constrained.

Revenue is recognized when (or as) control of a performance obligation is transferred to the customer. When combined performance obligations contain a promised license and related services or other promises, management judgment is required to determine the appropriate timing of revenue recognition. In doing so, we must identify the predominant promise or promises in the contract to determine whether revenue is recognized at a point in time or over time. If over time, we must determine the appropriate measure of progress. If a license is deemed to be the predominant promise in a performance obligation, we must determine the nature of the license, whether functional or symbolic intellectual property, to conclude whether point-in-time or over-time revenue recognition is most appropriate. The determination of functional or symbolic intellectual property requires an assessment of whether the customer is able to exploit and benefit from the license in its current condition, or if the utility of the license is dependent on or influenced by our ongoing activities or being associated with us.

At each reporting date, we calculate the measure of progress for the performance obligations transferred over time. The calculation generally uses an input measure based on costs incurred to-date relative to estimated total costs to complete the transfer of the performance obligation.

Research and Development Expenses

Research and development expenses consist primarily of costs incurred in connection with the development of our product candidates. We expense research and development costs as incurred.

We accrue an expense for preclinical studies and clinical trial activities performed by our vendors based upon estimates of the proportion of work completed. We determine the estimates by reviewing contracts, vendor agreements and purchase orders, and through discussions with our internal clinical personnel and external service providers as to the progress or stage of completion of trials or services and the agreed-upon fee to be paid for such services. However, actual costs and timing of clinical trials are highly uncertain, subject to risks and may change depending upon a number of factors, including our clinical development plan.

We make estimates of our prepaid/accrued expenses as of each balance sheet date in our financial statements based upon facts and circumstances known at that time. If the actual timing of the performance of services or the level of effort varies from the estimate, we will adjust the accrual accordingly. Nonrefundable advance payments for goods and services, including fees for clinical trial expenses, process development or manufacturing and distribution of clinical supplies that will be used in future research and development activities, are deferred and recognized as expense in the period that the related goods are consumed, or services are performed.

Share-Based Compensation

We measure compensation expense for all share-based awards based on the estimated fair value of the share-based awards on the grant date. We use the Black-Scholes option pricing model to value our share-based awards. We recognize compensation expense on a straight-line basis over the requisite service period, which is generally the vesting period of the award. We have not issued awards for which vesting is subject to market or performance conditions.

The Black-Scholes option-pricing model requires the use of subjective assumptions that include the expected stock price volatility and the fair value of the underlying common stock on the date of grant. See Note 10 to our audited financial statements included elsewhere in this prospectus for information concerning certain of the specific assumptions we used in applying the Black-Scholes option pricing model to determine the estimated fair value of our awards granted.

Estimating the Fair Value of Common Stock

We are required to estimate the fair value of the common stock underlying our share-based awards when performing the fair value calculations using the Black-Scholes option pricing model. Because our common stock is not currently publicly traded, the fair value of the common stock underlying our stock options has been approved on each grant date by our Board, with input from management.

The third-party valuations of our common stocks were performed using methodologies, approaches and assumptions consistent with the American Institute of Certified Public Accountants, Audit and Accounting Practice Aid Series: Valuation of Privately Held Company Equity Securities Issued as Compensation. In addition, our Board considered various objective and subjective factors to estimate the estimated fair value of our common stock, including:

- the prices of our preferred stock sold to outside investors in arm's length transactions, and the rights, preferences and privileges of our preferred stock as compared to those of our common stock, including the liquidation preferences of our preferred stock;
- the estimated value of each security both outstanding and anticipated;
- the anticipated capital structure, which will directly impact the value of the currently outstanding securities;
- our results of operations and financial position;
- the status of our research and development efforts;
- the composition of, and changes to, our management team and board of directors;
- the lack of liquidity of our common stock as a private company;
- our stage of development and business strategy and the material risks related to our business and industry;
- external market conditions affecting the life sciences and biotechnology industry sectors;
- U.S. and global economic conditions;
- the likelihood of achieving a liquidity event for the holders of our common stock, such as an initial public offering, or IPO, or a sale of our company, given prevailing market conditions; and
- the market value and volatility of comparable companies.

In determining the estimated fair value of our common stock, our Board considered the subjective factors discussed above in conjunction with the most recent valuations of our common stock that were prepared by an independent third party. An independent valuation specialist was utilized by our Board when determining the estimated fair value of common stock for the awards granted from October 2017 through December 2021. Our Board, relying on these third-party valuations, approved valuations of our common stock of $3.39 per share as of October 2017, $6.58 per share as of April 2019, $12.09 per share as of September 2020 and $11.05 per share as of December 2021.

Estimating the Fair Value of Warrants

We utilize a Black-Scholes method to value our outstanding warrants at each reporting period, with changes in fair value recognized in the statement of operations. The estimated fair value of the warrant liabilities is determined using Level 3 inputs. Inherent in a Black-Scholes model are assumptions related to expected share-price volatility, expected life, risk-free interest rate and dividend yield. We estimate the volatility of our common stock based on market participant assumptions and matches the volatility used to value our stock options. The risk-free interest rate is based on the U.S. Treasury zero-coupon yield curve on the grant date for a maturity similar to the expected remaining life of the warrants. The expected life of our outstanding warrants is assumed to be equivalent to their remaining contractual term. The dividend rate is based on the historical rate, which the Company anticipates to remain at zero.

Recent Accounting Pronouncements

See Note 2 to our audited financial statements found elsewhere in this prospectus for a description of recent accounting pronouncements applicable to our financial statements.

BUSINESS

Overview

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.

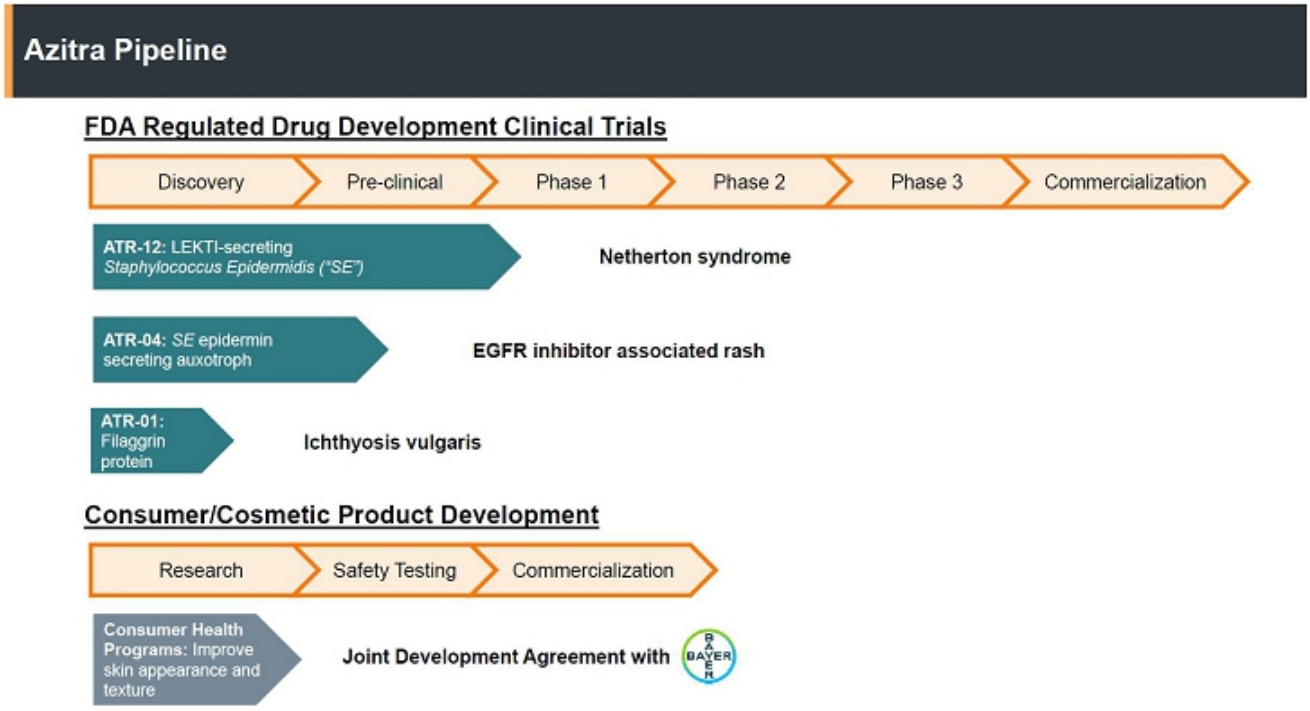
We are a pioneer in genetically engineering bacteria for therapeutic use in dermatology. Our goal is to leverage our platforms and internal microbial library bacterial strains to create new therapeutics that are either engineered living organisms or engineered proteins or peptides to treat skin diseases. 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 200,000, 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 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, 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. We expect to commence our Phase 1b clinical trial in the first half of 2023 and report initial results in the first half of 2024.
- **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. We intend to submit an IND for a Phase 1b clinical trial in certain cancer patients undergoing EGFRi, targeted therapy by the end of 2023. Subject to FDA approval of our IND, we expect to commence our Phase 1b clinical trial by early 2024 with initial results expected in late 2024.
- **ATR-01,** an engineered recombinant human filaggrin protein for treating ichthyosis vulgaris, a chronic, xerotic, 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 complete lead optimization and IND-enabling studies in 2023 to support an IND filing in late 2024.
- Two separate strains of microbes being investigated and developed by us and Bayer Consumer Care AG, the consumer products division of Bayer AG, 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 microbial strains and their products for key preclinical properties which we intend to develop as potential over-the-counter cosmetic products. After screening through hundreds of strains, we and Bayer have selected two particular strains to move forward. 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.

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 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 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 that in order to make genetic transformations that have never been previously achieved. Our collaboration with Fred Hutch is led by Dr. Christopher Johnston, an expert in microbial engineering, and the innovator behind the SyMPL technology.

Beyond our three lead product candidates and collaboration with Bayer, our goal is to develop a broad portfolio of product candidates focused on expanding the application of our platforms for precision dermatology. We believe that we have established a unique position in advancing the development of biologics for precision dermatology.



Our Business Strategies

We intend to create a broad portfolio of product candidates for precision dermatology through our development of genetically engineered proteins selected from our proprietary microbial library of approximately 1,500 unique bacterial strains. Our strategy is as follows:

- ***Build a sustainable precision dermatology company.*** Our goal is to build a leading precision dermatology company with a sustainable pipeline of product candidates. To that end, we are focused on rapidly advancing our current pipeline of live biotherapeutic candidates while actively developing additional product candidates. Each of our current product candidates are proprietary and subject to pending patent applications. We expect that most, if not all, genetically engineered product candidates we develop will be eligible for patent protection.

- ***Advance our lead product candidates, ATR-12 and ATR-04, through clinical trials.*** We are currently planning to begin two clinical trials in the next 12 months, including a Phase 1b trial of our ATR-12 in Netherton syndrome patients and a Phase 1b trial of our ATR-04 in certain cancer patients undergoing EGFRi therapy. We have successfully filed an IND for ATR-12 and expect to file an IND for ATR-04 by the end of 2023.

- ***Broaden our platform by selectively exploring strategic partnerships that maximize the potential of our precision dermatology programs.*** We intend to maintain significant rights to all of our core technologies and product candidates. However, we will continue to evaluate partnering opportunities in which a strategic partner could help us to accelerate development of our technologies and product candidates, provide access to synergistic combinations, or provide expertise that could allow us to expand into the treatment of different types of skin diseases. We may also broaden the reach of our platform by selectively in-licensing technologies or product candidates. In addition, we will consider potentially out-licensing certain of our proprietary technologies for indications and industries that we are not ourselves pursuing. We believe our genetic engineering techniques and technologies have applicability outside of the field of medicine, including cosmetics and in the generation of clean fuels and bioremediation.

- ***Leverage our academic partnerships.*** We currently have partnerships with investigators at the Fred Hutchinson Cancer Center, Yale University, Jackson Laboratory for Genomic Medicine, and Carnegie Mellon University. In January 2020, we entered into a clinical trial agreement with Yale University to evaluate the microbiome of approximately ten patients undergoing EGFR inhibitor therapy resulting in papulopustular rash. This is an observational trial meant to gain understanding of the microbial skin environment on these patients. Due to challenges with sample preservation, the commencement of patient enrollment was postponed and is planned to restart by late 2023. The estimated cost of the trial is expected to be less than $100,000, which will be paid by us. We have an ongoing scientific advisory board contract with Dr. Julia Oh of the Jackson Laboratories and have historically worked with Jackson Laboratories through sponsored research agreements for mouse experiments. We expect to leverage these partnerships and potentially expand them or form other academic partnerships to bolster our engineering platforms and expand our research and development pipeline.

- ***Management team***. We are led by Francisco D. Salva, our chief executive officer, and Travis Whitfill, our co-founder, who have more than 35 years of combined experience in the management of biotechnology companies and healthcare investing. Mr. Salva was previously a co-

founder of Acerta Pharma, which was sold to AstraZeneca for approximately $6.3 billion in a staged acquisition beginning in 2016. He also worked on the turnaround of Pharmacyclics, which subsequently sold to Abbvie for approximately $21 billion in 2015. Before that, Mr. Salva spent almost a decade in life sciences venture capital. Mr. Whitfill served as associate research scientist and assistant professor adjunct at Yale University with appointments in the Departments of Pediatrics and Emergency Medicine. He has led numerous grant-funded projects, holds nearly a dozen patents and has co-authored over 50 publications. Our board of directors, or Board, is comprised of renowned group of senior executives, scientists and investors in the biotechnology industry**.**

Our Microbial Library and Microbial Drug Delivery Platform

Commensal microorganisms reside on either the surface of the body or in the mucosa without harming human health. They act on the host's immune system to induce protective responses that prevent colonization and invasion by infectious pathogens, and thereby play a crucial role in maintaining human health across a number of organ systems, particularly in the skin. Diverse communities of microorganisms populate the skin, and a square centimeter can contain up to a billion microorganisms. These diverse communities of bacteria, fungi, mites and viruses can provide protection against disease and form dynamic, yet distinct niches on the skin. Together, they make up the skin microbiome.

Many genetically driven human diseases are systemically or partially related to the dysfunction of specific proteins that are missing or functionally inert due to a mutation. Since approximately 1982, the biopharmaceutical industry has been genetically engineering recombinant proteins in bacterial microorganisms for purposes providing therapies that mimic or support the body's normally functioning proteins and peptides. For decades, the vast majority of genetic engineering has been limited to primary *E. coli* and a handful of other bacterial species, many of which can become pathogenic, inducing infection. In contrast, we have chosen to focus on *S. epidermidis* because of its beneficial effects as a commensal, naturally occurring microbe on the skin. Our goal is to leverage our platform and internal microbial library of over 60 bacterial species to engineer and deliver commensal skin bacteria directly to the target through the stratum corneum of the skin. At these deeper levels in the skin, engineered microbes can produce the missing or inert proteins and thereby resolve the underlying disease cause.

S. epidermidis and Our Proprietary Microbial Library

S. epidermidis is a strong therapeutic candidate species due to a number of well-described properties in the skin. *S. epidermidis* is a gram-positive bacterium that is ubiquitous in the human skin and mucosal flora. As one of the earliest colonizers of the skin, *S. epidermidis* plays an important role in cutaneous immunity and maintaining microbial community homeostasis. *S. epidermidis* is known to have a beneficial relationship with its host as a skin commensal. The species has shown inhibition of the pathogenic strain, *Staphylococcus aureus, or S. aureus,* as well as the strain *Propionibacterium acnes*, or *P. acnes*. *S. epidermidis* induces keratinocytes to produce antimicrobial peptides and produces non-inflammatory T cell accumulation of both CD4+ and CD8+ T cells via immune cell signaling. The T cell responses induce re-epithelization of the skin after injury, accelerating repair and wound closure. For these reasons, we believe *S. epidermidis* offers several advantages as a vector for topical delivery of therapeutic proteins.

In their 2019 study, Stacy and Belkaid, world-leading experts in the skin microbiome, described *S. epidermidis* as "a 'poster child' of the skin microbiota to illustrate the remarkable diversity of functions a microbe can exert on skin physiology and health." We believe that *S. epidermidis* has enormous strain diversity that can be exploited for therapeutic purposes. In the 2020 Oh Study, Julia Oh's lab reported that 1,482 unique strains of *S. epidermidis* were present on only five individuals. These strains had not only significant genetic diversity but also large phenotypic diversity. We believe this large inter-strain variation among *S. epidermidis* can be exploited. To that end, we collected samples from healthy volunteers to develop and characterize our own strain library of *S. epidermidis* that includes over 900 unique *S. epidermidis* strains with potential for therapeutic use. We have used this microbial library to screen against selected properties, including antimicrobial peptide secretion, *S. aureus* killing, antibiotic sensitivity, and other therapeutically relevant characteristics. We have also collected other species in our library that includes roughly 60 different skin commensal species that can also be screened for therapeutic purposes.

Figure 1. Representative Species in Azitra Microbial Library

Staphylococcus epidermidis	Helicobacter pylori	Streptococcus pneumoniae	Vibrio cholerae
Escherichia coli	Kelbsiella oxytoca	Enterobacter cloacae	Yersinia enterocolitica
Staphylococcus aureus	Klebsiella pneumoniae	Salmonella oslo	Citrobacter freundii
Bacillus subtilis	Kluyveromyes lactis	Deinococcus radiodurans	Enterobacter aerogenes
Corynebacteria	Kocuria rhizophila	Enterococcus faecalis	Enterobacter cloacae
Saccharomyces cerevisiae	Micrococcus leteus	Morazella catarrhalis	Proteus mirabilis
Candida albicans	Moraxella catarrhalis	Streptococcus miltis group	Salmonella Senftenberg
Finegoldia magna	Morganella morganii	Streptococcus mitis/oralis	Serratia marcescens
Gardnerella vaginalis	Mucor circinelloides	Streptococcus pneumoniae	Shigella sonnei
Haemophilus influenzae	Staphylococcus haemolyticus	Streptococcus pyogenes	Neisseria gonorrhoeae
Haemophilus parainfluenzae	Staphylococcus haemolyticus	Streptomyces ambofaciens	Enterococcus faecium
Haemophilus parainfluenzae	Staphylococcus hominis	Thermoaerobacter marianensis	Salmonella typhimurium
Haloarclula marismortui	Staphylococcus lugdunensis	Thermus thermophilus	Acinetobacter baumannii
	Bacilus sterarothermophilus	Pseudomonas aeruginosa	

Predictive Analysis of Our Microbial Library

The biopharmaceutical industry has seen success in identifying and isolating thousands of bacterial species. Yet only a relatively few such species, believed to be less than 20, have been engineered to produce proteins or peptides with therapeutic potential. We have partnered with Chemia Biosciences, Inc., a research and development group from Carnegie Mellon University. Through our collaboration with Chemia Biosciences, we are able to use their proprietary genomic and peptidomic artificial intelligence and machine learning system, NRPMiner, to develop and confirm natural product predictions of the proteins, peptides and small molecules that are generated by our proprietary bacterial library. These predictions are confirmed via tandem mass spectroscopy or nuclear magnetic resonance. The information is then fed back into the machine learning algorithm to refine the predictions. It can also be compared to existing 2D and 3D protein databases to look for structural homology of our products to existing protein and peptide drugs. We believe our collaboration with the Carnegie Mellon based team provides us with a scalable and modification tolerant way to accelerate therapeutic discoveries within our microbial library.

The Delivery of our Microbially Produced Drugs

The delivery of genetically engineered proteins to the subcutaneous target sites is hindered by the natural barrier and the defenses of the stratum corneum. This is the skin's outermost layer which acts as a barrier that prevents unwanted materials from entering the body. To address this challenge, we have developed a proprietary process capable of facilitating protein delivery in a manner that bypasses the normally impenetrable stratum corneum. The strategy utilizes the ability of particular microbes to infiltrate into the deeper layers of the skin. There, the genetically modified microbes act as miniature factories to produce a therapeutic protein or molecule where it is needed.

Our protein delivery capability for treating skin conditions is based on engineering *S. epidermidis* and other microbes to secrete proteins for drug delivery into the skin. We believe any number of proteins can be engineered and encoded by our bacteria to be produced and delivered to the skin to treat a variety of skin conditions. We have also added key proprietary features in its platform to facilitate protein delivery. A key feature of this system is that it bypasses the normally impenetrable skin barrier, a problem of topical protein delivery. The skin barrier, composed of the stratum corneum, is sealed by enucleated keratinocytes and formed by numerous structural, physical, and biochemical properties. Other transdermal delivery challenges arise due to susceptibility of protein to enzymatic digestion by proteases and solubility and diffusion impediments due the hydrophobic surface and the layers of linked corneocytes comprising the stratum corneum. We address this issue by leveraging the natural homing of *S. epidermidis* to layers below the stratum corneum. In preclinical studies, we have shown that *S. epidermidis* homes to layers below the stratum corneum and delivers proteins into the deeper epidermis.

To expand upon our recombinant protein construction capabilities, we have acquired an exclusive license to proprietary technology that disguises our genetically engineered DNA sequences to enable the production of proteins in previously intractable bacterial species. The technology from the Fred Hutchinson Cancer Center or Fred Hutch, expands the universe of bacterial species that can be genetically modified. It is based upon a restriction modification system-silent SyMPL toolset. The SyMPL technology platform makes human-made DNA invisible to the bacteria's defenses. In theory, the method can be applied to any type of bacteria. Our current product candidates do not incorporate the SyMPL technology platform, but we expect that some or all of our future product candidates will do so.

Virtually all strains of naturally occurring bacteria have defense mechanisms called restriction modification systems. The four types of restriction modification systems recognize and defend against insertion of foreign DNA used to code recombinant proteins. Functional genetic engineering of S. *epidermidis* (as well as *S. aureus*) has previously been limited due to the presence of Type I and IV restriction systems in virtually all strains of these bacterial species. These restriction systems recognize methylated cytosine bases in DNA from standard clone expansion systems (such as *E. coli)* and hinder incorporation of foreign DNA in the microbe. *S. epidermidis* was once believed to be an "untransformable" strain due to its genetic intractability. However, we have been able to overcome *S. epidermidis'* defenses.

Current genetic engineering processes add specific modifications to disguise human made DNA to trick the bacterium into thinking the intruder is a part of its own DNA. This approach often takes considerable time and resources to try to match the right disguise to each particular recognition motif. In contrast, Fred Hutch's SyMPL technology platform is a systematic "stealth-by-engineering" approach to overcome restriction modification defense systems. These restriction modification defense systems protect microbes from foreign DNA and hinder the vast majority of genetic engineering approaches. The SyMPL technology platform is based on the ability to build minicircle DNA plasmids which lack any of the target recognition motifs for the microbe's defense systems to identify. The technology uses the genome and methylome from a target bacteria's genomic sequence to identify the restriction modification target motifs. They are then eliminated from the nucleotide sequence of the genetic tool *in silico*. The resulting sequence is used to build the restriction modification, SyMPL tools. These are propagated and then used for genetic transformations. Not only does the "stealth by engineering" approach enable transformations in genetically intractable bacterial strains, but it has also been shown to drastically increase transformational efficiency. Proof of principle experiments have shown improvements of over 10,000x in yields of genetically engineered colonies.

In January 2022, Fred Hutch granted us an exclusive worldwide, royalty bearing license to the patent rights, and a non-exclusive worldwide, royalty bearing license to the related know-how, for the SyMPL technology platform in all fields of use. For more information related to the intellectual property acquired pursuant to the Fred Hutch license agreement, see the section titled "*Business-Licenses and Intellectual Property Rights*."

Our Product Candidates

ATR-12 for the treatment of Netherton syndrome

ATR-12 is our proprietary and patent-pending drug candidate that contains a novel strain of *S. epidermidis* which has been genetically modified to express and secrete an active fragment of the full-length protein called the lympho-epithelial Kazal-type related inhibitor, or LEKTI. It has also been engineered to be auxotrophic, meaning that it requires the D-alanine nutrient in its formulation to survive and propagate. This provides an additional level of safety against potential systemic infection. ATR-12 is a topical application intended to address the underlying cause of Netherton syndrome, by replacing deficient LEKTI with an active segment of human recombinant LEKTI, or rhLEKTI-D6, to counter the dysregulated skin serine protease activity observed in Netherton syndrome patients. The uncontrolled serine protease activity leads to a profound skin barrier defect and the release of pro-inflammatory and pro-allergic mediators by keratinocytes and immune cells. As of the date of this prospectus, there is no known therapy for the cure or effective treatment of Netherton syndrome. We believe ATR-12 has the potential to be the first therapy to effectively treat this disease of the skin.

Netherton syndrome overview

Netherton syndrome is a rare, autosomal recessive disease estimated to affect approximately one in every 200,000, but its prevalence may be underestimated due to misdiagnosis. It is a chronic disease of the skin, characterized by severe inflammation, pruritus, scaling, red, and dehydrated skin. Infants born with Netherton syndrome may suffer from a failure to thrive, and it has been reported that approximately one in ten infants with Netherton syndrome die in their first year of life. Those that survive face a lifetime of skin disease challenges including red, scaly skin, hair defects and an ongoing higher than normal risk for infection and allergy.

Netherton syndrome is caused by mutations in the *SPINK5* gene, which codes for the serine protease inhibitor Lympho-epithelial Kazal-type related inhibitor, or LEKTI. The function of LEKTI is to inhibit enzymes in the epidermis, such as kalikreins 5, 7 and 14, or KLK5, KLK7 and KLK14, which facilitate the shedding of skin cells in a process known as desquamation. When LEKTI is absent or has reduced activity, excess shedding results and the skin is sensitive, open, and appears red and scaly. This is accompanied by the detachment of the stratum corneum, leading to severe barrier dysfunction, dehydration and potential exposure to environmental agents, such as chemicals. Histopathology and immunofluorescence staining of skin from a Netherton syndrome patient compared to healthy volunteer reveal an absence of LEKTI and abnormalities in the skin such hyperkeratosis, epidermal thickening, and reduction of the basophilic keratohyalin granules.

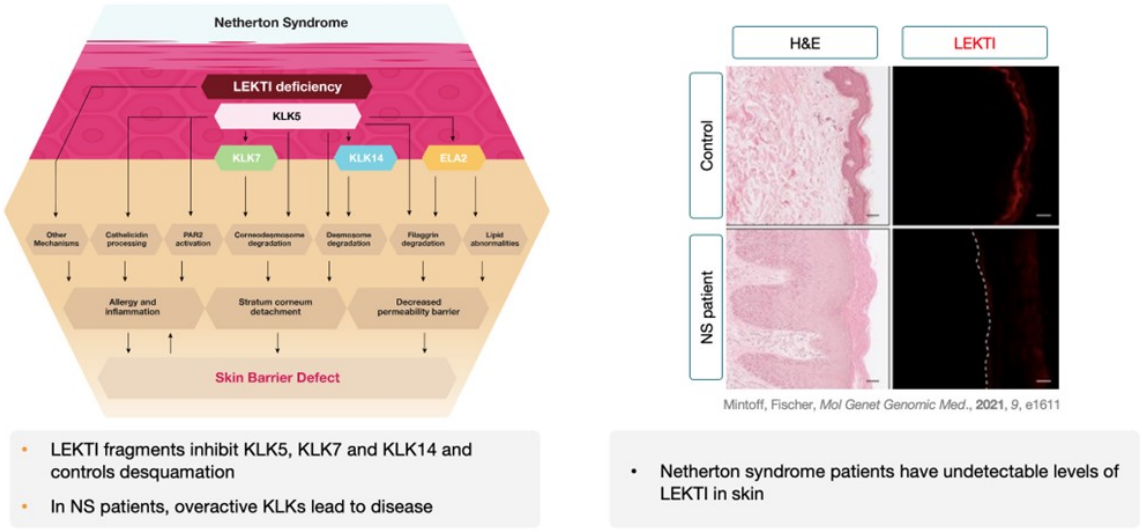


Figure 2: Netherton syndrome pathophysiology and LETKI deficiency

Netherton syndrome can range in severity from mild, such as red patchy areas of the skin, to life threatening. The degree of severity of the disease correlates directly with the extent of loss of function of LEKTI on the skin. Netherton syndrome appears shortly after birth and is most severe in the first year of an infant's life. Survival beyond the first year is common in most cases, but the implications of the disease are a lifelong challenge.

As of the date of this prospectus, there is no known cure for Netherton syndrome and treatment options are limited. Dermatologic interventions to treat the severe skin manifestations of Netherton syndrome include moisturizers, topical corticosteroids, and calcineurin inhibitors, all of which are limited in that they do not provide sustained remediation. Given the severity of disease during neonatal stages, fluid/electrolyte and diet support are needed in addition to treating infections that often arise in these patients. While immunoglobulin therapy to address immunodeficiencies associated with Netherton syndrome has shown limited success, a sustained remediation of skin barrier defects, induced by dysregulation of LEKTI, is currently unavailable.

Our solution – ATR-12 for the treatment of Netherton syndrome

ATR-12 is a topical ointment containing an *S. epidermidis* strain, SE351, that has been genetically modified to express LEKTI from the chromosome. The SE351 strain has also been engineered to be auxotrophic for D-alanine, which means it cannot survive without the exogenous D-alanine nutrient, provided in the formulation. ATR-12 is intended to address the underlying cause of Netherton syndrome by replacing deficient/dysfunctional LEKTI with an active, recombinant, human fragment of the full-length protein, rhLEKTI-D6. The treatment consists of applying ATR-12 to affected areas. rhLEKTI-D6 produced by SE351 will counter the dysregulated skin serine protease activity observed in Netherton syndrome patients, to restore skin barrier function and reduce inflammation. We believe that among the important advantages of this approach is the potential to deliver rhLEKTI-D6 over time into the lower layers of the stratum corneum and epidermis, the primary sites of dysregulation in patients with Netherton syndrome.

The *S. epidermidis* strain selected to deliver rhLEKTI-D6 to the skin, SE351, was selected from our proprietary strain collection. This strain is characterized by low virulence and is a non-biofilm forming host strain. To further enhance the safety of ATR-12, we have engineered the microbe for D-alanine to be auxotrophic. The key advantage to engineering auxotrophy is the ability to control growth and halt potential infection. Full length human LETKI, a 15-domain protein (145 kDa), is too large for reliable bacterial expression and secretion. Given evidence that fragments of the full-length protein are sufficient to counter the dysregulated skin serine protease activity observed in Netherton syndrome patients, we selected D6 for recombinant expression in *S. epidermidis*.

In May 2020, we received Rare Pediatric Disease Designation from the FDA for ATR-12. As a result, if we are able to obtain pre-market approval for ATR-12 from the FDA, we will be eligible to receive a Priority Review Voucher upon approval, which can be used by us to obtain FDA review of a New Drug Application for this or another drug candidate in an expedited period of six months. These vouchers are often transferable and have been sold for over $100 million.

Preclinical data for ATR-12

As of the date of this prospectus, we have conducted several *in vivo* and *ex vivo* experiments that collectively support the potential efficacy of ATR-12 as a disease modifying therapy for patients with Netherton syndrome. The genetically engineered strain of S. epidermidis used in the formulated ATR-12 drug product is called SE351. In 2021, we conducted *in vitro* studies to assess the ability of exogenously applied SE351 to colonize sterile reconstructed human epidermis. SE351 successfully colonized the reconstructed human epidermis and, furthermore, no *S. epidermidis* colonization occurred without D-alanine present, confirming that D-alanine must be supplied for SE351 growth on skin. These data suggest that SE351 is capable of colonizing human skin, and that colonization can be controlled with D-alanine supplementation.

Additionally, *in vitro* studies using tape stripped skin from healthy volunteers spiked with KLK5 to mimic Netherton syndrome showed that diluted SE351 culture supernatant dose-dependently inhibited trypsin-like activity (KLK5 activity). Trypsin-like activity in the Netherton syndrome surrogates returned to normal healthy levels when a solution containing ≥0.5% of the SE351 culture supernatant was added.

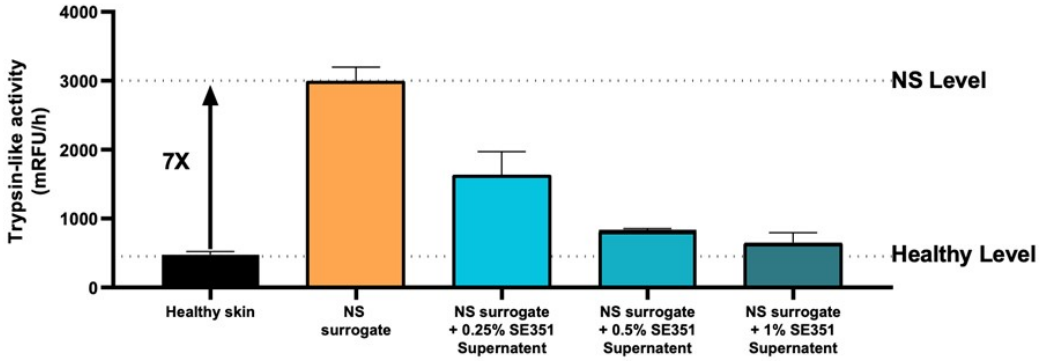


Figure 3: *In Vitro* Netherton Syndrome Model Using Human Skin Tape Strip Extracts Supplemented with Disease Level KLK5 Activity

In addition, results from an *ex vivo* pig skin model demonstrate that a single topical dose of ATR-12 at 3 dose levels led to secretion of active rhLEKTI-D6. Finally, data from an *ex vivo* healthy human skin model demonstrate that a single topical dose of ATR-12 administered at the maximum intended dose of 10^9 CFU/g delivers enough active rhLEKTI-D6 into the lower layers of the stratum corneum to effectively inhibit the protease, kallikrein 5 ("KLK5"), at levels typically observed in patients with Netherton syndrome.

In particular, data from an ex vivo healthy human skin model demonstrate that a single topical dose of ATR-12 administered at the maximum intended dose of 10^9 Colony Forming Units per gram (CFU/g) delivers enough active rhLEKTI-D6 into the lower layers of the stratum corneum to effectively inhibit KLK5 at levels typically observed in patients with Netherton syndrome. Amounts of LEKTI-activity in layers extracted were from tape strips samples from ex vivo human skin treated with placebo and ATR-12. The collection proceeded right after skin application (t = 0 hours, white bars) or after 8 hours incubation at 30°C (t = 8 hours, black bars). Total LEKTI activity levels were obtained by adding the pmol amounts through layers 1 to 30 of placebo (grey bars) or ATR-12 (black bars) samples. Data are the average ± a standard deviation (SD) of 3 independent samples (N = 3). Statistical analysis in I was carried out using two-way ANOVA, and ** represents p <0.01.

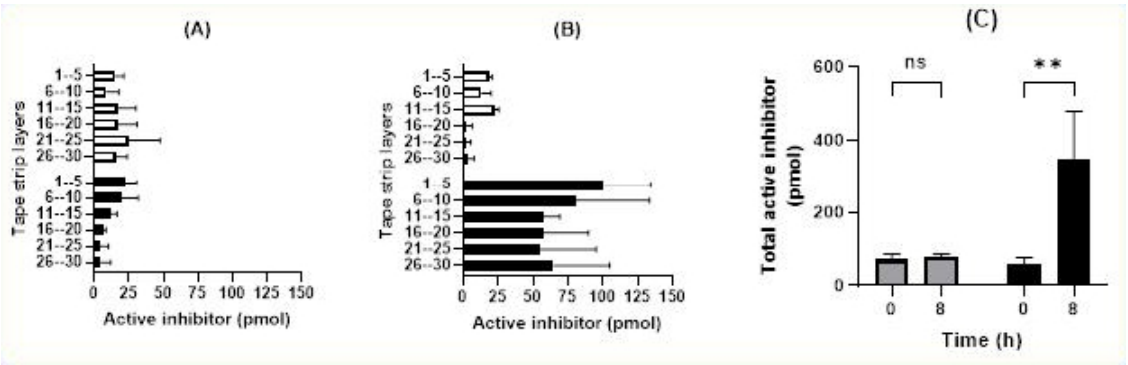


Figure 4: LETKI activity in Placebo and ATR-12-Treated Skin Samples Following 0- and 8-hour Incubation

In addition, a single therapeutic dose of ATR-12 over 24-hour incubation yielded ~2-fold higher LEKTI activity compared to 8-hour incubation. This indicates continuous production of functional rhLEKTI-D6 by ATR-12 over time.

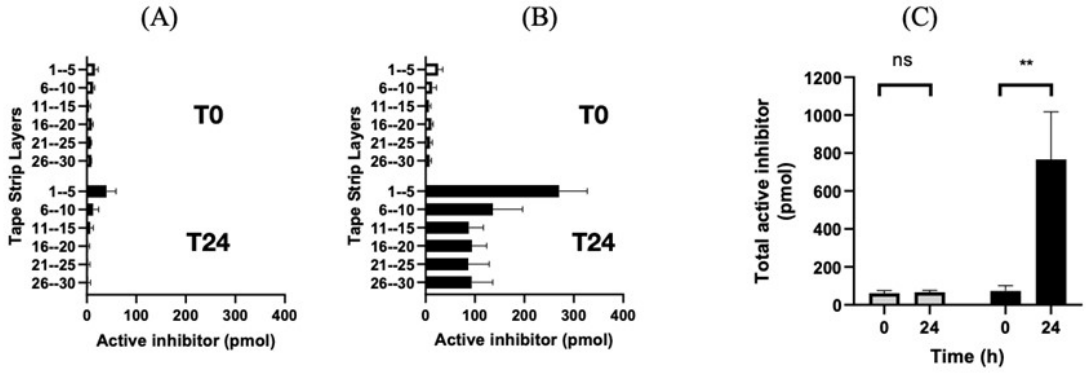


Figure 5: LETKI activity in Placebo and ATR-12-Treated Skin Samples Following 24-hour Incubation

In vitro stoichiometry work performed by Azitra indicates that KLK5 requires 2 molar equivalents on the LEKTI-D6 protein for inhibition (as measured by IC50). Historical studies have indicated that Netherton syndrome patients to show up to ~6 fold the amount of KLK5 that the amounts found in normal skin. This equates to 60 pmol of KLK5 per given area. The studies shown above indicate that SE351 delivered 350 pmol of LEKTI-D6 at 8 hours and it delivered 700 pmol of LEKTI-D6 at 24 hours. This represents a 5-to-11 fold amount above the predicted amount required for activity.

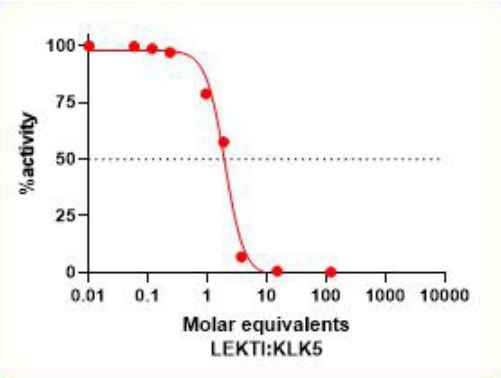


Figure 6: *In vitro* stoichiometry of LEKTI-D6 to inhibit KLK5

In 2022, we obtained pre-IND correspondence with the FDA for purposes of discussing our proposed regulatory pathway for ATR-12 and obtaining guidance from the FDA on the pre-clinical plan leading to the filing and acceptance of an IND application for ATR-12. In December 2022, we filed an IND for a first-in-human trial of ATR-12 in Netherton syndrome patients. Our IND proposes a Phase 1b multi-center, randomized, double-blind, single dose level, placebo-controlled clinical study of ATR-12 in patients with Netherton syndrome. The primary endpoint is safety and secondary endpoints will include signals of efficacy and pharmacokinetics. Exploratory endpoints include immune and inflammatory mechanism biomarkers. On January 27, 2023, we received notification from the FDA that the "study may proceed" with respect to the proposed Phase 1b clinical trial, and we expect to commence our Phase 1b clinical trial in the first half of 2023, with initial results expected in the first half of 2024.

ATR-04 for the Treatment of EGFRi-Associated Rash

ATR-04 is our proprietary and patent-pending drug candidate that contains a novel strain of *S. epidermidis*, SE484, which has been genetically modified to be auxotrophic tor D-alanine. ATR-04 is a topical application intended to address the papulopustular rash experienced by cancer patients undergoing epidermal growth factor receptor inhibitor, or EGFRi, targeted therapy.

EGFRi-Associated Rash Overview

Targeted cancer therapies have produced significant treatment advances for patients diagnosed with a variety of tumor types, but they are also associated with unique dermatologic toxicities that may hamper treatment efforts and cause significant physical and psychological discomfort for patients. Prevention and management of these toxicities may allow patients to tolerate treatments better, remain on therapy longer and thereby potentially receive maximum clinical benefit from the drug. One such class of targeted cancer therapy includes EGFR inhibitors. EGFR is a protein on the surface of cells that helps them grow and divide. It is also a key factor in certain malignancies, and its activity enhances tumor growth, invasion, and metastasis. While systemic exposure to EGFRi agents suppresses EGFR at the target cancer site, it also suppresses EGFR throughout the body. In the skin, EGFR regulates multiple keratinocyte functions including proliferation, adhesion and migration, survival, and differentiation. Consequently, inhibition of EGFR in the skin results in adverse skin reactions, which make it difficult for patients to stay on these effective therapies.

Dermatologic toxicities are amongst the most prevalent side effects seen with EGFRi-targeted therapies. The papulopustular rash is the earliest and most common dermatologic adverse event of EGFRi treatment, often occurring in 50-80% of patients, depending on the drug, the cancer being treated, and the treatment regimen. The appearance of the papulopustular rash is a dose-dependent skin drug reaction, which usually develops in the first one to two weeks and peaks at three to four weeks on therapy. The intensity of the rash may start to decrease after two weeks but can persists over the entire course of EGFRi treatment. The rash is characterized clinically as tender erythematous papules, which after a few days evolve into pustules and then into crusts on the face, scalp, chest, and upper back. The rash is often accompanied by severe xerosis and at times serious cutaneous bacterial infection, primarily *S. aureus*. While most skin rash episodes are considered mild to moderate, some are severe. In many cases the rash leads to severe quality of life issues and can even lead to the interruption or cessation of the EGFRi treatment.

The current standard of care for rash treatment in patients undergoing EGFRi treatment varies depending on the rash severity. Typically, skin moisturizers, topical steroids and doxycycline are administered prophylactically from the start of EGFRi therapy and are continued throughout the entire treatment period. If the rash continues to advance, oral steroids and/or antibiotics are administered. However, there are known systemic adverse events associated with these adjunctive therapies, and we believe that physicians and patients try to limit their use. In addition, research indicates that oral antibiotics lead to a disruption in the gut microbiome, which in turn leads to a decrease in the effectiveness of targeted therapies, including EGFRi. Given the high incidence rate of rash that continues with these patients, as well as the concerns related to potential impacts of antibiotics on these therapies, we believe there is a clear unmet medical need for additional safe and effective adjunctive therapies for addressing papulopustular skin rash.

Based on studies conducted by Satoh and Lichtenberger, the cytokine, Interleukin-36 gamma, or IL-36γ and *S. aureus* are linked to and play a significant role in the rashes experienced by patients treated with EGFRi's. IL-36γ, is elevated in the skin of patients undergoing EGFRi therapy. In 2020, Satoh used gene expression profiling to identify IL-36γ as a candidate driver of EGFRi/MEKi skin toxicity. It is induced by EGFR inhibition and *Cutibacterium acnes* that synergistically induce IL-36γ in the skin and subsequently IL-8 and NF-κB, which leads to cutaneous neutrophilia. IL-36γ could be a key therapeutic target in treating EGFRi-induced rashes. In 2013, Lichtenberger noted high rates (70%) of bacterial infection in patients (n=107) on EGFRi and proposed a mechanism of EGFR ablation leading to *S. aureus*-induced infection in mice. The study noted a majority of the patients were positive with *S. aureus* (54%). Mechanistically, the authors noted that EGFRi therapy impairs host defense: impaired expression of antimicrobial peptides, especially against *S. aureus*; and lowered expression of tight junctions. Also, the study revealed EGFR ablation leads to skin barrier defects as well as impaired cutaneous immune response and cytokine expression.

Our solution – ATR-04 for the treatment of EGFRi-associated rash

ATR-04 is our formulated, drug product candidate for the treatment of EGFRi associated rash. It includes a novel auxotrophic strain of *S. epidermidis* strain that was selected from our microbial strain library, based on desired properties of IL-36γ reduction and inhibition of *S. aureus* and its biofilms. The current lead strain is called SE484. We then genetically engineered SE484 to be auxotrophic tor D-alanine and to create our drug product candidate, ATR-04.

SE484 was chosen from our microbial library based on key characteristics such as inhibition of IL-36γ as well as its effect against *S. aureus*. Together, we expect these mechanisms of action to lead to significant reductions in rash severity among patients undergoing EGFRi therapy.

We believe that ATR-04 has the potential to address current limitations to treatment of EGFRi-associated rash:

- **Reduced antibiotic use.** From our surveys of clinicians and key opinion leaders, practitioners are reluctant to prescribe systemic antibiotics to patients undergoing EGFRi therapy. These patients can often be prescribed antibiotics for more than 12 months and suffer from antibiotic-related adverse events. We believe ATR-04 would reduce the need for antibiotics in these patients and lead to fewer adverse events due to EGFRi and antibiotic use.

- **Better EGFRi compliance.** Up to 20% of patients undergoing EGFRi therapy discontinue due to adverse events, primarily due to rashes. We believe we can reduce discontinuation rate in patients undergoing EGFRi therapy and thus increase compliance.

- **Higher quality of life.** Many patients on EGFRi therapy report a poor quality of life due to adverse events and papulopustular rashes. Current treatment options fail to adequately reduce these adverse events. We believe ATR-04 therapy in patients undergoing EGFRi therapy will have reduced rash severity and thus a higher quality of life.

Preclinical data of ATR-04

We screened over 100 strains based on safety (e.g., lack of antibiotic resistance) and biological activity (e.g., IL-36γ inhibition and activity versus *S. aureus*) and designated SE484 as our lead candidate strain. After engineering this strain to be auxotrophic for D-alanine, we nominated this candidate for use as the active microbe in the ATR-04 drug product formulation.

EGFRi is a condition that is characterized by redness, itchiness, and irritation of the skin, and is induced by certain cancer treatments. It was shown, by gene expression profiling (Satoh et al 2020), that skin biopsy samples from patients suffering from EGFRi had elevated levels of cytokines IL-36γ (IL-36 gamma) and IL-8 compared to skin from healthy donors. These are proinflammatory cytokines that are signaling molecules of the immune system that increase the intensity of an immune response and can cause tissue damage. In addition to elevated cytokine levels, EGFRi-treated patients have impaired skin barrier function. Infection with pathogenic strains of S. aureus exacerbates the EGFRi-induced cutaneous disease.

Our work was focused on identifying a Staphylococcus epidermidis strain, a skin commensal, that reduces IL-36γ levels and thus reduces the rash associated with EGFRi. We reasoned that many species of bacteria that live on human skin probably survive there because they have evolved ways to reduce the human immune system's response to their presence, and we might be able to identify a resident human skin commensal bacteria that survives thereby specifically reducing IL-36γ activity.

To identify such a Staphylococcus epidermidis strain, we developed an in vitro assay to measure the levels of IL-36γ and IL-8 that are produced by human skin cells that are grown in culture. The cell line we used is called HaCaT and is derived from human keratinocytes, which are a cell type in the epidermidis. In order to simulate the inflammatory manifestation of EGFRi-related disease of the skin, HaCaT cells are stimulated with an immunostimulant, Poly IC, which causes them to secrete elevated levels of IL-36γ and IL-8. This assay was used to identify and evaluate the ability of different S. epidermidis strains to lower IL-36γ and IL-8 levels.

We screened over 100 strains based on safety (e.g., lack of antibiotic resistance) and biological activity (IL-36γ inhibition and activity against S. aureus) and designated SE484 as our lead candidate strain. After engineering this strain to be auxotrophic for D-alanine, so that it will grow only if provided with D-alanine, we nominated this candidate for use as the active microbe in the ATR-04 drug product formulation.

Figure 7 shows the results of the IL36g in vitro assay to evaluate the ability of strain SE484 to reduce or inhibit IL-36γ levels in HaCaT cells. The black bars show the effect of adding Poly IC to HaCaT cells to induce IL-36γ levels approximately two-fold over normal levels. In the presence of culture supernatant (CS) of SE484, the level of IL-36g is reduced to baseline levels, similar to a chemical inhibitor of Poly IC (shown as Poly IC + inh). Panel A shows the results after 48 hours of exposure to the various treatments, while Panel B shows the results after 72 hours.

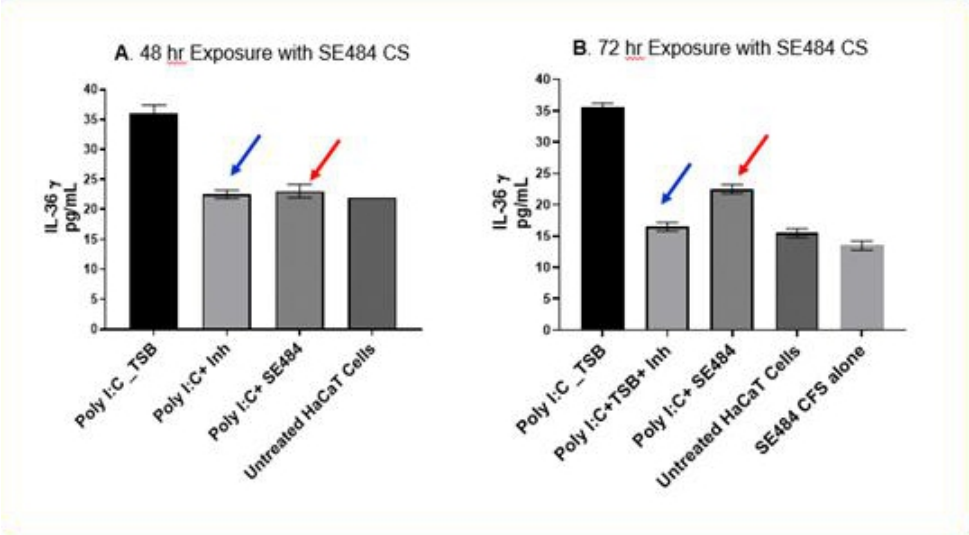


Figure 7. IL-36g induction by Poly IC is Reduced by CS of SE484. Black bars are the levels of IL-36g when HaCaT cells are stimulated with Poly IC. The presence of culture medium from SE484 prevents the stimulation and release of IL-36g by Poly IC (red arrow). An inhibitor of Poly IC is used as control (blue arrow). Panel A shows suppression of IL-36g after 48-hour exposure of SE484 and Panel B, 72-hour exposure. Data is representative of 2 independent experiments. CS= culture supernatant

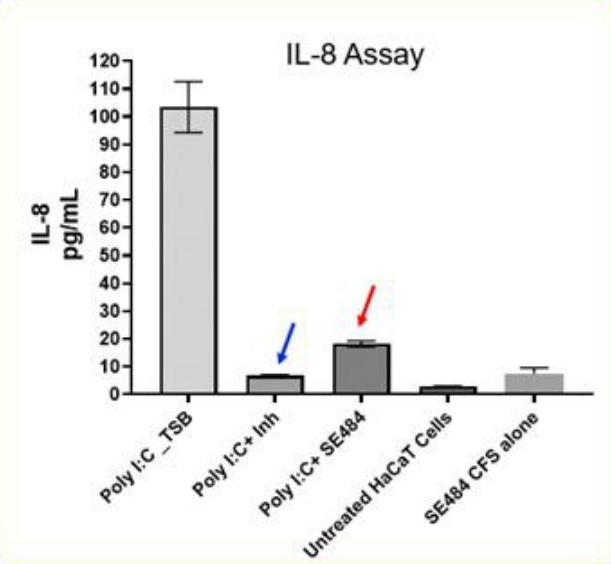


Figure 8. IL-8 induction by Poly IC is Reduced by CS of SE484. The presence of culture medium from SE484 prevents the stimulation and release of IL-8 by Poly IC (red arrow). An inhibitor of Poly IC is used as control (blue arrow). Data is representative of 2 independent experiments. CS= culture supernatant

Figure 8 shows the inhibitory effect of SE484 culture supernatant on the induction of IL-8 by Poly IC. Similar to IL-36g, when Poly IC are added to HaCaT cells, IL-8 are also secreted, several folds above background (as seen in "untreated HaCaT and SE484 treated HaCaT). However, in the presence of SE484, lower levels of IL-8 were detected, thus further demonstrating the efficacy of SE484 to inhibiting the proinflammatory pathway involved in EGFRi-related rash.

Our results show that culture media of S. epidermidis strain SE484, which was isolated from a healthy human volunteer, can reduce the level of IL-36g and IL-8 produced by HaCaT cells (Figure 7 and Figure 8, respectively) and thus help in the treatment of EGFRi- related rash. In addition to its anti-IL-36g property, SE484 also has broad activity against different MRSA strain types as well as methicillin sensitive S. aureus. The ability of SE484 to reduce IL-36g/IL- 8 levels as well as its activity against S. aureus and the engineered D-alanine auxotrophy enabled us to nominate strain SE484 for use as the active microbe in the ATR-04 drug product formulation to form the basis of a treatment and reduce the severity of EGFRi rash.

We have also shown that SE484 leads to *in vitro* inhibition of known virulent strains USA300, which is resistant to methicillin, and MSSA, which is sensitive to methicillin. The following data shows that ATR-04 reduces the ability of the pathogenic S. aureus bacterial species to grow and instigate infections that are seen in patients with EGFRi rash.

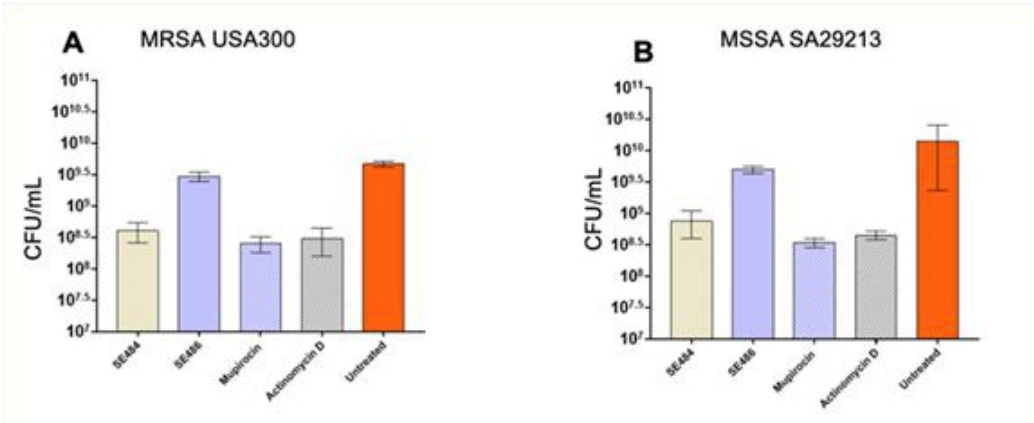
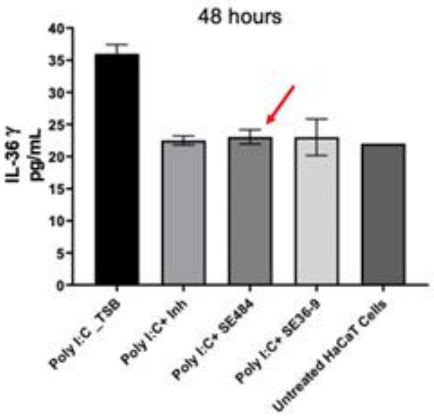
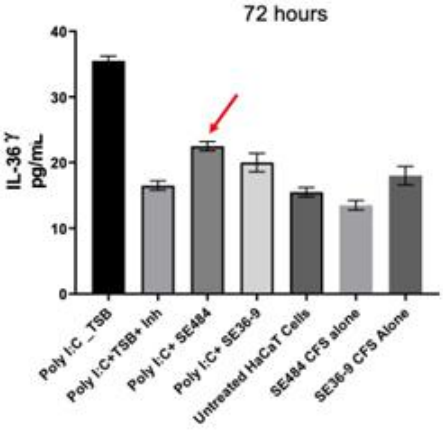


Figure 9. Epidermin-expressing SE484 kills S. aureus with similar activity as mupirocin on in vitro agar plates.


48 hours
IL-36 γ pg/mL
40
35
30
25
20
15
10
5
0
Poly I:C _TSB
Poly I:C+ Inh
Poly I:C+ SE484
Poly I:C+ SE36-9
Untreated HaCaT Cells


72 hours
IL-36 γ pg/mL
40
30
20
10
0
Poly I:C _TSB
Poly I:C+TSB+ Inh
Poly I:C+ SE484
Poly I:C+ SE36-9
Untreated HaCaT Cells
SE484 CFS alone
SE36-9 CFS Alone

We are proposing an initial study of SE484 in the ATR-04 formulation in patients. It is contemplated to be a Phase 1b multi-center, randomized, double-blind, single- dose, placebo-controlled trial in patients with colorectal or head and neck cancer who are initiating EGFRi monoclonal antibody therapies. The primary endpoint is safety and secondary endpoints will include efficacy and Quality of Life, or QoL We are planning to submit an IND by the end of 2023. Subject to FDA approval of our IND, we expect to commence our Phase 1b clinical trial in the first-half of 2024 with initial results expected in late 2024.

ATR-01 for the treatment of ichthyosis vulgaris

ATR-01 is our drug product candidate intended to treat ichthyosis vulgaris. The program is currently investigating a proprietary and patent-pending novel engineering segment of human filaggrin protein. ATR-01 is being developed as a topical application intended to address ichthyosis vulgaris, a chronic scaly skin disease with an estimated incidence and prevalence of 1 in 250, which gives a total patient population of 1.3 million in the United States. Ichthyosis vulgaris is caused by loss-of-function mutations in the gene encoding filaggrin Using synthetic biology tools for protein engineering, we attached a cell penetrating peptide to filaggrin, which helps facilitate deeper skin delivery for filaggrin. This is designed to overcome the impenetrability of the skin barrier, which would otherwise limit topical protein delivery.

Ichthyosis vulgaris overview

Ichthyosis vulgaris, or IV, is a chronic, xerotic, scaly skin disease with an estimated incidence and prevalence of 1 in 250, which gives a total patient population of 1.3 million in the United States. Clinical features of IV usually appear at around 2 months of age and include generalized xerosis and fine, white to gray scales that are prominent on the abdomen, chest, and extensor surfaces of the extremities. Although rare, some IV patients also experience hypohidrosis and heat intolerance. The pathogenesis of IV has long been identified as a decrease in the size or number, or even a complete absence of, epidermal keratohyaline granules. In addition, patients with IV are at increased risk for atopic dermatitis, asthma and allergies.

Ichthyosis vulgaris is an autosomal semidominant disease caused by loss-of-function mutations in the gene encoding filaggrin. Filaggrin is an essential structural protein that is derived from profilaggrin, which breaks down into individual filaggrin units in the stratum corneum. These reinforce the skin barrier by binding to keratins and other intermediate filament proteins in the keratinocyte cytoskeleton. Many studies have identified loss-of-function mutations in *FLG* in IV patients, and these mutations are associated with disorganized keratin filaments, skin barrier defects and microfractures in the stratum corneum leading to enhanced percutaneous allergen sensitization. Moreover, filaggrin and its breakdown products have significant additional functions in the skin including moisturizing the skin (via hygroscopic amino acids or “natural moisturizing factors”), effecting production of antimicrobial molecules (particularly against *S. aureus*) and maintaining both a beneficial lipid profile and pH in the skin.

There are few effective therapies for the treatment of IV. Current treatment options for IV include primarily topical water evaporation suppressants (e.g., sodium chloride, urea, lactic acid, salicylic acid), and, to a lesser extent, moisturizers (e.g., glycerol, propylene glycol,). Topical retinoids may also be prescribed in an effort to slow the body’s production of skin cells. However, long-term retinoid use is not ideal. Of particular concern is the teratogenic effect of all retinoids, which limits their use in women of child-bearing potential. Chronic toxicities from long term therapy with retinoids may result in skeletal abnormalities. Furthermore, the chronic use of retinoids in children may inhibit their growth. Notably, many patients with IV experience a significantly reduced quality of life, due to self-consciousness and social embarrassment, and see a negative impact on domestic life, educational/professional lives and even leisure/sports activities.

Our solution – ATR-01 for the treatment of ichthyosis vulgaris

It is now known that IV is caused by loss-of-function mutations in the gene encoding filaggrin, leading to disorganized keratin filaments, skin barrier defects and microfractures in the stratum corneum, and resulting in enhanced percutaneous allergen sensitization as well as bacterial and viral skin infection. We are developing ATR-01 as a novel treatment modality for IV that directly addresses the disease pathophysiology. ATR-01 consists of FLG5-6 functional unit of the human FLG protein with an attached cell penetrating peptide. The goal is to supplement the skin with stable delivery of hFLG via topical application and deeper skin penetration with a cell penetrating peptide.

Preclinical data for ATR-01

Human FLG units (domains 9-10) were evaluated on human skin explants (from plastic surgery) *ex vivo*. The skin barrier of the explants was compromised by repeated tape-stripping such that transepidermal water loss, or TEWL values were significantly increased compared to normal skin. As shown in the example below, daily topical application of a human filaggrin unit with a cell penetrating peptide for 5 days resulted in a dose -dependent (not shown) rapid improvement in TEWL, suggesting improved skin barrier. Thus, topical delivery of a recombinant hFLG unit coupled with a cell penetrating peptide can improve/accelerate the repair of damaged human skin barrier.

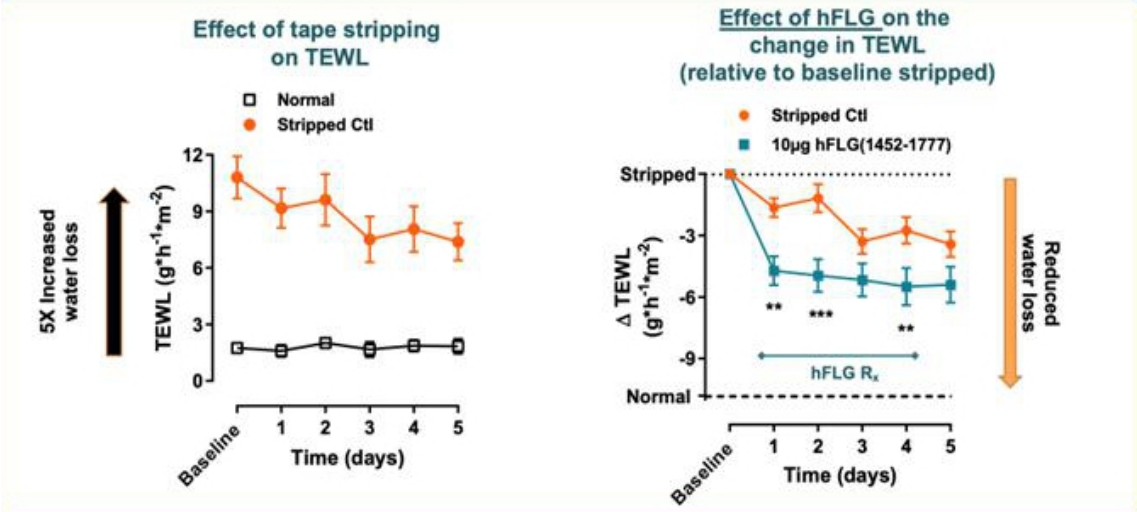
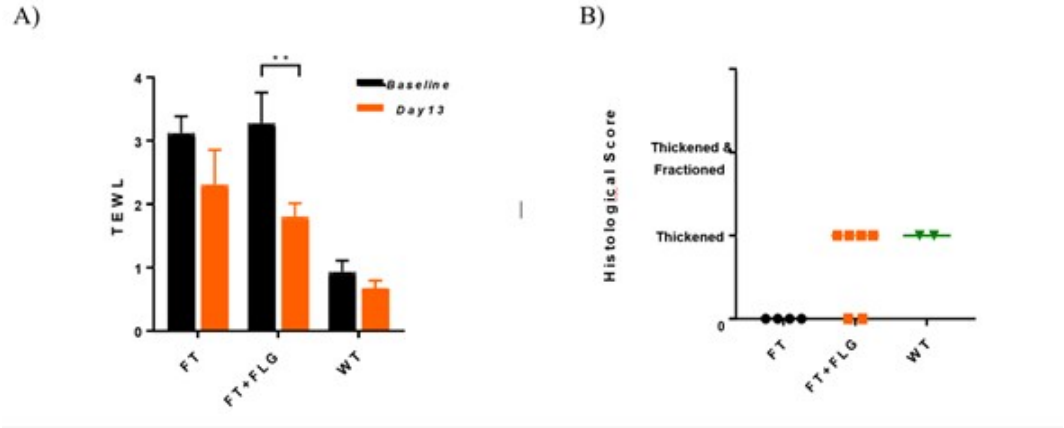


Figure 10: Topical filaggrin application on tape stripped *ex vivo* human skin following human filaggrin application.

Lastly, we have shown that topical filaggrin can improve skin barrier defects in filaggrin-deficient mouse models. Recombinant mouse filaggrin, or mFlg, was applied to the tail of flaky tail, or FT, mice (a mouse model that has a knockout in the *filaggrin* gene) once daily for 2 weeks (50µg total protein/tail sections or 15.2 µg total protein/cm^2). Daily treatment with mFlg significantly improved transepidermal water loss in FT mice when treated (FT+FLG group) compared to vehicle ("baseline" group). The third group on the X axis is a normal, control, wild type group (WT) that does not have the *filaggrin* gene knocked out. Treatment of damaged mouse skin with recombinant mFlg combined to a cell penetrating peptide improved damaged mouse skin barrier (Figure A below). Additionally, histological analysis of the epidermis of the mouse tail sections showed tendency for improved stratum corneum thickness with mFlg treatment (Figure B below). In this graph, the Y axis represents thickening of the stratum corneum, which starts to fractionate or scale after growing past a normal thickness. Treatment with mFlg improved the thickness in four of six of the samples.



Other Potential Product Candidates

Beyond our three lead product candidates, our goal is to develop a broad portfolio of product candidates focused on expanding the application of our platforms for precision dermatology. We have a proprietary platform for discovering and developing therapeutic products for precision dermatology. Our platform is built around a microbial library comprised of approximately 1,500 unique bacterial strains to allow screening for unique therapeutic characteristics and utilizes microbial genetic technology that analyzes, predicts and engineers the proteins, peptides and molecules made by skin microbes. Our ability to genetically engineer intractable microbial species is uniquely leveraged by our exclusive license to the SyMPL technology.

Bayer Joint Development Agreement

In December 2019, we entered into a Joint Development Agreement, or JDA, with Bayer pursuant to which we agreed to the joint development of certain strains selected from our proprietary microbial library. We and Bayer have agreed to cooperate in the identification and in vitro and ex vivo characterization of microbial strains for topical formulations. Bayer paid us a one-time $150,000 payment upon execution of the JDA and has agreed to reimburse us for our development costs. In October 2021, Bayer expanded the option agreement and paid us $375,000 for additional characterization work. We have granted Bayer an option to acquire an exclusive royalty bearing license for up to six strains subject to development activities under the JDA, including an exclusive royalty bearing license to any related patent rights. After screening through hundreds of strains, we and Bayer have selected two particular strains to move forward with in vitro and ex vivo characterization which we intend to develop as potential over-the-counter cosmetic products. We expect to complete the characterization work and deliver the data to Bayer in the third quarter of 2023, at which time Bayer will have 12 months to exercise its option to license the strains and related patents. Upon the conclusion of the characterization studies and our delivery of the data to Bayer, the

JDA will end but for Bayer's option to license the strains and related patents. As of the date of this prospectus, we have not negotiated a commercial license agreement with Bayer and we will not do so until such time, if ever, as Bayer exercises its option to acquire an exclusive royalty bearing license.

In September 2020, Bayer's venture capital group, LEAPS by Bayer, purchased $8 million of our Series B preferred stock.

Sales and Marketing

Given our stage of development, we have not yet established a commercial organization or distribution capabilities. We plan to build focused capabilities in the United States to commercialize our development programs focused on live biotherapeutic products and recombinant proteins for the treatment of skin diseases, where we believe the patient populations and medical specialists for the indications we are targeting are sufficiently concentrated to allow us to effectively promote our products, if approved for commercial sale, with a targeted sales team. In other markets for which commercialization may be less capital efficient for us, we may selectively pursue strategic collaborations with third parties in order to maximize the commercial potential of our product candidates.

Manufacturing

We do not own or operate manufacturing facilities for the production of our current product candidates. We currently rely on third-party contract manufacturers for all of our required raw materials, manufacturing devices and active pharmaceutical ingredients and for our preclinical research and clinical trials. Although we are able to manufacture finished product in our Groton Connecticut facility for our clinical trials, we will rely on third parties for the manufacture of our finished product for commercial sale. We do not have long-term agreements with any of these third parties. We also do not have any current contractual relationship for the manufacture of Phase 3 clinical trials or commercial supplies. We intend to enter into agreements with third-party contract manufacturers and one or more backup manufacturers for future production. We are analyzing the feasibility of building manufacturing capabilities for future development and commercial quantities of any products that we develop. Such products will need to be manufactured in facilities, and by processes, that comply with the requirements of the FDA and the regulatory agencies of other jurisdictions in which we are seeking approval.

Competition

The bio-pharmaceutical industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary drugs. While we believe that our knowledge, experience and scientific resources provide us with competitive advantages, we face potential competition from many different sources, including other biopharmaceutical companies, academic institutions and governmental agencies as well as public and private research institutions. Any drug candidates that we successfully develop and commercialize will compete with existing treatments and new treatments that may become available in the future.

Netherton syndrome

With respect to Netherton syndrome, no drug has been approved by the FDA, specifically for Netherton syndrome, to date. Standard of care includes cleansing of the skin with a gentle/soft non-detergent liquid cleansing oil, preferably with an acidic pH (5). Because Netherton syndrome patient skin is most often dry, scaly and peeling, emollients and moisturizers are also often used. Keratolytics such as salicylic acid, urea or alpha-hydroxy acids are often irritative and not well tolerated by Netherton syndrome patients. The skin of Netherton syndrome patients is prone to frequent bacterial infections. Limited infections are treated with topical antibiotics for a short period of up to 2 weeks. Oral antibiotics may also be used to treat the pathogenic *Staphylococcus aureus* and *Streptococcus* strains that can drive more extreme infections. Bleach baths are also recommended two to three times a week for their antimicrobial effects. Topical corticosteroids are often used to treat the inflammatory and hyperproliferation associated with non-infected Netherton syndrome lesions, but due to their adverse effects, must be limited. These adverse events include aminoaciduria, Cushing syndrome, skin atrophy, adrenal insufficiency, growth retardation, hypertension and weakness. Overuse of topical steroids can even aggravate the defective skin barrier by inducing loss of the stratum corneum. Systemic retinoids have shown varying degrees of efficacy in Netherton syndrome, but also carry bone toxicity and teratogenicity as adverse effects. Topical calcineurin inhibitors have been used to reduce erythema (redness) but patients have shown a tachyphylaxis and reduced efficacy with prolonged treatment. These immunomodulators also carry risks of serious adverse effects including increased risk of infections, swelling, burning sensations and tingling. Phototherapy (narrowband UVB (NB-UVB) and psoralen-UVA (PUVA)) has also been investigated in Netherton syndrome patients but has been limited due to its potential to cause erythema and increases in the risk of skin cancer.

We are also aware that Sixera Pharma initiated a clinical trial in Europe with SXR-1096, a topical small molecule KLK inhibitor in December 2021 for Netherton syndrome. Krystal Biotech, MatriSys, Quoin and BridgeBio have reported they are developing Netherton syndrome programs that are at a pre-clinical stage.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize drugs that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than ATR-12 or any other drug that we may develop. Our competitors also may obtain FDA or other regulatory approval for their drugs more rapidly than we may obtain approval for our drug, which could result in our competitors establishing a strong market position before we are able to enter the market. Many of the companies against which we are competing, or against which we may compete in the future, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved drugs than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and subject registration for clinical trials, as well as in acquiring technologies complementary to, or that may be necessary for, our programs.

EGFRi Associated Rash

To date, no drug has been specifically approved by the FDA for the treatment of EGFRi associated rash. The majority of patients (estimated to be up to 90%) treated continuously with anti-EGFR therapies suffer from dermatological adverse events, especially papulopustular rash, pruritus (itching), xerosis (dryness), and paronychia (nail infections). Papulopustular or acneiform rash is the most common adverse event of EGFRis on the skin. This rash negatively impacts compliance with EGFRi treatment in many patients. Dose modification or discontinuation treatment occurs in severe cases. Because evidence-based controlled trials are still very sparse, treatment of EGFRi skin toxicity primarily relies on physician experience, and recommendations from expert consensus conferences. As a result, there are geographical variations and even inconsistencies in the clinical treatment of EGFRi skin rash. Topical corticosteroids are avoided in Europe with respect to acneiform rash, but are often used in the United States. Furthermore, topical treatment is frequently customized to the individual patient and may change on a case-by-case basis. No topical treatment scheme is universally applicable for all patients.

We are aware of the following Phase 2 programs developing investigational drug candidates for EGFRi associated rash. Lutris Pharma is developing LUT014, a topical B-Raf inhibitor, in the US and Israel. Daewoong Pharmaceutical Co. Ltd. is developing DWP708 in Korea.

Intellectual Property

Overview

We actively seek to protect our proprietary technology, inventions, improvements to inventions and other intellectual property that is commercially important to the development of our business by a variety of means, such as seeking, maintaining and defending patent rights, whether developed internally or licensed from third parties. We also may rely on trade secrets and know-how relating to our proprietary technology platform, on continuing technological innovation and on future in-licensing opportunities to develop, strengthen and maintain the strength of our position in the field of gene therapy that may be important for the development of our business. Additional regulatory protection may also be afforded through data exclusivity, market exclusivity and patent-term extensions where available.

As of the date of this prospectus, we own or exclusively license two issued U.S. patents, four pending U.S. patent applications, one pending PCT application and 38 other foreign national-stage applications, including three European regional-phase applications that are important to the development of our business.

Our policy is to file patent applications to protect proprietary technology, inventions and improvements to inventions and other intellectual property that may be commercially important to the development of our business. We also intend to seek additional patent protection or rely upon know-how or trade secret rights to protect other technologies that may be used to manufacture and develop our live biotherapeutic products. As described below, we are a party to exclusive license agreements that grant us rights to use specific technologies in our live biotherapeutic products and in the manufacturing and development of our products."

Our Patent Portfolio

Our patent portfolio has broad coverage for therapeutic bacteria pharmaceutical compositions containing these therapeutic bacteria for treating abnormal skin conditions and methods of making and using these recombinant bacteria. In our broadest filing, we have secured a US patent that protects pharmaceutical compositions for treating abnormal skin conditions using a bacterial strain expressing a therapeutically effective amount of a recombinant polypeptide. This patent expires in May 2035. Specifically, this issued patent covers a pharmaceutical composition containing one or more of the following bacterial strains: Bifidobacterium, Brevibacterium, Propionibacterium, Lactococcus, Streptococcus, Staphylococcus, Lactobacillus, Enterococcus, Pediococcus, Leuconostoc, or Oenococcus, wherein the bacterial strain has been engineered to produce a therapeutical polypeptide for treating the abnormal skin conditions. We believe that this patent gives us broad protection for using recombinant bacteria to treat skin diseases and disorders. through its expiration in May 2035.

Patent applications directed to our most advanced programs are summarized below.

ATR-12

Our ATR-12 product candidate is subject to two issued US patents, four pending US patent applications, and 26 pending foreign applications. These patents and patent applications represent four families of claims covering the pharmaceutical composition of *S. epidermidis* expressing a recombinant therapeutic polypeptide, the auxotrophic strain of *S. epidermidis*, and the recombinant *S. epidermidis* strain expressing a therapeutic LEKTI protein. One of the issued US patents covers a recombinant bacteria containing a therapeutic polypeptide for treating abnormal skin conditions and expires in 2035. The second issued US patent covers an auxotrophic *S. epidermidis* that will expire in 2039. If additional patents were to grant from the pending patent applications, they would expire between 2035 and 2039.

ATR-04

Our ATR-12 product candidate is subject to one issued US patent, two pending US patent applications, and 17 pending foreign applications. These patents and patent applications represent two families of claims directed to auxotrophic strains of bacteria and their therapeutic use for treating disease. We have one issued US patent that covers ATR-04. If additional patents were to grant, they would also expire in 2039. Overall, these two families contain 1 issued US patent, 2 pending US applications, and 17 pending foreign applications.

Patent Term and Term Extension

Individual patents have terms for varying periods depending on the date of filing of the patent application or the date of patent issuance and the legal term of patents in the countries in which they are obtained. Generally, utility patents issued for applications filed in the United States are granted a term of 20 years from the earliest effective filing date of a non-provisional patent application. In addition, in certain instances, the term of a U.S. patent can be extended to recapture a portion of the United States Patent and Trademark Office, or the USPTO, delay in issuing the patent as well as a portion of the term effectively lost as a result of the FDA regulatory review period. However, as to the FDA component, the restoration period cannot be longer than five years and the restoration period cannot extend the patent term beyond 14 years from FDA approval. In addition, only one patent applicable to an approved drug is eligible for the extension, and only those claims covering the approved drug, a method for using it, or a method of manufacturing may be extended. The duration of foreign patents varies in accordance with provisions of applicable local law, but typically is also 20 years from the earliest effective filing date. All taxes, annuities or maintenance fees for a patent, as required by the USPTO and various foreign jurisdictions, must be timely paid in order for the patent to remain in force during this period of time.

The actual protection afforded by a patent may vary on a product-by-product basis, from country to country, and can depend upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions and the availability of legal remedies in a particular country and the validity and enforceability of the patent.

Our patents and patent applications may be subject to procedural or legal challenges by others. We may be unable to obtain, maintain and protect the intellectual property rights necessary to conduct our business, and we may be subject to claims that we infringe or otherwise violate the intellectual property rights of others, which could materially harm our business. For more information, see the section titled "*Risk Factors—Risks Related to Our Intellectual Property*."

Trade Secrets and Know-How

We may also rely on trade secrets, know-how, continuing technological innovation and confidential information to develop and maintain our proprietary position and protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection, including our proprietary processes for manufacturing our live biotherapeutic products. We seek to protect our proprietary technology and processes, in part, by confidentiality agreements and invention assignment agreements with our employees, consultants, scientific advisors, contractors and others who may have access to proprietary information, under which they are bound to assign to us inventions made during the term of their employment or term of service. These agreements may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our contractors, commercial partners, collaborators, employees, and consultants use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions. For more information, see the section titled "*Risk Factors—Risks Related to Our Intellectual Property*."

We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems.

Exclusive License Agreement with Fred Hutchison Cancer Center

In January 2022, we entered into an Exclusive License Agreement with the Fred Hutchinson Cancer Center, or Fred Hutch. Pursuant to our agreement with Fred Hutch, we obtained an exclusive worldwide license under certain patents related to SyMPL technologies developed and owned by Fred Hutch to develop, make, manufacture, have manufactured, distribute, have distributed, use, research, improve, import, offer to sell and sell and otherwise commercialize products that are covered by such patents. Such exclusive license is subject to certain rights retained by Fred Hutch and also the U.S. government. The patent rights licensed to us by Fred Hutch consist of two families of patent applications directed to methods of bypassing restriction modification systems in order to more easily introduce xenogeneic DNA. These patents applications and any patents that issue from these applications will allow us to produce more modified microbes for the treatment of disease. Our current product candidates do not incorporate the SyMPL technology platform, but we expect that some or all of our future product candidates will do so. If issued, these two families will expire in 2037 and 2040, respectively.

In consideration of the license granted to us under the Fred Hutch license agreement, we paid Fred Hutch a nominal upfront payment. In addition, we are required to pay Fred Hutch certain development and commercial milestone payments and running single digit royalty on net sales of the licensed products. The Fred Hutch agreement also requires us to reimburse Fred Hutch for the cost of the prosecution and maintenance of the licensed patents.

Pursuant to the Fred Hutch license agreement, we are required to use commercially reasonable efforts to bring a licensed product to market through a vigorous and diligent program for exploitation of the licensed patent rights. The term of the Fred Hutch license agreement will continue until the later of (i) the expiration of the licensed patents or (ii) ten years from the first sale of a licensed product. We may terminate the Fred Hutch license agreement at will at any time upon prior written notice to Fred Hutch. Fred Hutch has the right to terminate the Fred Hutch license agreement if we materially breach the agreement and fail to cure such breach within a specified cure period or if we become bankrupt or insolvent. For more information related to the intellectual property acquired pursuant to the Fred Hutch license agreement, see the section titled "*Business-Licenses and Intellectual Property Rights*."

We also hold registered trademarks for our corporate name and design in the U.S. and in seven foreign countries.

Government Regulations

Pharmaceutical companies are subject to extensive regulation by foreign, federal, state and local agencies, such as the U.S. FDA, and various similar agencies in most countries worldwide. The research, development, testing, manufacture, distribution, packaging, labeling, storage, recordkeeping, marketing and sale of pharmaceutical products are subject to government regulation in the U.S. and various foreign countries. Additionally, in the U.S., we must follow rules and regulations established by the FDA requiring the presentation of data indicating that our product candidates are safe and effective and are manufactured in accordance with cGMP regulations. If we do not comply with applicable requirements, we may be fined, the government may refuse to approve our marketing applications or allow us to manufacture or market our product candidates, and we may be criminally prosecuted. We, our manufacturers and clinical research organizations may also be subject to regulations under other foreign, federal, state and local laws, including, but not limited to, the U.S. Occupational Safety and Health Act, the Resource Conservation and Recovery Act, the Clean Air Act and import, export and customs regulations as well as the laws and regulations of other countries. The U.S. government has increased its enforcement activity regarding illegal marketing practices domestically and internationally. As a result, pharmaceutical companies must ensure their compliance with the Foreign Corrupt Practices Act and federal healthcare fraud and abuse laws, including the False Claims Act.

These regulatory requirements impact our operations and differ from one country to another, so that securing the applicable regulatory approvals of one country does not imply the approval of another country. The approval procedures involve high costs and are manpower intensive, usually extend over many years and require highly skilled and professional resources.

FDA Market Approval Process

In the U.S., our product candidates are regulated by the FDA as biologics under the Federal Food, Drug, and Cosmetic Act, or FDCA, the Public Health Service Act, or PHSA, and regulations promulgated by the FDA. The failure to comply with the applicable requirements at any time during the product development process, including preclinical testing, clinical testing, the approval process or post-approval process, may subject an applicant to delays in the conduct of clinical trials, regulatory review and approval, and/or administrative or judicial sanctions. These sanctions may include, but are not limited to, the FDA's refusal to allow an applicant to proceed with clinical testing, refusal to approve pending applications, license suspension or revocation, withdrawal of an approval, warning letters, adverse publicity, customer notification, product recalls, product seizures, refusal to grant export or import approval, total or partial suspension of production or distribution, consent decrees, injunctions, fines, and civil or criminal investigations and penalties brought by the FDA or the U.S. Department of Justice, or other governmental entities.

The steps usually required to be taken before a new biologic may be marketed in the U.S. generally include:

- completion of preclinical laboratory tests and animal studies performed in accordance with the FDA's current Good Laboratory Practices regulation;
- submission to the FDA of an IND, which must become effective before clinical trials may begin and must be updated annually or when significant changes are made;
- approval by an independent Institutional Review Board, or IRB, or ethics committee at each treatment site before the trial is commenced;
- performance of adequate and well controlled human clinical trials to establish the safety, purity and potency of the proposed biologic product candidate for its proposed indication for use;
- submission of data supporting safety and efficacy as well as detailed information on the manufacture and composition of the product in clinical development and proposed labeling;

- preparation of and submission to the FDA of a BLA after completion of all pivotal clinical trials;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with cGMP standards and to assure that the facilities, methods and controls are adequate to preserve the biological product's continued safety, purity and potency, and of selected clinical investigation sites to assess compliance with Good Clinical Practices, or GCP;
- satisfactory completion of any FDA audits of the non-clinical and clinical trial sites to assure compliance with CGP requirements and the integrity of clinical data in support of the BLA;
- payment of user fees and securing FDA approval of the BLA for the proposed indication for use;
- FDA review and approval of the BLA to permit commercial marketing of the product for particular indications for use in the United States; and
- Compliance with any post-approval requirements, including REMS and any post-approval studies required by the FDA.

Preclinical Studies and Investigational New Drug Application

Preclinical tests include laboratory evaluations of product chemistry, formulation and stability, as well as animal studies to evaluate the potential for efficacy and toxicity in animals. The conduct of the preclinical tests and formulation of the compounds for testing must comply with federal regulations and requirements. The results of the preclinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND application. Some preclinical tests may continue even after submission of the IND application. The IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions about the product or conduct of the proposed clinical trial, including concerns that human research volunteers will be exposed to unreasonable health risks. In that case, the IND sponsor and the FDA must resolve any outstanding FDA concerns before the clinical trial can begin.

As a result, submission of the IND may result in the FDA not allowing the clinical trials to commence or allowing the clinical trial to commence on the terms originally specified by the sponsor in the IND. If the FDA raises concerns or questions either during this initial 30-day period, or at any time during the IND process, it may choose to impose a partial or complete clinical hold. This order issued by the FDA would delay either a proposed clinical trial or cause delay in initiation of a phase of an ongoing clinical trial, until all outstanding concerns have been adequately addressed and the FDA has notified the company that investigations may proceed. This could cause significant delays or difficulties in completing planned clinical trials in a timely manner.

Clinical Trials

Clinical trials involve the administration of the investigational product candidate to healthy volunteers or patients with the disease to be treated under the supervision of a qualified principal investigator in accordance with good clinical practice, or GCP, requirements. Clinical studies are conducted under protocols detailing, among other things, the objectives of the study, what types of patients may enter the study, schedules of tests and procedures, drugs, dosages, and length of study, as well as the parameters to be used in monitoring safety, and the efficacy criteria to be evaluated. A protocol for each clinical study and any subsequent protocol amendments must be submitted to the FDA as part of the IND process.

A sponsor who wishes to conduct a clinical trial outside the U.S. may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a clinical trial outside the U.S. is not conducted under an IND, the sponsor may submit data from the clinical trial to the FDA in support of a BLA so long as the clinical trial is conducted consistent with the spirit of GCP and in compliance with an international guideline for the ethical conduct of clinical research known as the Declaration of Helsinki and/or the laws and regulations of the country or countries in which the clinical trial is performed, whichever provides the greater protection to the participants in the clinical trial.

An IRB, either centrally or individually, must also review each clinical trial at each institution at which the clinical trial will be conducted. The IRB will consider, among other things, clinical trial design, patient informed consent, ethical factors, the safety of human subjects, the possible liability of the institution, and, where appropriate, the protection of privacy of the human subjects. An IRB must operate in compliance with the FDA regulations. The FDA, IRB, or the clinical trial sponsor, or the principal investigator may suspend or discontinue a clinical trial at any time for various reasons, including a finding that the clinical trial is not being conducted in accordance with FDA requirements or the subjects or patients are being exposed to an unacceptable health risk. Clinical testing also must satisfy extensive GCP rules and the requirements for informed consent. Additionally, some clinical studies are overseen by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board or committee. This group recommends whether or not a trial may move forward at designated check points based on access to certain data from the study. The clinical study sponsor may also suspend or terminate a clinical trial based on evolving business objectives and/or competitive climate.

Clinical trials are usually conducted in three sequential phases, but the phases may overlap or be combined. Annual progress detailing the results of the clinical trial phases must be submitted to the FDA.

- *Phase 1* clinical trials are normally conducted in small groups of healthy volunteers to assess safety and tolerability of various dosing regimens and pharmacokinetics. For some products for orphan, severe or life-threatening diseases, especially if the product may be too toxic to administer to healthy humans, the initial clinical trials may be conducted in individuals having a specific disease for which use the tested product is indicated. These trials in patients are often referred to as Phase 1b trials. If they include a design to establish a particular dose, they are commonly referred to as Phase 1b/2a clinical trials. Nevertheless, additional Phase 2 (sometimes called Phase 2b) clinical trials are often necessary to refine the final dose chosen to take into a pivotal Phase 3 clinical trial.

- *Phase 2* clinical trials are generally conducted in a limited patient population to identify possible adverse effects and safety risks, evaluate the efficacy of the product candidate for specific targeted indications and determine does tolerance and optimal dosage. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more costly Phase 3 clinical trials.

- *Phase 3* clinical trials proceed if the Phase 2 clinical trials demonstrate that a dose range of the product candidate is potentially effective and has an acceptable safety profile. Phase 3 clinical trials are undertaken to further evaluate, in a larger number of patients, dosage, provide substantial evidence of clinical efficacy and further test for safety in an expanded and diverse patient population at multiple, geographically dispersed clinical trial sites. A well-controlled, statistically robust Phase 3 trial may be designed to deliver the data that regulatory authorities will use to decide whether or not to approve, and, if approved, how to appropriately label a drug: such Phase 3 studies are referred to as “pivotal.”

The FDA may order the temporary or permanent discontinuation of a clinical study at any time or impose other sanctions if it believes that the clinical study is not being conducted in accordance with FDA requirements or that the participants are being exposed to an unacceptable health risk. In some cases, the FDA may approve a BLA for a product candidate but require the sponsor to conduct additional clinical trials to further assess the drug’s safety and effectiveness after BLA approval. Such post-approval trials are typically referred to as Phase 4 clinical trials. These studies are used to gain additional experience data from the treatment of patients in the intended therapeutic indication and to document a clinical benefit in the case of drugs or biologics approved under accelerated approval regulations. If the FDA approves a product while a company has ongoing clinical trials that were not necessary for approval, a company may be able to use the data from these clinical trials to meet all or part of any Phase 4 clinical trial requirement or to request a change in the product labeling. Failure to exhibit due diligence with regard to conducting Phase 4 clinical trials could result in withdrawal of approval for products.

Compliance with cGMP Requirements

As a product candidate moves through the clinical testing phases, manufacturing processes are further defined, refined, controlled and validated. The level of control and validation required by the FDA increases as clinical studies progress. The FDA typically will not approve a BLA application unless it determines that the manufacturing processes and facilities are in full compliance with cGMP requirements and able to assure consistent production of the product within required specifications. The PHSA emphasizes the importance of manufacturing control for products like biologics whose attributes cannot be precisely defined.

We and the third-party manufacturers on which we rely for the manufacture of our product candidates and their respective components (including the API) are subject to requirements that drugs be manufactured, packaged and labeled in conformity with cGMPs. To comply with cGMP requirements, manufacturers must continue to spend time, money and effort to meet requirements relating to personnel, facilities, equipment, production and process, labeling and packaging, quality control, recordkeeping and other requirements.

Manufacturers and others involved in the manufacture and distribution of products must also register their establishments with the FDA and certain state regulatory bodies. Both U.S. and non-U.S. manufacturing establishments must register and provide additional information to the FDA upon their initial participation in the manufacturing process. Any product manufactured by or imported from a facility that has not registered, whether U.S. or non-U.S., is deemed misbranded under the FDCA. Establishments may be subject to periodic unannounced inspections by government authorities to ensure compliance with cGMPs and other laws. Inspections must follow a "risk-based schedule" that may result in certain establishments being inspected more frequently. Manufacturers may also have to provide, on request, electronic or physical records regarding their establishments. Delaying, denying, limiting, or refusing inspection by the FDA may lead to a product being deemed to be adulterated.

BLA Submission and Review

Assuming completion of all required testing in accordance with all applicable regulatory requirements, detailed information on the product candidate is submitted to the FDA in the form of a BLA, requesting approval to market the product for one or more indications, together with payment of a user fee, unless waived. A BLA includes all relevant data available from pertinent nonclinical and clinical studies, including negative or ambiguous results as well as positive findings, together with detailed information on the chemistry, manufacture, controls and proposed labeling, among other things. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the product candidate for its intended use to the satisfaction of the FDA. The FDA also conducts a pre-approval inspection of the manufacturer and laboratory prior to approval of the BLA.

If a BLA submission is accepted for filing, the FDA begins an in-depth review of the BLA. Under the Prescription Drug User Fee Act, or PDUFA, the FDA's goal is to complete its initial review and respond to the applicant within ten months of submission, unless the application relates to an unmet medical need, or is for a serious or life-threatening indication, in which case the goal may be within six months of BLA submission. However, PDUFA goal dates are not legal mandates and the FDA response often occurs several months beyond the original PDUFA goal date. Further, the review process and the target response date under PDUFA may be extended if the FDA requests or the BLA sponsor otherwise provides additional information or clarification regarding information already provided in the BLA. The BLA review process can, accordingly, be very lengthy. During its review of a BLA, the FDA may refer the application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it typically follows such recommendations. Data from clinical studies are not always conclusive and the FDA and/or any advisory committee it appoints may interpret data differently than the applicant.

After the FDA evaluates the BLA and inspects manufacturing facilities where the drug product and/or its API will be produced and tested, it will either approve commercial marketing of the drug product with prescribing information for specific indications or issue a complete response letter indicating that the application is not ready for approval and stating the conditions that must be met in order to secure approval of the BLA. If the complete response letter requires additional data and the applicant subsequently submits that data, the FDA nevertheless may ultimately decide that the BLA does not satisfy its criteria for approval. The FDA could also approve the BLA with a Risk Evaluation and Mitigation Strategies, or REMS, plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling, development of adequate controls and specifications, or a commitment to conduct post-marketing testing. Such post-marketing testing may include Phase 4 clinical trials and surveillance to further assess and monitor the product's safety and efficacy after approval. Regulatory approval of products for serious or life-threatening indications may require that participants in clinical studies be followed for long periods to determine the overall survival benefit of the drug.

If the FDA approves one of our product candidates, we will be required to comply with a number of post-approval regulatory requirements. We would be required to report, among other things, certain adverse reactions and production problems to the FDA, provide updated safety and efficacy information and comply with requirements concerning advertising and promotional labeling for any of our product candidates. Also, quality control and manufacturing procedures must continue to conform to cGMPs after approval, and the FDA periodically inspects manufacturing facilities to assess compliance with cGMPs, which imposes extensive procedural, substantive and record keeping requirements. If we seek to make certain changes to an approved product, such as certain manufacturing changes, we may need FDA review and approval before the change can be implemented.

While physicians may use products for indications that have not been approved by the FDA, we may not label or promote the product for an indication that has not been approved. Securing FDA approval for new indications is similar to the process for approval of the original indication and requires, among other things, submitting data from adequate and well-controlled studies that demonstrate the product's safety and efficacy in the new indication. Even if such studies are conducted, the FDA may not approve any change in a timely fashion, or at all.

The FDA may also require post-marketing testing, or Phase 4 testing, as well as risk minimization action plans and surveillance to monitor the effects of an approved product or place conditions or an approval that could otherwise restrict the distribution or use of the product.

Fast Track, Breakthrough Therapy and Priority Review Designations

The FDA is authorized to designate certain products for expedited review if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition, or in the event of an emergency. These programs are fast track designation, breakthrough therapy designation and priority review designation.

Specifically, the FDA may designate a product for fast track review if it is intended, whether alone or in combination with one or more other products, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. For fast track products, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a fast track product's application before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a fast track product may be effective. The sponsor must also provide, and the FDA must approve, a schedule for the submission of the remaining information and the sponsor must pay applicable user fees. However, the FDA's time period goal for reviewing a fast track application does not begin until the last section of the application is submitted. In addition, the fast track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Second, in 2012, Congress enacted the Food and Drug Administration Safety and Innovation Act, or FDASIA. This law established a new regulatory scheme allowing for expedited review of products designated as "breakthrough therapies." A product may be designated as a breakthrough therapy if it is intended, either alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The FDA may take certain actions with respect to breakthrough therapies, including holding meetings with the sponsor throughout the development process; providing timely advice to the product sponsor regarding development and approval; involving more senior staff in the review process; assigning a cross-disciplinary project lead for the review team; and taking other steps to design the clinical trials in an efficient manner.

Third, the FDA may designate a product for priority review if it is a product that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA determines, on a case-by-case basis, whether the proposed product represents a significant improvement when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting product reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, and evidence of safety and effectiveness in a new subpopulation. A priority designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on a marketing application from ten months to six months.

Fourth, the Secretary of Health and Human Services may authorize unapproved drugs and biologics to be marketed in the event an actual or potential emergency has been designated by the U.S. government. After an emergency has been designated, the FDA may issue an Emergency Use Authorization, or EUA, for the use of a specific product based on criteria established by the FDCA. An EUA is product specific and is subject to specific conditions and restrictions. Once the emergency underlying the EUA ends, then the EUA terminates.

Pediatric Rare Disease Designation and Priority Review Vouchers

Under the FDCA, as amended, the FDA incentivizes the development of drugs and biologics that meet the definition of a "rare pediatric disease," defined to mean a serious or life-threatening disease in which the serious of life-threatening manifestations primarily affect individuals aged from birth to 18 years and the disease affects fewer than 200,000 individuals in the United States or affects 200,000 or more in the United States and for which there is no reasonable expectation that the cost of developing and making in the United States a drug or biologic for such disease or condition will be received from sales in the United States of such drug or biologic. The sponsor of a product candidate for a rare pediatric disease may be eligible for a voucher that can be used to obtain a priority review for a subsequent human drug or biologic application after the date of approval of the rare pediatric disease drug product, referred to as a priority review voucher, or PRV. A sponsor may request rare pediatric disease designation from the FDA prior to the submission of its NDA or BLA. A rare pediatric disease designation does not guarantee that a sponsor will receive a PRV upon approval of its NDA or BLA. Moreover, a sponsor who chooses not to submit a rare pediatric disease designation request may nonetheless receive a PRV upon approval of their marketing application if they request such a voucher in their original. marketing application and meet all of the eligibility criteria. If a PRV is received, it may be sold or transferred an unlimited number of times. Congress has extended the PRV program until September 30, 2024, with the potential for PRVs to be granted until 2026.

Post-Approval Regulation

Once regulatory approval for marketing of a product or new indication for an existing product is obtained, the sponsor will be required to comply with post-approval regulatory requirements, including any post-approval requirements that the FDA may have imposed as a condition of approval. The sponsor will be required to report certain adverse reactions and production problems to the FDA, provide updated safety and efficacy information and comply with requirements concerning advertising and promotional labeling requirements. Manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including cGMP regulations, which impose certain procedural and documentation requirements upon drug manufacturers. Accordingly, the sponsor and its third-party manufacturers must continue to expend time, money and effort in the areas of production and quality control to maintain compliance with cGMP regulations and other regulatory requirements.

A product may also be subject to official lot release, meaning that the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release, the manufacturer must submit samples of each lot, together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot, to the FDA. The FDA may in addition perform certain confirmatory tests on lots of some products before releasing the lots for distribution. Finally, the FDA will conduct laboratory research related to the safety, purity, potency, and effectiveness of pharmaceutical products.

After an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending BLAs or supplements to approved BLAs, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs and biologics may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug intended to treat a rare disease or condition affecting fewer than 200,000 individuals in the United States, or in other limited cases. Orphan drug designation (ODD) provides for seven years of market exclusivity, independent of patent protection, to the company with ODD that brings a particular product to market. In addition, companies developing orphan drugs are eligible for certain incentives, including tax credits for qualified clinical testing. In addition, a BLA for a product that has received orphan drug designation is not subject to a prescription drug user fee unless the application includes an indication other than the rare disease or condition for which the drug was designated.

To gain exclusivity, if a product that has orphan drug designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to the orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same active moiety for the same indication for seven years, except in limited circumstances, such as another drug's showing of clinical superiority over the drug with orphan exclusivity. In addition, doctors may prescribe products for off-label uses and undermine our exclusivity. Orphan drug exclusivity could block the approval of one of our product candidates for seven years if a competitor obtains approval for the same active moiety for the same indication before we do, unless we are able to demonstrate that our product is clinically superior.

A sponsor may request orphan drug designation of a previously unapproved product or new orphan indication for an already marketed product. In addition, a sponsor of a product that is otherwise the same product as an already approved orphan drug may seek and obtain orphan drug designation for the subsequent product for the same rare disease or condition if it can present a plausible hypothesis that its product may be clinically superior to the first, approved product. More than one sponsor may receive orphan drug designation for the same product for the same rare disease or condition, but each sponsor seeking orphan drug designation must file a complete request for designation, and only the first sponsor that obtains approval for that drug for the orphan indication will obtain market exclusivity, effectively preventing the FDA from approving products under development by competitors for the same drug and same indication, unless the competitor is able to demonstrate that the product under development is clinically superior to the approved product or the approved product is not available in sufficient quantities. To permit the FDA to end another manufacturer's orphan exclusivity period, the FDA must determine that the manufacturer has demonstrated clinical superiority by showing the later drug is safer, more effective, or otherwise makes a major contribution to patient care.

The period of exclusivity begins on the date that the marketing application is approved by the FDA and applies only to the indication for which the product has been designated. The FDA may approve a second application for the same product for a different use or a subsequent application for a different drug for the same indication. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

We may plan to pursue orphan drug designation and exclusivity for some of our product candidates in the United States, European Union, and other geographies of interest for specific products. We cannot guarantee that we will obtain orphan drug designation for any products in any jurisdiction. Even if we are able to obtain orphan drug designation for a product, we cannot be sure that such product will be approved, that we will be able to obtain orphan drug exclusivity upon approval, if ever, or that we will be able to maintain any exclusivity that is granted.

Biosimilars and Exclusivity

The Patient Protection and Affordable Care Act, or ACA, which was signed into law on March 23, 2010, included a subtitle called the Biologics Price Competition and Innovation Act of 2009 or BPCIA. The BPCIA established a regulatory scheme authorizing the FDA to approve biosimilars and interchangeable biosimilars. The FDA has issued several draft guidance documents outlining an approach to review and approval of biosimilars. Complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation, which are still being worked out by the FDA.

Under the BPCIA, a manufacturer may submit an application for licensure of a biologic product that is "biosimilar to" or "interchangeable with" a previously approved biological product or "reference product." In order for the FDA to approve a biosimilar product, it must find that there are no clinically meaningful differences between the reference product and proposed biosimilar product in terms of safety, purity, and potency. For the FDA to approve a biosimilar product as interchangeable with a reference product, the agency must find that the biosimilar product can be expected to produce the same clinical results as the reference product, and (for products administered multiple times) that the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until 4 years following the date of approval of the reference product. The FDA may not approve a biosimilar product until 12 years from the date on which the reference product was approved. Even if a product is considered to be a reference product eligible for exclusivity, another company could market a competing version of that product if the FDA approves a full BLA for such product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products.

Regulation Outside the United States

In order to market any product outside of the United States, a company must also comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy that govern, among other things, clinical trials, marketing authorization, commercial sales and distribution of drug products. Whether or not it obtains FDA approval for a product, the company would need to obtain the necessary approvals by the comparable non-U.S. regulatory authorities before it can commence clinical trials or marketing of the product in those countries or jurisdictions. The approval process ultimately varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

Regulation and Marketing Authorization in the European Union

The European Medicines Agency, or EMA, is the scientific agency of the European Union, or EU, that coordinates the evaluation and monitoring of new and approved medicinal products such as drugs and biologics. It is responsible for the scientific evaluation of applications for EU marketing authorizations, as well as the development of technical guidance and the provision of scientific advice to sponsors.

The process regarding approval of medicinal products in the EU follows roughly the same lines as in the United States and likewise generally involves satisfactorily completing each of the following:

- preclinical laboratory tests, animal studies and formulation studies all performed in accordance with the applicable EU Good Laboratory Practice regulations;
- submission to the relevant regulatory agencies in EU member states, or national authorities, of a clinical trial application, or CTA, for each clinical trial, which must be approved before human clinical trials may begin;
- performance of adequate and well-controlled clinical trials to establish the safety and efficacy of the product for each proposed indication;
- submission to the relevant national authorities of a Marketing Authorisation Application, or MAA, which includes the data supporting safety and efficacy as well as detailed information on the manufacture and composition of the product in clinical development and proposed labeling;
- satisfactory completion of an inspection by the relevant national authorities of the manufacturing facility or facilities, including those of third parties, at which the product is produced to assess compliance with cGMP;
- potential audits of the non-clinical and clinical trial sites that generated the data in support of the MAA; and
- review and approval by the relevant national authority of the MAA before any commercial marketing, sale or shipment of the product.

Preclinical Studies

Preclinical tests include laboratory evaluations of product chemistry, formulation and stability, as well as studies to evaluate the potential efficacy and toxicity in animals. The conduct of the preclinical tests and formulation of the compounds for testing must comply with the relevant EU regulations and requirements. The results of the preclinical tests, together with relevant manufacturing information and analytical data, are submitted as part of the CTA when seeking approval to start a clinical trial, and with the MAA when seeking marketing authorization.

Clinical Trial Approval

Requirements for the conduct of clinical trials in the EU including cGCP, are implemented in the currently Clinical Trials Directive 2001/20/EC and the GCP Directive 2005/28/EC. Pursuant to Directive 2001/20/EC and Directive 2005/28/EC, as amended, a system for the approval of clinical trials in the EU has been implemented through national legislation of the EU member states. Under this system, approval must be obtained from the competent national authority in which a trial is planned to be conducted, or in multiple member states if the clinical trial is to be conducted in a number of member states. To this end, a CTA is submitted, which must be supported by an investigational medicinal product dossier, or IMPD, and further supporting information prescribed by Directive 2001/20/EC and Directive 2005/28/EC and other applicable guidance documents. Furthermore, a clinical trial may only be started after a competent ethics committee has issued a favorable opinion on the clinical trial application in that country.

On January 31, 2022, the Clinical Trials Regulation (EU) No. 536/2014 replaced the current Clinical Trials Directive 2001/20/EC. To ensure that the rules for clinical trials are identical throughout the EU, the Clinical Trials Regulation (EU) No. 536/2014 was passed as a regulation which is directly applicable in all EU member states. The Clinical Trials Directive 2001/20/EC will, however, still apply three years from the date of entry into application of the Clinical Trials Regulation to (i) clinical trials applications submitted before the entry into application and (ii) clinical trials applications submitted within one year after the entry into application if the sponsor opts for the old system.

Regulation (EU) No 536/2014 aims to simplify and streamline the approval of clinical trial in the EU. The main characteristics of the regulation include:

- A streamlined application procedure via a single entry point, known as the Clinical Trials Information System;
- A single set of documents to be prepared and submitted for the application as well as simplified reporting procedures which will spare sponsors from submitting broadly identical information separately to various and different national authorities;
- A harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts;
- Strictly defined deadlines for the assessment of clinical trial application; and
- The involvement of the ethics committees in the assessment procedure in accordance with the national law of the member state concerned but within the overall timelines defined by the Regulation (EU) No 536/2014.

Marketing Authorization

Authorization to market a product in the member states of the EU proceeds under one of four procedures: a centralized procedure, a mutual recognition procedure, a decentralized procedure or a national procedure.

Centralized Procedure

The centralized procedure enables applicants to obtain a marketing authorization that is valid in all EU member states based on a single application. Certain medicinal products, including products developed by means of biotechnological processes must undergo the centralized authorization procedure for marketing authorization, which, if granted by the European Commission, based on the opinion of the EMA, is automatically valid in all EU member states. Sponsors may elect to file an MAA through the centralized procedures for other classes of products.

The centralized procedure is mandatory for certain types of products such as, medicines derived from biotechnology processes such as genetic engineering, advanced-therapy medicines such as gene-therapy or tissue engineered medicine, orphan medicines, and medicinal products containing a new active substance indicated for the treatment of HIV, AIDS, cancer, diabetes, neurodegenerative disorders, autoimmune and other immune dysfunctions, and viral diseases.

The centralized authorization procedure is optional for other medicinal products if they contain a new active substance, if the applicant shows that the medicinal product concerned constitutes a significant therapeutic, scientific or technical innovation, or that the granting of authorization is in the public interest of the EU.

Administration Procedure

Under the centralized procedure, the EMA's Committee for Human Medicinal Products, or CHMP serves as the scientific committee that renders opinions about the safety, efficacy and quality of medicinal products for human use on behalf of the EMA. The CHMP is composed of experts nominated by each member state's national authority for medicinal products, with one of them appointed to act as Rapporteur for the co-ordination of the evaluation with the possible assistance of a further member of the Committee acting as a Co-Rapporteur. After approval, the Rapporteur(s) continue to monitor the product throughout its life cycle. The CHMP has 210 active days, to adopt an opinion as to whether a marketing authorization should be granted. The process usually takes longer in case additional information is requested, which triggers clock-stops in the procedural timelines. The process is complex and involves extensive consultation with the regulatory authorities of member states and a number of experts. When an application is submitted for a marketing authorization in respect of a drug which is of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation, the applicant may, pursuant to Article 14(9) Regulation (EC) No 726/2004, request an accelerated assessment procedure. If the CHMP accepts such request, the time-limit of 210 days will be reduced to 150 days but it is possible that the CHMP can revert to the standard time-limit for the centralized procedure if it considers that it is no longer appropriate to conduct an accelerated assessment. Once the procedure is completed, a European Public Assessment Report, or EPAR, is produced. If the opinion is negative, information is given as to the grounds on which this conclusion was reached. After the adoption of the CHMP opinion, a decision on the MAA must be adopted by the European Commission, after consulting the EU member states, which in total can take more than 60 days. After a drug has been authorized and launched, it is a condition of maintaining the marketing authorization that all aspects relating to its quality, safety and efficacy must be kept under review.

Conditional Approval

In specific circumstances, EU legislation (Article 14(7) Regulation (EC) No. 726/2004 and Regulation (EC) No. 507/2006 on Conditional Marketing Authorisations for Medicinal Products for Human Use) enables applicants to obtain a conditional marketing authorization prior to obtaining the comprehensive clinical data required for an application for a full marketing authorization. Such conditional approvals may be granted for products (including medicines designated as orphan medicinal products), if (1) the risk-benefit balance of the product is positive, (2) it is likely that the applicant will be in a position to provide the required comprehensive clinical trial data, (3) the product fulfills unmet medical needs, and (4) the benefit to public health of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent in the fact that additional data are still required. A conditional marketing authorisation may contain specific obligations to be fulfilled by the marketing authorization holder, including obligations with respect to the completion of ongoing or new studies, and with respect to the collection of pharmacovigilance data. Conditional marketing authorisations are valid for one year, and may be renewed annually, if the risk-benefit balance remains positive, and after an assessment of the need for additional or modified conditions and/or specific obligations. The timelines for the centralized procedure described above also apply with respect to the review by the CHMP of applications for a conditional marketing authorization.

Marketing Authorization Under Exceptional Circumstances

As per Article 14(8) Regulation (EC) No 726/2004, products for which the applicant can demonstrate that comprehensive data (in line with the requirements laid down in Annex I of Directive 2001/83/EC, as amended) cannot be provided (due to specific reasons foreseen in the legislation) might be eligible for marketing authorization under exceptional circumstances. This type of authorization is reviewed annually to reassess the risk-benefit balance. The fulfillment of any specific procedures/obligations imposed as part of the marketing authorization under exceptional circumstances is aimed at the provision of information on the safe and effective use of the product and will normally not lead to the completion of a full dossier/approval.

Pediatric Studies

Prior to obtaining a marketing authorization in the EU, applicants have to demonstrate compliance with all measures included in an EMA-approved Pediatric Investigation Plan, or PIP, covering all subsets of the pediatric population, unless the EMA has granted (1) a product-specific waiver, (2) a class waiver, or (3) a deferral for one or more of the measures included in the PIP. The respective requirements for all marketing authorization procedures are laid down in Regulation (EC) No 1901/2006, the so called Pediatric Regulation. This requirement also applies when a company wants to add a new indication, pharmaceutical form or route of administration for a medicine that is already authorized. The Pediatric Committee of the EMA, or PDCO, may grant deferrals for some medicines, allowing a company to delay development of the medicine in children until there is enough information to demonstrate its effectiveness and safety in adults. The PDCO may also grant waivers when development of a medicine in children is not needed or is not appropriate, such as for diseases that only affect the elderly population.

Before a marketing authorization application can be filed, or an existing marketing authorization can be amended, the EMA determines that companies actually comply with the agreed studies and measures listed in each relevant PIP.

Period of Authorization and Renewals

A marketing authorization will be valid for five years in principle, and the marketing authorization may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by a national authority. To this end, the marketing authorization holder must provide the EMA or the competent authority with a consolidated version of the file in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least nine months before the marketing authorization ceases to be valid. Once renewed, the marketing authorization will be valid for an unlimited period, unless the European Commission or the national authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal. Any authorization that is not followed by the actual placing of the drug on the EU market (in case of centralized procedure) or on the market of the authorizing member state within three years after authorization will cease to be valid, the so-called "sunset clause."

Orphan Drug Designation and Exclusivity

The European Commission can grant orphan medicinal product designation to products for which the sponsor can establish that it is intended for the diagnosis, prevention, or treatment of (1) a life-threatening or chronically debilitating condition affecting not more than five in 10,000 people in the EU, or (2) a life threatening, seriously debilitating or serious and chronic condition in the EU and that without incentives it is unlikely that sales of the drug in the EU would generate a sufficient return to justify the necessary investment. In addition, the sponsor must establish that there is no other satisfactory method approved in the EU of diagnosing, preventing or treating the condition, or if such a method exists, the proposed orphan drug will be of significant benefit to patients.

Orphan drug designation provides a number of benefits, including fee reductions, regulatory assistance, and the possibility to apply for a centralized EU marketing authorization (see "—Government Regulation and Product Approval—Regulation Outside the United States—Centralized Authorization Procedure"), as well as 10 years of market exclusivity following a marketing authorization. During this market exclusivity period, neither the EMA, nor the European Commission nor the Member States can accept an application or grant a marketing authorization for a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication. The market exclusivity period for the authorized therapeutic indication may be reduced to six years if, at the end of the fifth year, it is established that the orphan drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity. In addition, a competing similar medicinal product may be authorized prior to the expiration of the market exclusivity period, including if it is shown to be safer, more effective or otherwise clinically superior to the already approved orphan drug or if the holder of the marketing authorization for the already approved orphan drug is unable to supply sufficient quantities of the product.

If the MAA of a medicinal product designated as an orphan drug includes the results of all studies conducted in compliance with an agreed PIP, and a corresponding statement is subsequently included in the marketing authorization granted, the ten-year period of market exclusivity will be extended to twelve years.

Regulatory Data Protection

EU legislation also provides for a system of regulatory data and market exclusivity. Upon receiving marketing authorization, new chemical entities approved on the basis of complete independent data package benefit from eight years of data exclusivity and an additional two years of market exclusivity. Data exclusivity prevents regulatory authorities in the EU from referencing the innovator's data to assess a generic or biosimilar (abbreviated) application. During the additional two-year period of market exclusivity, a generic or biosimilar marketing authorization can be submitted, and the innovator's data may be referenced, but no generic or biosimilar medicinal product can be marketed until the expiration of the market exclusivity. The overall ten-year period will be extended to a maximum of eleven years if, during the first eight years of those 10 years, the marketing authorization holder, or MAH, obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. Even if a compound is considered to be a new chemical entity and the innovator is able to gain the period of data exclusivity, another company nevertheless could also market another version of the drug if such company obtained marketing authorization based on an MAA with a complete independent data package of pharmaceutical test, pre-clinical tests and clinical trials. However, products designated as orphan medicinal products enjoy, upon receiving marketing authorization, a period of 10 years of orphan market exclusivity (see also "Item 4.B—Government Regulation and Product Approval—Regulation and Marketing Authorization in the European Union—Orphan Drug Designation and Exclusivity"). Depending upon the timing and duration of the EU marketing authorization process, products may be eligible for up to five years' supplementary protection certificates, or SPCs. Such SPCs extend the rights under the basic patent for the drug.

Regulatory Requirements After a Marketing Authorization Has Been Obtained

If we obtain authorization for a medicinal product in the EU, we will be required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of medicinal products:

Pharmacovigilance

We will, for example, have to comply with the EU's stringent pharmacovigilance or safety reporting rules, pursuant to which post-authorization studies and additional monitoring obligations can be imposed.

Other requirements relate to, for example, the manufacturing of products and APIs in accordance with good manufacturing practice standards. EU regulators may conduct inspections to verify our compliance with applicable requirements, and we will have to continue to expend time, money and effort to remain compliant. Non-compliance with EU requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population, can also result in significant financial penalties in the EU. Similarly, failure to comply with the EU's requirements regarding the protection of individual personal data can also lead to significant penalties and sanctions. Individual EU member states may also impose various sanctions and penalties in case we do not comply with locally applicable requirements.

Manufacturing

The manufacturing of authorized drugs, for which a separate manufacturer's license is mandatory, must be conducted in compliance with the EMA's cGMP requirements and comparable requirements of other national authorities, which mandate the methods, facilities and controls used in manufacturing, processing and packing of drugs to assure their safety and identity. The EMA enforces its cGMP requirements through mandatory registration of facilities and inspections of those facilities. The EMA may have a coordinating role for these inspections while the responsibility for carrying them out rests with the member states competent authority under whose responsibility the manufacturer falls. Failure to comply with these requirements could interrupt supply and result in delays, unanticipated costs and lost revenues, and could subject the applicant to potential legal or regulatory action, including but not limited to warning letters, suspension of manufacturing, seizure of product, injunctive action or possible civil and criminal penalties.

Marketing and Promotion

The marketing and promotion of authorized drugs, including industry-sponsored continuing medical education and advertising directed toward the prescribers of drugs and/or the general public, are strictly regulated in the EU. The applicable regulations aim to ensure that information provided by holders of marketing authorizations regarding their products is truthful, balanced and accurately reflects the safety and efficacy claims authorized by the EMA or by the national authority of the authorizing member state. Failure to comply with these requirements can result in adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties.

Other U.S. Healthcare Laws and Compliance Requirements

For products distributed in the United States, we will also be subject to additional healthcare regulation and enforcement by the federal government and the states in which we conduct our business. Applicable federal and state healthcare laws and regulations include the following:

- The federal healthcare anti-kickback statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving, or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order, or recommendation of, any good or service, for which payment may be made under federal healthcare programs such as Medicare, Medicaid, or other governmental programs. A person or entity does not need to have actual knowledge of the federal anti-kickback statute or specific intent to violate it to have committed a violation; in addition, items or services resulting from a violation of the federal anti-kickback statute may constitute a false or fraudulent claim for purposes of the False Claims Act;

- The Ethics in Patient Referrals Act, commonly referred to as the Stark Law, and its corresponding regulations, prohibit physicians from referring patients for designated health services (including outpatient drugs) reimbursed under the Medicare or Medicaid programs to entities with which the physicians or their immediate family members have a financial relationship or an ownership interest, subject to narrow regulatory exceptions, and prohibits those entities from submitting claims to Medicare or Medicaid for payment of items or services provided to a referred beneficiary;

- The federal False Claims Act imposes criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government claims for payment that are false or fraudulent or making a false statement to avoid, decrease, or conceal an obligation to pay money to the federal government;

- Health Insurance Portability and Accountability Act of 1996, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information. This statute also prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items, or services;

- The federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for health care benefits, items or services;

- The Physician Payments Sunshine Act, created under the ACA, and its implementing regulations, which requires specified manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to payments or other "transfers of value" made to physicians. All such reported information is publicly available; and

- Analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our future business activities could be subject to challenge under one or more of such laws. Efforts to ensure that our business arrangements with third parties will comply with applicable laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other health care laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded health care programs.

Reimbursement

Sales of our product candidates in the United States may depend, in part, on the extent to which the costs of the product candidates may be covered by third-party payers, such as government health programs, commercial insurance and managed health care organizations. These third-party payers are increasingly challenging the prices charged for medical products and services. Additionally, the containment of health care costs has become a priority of federal and state governments, and the prices of drugs have been a focus in this effort. The United States government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. If these third-party payers do not consider our product candidates to be cost-effective compared to other available therapies, they may not cover our product candidates after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our product candidates on a profitable basis.

In order to secure coverage and reimbursement for any product that might be approved for sale, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costs required to obtain FDA, EMA or other comparable regulatory approvals. Our product candidates may not be considered medically necessary or cost-effective. A payer's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Third-party reimbursement may not be sufficient to enable us to maintain price levels high enough to realize an appropriate return on our investment in product development.

Pricing and reimbursement schemes vary widely from country to country. Some countries provide that drug products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies. The conduct of such studies could be expensive and result in delays in our commercializing efforts. The EU provides options for its member states to restrict the range of drug products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. EU member states may approve a specific price for a drug product or may instead adopt a system of direct or indirect controls on the profitability of the company placing the drug product on the market. Other member states allow companies to fix their own prices for drug products but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert competitive pressure that may reduce pricing within a country. There can be no assurance that any country that has price controls or reimbursement limitations for drug products will allow favorable reimbursement and pricing arrangements for any of our products.

The marketability of any products for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care in the United States has increased and we expect will continue to increase the pressure on drug pricing. Coverage policies, third-party reimbursement rates and drug pricing regulation may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Healthcare Reform

In the United States, there have been and continue to be a number of significant legislative initiatives to contain healthcare costs. The ACA was enacted in the United States in March 2010 and contains provisions that may reduce the profitability of drug products, including, for example, increased rebates for drugs subject to the Medicaid Drug Rebate Program, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal health care programs.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. These changes included aggregate reductions to Medicare payments to providers of 2% per fiscal year, effective April 1, 2013 and, due to subsequent legislative amendments to the statute, will stay in effect through 2027, unless additional Congressional action is taken; however, pursuant to the CARES Act, and subsequent legislation, these reductions are suspended from May 1, 2020 through March 31, 2022 due to the COVID-19 pandemic. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our drugs, if approved, and, accordingly, our financial operations.

Moreover, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their commercial products. There have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare, and reform government program reimbursement methodologies for drugs. The FDA released a final rule on September 24, 2020, effective November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, the U.S. Department of Health and Human Services, or HHS, finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Although a number of these, and other proposed measures may require authorization through additional legislation to become effective, Congress has indicated that it will continue to seek new legislative measures to control drug costs.

CMS issued a final rule, effective on July 9, 2019, that requires direct-to-consumer advertisements of prescription drugs and biological products, for which payment is available through or under Medicare or Medicaid, to include in the advertisement the Wholesale Acquisition Cost, or list price, of that drug or biological product if it is equal to or greater than $35 for a monthly supply or usual course of treatment. Prescription drugs and biological products that are in violation of these requirements will be included on a public list.

Any adopted health reform measure could reduce the ultimate demand for our products, if approved, or put pressure on our product pricing. Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. We expect that additional state and federal healthcare reform measures will be adopted in the future.

We expect that additional state and federal healthcare reform measures, as well as legal changes by foreign governments, will be adopted in the future, any of which could limit the amounts that governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

Employees

As of the date of this prospectus, we have ten employees and full-time consultants, including our executive officers, providing management and financial services, and general administrative responsibilities. We believe that we maintain a satisfactory working relationship with our employees, and we have not experienced any significant labor disputes or any difficulty in recruiting staff for our operations. None of our employees is represented by a labor union.

Human Capital Resources

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants. The principal purposes of our equity and cash incentive plans are to attract, retain and reward personnel through the granting of stock-based and cash-based compensation awards, in order to increase stockholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives.

Legal Proceedings

We are not a party to any material legal proceedings. From time to time, we may be involved in legal proceedings or subject to claims incident to the ordinary course of business. Regardless of the outcome, such proceedings or claims can have an adverse impact on us because of defense and settlement costs, diversion of resources and other factors, and there can be no assurances that favorable outcomes will be obtained.

Facilities

Our executive offices are located in approximately 12,030 square feet of leased office and laboratory space at 21 Business Park Drive, Branford, Connecticut 06405. The lease expires in 2027, subject to our option to extend the lease for two additional five-year terms. We currently pay $13,694 per month under the lease, which will increase to $14,035 in 2023, plus our pro rata share of certain operating expenses of the property.

We also lease approximately 1,093 square feet of additional laboratory space, which is located at 93 Shennecossett Road, Groton, Connecticut. The lease expires in April 2023, however, we have the option to extend the lease for two additional one-year terms. We pay $7,235 per month under the lease plus our pro rata share of certain operating expenses of the property.

We also lease approximately 1,868 square feet of office and laboratory space, which is located at 500 Cartier Boulevard, Laval, Quebec, Canada. The lease expires in April 2023, however, we have the option to extend the lease for an additional 12 month term. We pay $6,583 per month under the lease.

We believe that our facilities are adequate to meet our current needs and that additional space can be obtained on commercially reasonable terms as needed.

MANAGEMENT

Executive Officers, Directors and Director Nominees

The following table sets forth the names, ages and positions of (i) our current executive officers and directors, (ii) our Chief Operating Officer upon the close of this offering and (iii) our director nominees who will become directors upon the close of this offering.

Name	Age	Position
Francisco D. Salva	53	President, Chief Executive Officer and Director
Norman Staskey	53	Chief Financial Officer
Travis Whitfill	33	Chief Operating Officer and Director
Andrew McClary, MD	37	Independent Director
Barbara Ryan	63	Independent Director Nominee[(1)]
John Schroer	57	Independent Director Nominee[(1)]

[(1)] The director nominees are expected to transition on to our board of directors upon the close of this offering.

Information about our Executive Officers, Directors and Director Nominees

Francisco D. Salva has served as our president and chief executive officer and a member of our Board since April 2021. Mr. Salva has over 15 years of experience in senior leadership roles in the biotechnology and pharmaceutical industries. Mr. Salva served as president and chief executive officer of Complexa, Inc., an inflammation and fibrosis focused biopharmaceutical company, from May 2018 to August 2020. From February 2011 to November 2016, Mr. Salva served as a co-founder and vice president of operations of Acerta Pharma B.V., Inc, a cancer and autoimmune focused biopharmaceutical company. Mr. Salva serves as a director of Vincerx Pharma, Inc. (Nasdaq: VINC). Prior to his operating roles, Mr. Salva served in various senior positions in the venture capital and investment banking industries focusing on healthcare, biotechnology and pharmaceuticals companies. Mr. Salva received a B.A. from Brown University and a MSc. In economics and philosophy from the London School of Economics. We believe that Mr. Salva's experience as a senior executive, venture capitalist and investment banker in the biotech and pharmaceutical industries qualifies him to serve on our Board.

Norman Staskey has served as our chief financial officer since October 2022. Since May 15, 2021, Mr. Staskey has also served as a senior director of Danforth Advisors, a national consulting firm providing financial, accounting and reporting services to the life science industry. From September 2014 to May 2021, Mr. Staskey was employed by EY (formally Ernst & Young), most recently as a managing director in EY's Financial Accounting and Advisory services practice.

Travis Whitfill is a co-founder of Azitra and has served on our Board since inception. Mr. Whitfill has served in various roles at Azitra, including chief scientific officer from January 2014 to September 2019 and director of advanced technology since September 2019, and will serve as Chief Operating Officer upon the completion of this offering. Mr. Whitfill has served as a partner at Bios Equity Partners, LP, a biotechnology-focused venture capital firm, since October 2015 and a senior analyst at Bios Research since September 2014. He has also served as an associate research scientist at Yale University from July 2016 to March 2022, with appointments in the Departments of Pediatrics and Emergency Medicine. Mr. Whitfill has served on the board of directors of IN8Bio, Inc. (Nasdaq: INAB) since March 2018, 410 Medical from September 2017 to July 2019 and SIRPant Immunotherapeutics since September 2021. Mr. Whitfill has led numerous grant-funded projects, holds several patents and has co-authored over 50 publications. Mr. Whitfill received a B.S. from Dallas Baptist University, an MPH from Yale University and an MPhil from University College London. We believe that Mr. Whitfill's strong background in entrepreneurship and in the biotech and healthcare industries qualifies him to serve on our Board.

Andrew McClary, MD has served as a member of our Board since March 2019. Dr. McClary is the founding general partner at KdT Ventures LP, a biotechnology focused venture firm founded in 2017. At KdT, Dr. McClary invests in companies leveraging the intersection of the physical sciences and engineering, both computational and biochemical. In addition to leading KdT's investment in Azitra, Dr. McClary has also led KdT's investments in PathAI, Dyno Therapeutics, Solugen, Terray Therapeutics, STRM Therapeutics, Elegen, and Checkerspot. Prior to KdT, Dr. McClary served on faculty as a Pathologist at Stanford University and was an early employee at Included Health (formerly known as Grand Rounds), where he was the physician lead for the Data Science and Analytics team. Dr. McClary received his M.D. from Tulane University, where he has held prior academic appointments and was a HHMI/NIH Fellow, and his Sc.B. in Biochemistry and Molecular Biology from Brown University. We believe that Dr. McClary's medical and scientific expertise as a physician-scientist coupled with his experience working in the venture capital industry qualifies him to serve on our Board.

Barbara Ryan will become a member of our Board upon the closing of this offering. Ms. Ryan founded Barbara Ryan Advisors, a capital markets and communications firm, in 2012 following a more than 30-year career on Wall Street as a sell-side research analyst covering the U.S. pharmaceutical industry. Ms. Ryan has deep experience in equity and debt financings, M&A, valuation, SEC reporting, financial analysis and corporate strategy across a broad range of life sciences companies. Ms. Ryan worked on several of the industry's largest M&A transactions, including Shire's defense versus a hostile takeover attempt by Abbvie, Shire's takeover of Baxalta, Allergan's defense against Valeant and Perrigo's defense versus Mylan Ms. Ryan served as an executive team member and on the disclosure committee for Radius Health from January 2014 to December 2017. Previously, Ms. Ryan was a managing director at Deutsche Bank/Alex Brown and head of the company's pharmaceutical research team for 19 years and began her research career covering the pharmaceutical industry at Bear Stearns in 1982. Ms. Ryan currently serves as a director on the board of MiNK Therapeutics, Inc. (Nasdaq: INKT), where she chairs the audit committee, INVO Bioscience, Inc, (Nasdaq: INVO), Invidior, PLC (LON:INDV). and The Red Door Community (formerly Gilda's Club NYC), a non-profit organization. Ms. Ryan is the founder of Fabulous Pharma Females, a non-profit whose mission is to advance women in the biopharma industry, is a member of the editorial advisory board of Pharmaceutical Executive Magazine, a faculty member of the GLG Institute and a member of the Prix Galien executive advisory board. We believe that Ms. Ryan is qualified to serve as a member of our Board because of her experience and knowledge of corporate finance, mergers and acquisitions, corporate governance, as well as other operational, financial and accounting matters gained as a past and present executive officer and/or director of other public and private companies.

John Schroer will become a member of our Board upon the closing of this offering. Mr. Schroer has served as chief financial officer of Alumis, Inc., a privately held biotechnology company developing precision immunology therapies, since March 2022. Mr. Schroer was chief financial officer of Arsenal Biosciences, Inc., a privately held biotechnology company developing programmable cell therapy for solid tumors, from February 2021 to February 2022. Mr. Schroer was chief financial officer of Translate Bio, Inc., a biotechnology company developing mRNA therapeutics and vaccines acquired by Sanofi in September 2021 for $3.2 billion, from May 2018 to December 2020. Previously, Mr. Schroer was Sector Head – Global Health Care for Allianz Global Investors, an international asset management firm, from January 2014 to May 2018. Mr. Schroer received his B.S. and M.B.A from the University of Wisconsin – Madison. We believe that Mr. Schroer's strong background holding leadership positions in the biotechnology industry and almost 30 years of investing in the life sciences sector qualifies him to serve on our Board.

Family Relationships

There are no family relationships among any of our executive officers, directors or director nominees.

Involvement in Certain Legal Proceedings

To the best of our knowledge, none of our executive officers, directors or director nominees were involved in any legal proceedings described in Item 401(f) of Regulation S-K in the past ten years.

Board Composition

Our Board may establish the authorized number of directors from time to time by resolution. Upon the completion of this offering, our Board will consist of five members, three of whom will qualify as independent under the listing rules of the NYSE American. Neither Mr. Salva nor Mr. Whitfill are considered to be independent due to their roles as executive officers of the Company. However, our Board has determined that Dr. McClary, Ms. Ryan and Mr. Schroer do not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that he or she is "independent" as that term is defined under the applicable rules and regulations of the SEC and the listing requirements and rules of the NYSE American. In making this determination, our Board considered the current and prior relationships that each of Dr. McClary, Ms. Ryan and Mr. Schroer has with our Company and all other facts and circumstances our Board deemed relevant in determining their independence, including their beneficial ownership of our capital stock.

Role of the Board in Risk Oversight

One of the key functions of our Board is informed oversight of our risk management process. Our Board does not have a standing risk management committee, but rather intends to administer this oversight function directly through the board of directors as a whole, as well as through various standing committees of our Board that will address risks inherent in their respective areas of oversight. In particular, our Board will be responsible for monitoring and assessing strategic risk exposure and our audit committee will have the responsibility to consider and discuss our major financial risk exposures and the steps our management has taken to monitor and control these exposures, including guidelines and policies to govern the process by which risk assessment and management is undertaken. The audit committee will also monitor compliance with legal and regulatory requirements.

Board Committees

Our Board has established an audit committee, compensation committee and nominating and corporate governance committee, each of which operates pursuant to a committee charter. Our Board may establish other committees to facilitate the management of our business. The composition and functions of each committee are described below.

Audit Committee

Upon the close of this offering, our audit committee will consist of Dr. McClary, Ms. Ryan and Mr. Schroer, with Mr. Schroer serving as Chairperson. Our Board has determined that each member meets the independence requirements of the Sarbanes-Oxley Act, Rule 10A-3 under the Exchange Act and the applicable listing standards of the NYSE American. Each member of our audit committee can read and understand fundamental financial statements in accordance with the SEC and NYSE American audit committee requirements. In arriving at this determination, the Board has examined each audit committee member's scope of experience and the nature of their prior and/or current employment.

Our Board has determined that Mr. Schroer qualifies as an audit committee financial expert within the meaning of SEC regulations and meets the financial sophistication requirements of the NYSE American listing rules. Both our independent registered public accounting firm and management periodically meet privately with our audit committee.

The functions of this committee include, among other things:

- select a qualified firm to serve as the independent registered public accounting firm to audit our financial statements;
- discuss the scope and results of the audit with the independent registered public accounting firm, and review, with management and the independent registered public accounting firm, our interim and year-end operating results;
- reviewing and approving the engagement of our independent auditors to perform audit services and any permissible non-audit services;
- develop procedures for employees to submit concerns anonymously about questionable accounting or audit matters;
- review our policies on risk assessment and risk management;
- review related-party transactions; and
- reviewing and evaluating on an annual basis the performance of the audit committee and the audit committee charter.

We believe that the composition and functioning of our audit committee complies with all applicable requirements of the Sarbanes-Oxley Act, and all applicable SEC and NYSE American rules and regulations. We intend to comply with future requirements to the extent they become applicable to us.

Compensation Committee

Upon the close of this offering, our compensation committee will consist of Ms. Ryan and Mr. Schroer, with Ms. Ryan serving as Chairperson. Each of the members is a non-employee director, as defined in Rule 16b-3 promulgated under the Exchange Act. Our Board has determined that each member is "independent" as defined under the applicable listing standards of the NYSE American, including the standards specific to members of a compensation committee. The functions of this committee include, among other things:

- reviewing, modifying and approving (or if it deems appropriate, making recommendations to the full Board regarding) our overall compensation strategy and policies;
- reviewing, modifying and approving (or if it deems appropriate, making recommendations to the full Board regarding) the compensation and other terms of employment of our executive officers;
- reviewing and approving (or if it deems it appropriate, making recommendations to the full Board regarding) the equity incentive plans, compensation plans and similar programs advisable for us, as well as modifying, amending or terminating existing plans and programs;
- administering our equity incentive plans;
- establishing policies with respect to equity compensation arrangements; and
- reviewing and evaluating on an annual basis the performance of the compensation committee and the compensation committee charter.

We believe that the composition and functioning of our compensation committee complies with all applicable requirements of the Sarbanes-Oxley Act, and all applicable SEC and the NYSE American rules and regulations. We intend to comply with future requirements to the extent they become applicable to us.

Nominating and Corporate Governance Committee

Upon the close of this offering, our nominating and corporate governance committee will consist of Dr. McClary and Ms. Ryan, with Dr. McClary serving as Chairperson. The composition of our nominating and corporate governance committee meets the requirements for independence under the NYSE American listing standards and SEC rules and regulations. Our nominating and corporate governance committee will, among other things:

- identify, evaluate and make recommendations to our board of directors regarding nominees for election to our board of directors and its committees;
- evaluate the performance of our board of directors and of individual directors;
- consider and make recommendations to our board of directors regarding the composition of our board of directors and its committees;
- review developments in corporate governance practices;
- evaluate the adequacy of our corporate governance practices and reporting; and
- develop and make recommendations to our board of directors regarding corporate governance guidelines and matters.

Each of our committees operates under a written charter that satisfies the applicable listing requirements and rules of the NYSE American.

Code of Business Conduct and Ethics

We intend to adopt a Code of Business Conduct and Ethics, or the Code of Conduct, applicable to all of our employees, executive officers and directors. Once adopted, the Code of Conduct will be available on our website at www.azitrainc.com. The audit committee of our Board of directors will be responsible for overseeing the Code of Conduct and must approve any waivers of the Code of Conduct for employees, executive officers and directors. In addition, we intend to post on our website all disclosures that are required by law or the listing standards of the applicable stock exchange concerning any amendments to, or waivers from, any provision of the Code of Conduct.

Executive Compensation

Officer Compensation

The following table sets forth the compensation awarded to or earned by our chief executive officer and our two other highest paid executive officers for the years ended December 31, 2022 and 2021. In reviewing the table, please note that:

- Francisco D. Salva was appointed to serve as our president and chief executive officer in April 2021;
- Jeanne Bertonis served as our chief operating officer throughout 2021 and 2022 until April 2022; and
- Norman Staskey was appointed to serve as our chief financial officer in October 2022.

	Year	Salary ($)	Bonus ($)	Option Awards $ (1)	All Other Compensation (2)	Total
Francisco D. Salva,	2022	$ 403,846	$ —	$ —	$ 202	$ 404,048
Pres. and CEO	2021	$ 281,615	$ —	$ 724,880	$ 19,125	$ 1,025,620
Norman Staskey,	2022	$ —	$ —	$ —	$ 63,200	$ 63,200
CFO	2021	$ —	$ —	$ —	$ —	$ —
Jeanne Bertonis,	2022	$ 87,610	$ —	$ —	$ 169,523	$ 257,133
COO	2021	$ 303,714	$ —	$ —	$ 185	$ 303,899

(1) The dollar amounts in the Option Awards columns above reflect the values of options as of the grant date for the years ended December 31, 2022 and 2021, in accordance with ASC 718, *Compensation-Stock Compensation* ("ASC 718") and, therefore, do not necessarily reflect actual benefits received by the individuals. Assumptions used in the calculation of these amounts are included in Note 11 to our audited financial statements.

(2) All other compensation includes commuter benefits, vacation payouts, relocation reimbursements, 401K match contributions, and life insurance premiums, plus a separation benefit payment to Ms. Bertonis and consulting fees paid for Mr. Staskey's services as chief financial officer.

Narrative Disclosure to Officer Compensation Table

All of our current named executive officers are at-will employees and set forth below is a summary of the current terms of their compensatory arrangements.

Francisco D. Salva

We have entered into an executive employment agreement dated April 22, 2021 with Mr. Salva, pursuant to which Mr. Salva serves as our president and chief executive officer. We have agreed to pay Mr. Salva an annual base salary of $420,000 under the agreement. Mr. Salva is also eligible to receive a bonus of up to 35% of his base salary based on performance parameters set by our Board. Mr. Salva's executive employment agreement entitles him to participate in health insurance and other benefits, at our expense, made available to other executive officers. In the event of Mr. Salva's termination by us without cause or his resignation for good reason, as such terms are defined in the executive employment agreement, Mr. Salva will be entitled to the continuation of his base salary and health insurance coverage for a period of 12 months and a prorated amount of his annual bonus for the year in which the termination occurred, subject to the achievement of applicable performance targets. Mr. Salva's executive employment agreement is an "at will" agreement subject to termination by either party at any time and for any reason, subject to certain notice requirements. The agreement contains customary provisions relating to intellectual property assignment, confidentiality and indemnification.

In connection with our execution of the executive employment agreement, we granted to Mr. Salva an option to purchase up to 465,760 shares of our common stock at an exercise price of $1.56 per share under the 2016 Plan. The options vest and become exercisable as follows. 80% of the options, or options to purchase 372,608 common shares, are subject to time-based vesting, with options to purchase 93,152 shares (25%) vesting on the first anniversary of the grant and options to purchase 279,456 shares (75%) vesting in equal monthly installments over the 36 months following the first anniversary. 20% of the options, or options to purchase 13,120 common shares, shall vest upon patient dosing in the first in-human clinical trial of ATR-12 or a substitute live biotherapeutic product, as determined by our Board in its reasonable discretion. The options expire on the ten-year anniversary of the date of grant.

Norman Staskey

Mr. Staskey serves as our chief financial officer pursuant to a Consulting Agreement dated October 12, 2002 between us and Danforth Advisors, LLC. Pursuant to the Consulting Agreement, Danforth Advisors provides to us certain strategic and financial advice and support services, including Mr. Staskey's services as chief financial officer, at hourly rates between $135 and $575 per hour, depending on the level of service and the seniority of the service provider. The Consulting Agreement is subject to termination by either party on 30 days written notice and contains customary provisions relating to intellectual property assignment, confidentiality and indemnification.

Jeanne Bertonis

Ms. Bertonis served as our chief operating officer from September 2019 to April 2022 pursuant to an executive employment agreement dated September 1, 2019. Ms. Bertonis was paid a base salary of $303,714 in 2022 and in 2021 and was eligible to receive a bonus of up to 25% of her base salary based on performance parameters set by our Board. Ms. Bertonis' executive employment agreement entitled her to participate in health insurance and other benefits, at our expense, made available to other executive officers. Ms. Bertonis' employment ended in April 2022 and pursuant to the severance provisions of her agreement she received the continuation of her base salary and health benefits for a period of six months from the date of separation. We paid Ms. Bertonis a total of $156,877 in severance and $12,579 in vacation payout during 2022.

Non-Employee Director Compensation

We have not paid any directors' fees or other compensation to our directors for their services as directors. All of our directors receive reimbursement for out-of-pocket expenses for attending board of directors meetings. We intend to commence the payment of our non-executive directors, including the payment of cash and equity awards, or a combination of both, but we have not adopted any such plans or policies as of this date. From time to time, we may also engage certain future outside members of the board of directors to perform services on our behalf and we will compensate such persons for the services which they perform.

Stock Incentive Plans

We have adopted the Azitra Inc 2016 Stock Incentive Plan, or 2016 Plan, providing for the grant of non-qualified stock options and incentive stock options to purchase shares of our common stock and for the grant of restricted and unrestricted share grants and restricted stock units. We currently have reserved 157,989 shares of our common stock under the 2016 Plan. The purpose of the 2016 Plan is to provide eligible participants with an opportunity to acquire an ownership interest in our company. All officers, directors, employees and consultants to our company are eligible to participate under the 2016 Plan. The 2016 Plan provides that options may not be granted at an exercise price less than the fair market value of our common shares on the date of grant. As of the date of this prospectus, we have outstanding options granted under the 2016 Plan to purchase an aggregate of 1,290,319 shares of our common stock at an average exercise price of $1.33 per share.

In March 2023, our Board and stockholders approved and adopted the Azitra Inc 2023 Stock Incentive Plan, or 2023 Plan, providing for the grant of non-qualified stock options and incentive stock options to purchase shares of our common stock and for the grant of restricted and unrestricted share grants and restricted stock units. We currently have reserved 2,000,000 shares of our common stock under the 2023 Plan. The purpose of the 2023 Plan is to provide eligible participants with an opportunity to acquire an ownership interest in our company. All officers, directors, employees and consultants to our company are eligible to participate under the 2023 Plan. The 2023 Plan provides that options may not be granted at an exercise price less than the fair market value of our common shares on the date of grant. As of the date of this prospectus, we have not granted any awards under the 2023 Plan.

Related Party Transactions

Except as set forth below, since January 1, 2020, we have not been a party to any transaction in which the amount involved in the transaction exceeded the lesser of $120,000 or one percent of the average of our total assets as of December 31, 2022 and 2021, and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our voting securities or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than compensation arrangements, which include equity and other compensation, termination, change in control and other arrangements, which are described under "*Executive Compensation*." We have adopted a policy that any transactions with directors, officers, beneficial owners of five percent or more of our common stock, any immediate family members of the foregoing or entities of which any of the foregoing are also officers or directors or in which they have a financial interest, will only be on terms consistent with industry standards and approved by a majority of the disinterested directors of our Board.

In September 2022, we issued unsecured convertible promissory notes in the aggregate principal amount of $4.35 million to five existing stockholders, including notes in the aggregate principal amount of $4 million to three funds under common control, namely Bios Fund III, LP, Bios Fund III QP, LP, and Bios Fund III NT, LP. The Bios entities beneficially own a collective 4,883,658 shares, or approximately 43.0%, of our outstanding common stock immediately prior to this offering. 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 Bios representative who served on our Board from April 2016 to the date preceding the date of this prospectus. In addition, Travis Whitfill, our co-founder and a member of our Board, is a partner of Bios Equity Partners, LP, the general partner of the aforementioned Bios entities,

In December 2019, we entered into a Joint Development Agreement, or JDA, with Bayer pursuant to which we agreed to the joint development of certain strains selected from our proprietary microbial library. Bayer paid us a one-time low six figure payment upon execution of the JDA. Pursuant to the JDA, Bayer is responsible for reimbursing us for our development costs, and in 2022 Bayer has paid us a mid-six figure dollar amount for our development costs. We have granted Bayer an option to acquire an exclusive royalty bearing license for up to six (6) strains subject to development activities sunder the JDA, including an exclusive royalty bearing license to any related patent rights.

In September 2020, Bayer's venture capital group, LEAPS by Bayer, purchased $8 million of our Series B preferred stock. In connection with the investment, we granted Bayer certain board appointment rights pursuant to which they appointed to our Board a Bayer representative who served on our Board from September 2020 to the date preceding the date of this prospectus.

Indemnification Agreements

Prior to the closing of this offering, we expect to enter into indemnification agreements with each of our directors and executive officers that may be broader than the specific indemnification provisions contained in the DGCL. These indemnification agreements will require us, among other things, to indemnify our directors and executive officers against liabilities that may arise by reason of their status or service. These indemnification agreements will also require us to advance all expenses incurred by the directors and executive officers in investigating or defending any such action, suit, or proceeding. We believe that these agreements are necessary to attract and retain qualified individuals to serve as directors and executive officers.

Limitation of Liability of Directors and 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.

The above provisions in our amended and restated certificate of incorporation to be adopted upon the completion of this offering 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.

PRINCIPAL STOCKHOLDERS

The following table sets forth certain information regarding the beneficial ownership of our shares of common stock as of the date of this prospectus by:

- each person who is known by us to be the beneficial owner of more than five percent (5%) of our issued and outstanding shares of common stock;
- each of our executive officers, directors, and director nominees who will serve as such upon the completion of this offering; and
- all of the aforementioned directors, executive officers and director nominees as a group.

The beneficial ownership of each person was calculated based on 10,557,134 shares of common stock issued and outstanding prior to the offering, including 2,400,000 shares issued and outstanding as of the date of this prospectus, and approximately 9,513,143 shares issuable upon the conversion of our convertible preferred stock and convertible promissory notes outstanding as of the date of this prospectus, based on the assumed initial public offering price of $5.00 per share (which is the midpoint of the price range set forth on the cover page of this prospectus). 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. Unless otherwise indicated, the address for each reporting person is c/o Azitra Inc, 21 Business Park Drive, Branford, Connecticut 06405.

Name of Director, Executive Officer or Director Nominee	Number of Shares	Percentage Owned Prior to Offering[1]	Percentage Owned After Offering[2]
Francisco D. Salva [1]	186,304	1.7%	1.4%
Norman Staskey	—	—	—
Travis Whitfill [2]	412,652	3.8%	3.1%
Andrew McClary [3]	291,049	2.7%	2.2%
Barbara Ryan	—	—	—
John Schroer	—	—	—
Directors, executive officers and director nominees, as a group (6 persons)	890,005	8.2%	6.7%

Name and Address of Five Percent Stockholders	Number of Shares	Percentage Owned Prior to Offering	Percentage Owned After Offering
Bios Equity Entities [4]	4,883,657	43.0%	35.5%
Bayer Health Care, LLC [5]	1,307,401	11.0%	9.2%
Connecticut Innovations, Inc. [6]	689,054	6.1%	5.0%

(1) Includes 186,304 common shares issuable upon exercise of presently exercisable options.

(2) Includes 93,152 shares issuable upon exercise of presently exercisable options.

(3) Includes 21,804 shares issuable upon exercise of presently exercisable warrants.

(4) Consists of (i) 799,467 shares of common stock issuable to Bios Fund I, LP upon conversion of our convertible preferred stock following the close of this offering, (ii) 397,600 shares of common stock issuable to Bios Azitra Co-Invest I, LP upon conversion of our convertible preferred stock following the close of this offering and 39,760 shares of common stock issuable upon the exercise of warrants, (iii) 284,987 shares of common stock issuable to Bios Fund II, LP upon conversion of our convertible preferred stock following the close of this offering and 22,727 shares of common stock issuable upon the exercise of warrants, (iv) 123,718 shares of common stock issuable to Bios Fund III, LP upon conversion of our convertible preferred stock and 77,953 shares of common stock issuable upon the conversion of the convertible promissory notes following the close of this offering, (v) 467,613 shares of common stock issuable to Bios Fund I QP, LP upon conversion of our convertible preferred stock following the close of this offering, (vi) 931,094 shares of common stock issuable to Bios Fund II QP, LP upon conversion of our convertible preferred following the close of this offering and 74,238 shares of common stock issuable upon the exercise of warrants, (vii) 808,058 shares of common stock issuable to Bios Fund III QP, LP upon conversion of our convertible preferred stock and 509,141 shares of common stock issuable upon the conversion of the convertible promissory notes following the close of this offering, (viii) 124,641 shares of common stock issuable to Bios Fund II NT, LP upon conversion of our convertible preferred stock following the close of this offering and 9,940 shares of common stock issuable upon the exercise of warrants, (ix) 130,498 shares of common stock issuable to Bios Fund III NT, LP upon conversion of our convertible preferred stock and 82,223 shares of common stock issuable upon the conversion of the convertible promissory notes following the close of this offering. Bios Equity Partners, LP is the general partner of the following entities: Bios Fund I, LP and Bios Fund I QP, LP. Bios Equity Partners II, LP is the general partner of Bios Fund II, LP, QP, LP, Bios Fund II, LP and Bios Fund II NT, LP. Cavu Management, LP, an entity managed and controlled by Mr. Les Kreis, and Bios Capital Management, LP, an entity managed and controlled by Mr. Aaron Fletcher, are the general partners of Bios Equity I, LP and Bios Equity II, LP. Cavu Advisors LLC, an entity that is managed and controlled by Mr. Kreis, is the general partner of Cavu Management LP. Bios Advisors GP, LLC, an entity that is managed and controlled by Mr. Fletcher, is the general partner of Bios Capital Management, LP. The shares owned by Bios Fund I, Bios Fund I QP, Bios Fund II, Bios Fund II QP, Bios Fund II NT and Bios Fund III NT ("Bios Equity Entities") are aggregated for purposes of reporting share ownership information. Mr. Kreis and Mr. Fletcher share voting and investment control with respect to shares held by the Bios Equity Entities. Travis Whitfill, a director of the Company, is a partner at Bios Equity Partners, LP. but does not have voting or investment power over the shares described in this footnote 4. The address for Bios Equity Entities is 1751 River Run, Suite 400, Fort Worth, Texas 76107.

(5) Consists of 1,307,401 shares of common stock issuable upon conversion of our convertible preferred stock following the close of this offering. The address for Bayer HealthCare, LLC is 610 Main Street Cambridge, Massachusetts 02139.

(6) Consists of (i) 605,907 shares of common stock issuable upon conversion of our convertible preferred stock following the close of this offering, (ii) 41,315 shares of common stock issuable upon the exercise of warrants and (iii) 41,832 shares of common stock upon the conversion of the convertible promissory notes following the close of this offering. The address for Connecticut Innovations, Inc. is 470 James Street, Suite 8 New Haven, CT 06513.

DESCRIPTION OF SECURITIES

General

The following description summarizes the most important terms of our capital stock, as they are expected to be in effect upon the closing of this offering. We intend to adopt an amended and restated certificate of incorporation and amended and restated bylaws in connection with this offering, and this description summarizes the provisions that are expected to be included in such documents. Because it is only a summary, it does not contain all the information that may be important to you. For a complete description of the matters set forth in this "Description of Securities," you should refer to our amended and restated certificate of incorporation and amended and restated bylaws and investor rights agreement, which are or will be included as exhibits to the registration statement of which this prospectus forms a part, and to the applicable provisions of Delaware law.

Immediately following the closing of this offering, our authorized capital stock will consist of 100,000,000 shares of common stock, $0.0001 par value per share, and 10,000,000 shares of undesignated preferred stock, $0,0001 par value per share.

Assuming (i) a forward stock split to be effected upon the effectiveness of the registration statement of which this prospectus forms a part at a ratio of 7.1-for-1, and (ii) the automatic conversion of all shares of our convertible preferred stock and convertible promissory notes outstanding as of the date of this prospectus, which conversion will occur immediately upon the closing of this offering, there are 10,557,134 shares of our common stock outstanding and no shares of our preferred stock outstanding as of the date of this prospectus, based on the initial public offering price of $5.00 per share (which is the midpoint of the price range set forth on the cover page of this prospectus).

As of the date of this prospectus, we had 11 stockholders of record.

Common Stock

The holders of common stock are entitled to one vote for each share of common stock. The holders of common stock are entitled to any dividends that may be declared by the Board out of funds legally available for payment of dividends at such times and in such amounts as the Board in its discretion. In the event of any liquidation, dissolution or winding up of the Company, holders of common stock are entitled to receive the assets of the Company available for distribution to its stockholders ratably in proportion to the number of shares of common stock held by the holders of common stock. The holders of shares of common stock have no preemptive, conversion, subscription rights or cumulative voting rights.

Preferred Stock

As of the date of this prospectus, there are a total of 1,437,150 shares of convertible preferred stock authorized for issuance, including 205,385 shares of Series A convertible preferred stock, 380,657 shares of Series A-1 convertible preferred stock and 414,638 shares Series B convertible preferred stock issued and outstanding. Immediately upon the completion of this offering, all outstanding shares of our convertible preferred stock will convert into a total of 7,693,436 shares of our common stock.

Upon the completion of this offering plan to adopt an amended and restated certificate of incorporation pursuant to which we will authorized to issue 10,000,000 shares of preferred stock. Our Board will be authorized, without further action by our stockholders, to provide from time to time out of the unissued shares of preferred stock for one or more series of preferred stock, and with respect to each such series, to fix the number of shares constituting such series and the designation of such series, the powers (including voting powers), if any, of the shares of such series and the preferences and relative, participating, optional, special or other rights, if any, and the qualifications, limitations, or restrictions, if any, of the shares of such series. The issuance of our preferred stock could adversely affect the voting power of holders of our common stock and the likelihood that such holders will receive dividend payments and payments upon liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring, or preventing a change of control or other corporate action.

Warrants

Upon the completion of this offering, we will have outstanding the following warrants to purchase shares of our common stock:

- Warrants issued in connection with our April 2018 placement of unsecured convertible promissory notes to purchase up to an aggregate of 47,890 shares of our common stock, at a per share exercise price equal to $0.48. The warrants expire in April 2028.
- Warrants issued in connection with our February 2019 placement of Series A-1 convertible preferred shares to purchase up to an aggregate of 215,854 shares of our common stock, at a per share exercise price equal to $5.28. The warrants expire in February 2029.
- Warrants to be issued to ThinkEquity and its designees at the close of this offering to purchase shares of our common stock equal to 4% of the shares of common stock sold in this offering. This warrant is exercisable at $6.25 per share (125% of the price of the common stock sold in this offering), expiring five years from the date of this prospectus.

Stock Incentive Plans

We have adopted the Azitra Inc 2016 Stock Incentive Plan, or 2016 Plan, providing for the grant of non-qualified stock options and incentive stock options to purchase shares of our common stock and for the grant of restricted and unrestricted share grants and restricted stock units. We currently have reserved 157,989 shares of our common stock under the 2016 Plan. The purpose of the 2016 Plan is to provide eligible participants with an opportunity to acquire an ownership interest in our company. All officers, directors, employees and consultants to our company are eligible to participate under the 2016 Plan. The 2016 Plan provides that options may not be granted at an exercise price less than the fair market value of our common shares on the date of grant. As of the date of this prospectus, we have outstanding options granted under the 2016 Plan to purchase an aggregate of 1,290,319 shares of our common stock at an average exercise price of $1.33 per share.

In March 2023, our Board and stockholders approved and adopted the Azitra Inc 2023 Stock Incentive Plan, or 2023 Plan, providing for the grant of non-qualified stock options and incentive stock options to purchase shares of our common stock and for the grant of restricted and unrestricted share grants and restricted stock units. We currently have reserved 2,000,000 shares of our common stock under the 2023 Plan. The purpose of the 2023 Plan is to provide eligible participants with an opportunity to acquire an ownership interest in our company. All officers, directors, employees and consultants to our company are eligible to participate under the 2023 Plan. The 2023 Plan provides that options may not be granted at an exercise price less than the fair market value of our common shares on the date of grant. As of the date of this prospectus, we have not granted any awards under the 2023 Plan.

Dividends

We do not anticipate the payment of cash dividends on our common stock in the foreseeable future.

Registration Rights

Upon completion of this offering, certain holders of our common stock, or their permitted transferees, will be entitled to the registration rights described below. The registration of shares of our common stock pursuant to the exercise of registration rights described below would enable the holders to sell these shares without restriction under the Securities Act when the applicable registration statement is declared effective. We will pay the registration expenses, other than the underwriting discounts and commissions, of the shares registered pursuant to the registrations described below. The registration rights described below will expire upon the earlier of three years following the completion of this offering, or when all investors, considered with their affiliates, can sell all of their shares in a three-month period under Rule 144.

Convertible Preferred Stock Registration Rights. In connection with our convertible preferred stock financings, we entered into an investor rights agreement, as amended, pursuant to which we have granted the purchasers of our convertible preferred stock certain demand and piggyback respiration rights. Following the completion of this offering, those parties will beneficially hold approximately 9,513,143 shares of our common stock, including 7,693,437 shares of our common stock issued upon conversion of our outstanding our convertible preferred stock and unsecured convertible notes and 1,819,706 shares of our common stock issuable upon exercise of warrants issued to the parties in connection with our 2018 placement of our unsecured convertible promissory notes and our 2019 placement of Series A-1 convertible preferred shares.

Pursuant to the investor rights agreement, we will be required, upon the written request at any time more than 180 days after the completion of this offering by the holders of at least 50% of the shares that are entitled to registration rights under the investor rights agreement, to register, as soon as practicable, all or a portion of these shares for public resale. We are required to effect two demand registrations pursuant to a registration statement on Form S-1, provided such requests for registration be for an aggregate offering price, net of the underwriting discounts and commissions, equal or greater than $20.0 million. Subject to our eligibility to use a registration statement on Form S-3, we are required to effect an unlimited number of demand registrations pursuant to Form S-3, provided such requests for registration be for an aggregate offering price, net of the underwriting discounts and commissions, equal or greater than $1 million. Pursuant to the investor rights agreement, we have also granted to the piggyback registration rights and demand registration rights. These demand and piggyback registration rights terminate as to each investor when their shares subject to the registration rights agreement may be sold by the investor pursuant to Rule 144 under the Securities Act without regard to both the volume limitations for sales as provided in Rule 144.

Underwriter Registration Rights. In connection with this offering, we have agreed to issue to the representative of the underwriters or its designees warrants, referred to as the Representative's Warrants, to purchase up to a total of 96,000 (or 110,400 if the over-allotment option is exercised in full) shares of our common stock (4% of the aggregate number of shares of common stock sold in this offering). The Representative's Warrants will provide for registration rights (including a one-time demand registration right and unlimited piggyback rights) consistent with FINRA Rule 5110.05. The demand for registration may be made at any time beginning on the initial exercise date of the Representative's Warrants and expiring on the fifth anniversary of the effective date of this registration statement in accordance with FINRA Rule 5110(g)(8)(C). In addition to the one-time demand registration right, the Representative's Warrants shall have unlimited piggyback rights, for a period of no more than two years from the initial exercise date of the Representative's Warrants in accordance with FINRA Rule 5110(g)(8)(D).

Anti-Takeover Effects of Certain Provisions of Delaware Law and Our Charter Documents

The following is a summary of certain provisions of Delaware law and our amended and restated certificate of incorporation and amended and restated bylaws to be adopted upon the completion of this offering. This summary does not purport to be complete and is qualified in its entirety by reference to the corporate law of Delaware and our amended and restated certificate of incorporation and amended and restated bylaws.

Delaware Law

We are subject to Section 203 of the Delaware General Corporation Law, an anti-takeover law. In general, Section 203 prohibits a Delaware corporation from engaging in any business combination (as defined below) with any interested stockholder (as defined below) for a period of three years following the date that the stockholder became an interested stockholder, unless:

- prior to that date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares of voting stock outstanding (but not the voting stock owned by the interested stockholder) those shares owned by persons who are directors and officers and by excluding employee stock plans in which employee participants do not have the right to determine whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or subsequent to that date, the business combination is approved by the board of directors of the corporation and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

Section 203 defines "business combination" to include the following:

- any merger or consolidation involving the corporation and the interested stockholder;

- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;
- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- subject to limited exceptions, any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation, or who beneficially owns 15% or more of the outstanding voting stock of the corporation at any time within a three-year period immediately prior to the date of determining whether such person is an interested stockholder, and any entity or person affiliated with or controlling or controlled by any of these entities or persons.

Our Charter Documents

Our charter documents include provisions that could have the effect of discouraging others from making tender offers for our shares and may have the effect of deterring hostile takeovers or delaying changes in our control or management. These provisions are intended to enhance the likelihood of continued stability in the composition of our Board and its policies and to discourage certain types of transactions that may involve an actual or threatened acquisition of us. These provisions are also designed to reduce our vulnerability to an unsolicited acquisition proposal and to discourage certain tactics that may be used in proxy fights. However, such provisions may have the effect of discouraging, delaying or preventing a change in control or an unsolicited acquisition proposal that a stockholder might consider favorable, including a proposal that might result in the payment of a premium over the market price for the shares held by our stockholders. Certain of these provisions are summarized in the following paragraphs.

Effects of authorized but unissued common stock and preferred stock. One of the effects of the existence of authorized but unissued common stock and preferred stock may be to enable our Board to make more difficult or to discourage an attempt to obtain control of our Company by means of a merger, tender offer, proxy contest or otherwise, and thereby to protect the continuity of management. If, in the due exercise of its fiduciary obligations, the Board were to determine that a takeover proposal was not in our best interest, such shares could be issued by the Board without stockholder approval in one or more transactions that might prevent or render more difficult or costly the completion of the takeover transaction by diluting the voting or other rights of the proposed acquirer or insurgent stockholder group, by putting a substantial voting block in institutional or other hands that might undertake to support the position of the incumbent Board, by effecting an acquisition that might complicate or preclude the takeover, or otherwise.

Cumulative Voting. Our amended and restated certificate of incorporation does not provide for cumulative voting in the election of directors, which would allow holders of less than a majority of the stock to elect some directors.

Vacancies. Our amended and restated bylaws provide that all vacancies may be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum.

Special Meeting of Stockholders and Stockholder Action by Written Consent. A special meeting of stockholders may only be called by our Board or the chairperson of our Board. All stockholder actions must be effected at a duly called meeting of stockholders and not by written consent.

Advance Notice Provisions. Our amended and restated bylaws provide advance notice procedures for stockholders seeking to bring business before our annual meeting of stockholders or to nominate candidates for election as directors at our annual meeting of stockholders. Our amended and restated bylaws will also specify certain requirements regarding the form and content of a stockholder's notice. These provisions might preclude our stockholders from bringing matters before our annual meeting of stockholders or from making nominations for directors at our annual meeting of stockholders if the proper procedures are not followed. We expect that these provisions may also discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of our company.

Choice of Forum. Our amended and restated certificate of incorporation and amended and restated bylaws will provide that the Court of Chancery of the State of Delaware will be the exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation or our bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine.

Transfer Agent and Registrar

Upon the closing of this offering, the transfer agent and registrar for our shares of common stock will be VStock Transfer, LLC. The transfer agent and registrar's address is 18 Lafayette Place, Woodmere, New York 11598.

National Securities Exchange Listing

We have applied to have our shares of common stock listed on the NYSE American under the symbol "AZTR."

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for shares of our common stock. Future sales of substantial amounts of shares of common stock, including shares issued upon the exercise of outstanding warrants and options, in the public market after this offering, or the possibility of these sales occurring, could adversely affect the prevailing market price for our common stock or impair our ability to raise equity capital.

Upon the completion of this offering, a total of 12,957,134 shares of common stock will be outstanding, assuming the automatic conversion of all outstanding convertible preferred stock and convertible promissory notes into shares of common stock in connection with the completion of this offering, based on the initial public offering price of $5.00 per share (which is the midpoint of the price range set forth on the cover page of this prospectus). All 2,400,000 shares of common stock sold in this offering by us, plus any shares sold upon exercise of the underwriter's over-allotment option, will be freely tradable in the public market without restriction or further registration under the Securities Act, unless these shares are held by "affiliates," as that term is defined in Rule 144 under the Securities Act.

The remaining 10,557,134 shares of common stock will be "restricted securities," as that term is defined in Rule 144 under the Securities Act. These restricted securities are eligible for public sale only if they are registered under the Securities Act or if they qualify for an exemption from registration under Rules 144 or 701 under the Securities Act, which are summarized below.

Subject to the lock-up agreements described below and the provisions of Rules 144 and 701 under the Securities Act, these restricted securities will be available for sale in the public market beginning more than 90 days after the date of this prospectus.

Rule 144

In general, under Rule 144 as currently in effect, once we have been subject to public company reporting requirements for at least 90 days, a person who is not deemed to have been one of our affiliates for purposes of the Securities Act at any time during the 90 days preceding a sale and who has beneficially owned the shares proposed to be sold for at least six months, including the holding period of any prior owner other than our affiliates, is entitled to sell such shares without complying with the manner of sale, volume limitation, or notice provisions of Rule 144, subject to compliance with the public information requirements of Rule 144. If such a person has beneficially owned the shares proposed to be sold for at least one year, including the holding period of any prior owner other than our affiliates, then such person is entitled to sell such shares without complying with any of the requirements of Rule 144.

In general, under Rule 144, as currently in effect, our affiliates or persons selling shares on behalf of our affiliates are entitled to sell upon expiration of the lock-up agreements described below, within any three-month period beginning 90 days after the date of this prospectus, a number of shares that does not exceed the greater of:

- 1% of the number of shares of common stock then outstanding; or
- the average weekly trading volume of the common stock during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Sales under Rule 144 by our affiliates or persons selling shares on behalf of our affiliates are also subject to certain manner of sale provisions and notice requirements and to the availability of current public information about us.

Rule 701

Rule 701 generally allows a stockholder who purchased shares of our common stock pursuant to a written compensatory plan or contract and who is not deemed to have been one of our affiliates during the immediately preceding 90 days to sell these shares in reliance upon Rule 144, but without being required to comply with the public information, holding period, volume limitation, or notice provisions of Rule 144. Rule 701 also permits our affiliates to sell their Rule 701 shares under Rule 144 without complying with the holding period requirements of Rule 144. However, all holders of Rule 701 shares are required to wait until 90 days after the date of this prospectus before selling such shares pursuant to Rule 701.

Lock-Up Agreements

Each of our directors and officers have agreed, subject to certain exceptions, not to offer, pledge, sell, contract to sell, grant, lend, or otherwise transfer or dispose of, directly or indirectly, or enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of any shares of our capital stock or any securities convertible into or exercisable or exchangeable for shares of our common stock, for a period of twelve (12) months after the date of this prospectus, without the prior written consent of the representative. We, subject to certain exceptions, and all of our other stockholders of 0.5% or more of the outstanding shares of common stock (or securities convertible into shares of common stock, including options and warrants), have agreed, subject to certain exceptions, not offer, pledge, sell, contract to sell, grant, lend, or otherwise transfer or dispose of, directly or indirectly, or enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of any shares of our capital stock or any securities convertible into or exercisable or exchangeable for shares of our common stock, for a period of six (6) months after the date of this prospectus, without the prior written consent of the representative.

Equity Plans

We intend to file a registration statement on Form S-8 under the Securities Act to register all of the shares of common stock to be issued or reserved for issuance under our 2016 Plan and 2023 Plans. Shares covered by this registration statement will be eligible for sale in the public market, upon the expiration or release from the terms of the lock-up agreements and subject to vesting of such shares.

MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES FOR NON-U.S. HOLDERS

The following discussion is a summary of the material U.S. federal income tax consequences to Non-U.S. Holders (as defined below) of the purchase, ownership, and disposition of our common stock issued pursuant to this offering but does not purport to be a complete analysis of all potential tax effects. The effects of other U.S. federal tax laws, such as estate and gift tax laws, and any applicable state, local, or non-U.S. tax laws are not discussed. This discussion is based on the U.S. Internal Revenue Code of 1986, as amended, or the Code, Treasury Regulations promulgated thereunder, judicial decisions, and published rulings and administrative pronouncements of the U.S. Internal Revenue Service, or the IRS, in each case in effect as of the date hereof. These authorities may change or be subject to differing interpretations. Any such change or differing interpretation may be applied retroactively in a manner that could adversely affect a Non-U.S. Holder. We have not sought and will not seek any rulings from the IRS regarding the matters discussed below. There can be no assurance the IRS or a court will not take a contrary position to that discussed below regarding the tax consequences of the purchase, ownership, and disposition of our common stock.

This discussion is limited to Non-U.S. Holders that hold our common stock as a "capital asset" within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all U.S. federal income tax consequences relevant to a Non-U.S. Holder's particular circumstances, including the impact of the Medicare contribution tax on net investment income and the alternative minimum tax. In addition, it does not address consequences relevant to Non-U.S. Holders subject to special rules, including, without limitation:

- U.S. expatriates and former citizens or long-term residents of the United States;
- persons holding our common stock as part of a hedge, straddle, or other risk reduction strategy or as part of a conversion transaction or other integrated investment;
- banks, insurance companies, and other financial institutions;
- brokers, dealers, or traders in securities;
- "controlled foreign corporations," "passive foreign investment companies," and corporations that accumulate earnings to avoid U.S. federal income tax;
- partnerships or other entities or arrangements treated as partnerships for U.S. federal income tax purposes (and investors therein);
- tax-exempt organizations or governmental organizations;
- persons deemed to sell our common stock under the constructive sale provisions of the Code;
- persons who hold or receive our common stock pursuant to the exercise of any employee stock option or otherwise as compensation;
- tax-qualified retirement plans; and
- "qualified foreign pension funds" as defined in Section 897(l)(2) of the Code and entities all of the interests of which are held by qualified foreign pension funds.

If an entity treated as a partnership for U.S. federal income tax purposes holds our common stock, the tax treatment of a partner in the partnership will depend on the status of the partner, the activities of the partnership, and certain determinations made at the partner level. Accordingly, partnerships holding our common stock and the partners in such partnerships should consult their tax advisors regarding the U.S. federal income tax consequences to them.

THIS DISCUSSION IS FOR INFORMATIONAL PURPOSES ONLY AND IS NOT TAX ADVICE. INVESTORS SHOULD CONSULT THEIR TAX ADVISORS WITH RESPECT TO THE APPLICATION OF THE U.S. FEDERAL INCOME TAX LAWS TO THEIR PARTICULAR SITUATIONS AS WELL AS ANY TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP, AND DISPOSITION OF OUR COMMON STOCK ARISING UNDER THE U.S. FEDERAL ESTATE OR GIFT TAX LAWS OR UNDER THE LAWS OF ANY STATE, LOCAL, OR NON-U.S. TAXING JURISDICTION OR UNDER ANY APPLICABLE INCOME TAX TREATY.

Definition of a Non-U.S. Holder

For purposes of this discussion, a "Non-U.S. Holder" is any beneficial owner of our common stock that is neither a "U.S. person" nor an entity treated as a partnership for U.S. federal income tax purposes. A U.S. person is any person that, for U.S. federal income tax purposes, is or is treated as any of the following:

- an individual who is a citizen or resident of the United States;
- a corporation created or organized under the laws of the United States, any state thereof, or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust that (1) is subject to the primary supervision of a U.S. court and the control of one or more "United States persons" (within the meaning of Section 7701(a)(30) of the Code), or (2) has a valid election in effect to be treated as a United States person for U.S. federal income tax purposes.

Distributions

As described in the section entitled "Dividend Policy," we do not anticipate declaring or paying dividends to holders of our common stock in the foreseeable future. However, if we do make distributions of cash or property on our common stock, such distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and first be applied against and reduce a Non-U.S. Holder's adjusted tax basis in its common stock, but not below zero. Any excess will be treated as capital gain and will be treated as described below under "—Sale or Other Taxable Disposition."

Subject to the discussion below on effectively connected income, dividends paid to a Non-U.S. Holder will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends (or such lower rate specified by an applicable income tax treaty, provided the Non-U.S. Holder furnishes a valid IRS Form W-8BEN or W-8BEN-E (or other applicable documentation) certifying qualification for the lower treaty rate). A Non-U.S. Holder that does not timely furnish the required documentation, but that qualifies for a reduced treaty rate, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. Non-U.S. Holders should consult their tax advisors regarding their entitlement to benefits under any applicable income tax treaty.

If dividends paid to a Non-U.S. Holder are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment in the United States to which such dividends are attributable), the Non-U.S. Holder will be exempt from the U.S. federal withholding tax described above. To claim the exemption, the Non-U.S. Holder must furnish to the applicable withholding agent a valid IRS Form W-8ECI, certifying that the dividends are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States.

Any such effectively connected dividends will be subject to U.S. federal income tax on a net income basis at the regular rates. A Non-U.S. Holder that is a corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on such effectively connected dividends, as adjusted for certain items. Non-U.S. Holders should consult their tax advisors regarding any applicable tax treaties that may provide for different rules.

Sale or Other Taxable Disposition

A Non-U.S. Holder will not be subject to U.S. federal income tax on any gain realized upon the sale or other taxable disposition of our common stock unless:

- the gain is effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment in the United States to which such gain is attributable);

- the Non-U.S. Holder is a nonresident alien individual present in the United States for 183 days or more during the taxable year of the disposition and certain other requirements are met; or

- our common stock constitutes a U.S. real property interest, or USRPI, by reason of our status as a U.S. real property holding corporation, or USRPHC, for U.S. federal income tax purposes.

Gain described in the first bullet point above generally will be subject to U.S. federal income tax on a net income basis at the regular rates. A Non-U.S. Holder that is a corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on such effectively connected gain, as adjusted for certain items.

A Non-U.S. Holder described in the second bullet point above will be subject to U.S. federal income tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on gain realized upon the sale or other taxable disposition of our common stock, which may be offset by U.S. source capital losses of the Non-U.S. Holder (even though the individual is not considered a resident of the United States), provided the Non-U.S. Holder has timely filed U.S. federal income tax returns with respect to such losses.

With respect to the third bullet point above, we believe we currently are not, and do not anticipate becoming, a USRPHC. Because the determination of whether we are a USRPHC depends, however, on the fair market value of our USRPIs relative to the fair market value of our USRPIs and our other business assets, there can be no assurance we currently are not a USRPHC or will not become one in the future. Even if we are or were to become a USRPHC, gain arising from the sale or other taxable disposition of our common stock by a Non-U.S. Holder will not be subject to U.S. federal income tax if our common stock is "regularly traded," as defined by applicable Treasury Regulations, on an established securities market and such Non-U.S. Holder owned, actually and constructively, 5% or less of our common stock throughout the shorter of the five-year period ending on the date of the sale or other taxable disposition or the Non-U.S. Holder's holding period.

Non-U.S. Holders should consult their tax advisors regarding potentially applicable income tax treaties that may provide for different rules.

Information Reporting and Backup Withholding

Payments of dividends on our common stock will not be subject to backup withholding, provided the applicable withholding agent does not have actual knowledge or reason to know the holder is a United States person and the holder either certifies its non-U.S. status, such as by furnishing a valid IRS Form W-8BEN, W-8BEN-E, or W-8ECI, or otherwise establishes an exemption. However, information returns are required to be filed with the IRS in connection with any distributions on our common stock paid to the Non-U.S. Holder, regardless of whether such distributions constitute dividends or whether any tax was actually withheld. In addition, proceeds of the sale or other taxable disposition of our common stock within the United States or conducted through certain U.S.-related brokers generally will not be subject to backup withholding or information reporting if the applicable withholding agent receives the certification described above and does not have actual knowledge or reason to know that such holder is a United States person or the holder otherwise establishes an exemption. Proceeds of a disposition of our common stock conducted through a non-U.S. office of a non-U.S. broker generally will not be subject to backup withholding or information reporting.

Copies of information returns that are filed with the IRS may also be made available under the provisions of an applicable treaty or agreement to the tax authorities of the country in which the Non-U.S. Holder resides or is established.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against a Non-U.S. Holder's U.S. federal income tax liability, provided the required information is timely furnished to the IRS.

Additional Withholding Tax on Payments Made to Foreign Accounts

Withholding taxes may be imposed under Sections 1471 to 1474 of the Code (such Sections commonly referred to as the Foreign Account Tax Compliance Act, or FATCA) on certain types of payments made to non-U.S. financial institutions and certain other non-U.S. entities. Specifically, a 30% withholding tax may be imposed on dividends on, or (subject to the proposed Treasury Regulations discussed below) gross proceeds from the sale or other disposition of, our common stock paid to a "foreign financial institution" or a "non-financial foreign entity" (each as defined in the Code), unless (1) the foreign financial institution undertakes certain diligence and reporting obligations, (2) the non-financial foreign entity either certifies it does not have any "substantial United States owners" (as defined in the Code) or furnishes identifying information regarding each substantial United States owner, or (3) the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from these rules. If the payee is a foreign financial institution and is subject to the diligence and reporting requirements in (1) above, it must enter into an agreement with the U.S. Department of the Treasury requiring, among other things, that it undertake to identify accounts held by certain "specified United States persons" or "United States owned foreign entities" (each as defined in the Code), annually report certain information about such accounts, and withhold 30% on certain payments to non-compliant foreign financial institutions and certain other account holders. Foreign financial institutions located in jurisdictions that have an intergovernmental agreement with the United States governing FATCA may be subject to different rules.

Under the applicable Treasury Regulations and administrative guidance, withholding under FATCA generally applies to payments of dividends on our common stock. While withholding under FATCA would have applied also to payments of gross proceeds from the sale or other disposition of stock on or after January 1, 2019, proposed Treasury Regulations eliminate FATCA withholding on payments of gross proceeds entirely. Taxpayers generally may rely on these proposed Treasury Regulations until final Treasury Regulations are issued.

Prospective investors should consult their tax advisors regarding the potential application of withholding under FATCA to their investment in our common stock.

UNDERWRITING

ThinkEquity LLC is acting as representative of the underwriters of this offering. Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to each underwriter named below, and each underwriter named below has severally agreed to purchase, at the public offering price less the underwriting discounts set forth on the cover page of this prospectus, the number of shares of common stock listed next to its name in the following table:

Underwriter	Number of Shares
ThinkEquity LLC	
Total	

The underwriters are committed to purchase all shares offered by us other than those covered by the over-allotment option described below, if any are purchased. The obligations of the underwriters may be terminated upon the occurrence of certain events specified in the underwriting agreement. Furthermore, pursuant to the underwriting agreement, the underwriters' obligations are subject to customary conditions, representations and warranties contained in the underwriting agreement, such as receipt by the underwriters of officers' certificates and legal opinions.

The underwriters are offering the shares subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel, and other conditions. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

The underwriters propose to offer the shares offered by us to the public at the public offering price set forth on the cover of the prospectus. After the shares are released for sale to the public, the underwriters may change the offering price and other selling terms at various times.

Over-Allotment Option

We have granted the underwriters an over-allotment option. This option, which is exercisable for up to 45 days after the date of this prospectus, permits the representative to purchase a maximum of additional shares of common stock (15% of the shares sold in this offering) from us to cover over-allotments, if any. If the representative exercises all or part of this option, it will purchase shares covered by the option at the initial public offering price per share that appears on the cover page of this prospectus, less the underwriting discount. If this option is exercised in full, the total offering price to the public will be $13.8 million and the total net proceeds, before expenses, to us will be $12.7 million, assuming an initial public offering price of $5.00 per share (which is the midpoint of the price range set forth on the cover page of this prospectus).

Discount

The following table shows the initial public offering price, underwriting discounts and proceeds, before expenses, to us. The information assumes either no exercise or full exercise by the underwriters of their over-allotment option.

	Per Share	Total Without Over- Allotment Option	Total With Over- Allotment Option
Initial public offering price	$	$	$
Underwriting discount (7.5%)	$	$	$
Proceeds, before expense, to us	$	$	$

We have agreed to pay a non-accountable expense allowance to the underwriters equal to 1.0% of the gross proceeds received in this offering (excluding proceeds received from exercise of the underwriters' over-allotment option).

We have paid an expense deposit of $35,000 to the representative for out-of-pocket-accountable expenses, which will be returned to us to the extent such out-of-pocket accountable expenses are not actually incurred in accordance with FINRA Rule 5110(f)(2)(C).

In addition, we have agreed to reimburse the representative for (i) fees and expenses of legal counsel to the underwriters in an amount not to exceed $125,000; (ii) fees and expenses related to the use of Ipreo's book building, prospectus tracking and compliance software for the offering in the amount of $29,500; (iii) up to $15,000 for background checks of our officers and directors; (iv) all fees, expenses and disbursements relating to the registration, qualification or exemption of such shares under the securities laws of such foreign jurisdictions as the representative may reasonably designate; (iv) all fees, expenses and disbursements relating to the registration, qualification or exemption of such shares under the "blue sky" securities laws of such states, if applicable, and other jurisdictions as the representative may reasonably designate; (v) $10,000 for data services and communications expenses; (vi) $3,000 for the costs associated with bound volumes of the public offering materials as well as commemorative mementos and lucite tombstones; (vii) up to $10,000 for actual accountable "road show" expenses; and (viii) up to $30,000 for market making and trading, and clearing firm settlement expenses for the offering.

We estimate that the total expenses of the offering payable by us, excluding the total underwriting discount and non-accountable expense allowance, will be approximately $1,035,000.

Representative's Warrants

We have agreed to issue to the representative or its designees warrants to purchase up to a total of 96,000 (or 110,400 if the over-allotment option is exercised in full) shares of our common stock (4% of the aggregate number of shares of common stock sold in this offering), or the Representative's Warrants. The Representative's Warrants will be exercisable at a per share exercise price equal to 125% of the public offering price per share of the shares of common stock sold in this offering. The Representative'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 Representative's Warrants and the shares of common stock underlying the Representative's Warrants have been deemed compensation by FINRA and are, therefore, subject to a 180-day lock-up pursuant to FINRA Rule 5110(g)(1). The representative or permitted assignees under such rule may not sell, transfer, assign, pledge, or hypothecate the representative's Warrants or the securities underlying the Representative's Warrants, nor will the representative engage in any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of the Representative's Warrants or the underlying shares of common stock for a period of 180 days from the effective date of the registration statement. Additionally, the Representative's Warrants may not be sold, transferred, assigned, pledged, or hypothecated for a 180-day period following the effective date of the registration statement, except to any underwriter and selected dealer participating in the offering and their bona fide officers or partners. The Representative's Warrants will provide for adjustment in the number and price of the Representative's Warrants and the shares of common stock underlying the Representative's Warrants in the event of recapitalization, merger, stock split, or other structural transaction, or a future financing undertaken by us. The Representative's Warrants will provide for registration rights (including a one-time demand registration right and unlimited piggyback rights) consistent with FINRA Rule 5110.05. The demand for registration may be made at any time beginning on the initial exercise date of the Representative's Warrants and expiring on the fifth anniversary of the effective date of this registration statement in accordance with FINRA Rule 5110(g)(8)(C). In addition to the one-time demand registration right, the Representative's Warrants shall have unlimited piggyback rights, for a period of no more than two years from the initial exercise date of the Representative's Warrants in accordance with FINRA Rule 5110(g)(8)(D). The Representative's Warrants will also provide for customary anti-dilution provisions (for stock dividends and splits and recapitalizations) consistent with FINRA Rule 5110, and further, the number of shares underlying the Representative's Warrants shall be reduced if necessary to comply with FINRA rules and regulations.

Discretionary Accounts

The underwriters do not intend to confirm sales of the securities offered hereby to any accounts over which they have discretionary authority.

Lock-Up Agreements

Each of our directors and officers have agreed, subject to certain exceptions, not to offer, pledge, sell, contract to sell, grant, lend, or otherwise transfer or dispose of, directly or indirectly, or enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of any shares of our capital stock or any securities convertible into or exercisable or exchangeable for shares of our common stock, for a period of twelve (12) months after the date of this prospectus, without the prior written consent of the representative. We, subject to certain exceptions, and all of our other stockholders of 0.5% or more of the outstanding shares of common stock (or securities convertible into shares of common stock, including options and warrants), have agreed, subject to certain exceptions, not offer, pledge, sell, contract to sell, grant, lend, or otherwise transfer or dispose of, directly or indirectly, or enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of any shares of our capital stock or any securities convertible into or exercisable or exchangeable for shares of our common stock, for a period of six (6) months after the date of this prospectus, without the prior written consent of the representative.

We agreed to file a customary universal shelf registration statement on Form S-3 within 30 days of the earlier of (i) the expiration of the restricted period described above and (ii) the date of its initial eligibility to do so. Additionally, we agreed that for a period of twelve (12) months after this offering we will not directly or indirectly in any "at-the-market", continuous equity, equity lines, or variable rate transaction, offer to sell, sell, contract to sell, grant any option to sell or otherwise dispose of shares of our capital stock or any securities convertible into or exercisable or exchangeable for our shares of capital stock, without the prior written consent of ThinkEquity.

Following the expiration of the applicable lock-up period, all of the issued and outstanding shares of our common stock will be eligible for future sale, subject to the applicable volume, manner of sale, holding period, and other limitations of Rule 144.

Right of First Refusal

The Underwriting Agreement will provide that for a period of fifteen (15) months from the closing of the offering, we will grant the representative an irrevocable right of first refusal to act as sole investment banker, sole book-runner, sole financial advisor, sole underwriter and/or sole placement agent, at the representative's sole discretion, for each and every future public and private equity and debt offering, including all equity linked financings, during such fifteen (15) month period for us, or any successor to or any subsidiary of us, on terms customary to the representative. The representative has the sole right to determine whether or not any other broker dealer shall have the right to participate in any such offering and the economic terms of any such participation.

Indemnification

To the extent permitted by law, we have agreed to indemnify the underwriters and its affiliates, stockholders, directors, officers, employees, members and controlling persons against certain liabilities, including liabilities under the Securities Act, and to contribute to payments that the underwriters may be required to make for these liabilities.

Electronic Offer, Sale and Distribution of Shares

A prospectus in electronic format may be made available on the websites maintained by one or more underwriters or selling group members, if any, participating in this offering and one or more of the underwriters participating in this offering may distribute prospectuses electronically. The representative may agree to allocate a number of shares to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the underwriters and selling group members that will make internet distributions on the same basis as other allocations. Other than the prospectus in electronic format, the information on the underwriters' websites is not part of, nor incorporated by reference into, this prospectus or the registration statement of which this prospectus forms a part, has not been approved or endorsed by us or any underwriter in its capacity as underwriter, and should not be relied upon by investors.

Stabilization

In connection with this offering, the underwriters may engage in stabilizing transactions, over-allotment transactions, syndicate-covering transactions, penalty bids and purchases to cover positions created by short sales.

Stabilizing transactions permit bids to purchase securities so long as the stabilizing bids do not exceed a specified maximum and are engaged in for the purpose of preventing or retarding a decline in the market price of the securities while the offering is in progress.

Over-allotment transactions involve sales by the underwriters of securities in excess of the number of securities that underwriters are obligated to purchase. This creates a syndicate short position which may be either a covered short position or a naked short position. In a covered short position, the number of securities over-allotted by the underwriters is not greater than the number of securities that they may purchase in the over-allotment option. In a naked short position, the number of securities involved is greater than the number of securities in the over-allotment option. The underwriters may close out any short position by exercising their over-allotment option and/or purchasing securities in the open market.

Syndicate covering transactions involve purchases of securities in the open market after the distribution has been completed in order to cover syndicate short positions. In determining the source of securities to close out the short position, the underwriters will consider, among other things, the price of securities available for purchase in the open market as compared with the price at which they may purchase securities through exercise of the over-allotment option. If the underwriters sell more securities than could be covered by exercise of the over-allotment option and, therefore, have a naked short position, the position can be closed out only by buying securities in the open market. A naked short position is more likely to be created if the underwriters are concerned that after pricing there could be downward pressure on the price of the securities in the open market that could adversely affect investors who purchase in the offering.

Penalty bids permit the representative to reclaim a selling concession from a syndicate member when the securities originally sold by that syndicate member are purchased in stabilizing or syndicate covering transactions to cover syndicate short positions.

These stabilizing transactions, syndicate covering transactions and penalty bids may have the effect of raising or maintaining the market price of our securities or preventing or retarding a decline in the market price of our securities. As a result, the price of our securities in the open market may be higher than it would otherwise be in the absence of these transactions. Neither we nor the underwriters make any representation or prediction as to the effect that the transactions described above may have on the price of our securities. These transactions may be effected on the NYSE American, in the over-the-counter market or otherwise and, if commenced, may be discontinued at any time.

Passive Market Making

In connection with this offering, underwriters and selling group members may engage in passive market making transactions in our common stock on the NYSE American or on the OTCQB in accordance with Rule 103 of Regulation M under the Exchange Act, during a period before the commencement of offers or sales of the securities and extending through the completion of the distribution. A passive market maker must display its bid at a price not in excess of the highest independent bid of that security. However, if all independent bids are lowered below the passive market maker’s bid, then that bid must then be lowered when specified purchase limits are exceeded.

Other Relationships

Certain of the underwriters and their affiliates 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 may receive customary fees and commissions. However, we have not yet had, and have no present arrangements with any of the underwriters for any further services.

Offer Restrictions Outside the United States

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to this offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

Australia

This prospectus is not a disclosure document under Chapter 6D of the Australian Corporations Act, has not been lodged with the Australian Securities and Investments Commission and does not purport to include the information required of a disclosure document under Chapter 6D of the Australian Corporations Act. Accordingly, (i) the offer of the securities under this prospectus is only made to persons to whom it is lawful to offer the securities without disclosure under Chapter 6D of the Australian Corporations Act under one or more exemptions set out in section 708 of the Australian Corporations Act, (ii) this prospectus is made available in Australia only to those persons as set forth in clause (i) above, and (iii) the offeree must be sent a notice stating in substance that by accepting this offer, the offeree represents that the offeree is such a person as set forth in clause (i) above, and, unless permitted under the Australian Corporations Act, agrees not to sell or offer for sale within Australia any of the securities sold to the offeree within 12 months after its transfer to the offeree under this prospectus.

China

The information in this document does not constitute a public offer of the securities, whether by way of sale or subscription, in the People's Republic of China (excluding, for purposes of this paragraph, Hong Kong Special Administrative Region, Macau Special Administrative Region and Taiwan). The securities may not be offered or sold directly or indirectly in the PRC to legal or natural persons other than directly to "qualified domestic institutional investors."

European Economic Area—Belgium, Germany, Luxembourg and Netherlands

The information in this document has been prepared on the basis that all offers of securities will be made pursuant to an exemption under the Directive 2003/71/EC ("Prospectus Directive"), as implemented in Member States of the European Economic Area (each, a "Relevant Member State"), from the requirement to produce a prospectus for offers of securities.

An offer to the public of securities has not been made, and may not be made, in a Relevant Member State except pursuant to one of the following exemptions under the Prospectus Directive as implemented in that Relevant Member State:

- to legal entities that are authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities;

- to any legal entity that has two or more of (i) an average of at least 250 employees during its last fiscal year; (ii) a total balance sheet of more than €43,000,000 (as shown on its last annual unconsolidated or consolidated financial statements) and (iii) an annual net turnover of more than €50,000,000 (as shown on its last annual unconsolidated or consolidated financial statements);

- to fewer than 100 natural or legal persons (other than qualified investors within the meaning of Article 2(1)(e) of the Prospectus Directive) subject to obtaining the prior consent of the Company or any underwriter 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 the Company of a prospectus pursuant to Article 3 of the Prospectus Directive.

France

This document is not being distributed in the context of a public offering of financial securities (offre au public de titres financiers) in France within the meaning of Article L.411-1 of the French Monetary and Financial Code (Code monétaire et financier) and Articles 211-1 et seq. of the General Regulation of the French Autorité des marchés financiers ("AMF"). The securities have not been offered or sold and will not be offered or sold, directly or indirectly, to the public in France.

This document and any other offering material relating to the securities have not been, and will not be, submitted to the AMF for approval in France and, accordingly, may not be distributed or caused to distributed, directly or indirectly, to the public in France.

Such offers, sales and distributions have been and shall only be made in France to (i) qualified investors (investisseurs qualifiés) acting for their own account, as defined in and in accordance with Articles L.411-2-II-2 and D.411-1 to D.411-3, D. 744-1, D.754-1 and D.764-1 of the French Monetary and Financial Code and any implementing regulation and/or (ii) a restricted number of non-qualified investors (cercle restreint d'investisseurs) acting for their own account, as defined in and in accordance with Articles L.411-2-II-2 and D.411-4, D.744-1, D.754-1 and D.764-1 of the French Monetary and Financial Code and any implementing regulation.

Pursuant to Article 211-3 of the General Regulation of the AMF, investors in France are informed that the securities cannot be distributed (directly or indirectly) to the public by the investors otherwise than in accordance with Articles L.411-1, L.411-2, L.412-1 and L.621-8 to L.621-8-3 of the French Monetary and Financial Code.

Ireland

The information in this document does not constitute a prospectus under any Irish laws or regulations and this document has not been filed with or approved by any Irish regulatory authority as the information has not been prepared in the context of a public offering of securities in Ireland within the meaning of the Irish Prospectus (Directive 2003/71/EC) Regulations 2005 (the "Prospectus Regulations"). The securities have not been offered or sold, and will not be offered, sold or delivered directly or indirectly in Ireland by way of a public offering, except to (i) qualified investors as defined in Regulation 2(l) of the Prospectus Regulations and (ii) fewer than 100 natural or legal persons who are not qualified investors.

Israel

The securities offered by this prospectus have not been approved or disapproved by the Israeli Securities Authority (the ISA), or ISA, nor have such securities been registered for sale in Israel. The shares may not be offered or sold, directly or indirectly, to the public in Israel, absent the publication of a prospectus. The ISA has not issued permits, approvals or licenses in connection with this offering or publishing the prospectus; nor has it authenticated the details included herein, confirmed their reliability or completeness, or rendered an opinion as to the quality of the securities being offered. Any resale in Israel, directly or indirectly, to the public of the securities offered by this prospectus is subject to restrictions on transferability and must be effected only in compliance with the Israeli securities laws and regulations.

Italy

The offering of the securities in the Republic of Italy has not been authorized by the Italian Securities and Exchange Commission (Commissione Nazionale per le Societa e la Borsa, or CONSOB), pursuant to the Italian securities legislation and, accordingly, no offering material relating to the securities may be distributed in Italy and such securities may not be offered or sold in Italy in a public offer within the meaning of Article 1.1(t) of Legislative Decree No. 58 of 24 February 1998 ("Decree No. 58"), other than:

- to Italian qualified investors ("Qualified Investors"), as defined in Article 100 of Decree no. 58 by reference to Article 34-ter of CONSOB Regulation no. 11971 of 14 May 1999, as amended ("Regulation no. 1197l"); and

- in other circumstances that are exempt from the rules on public offer pursuant to Article 100 of Decree No. 58 and Regulation no. 1197l.

Any offer, sale or delivery of the securities or distribution of any offer document relating to the securities in Italy (excluding placements where a Qualified Investor solicits an offer from the issuer) under the paragraphs above must be:

- made by investment firms, banks or financial intermediaries permitted to conduct such activities in Italy in accordance with Legislative Decree No. 385 of 1 September 1993, as amended, Decree No. 58, CONSOB Regulation No. 16190 of 29 October 2007, and any other applicable laws; and

- in compliance with all relevant Italian securities, tax and exchange controls and any other applicable laws.

Any subsequent distribution of the securities in Italy must be made in compliance with the public offer and prospectus requirement rules provided under Decree No. 58 and the Regulation No. 11971 as amended, unless an exception from those rules applies. Failure to comply with such rules may result in the sale of such securities being declared null and void and in the liability of the entity transferring the securities for any damages suffered by the investors.

Japan

The securities have not been and will not be registered under Article 4, paragraph 1 of the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948), as amended (the "FIEL") pursuant to an exemption from the registration requirements applicable to a private placement of securities to Qualified Institutional Investors (as defined in and in accordance with Article 2, paragraph 3 of the FIEL and the regulations promulgated thereunder). Accordingly, the securities may not be offered or sold, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan other than Qualified Institutional Investors. Any Qualified Institutional Investor who acquires securities may not resell them to any person in Japan that is not a Qualified Institutional Investor, and acquisition by any such person of securities is conditional upon the execution of an agreement to that effect.

Portugal

This document is not being distributed in the context of a public offer of financial securities (oferta pública de valores mobiliários) in Portugal, within the meaning of Article 109 of the Portuguese Securities Code (Código dos Valores Mobiliários). The securities have not been offered or sold and will not be offered or sold, directly or indirectly, to the public in Portugal. This document and any other offering material relating to the securities have not been, and will not be, submitted to the Portuguese Securities Market Commission (Comissão do Mercado de Valores Mobiliários) for approval in Portugal and, accordingly, may not be distributed or caused to distributed, directly or indirectly, to the public in Portugal, other than under circumstances that are deemed not to qualify as a public offer under the Portuguese Securities Code. Such offers, sales and distributions of securities in Portugal are limited to persons who are "qualified investors" (as defined in the Portuguese Securities Code). Only such investors may receive this document and they may not distribute it or the information contained in it to any other person.

Sweden

This document has not been, and will not be, registered with or approved by Finansinspektionen (the Swedish Financial Supervisory Authority). Accordingly, this document may not be made available, nor may the securities be offered for sale in Sweden, other than under circumstances that are deemed not to require a prospectus under the Swedish Financial Instruments Trading Act (1991:980) (Sw. lag (1991:980) om handel med finansiella instrument). Any offering of securities in Sweden is limited to persons who are "qualified investors" (as defined in the Financial Instruments Trading Act). Only such investors may receive this document and they may not distribute it or the information contained in it to any other person.

Switzerland

The securities may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange ("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 material relating to the securities may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering material relating to 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).

This document is personal to the recipient only and not for general circulation in Switzerland.

United Arab Emirates

Neither this document nor the securities have been approved, disapproved or passed on in any way by the Central Bank of the United Arab Emirates or any other governmental authority in the United Arab Emirates, nor has the Company received authorization or licensing from the Central Bank of the United Arab Emirates or any other governmental authority in the United Arab Emirates to market or sell the securities within the United Arab Emirates. This document does not constitute and may not be used for the purpose of an offer or invitation. No services relating to the securities, including the receipt of applications and/or the allotment or redemption of such shares, may be rendered within the United Arab Emirates by the Company.

No offer or invitation to subscribe for securities is valid or permitted in the Dubai International Financial Centre.

United Kingdom

Neither the information in this document nor any other document relating to the offer has been delivered for approval to the Financial Services Authority in the United Kingdom and no prospectus (within the meaning of section 85 of the Financial Services and Markets Act 2000, as amended ("FSMA")) has been published or is intended to be published in respect of the securities. This document is issued on a confidential basis to "qualified investors" (within the meaning of section 86(7) of FSMA) in the United Kingdom, and the securities may not be offered or sold in the United Kingdom by means of this document, any accompanying letter or any other document, except in circumstances which do not require the publication of a prospectus pursuant to section 86(1) FSMA. This document should not be distributed, published or reproduced, in whole or in part, nor may its contents be disclosed by recipients to any other person in the United Kingdom.

Any invitation or inducement to engage in investment activity (within the meaning of section 21 of FSMA) received in connection with the issue or sale of the securities has only been communicated or caused to be communicated and will only be communicated or caused to be communicated in the United Kingdom in circumstances in which section 21(1) of FSMA does not apply to the Company. In the United Kingdom, this document is being distributed only to, and is directed at, persons (i) who have professional experience in matters relating to investments falling within Article 19(5) (investment professionals) of the Financial Services and Markets Act 2000 (Financial Promotions) Order 2005 ("FPO"), (ii) who fall within the categories of persons referred to in Article 49(2)(a) to (d) (high net worth companies, unincorporated associations, etc.) of the FPO or (iii) to whom it may otherwise be lawfully communicated (together "relevant persons"). The investments to which this document relates are available only to, and any invitation, offer or agreement to purchase will be engaged in only with, relevant persons. Any person who is not a relevant person should not act or rely on this document or any of its contents.

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 (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 underwriters are not required to comply with the disclosure requirements of NI33-105 regarding underwriter conflicts of interest in connection with this offering.

LEGAL MATTERS

Greenberg Traurig, LLP, Irvine, California, will pass upon the validity of the shares of common stock offered hereby. Venable LLP, New York, New York has acted as counsel for the underwriters in connection with certain legal matters related to this offering.

EXPERTS

The financial statements as of and for the fiscal years ended December 31, 2022 and 2021 included in this prospectus 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.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock offered by this prospectus. This prospectus, which constitutes a part of the registration statement, does not contain all the information set forth in the registration statement, some of which is contained in exhibits to the registration statement as permitted by the rules and regulations of the SEC. For further information with respect to us and our shares of common stock, we refer you to the registration statement, including the exhibits filed as a part of the registration statement. Statements contained in this prospectus concerning the contents of any contract or any other document is not necessarily complete. If a contract or document has been filed as an exhibit to the registration statement, please see the copy of the contract or document that has been filed. Each statement is this prospectus relating to a contract or document filed as an exhibit is qualified in all respects by the filed exhibit. You may read and copy the registration statement, the related exhibits and other material we file with the SEC at the SEC's public reference room in Washington, D.C. at 100 F Street, Room 1580, N.E., Washington, D.C. 20549. You can also request copies of those documents, upon payment of a duplicating fee, by writing to the SEC. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference rooms. The SEC also maintains an Internet website that contains reports, proxy statements and other information about issuers, like us, that file electronically with the SEC. The address of that website is www.sec.gov.

Upon completion of this offering, we will become subject to the information and reporting requirements of the Securities Exchange Act of 1934, as amended, and, in accordance with this law, will be required to file periodic reports, proxy statements and other information with the SEC. These periodic reports, proxy statements and other information will be available on the website of the SEC referred to above. We also maintain a 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. If you are given any information or representations about these matters that is not discussed in this prospectus, you must not rely on that information. This prospectus 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.

AZITRA INC

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
Azitra Inc
Branford, CT

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Azitra Inc (the "Company") as of December 31, 2022 and 2021, and the related statements of operations, stockholders' equity, and cash flows for the years then ended, and the related notes (collectively referred to as the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Substantial Doubt Regarding the Company's Ability to Continue as a Going Concern

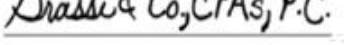
The accompanying financial statements have been prepared assuming that Azitra Inc, will continue as a going concern. As discussed in Note 1 to the financial statements, the Company's significant operating losses raise substantial doubt about its ability to continue as a going concern. Management's evaluation of the events and conditions, and management's plans regarding those matters, are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB and in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.



GRASSI & CO., CPAs, P.C.
We have served as the Company's auditor since 2022.
Jericho, New York
February 20, 2023, except for Note 19, as to which the date is April 10, 2023.

Azitra Inc
Balance Sheets

	December 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	**$ 3,492,656**	$ 8,044,262
Accounts receivable	**182,820**	160,867
Tax credits receivable	**69,666**	173,311
Income tax receivable	**13,722**	-
Deferred offering costs	**216,886**	-
Prepaid expenses	**160,133**	110,289
Total current assets	**4,135,883**	8,488,729
Property and equipment, net	**846,958**	946,681
Other assets		
Other assets	**47,507**	48,201
Operating lease right-of-use asset	**1,116,697**	-
Intangible assets, net	**219,567**	97,693
Deferred patent costs	**800,831**	620,029
Total other assets	**2,184,602**	765,923
Total assets	**$ 7,167,443**	$ 10,201,333
Liabilities, convertible preferred stock, and stockholders' deficit		
Current liabilities:		
Accounts payable	**$ 784,687**	$ 717,800
Current operating lease liability	**287,384**	-
Income tax payable	**-**	1,302
Accrued expenses	**993,961**	475,485
Contract liabilities	**156,000**	15,000
Total current liabilities	**2,222,032**	1,209,587
Long-term operating lease liability	**840,896**	-
Warrant liability	**70,283**	71,104
Convertible notes payable, net	**6,600,000**	992,019
Total liabilities	**9,733,211**	2,272,710
Convertible preferred stock:		
Series A convertible preferred stock; $0.0001 par value; 205,385 shares authorized at December 31, 2022 and 2021; 205,385 shares issued and outstanding at December 31, 2022 and 2021; liquidation value of $3,337,506 as of December 31, 2022 and 2021	**3,272,944**	3,272,944
Series A-1 convertible preferred stock; $0.0001 par value; 380,657 shares authorized at December 31, 2022 and 2021; 380,657 shares issued and outstanding at December 31, 2022 and 2021; liquidation value of $14,274,638 as of December 31, 2022 and 2021	**14,100,533**	14,100,533
Series B convertible preferred stock; $0.0001 par value; 851,108 and 392,000 shares authorized at December 31, 2022 and 2021, respectively; 391,303 shares issued and outstanding at December 31, 2022 and 2021; liquidation value of $17,000,159 as of December 31, 2022 and 2021	**16,321,065**	16,321,065
Stockholders' deficit:		
Common stock; $0.01 par value; 1,950,000 and 1,400,000 authorized at December 31, 2022 and 2021, respectively; 147,041 and 146,916 shares issued and outstanding at December 31, 2022 and 2021, respectively	**1,470**	1,469
Additional paid-in capital	**1,052,772**	866,798
Accumulated deficit	**(37,314,552)**	(26,634,186)
Total stockholders' deficit	**(36,260,310)**	(25,765,919)
Total liabilities, convertible preferred stock, and stockholders' deficit	**$ 7,167,443**	$ 10,201,333

See accompanying notes

Azitra Inc
Statements of Operations

	Years ended December 31,	
	2022	**2021**
Service revenue - related party	**$ 284,000**	$ 110,000
Total revenue	**284,000**	110,000
Operating expenses:		
General and administrative	**3,639,666**	3,951,352
Research and development	**6,097,938**	5,380,102
Total operating expenses	**9,737,604**	9,331,454
Loss from operations	**(9,453,604)**	(9,221,454)
Other income (expense):		
Interest income	**4,818**	8,759
Interest expense	**(251,891)**	(66,968)
Other income	**65,849**	112,141
Employee retention credit	**229,813**	-
Forgiveness of Payroll Protection Program loan	**-**	232,506
Change in fair value of convertible note	**(1,250,000)**	-
Other expense	**(25,351)**	(4,659)
Total other income (expense)	**(1,226,762)**	281,779
Net loss before income taxes	**(10,680,366)**	(8,939,675)
Income tax benefit (expense)	**-**	-
Net loss	**$ (10,680,366)**	$ (8,939,675)
Dividends on preferred stock	**(2,768,984)**	(2,768,984)
Net loss attributable to common shareholders	**$ (13,449,350)**	$ (11,708,659)
Net loss per share, basic and diluted	**$ (90.47)**	$ (79.49)
Weighted average common stock outstanding, basic and diluted	**148,656**	147,291

See accompanying notes

Azitra Inc
Statements of Convertible Preferred Stock and Stockholders' Deficit
For the Years ended December 31, 2022 and 2021

	Series A Convertible Preferred Stock		Series A-1 Convertible Preferred Stock		Series B Convertible Preferred Stock		Common Stock		Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	Deficit
Balance, December 31, 2020	205,385	$ 3,272,944	380,657	$ 14,100,533	391,303	$ 16,321,065	144,416	$ 1,444	$ 552,293	$ (17,694,511)	$ (17,140,774)
Stock-based compensation	-	-	-	-	-	-	-	-	306,055	-	306,055
Exercise of stock options	-	-	-	-	-	-	2,500	25	8,450	-	8,475
Net loss	-	-	-	-	-	-	-	-	-	(8,939,675)	(8,939,675)
Balance, December 31, 2021	**205,385**	**3,272,944**	**380,657**	**14,100,533**	**391,303**	**16,321,065**	**146,916**	**1,469**	**866,798**	**(26,634,186)**	**(25,765,919)**
Stock-based compensation	-	-	-	-	-	-	-	-	**184,465**	-	**184,465**
Exercise of stock options	-	-	-	-	-	-	**125**	**1**	**1,509**	-	**1,510**
Net loss	-	-	-	-	-	-	-	-	-	**(10,680,366)**	**(10,680,366)**
Balance, December 31, 2022	**205,385**	**$ 3,272,944**	**380,657**	**$ 14,100,533**	**391,303**	**$ 16,321,065**	**147,041**	**$ 1,470**	**$ 1,052,772**	**$ (37,314,552)**	**$ (36,260,310)**

See accompanying notes

Azitra Inc
Statements of Cash Flows

	Years Ended December 31,	
	2022	**2021**
Cash flows from operating activities:		
Net loss	**$ (10,680,366)**	$ (8,939,675)
Adjustments to reconcile net loss to net cash and cash equivalents used by operating activities:		
Depreciation and amortization	**125,885**	84,772
Amortization of debt discount	**7,981**	7,632
Amortization of right-of-use assets	**280,092**	-
Accrued interest on convertible notes	**164,611**	59,181
Stock-based compensation	**184,465**	306,055
Change in fair value of warrant liability	**(821)**	(989)
Change in fair value of convertible notes	**1,250,000**	-
Forgiveness of Payroll Protection Program loan	**-**	(230,685)
Loss on disposal of property and equipment	**7,923**	-
Changes in operating assets and liabilities:		
Accounts receivable	**(21,953)**	(37,573)
Prepaid expenses	**(49,844)**	163,952
Other assets	**694**	(919)
Tax credits receivable	**103,645**	231,745
Income tax receivable	**(15,024)**	-
Accounts payable and accrued expenses	**420,752**	282,976
Operating lease liability	**(268,509)**	-
Income tax payable	**-**	(8,831)
Contract liabilities	**141,000**	15,000
Net cash and cash equivalents used by operating activities	**(8,349,469)**	(8,067,359)
Cash flows from investing activities:		
Purchases of property and equipment	**(33,101)**	(446,136)
Proceeds from sale of property and equipment	**4,250**	-
Capitalization of deferred patent costs	**(180,802)**	(196,267)
Capitalization of license	**(65,510)**	-
Capitalization of patent and trademark costs	**(61,598)**	(9,872)
Net cash and cash equivalents used by investing activities	**(336,761)**	(652,275)
Cash flows from financing activities:		
Proceeds from convertible notes, net of issuance costs	**4,350,000**	984,387
Payment of deferred offering costs	**(216,886)**	-
Proceeds from exercise of stock options	**1,510**	8,475
Net cash and cash equivalents provided by financing activities	**4,134,624**	992,862
Net decrease in cash and cash equivalents	**(4,551,606)**	(7,726,772)
Cash and cash equivalents at the beginning of the year	**8,044,262**	15,771,034
Cash and cash equivalents at the end of the year	**$ 3,492,656**	$ 8,044,262

See accompanying notes

1. Organization and Nature of Operations

Azitra Inc was founded on January 2, 2014. It is a synthetic biology company focused on screening and genetically engineering microbes of the skin. The mission is to discover and develop novel therapeutics to create a new paradigm for treating skin disease. The Company's discovery platform is screened for naturally occurring bacterial cells with beneficial effects. These microbes are then genomically sequenced and engineered to make cellular therapies, recombinant therapeutic proteins, peptides and small molecules for precision treatment of dermatology diseases.

The Company maintains a location in Montreal, Canada for certain research activities. This location and operations completed there remained consistent throughout 2021 and 2022. The Company also opened a manufacturing and laboratory space in Groton, Connecticut during 2021.

Going Concern Matters

The financial statements have been prepared on the going concern basis, which assumes that the Company will continue in operation for the foreseeable future and which contemplates the realization of assets and liquidation of liabilities in the normal course of business. However, management has identified the following conditions and events that created an uncertainty about the ability of the Company to continue as a going concern. As of and for the year ended December 31, 2022, the Company has an accumulated deficit of $37.3 million, a loss from operations of $9.5 million and used $8.6 million to fund operations. These factors among others raise substantial doubt about the Company's ability to continue as a going concern.

Management plans to continue to raise funds through equity and debt financing to fund operating and working capital needs, however, the Company will require a significant amount of additional funds to complete the development of its product and to fund additional losses which the Company expects to incur over the next few years. The Company is in an early clinical phase and therefore does not yet have product revenue. In 2022, the Company issued convertible notes resulting in net cash proceeds of $4.4 million (see Note 7). There can be no assurance that the Company will be successful in securing additional financing, if needed, to meet its operating needs.

These conditions and events create an uncertainty about the ability of the Company to continue as a going concern through February 20, 2024 (one year after the date that the financial statements are available to be issued). The financial statements do not include any adjustments that might be necessary should the Company be unable to continue as a going concern.

2. Summary of Significant Accounting Policies

Basis of Accounting

The financial statements of the Company are prepared in accordance with United States generally accepted accounting principles.

Use of Estimates

The preparation of the financial statement in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the balance sheet. While management believes the estimates and assumptions used in the preparation of the financial statement are appropriate, actual results could differ from those estimates.

Cash and Cash Equivalents

For purposes of the balance sheets and statements of cash flows, the Company considers all cash on hand, demand deposits and all highly liquid investments with original maturities of three months or less to be cash equivalents.

Accounts Receivable

The Company carries its accounts receivable at cost less an allowance for doubtful accounts. On a periodic basis, the Company evaluates its accounts receivable and establishes an allowance for doubtful accounts based on a history of past write-offs, collections and current conditions. There was no allowance for doubtful accounts at December 31, 2022 or 2021. Accounts receivable are written off when deemed uncollectible. Recoveries of accounts receivable previously written off are recorded when received.

Deferred offering costs

The Company capitalizes deferred offering costs, which primarily consist of direct, incremental legal, professional, accounting, and other third-party fees relating to the Company's initial public offering. The deferred offering costs will be offset against IPO proceeds upon the consummation of an offering. Should the planned IPO prove to be unsuccessful, these deferred costs, as well as additional expenses to be incurred, will be charged to operations.

Property and Equipment

Property and equipment are recorded at cost. Depreciation is computed using the straight-line method over the estimated useful lives, which range from 3 to 10 years. Expenditures for maintenance and repairs, which do not extend the economic useful life of the related assets, are charged to operations as incurred. Gains or losses on disposal of property and equipment are reflected in the statements of operations in the period of disposal.

2. Summary of Significant Accounting Policies (continued)

Right of Use Assets

In February 2016, the Financial Accounting Standards Board ("FASB") issued ASU No. 2016-02, Leases ("Topic 842"). ASU 2016-02 requires lessees to present right-of-use ("ROU") assets and lease liabilities on the balance sheet for all leases with terms longer than 12 months. See Note 2 – Recently Adopted Accounting Pronouncements.

In calculating the effect of ASU 2016-02, the Company elected the transition method thereby not restating comparable periods. The Company elected to account for non-lease components as part of the lease component to which they relate. Lease accounting involves significant judgments, including making estimates related to the lease term, lease payments, and discount rate. In accordance with the guidance, the Company recognized ROU assets and lease liabilities for all leases with a term greater than 12 months.

The Company has operating leases for buildings. Currently, the Company has 3 operating leases with a ROU asset and lease liability totaling $1,418,502 as of January 1, 2022. The basis, terms and conditions of the leases are determined by the individual agreements. The Company's option to extend certain leases ranges from 36 – 52 months. All options to extend have been included in the calculation of the ROU asset and lease liability. The leases do not contain residual value guarantees, restrictions, or covenants that could incur additional financial obligations to the Company. There are no subleases, sale-leaseback, or related party transactions.

At December 31, 2022, the Company had operating right-of-use assets with a net value of $1,116,697 and current and long-term operating lease liabilities of $287,384 and $840,896, respectively.

Intangible Assets

Intangible assets consist of trademarks and patents. All costs directly related to the filing and prosecution of patent and trademark applications are capitalized. Patents are amortized over their respective remaining useful lives upon formal approval. Trademarks have an indefinite life.

The Company accounts for other indefinite life intangible assets in accordance ASC Topic 350, *Goodwill and Other Intangible Assets* (ASC 350). ASC 350 requires that intangible assets that have indefinite lives are required to be tested at least annually for impairment or whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. Intangible assets that have finite lives will continue to be amortized over their useful lives. No impairment losses relating to intangible assets were recorded in 2022 or 2021.

2. Summary of Significant Accounting Policies (continued)

Deferred Patent Costs

Deferred patent costs represent legal and filing expenses incurred related to the submission of patent applications for patents pending approval. These deferred costs will begin to be amortized over their estimated useful lives upon the formal approval of the patent. If the patent is not approved, the costs associated with the patent will be expensed in the year the patent was rejected. No impairment losses relating to deferred patent costs were recorded in the years ended December 31, 2022 and 2021.

Impairment of Long-Lived Assets

In accordance with ASC Topic 360-10, *Accounting for the Impairment or Disposal of Long-Lived Assets* (ASC 360-10), the Company's policy is to review its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. In connection with this review, the Company also reevaluates the periods of depreciation for these assets. The Company recognizes an impairment loss when the sum of the undiscounted expected future cash flows from the use and eventual disposition of the asset is less than its carrying amount. If an asset is considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the asset exceeds the fair value of the asset, which is determined using the present value of the net future operating cash flows generated by the asset.

Convertible Debt and Warrant Accounting

Warrants

The Company accounts for warrants as either equity-classified or liability-classified instruments based on an assessment of the warrant's specific terms and applicable authoritative guidance in ASC 480, *Distinguishing Liabilities from Equity* ("ASC 480") and ASC 815, *Derivatives and Hedging* ("ASC 815"). The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, meet the definition of a liability pursuant to ASC 480, and whether the warrants meet all of the requirements for equity classification under ASC 815, including whether the warrants are indexed to the Company's own common stock, among other conditions for equity classification. This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance and as of each subsequent quarterly period end date while the warrants are outstanding.

2. Summary of Significant Accounting Policies (continued)

Convertible Debt and Warrant Accounting (continued)

Warrants (continued)

For issued warrants that meet all of the criteria for equity classification, the warrants are required to be recorded as a component of additional paid-in capital at the time of issuance. For issued warrants that do not meet all the criteria for equity classification, the warrants are required to be recorded at their initial fair value on the date of issuance, and each balance sheet date thereafter. Changes in the estimated fair value of the warrants are recognized as a non-cash gain or loss on the statements of operations under Other Income/loss.

Convertible Debt

When the Company issues debt with a conversion feature, it first assesses whether the conversion feature meets the requirements to be accounted for as stock settled debt. If it does not meet those requirements then it is assessed on whether the conversion feature should be bifurcated and treated as a derivative liability, as follows: a) one or more underlyings, typically the price of our common stock; b) one or more notional amounts or payment provisions or both, generally the number of shares upon conversion; c) no initial net investment, which typically excludes the amount borrowed; and d) net settlement provisions, which in the case of convertible debt generally means the stock received upon conversion can be readily sold for cash. An embedded equity-linked component that meets the definition of a derivative does not have to be separated from the host instrument if the component qualifies for the scope exception for certain contracts involving an issuer's own equity. The scope exception applies if the contract is both a) indexed to its own stock; and b) classified in stockholders' equity in its statement of financial position.

Convertible Preferred Stock

As the Convertible Preferred stockholders have liquidation rights in the event of a deemed liquidation event that, in certain situations, are not solely within the control of the Company and would require the redemption of the then-outstanding Convertible Preferred Stock, the Company classifies the Convertible Preferred Stock in mezzanine equity on the balance sheet. Due to the fact that the occurrence of a deemed liquidation event is not currently probable, the carrying value of the Convertible Preferred Stock is not being accreted to its redemption value. Subsequent adjustments to the carrying value of the Convertible Preferred Stock would be made only when a deemed liquidation event becomes probable.

2. Summary of Significant Accounting Policies (continued)

Revenue

The Company follows the five steps to recognize revenue from contracts with customers under ASC *606,* Revenue from Contracts with Customers ("ASC *606"*), which are:

- Step *1:* Identify the contract(s) with a customer
- Step 2: Identify the performance obligations in the contract
- Step *3:* Determine the transaction price
- Step *4:* Allocate the transaction price to the performance obligations in the contract
- Step 5: Recognize revenue when (or as) a performance obligation is satisfied

The Company generates service revenue through a joint development agreement with a research partner. The Company recognizes revenue related to the research and development aspects of the agreement over time using the input method as work is performed on the contract.

The Company also generates grant revenue, which represents monies received on contracts with various federal agencies and nonprofit research institutions for general research conducted by the Company to further their product development and are therefore considered contributions to the Company. The contracts are generally for periods of one year or more and can be cancelled by either party. The Company concluded that the grant arrangements do not meet the criteria to be treated as a collaborative arrangement under FASB ASC Topic 808 as the Company is the only active participant in the arrangement. The grant arrangements also do not meet the criteria for revenue recognition under Topic 606, as the U.S. Government would not meet the definition of a customer.

Amounts earned under these grant contracts are recorded as a negative research & development expense when eligible expenses are incurred and the right to payment is realizable or realized and earn The Company believes this policy is consistent with Topic 606, to ensure that recognition reflects the transfer of promised goods or services to customers in an amount that reflects the consideration that the Company expects to be entitled to in exchange for those goods or services, even though there is no exchange as defined in Topic 606. Additionally, the Company has determined that the recognition of amounts received as costs are incurred and amounts become realizable is analogous to the concept of transfer of control of a service over time under Topic 606.

2. Summary of Significant Accounting Policies (continued)

Revenue (continued)

Receipts of grant awards in advance, which are payable back to the funding agency if not used in accordance with conditions in the grants related to allowable costs or receipt of funding from research partners related to service revenue arrangements before work is performed on the contract are classified as contract liabilities in the accompanying balance sheets.

Research and Development

The Company accounts for research and development costs in accordance with Accounting Standards Codification (ASC) subtopic 730-10, *Research and Development*. Accordingly, internal research and development costs are expensed as incurred. Research and development costs consist of costs related to labor, materials and supplies. Research and development costs incurred were $5,920,538 and $5,380,102 during the years ended 2022 and 2021, respectively.

At December 31, 2022 and 2021, the Company has a state tax credit receivable of $32,459 and $71,396, respectively, for pending refunds related to the selling of research and development tax credits back to the State of Connecticut. At December 31, 2022 and 2021, the Company has $28,925 and $89,855, respectively for pending refunds related to Canadian Scientific Research and Experimental Development credits. At December 31, 2022 and 2021, the Company has also recorded $8,282 and $12,060, respectively, related to refunds of Canadian Goods and Services Tax (GST) and Quebec Sales Tax (QST). Receipts of refunds are recorded in other income on the statements of operations.

Stock-Based Compensation

The Company accounts for stock-based compensation in accordance with ASC 718, *Compensation-Stock Compensation* (ASC 718). ASC 718 requires employee stock options and rights to purchase shares under stock participation plans to be accounted for at fair value. ASC 718 requires that compensation costs related to share-based payment transactions be recognized as operating expenses in the financial statements. Under this method, compensation costs for all awards granted or modified are measured at estimated fair value at date of grant and are included as compensation expense over the vesting period during which an employee provides service in exchange for the award. For awards with a performance condition that affects vesting, the Company recognizes compensation expense when it is determined probable that the performance condition will be achieved.

2. Summary of Significant Accounting Policies (continued)

Stock-Based Compensation (continued)

The Company uses a Black-Scholes option pricing model to determine fair value of its stock options. The Black-Scholes model includes various assumptions, including the value of the underlying common stock, the expected life of stock options, the expected volatility and the expected risk-free interest rate. These assumptions reflect the Company's best estimates, but they involve inherent uncertainties based on market conditions generally outside of the control of the Company. As a result, if other assumptions had been used, stock-based compensation cost could have been materially impacted. Furthermore, if the Company uses different assumptions for future grants, stock-based compensation cost could be materially impacted in future periods.

The Company accounts for equity instruments issued to non-employees in accordance with the provisions of ASC 718 as updated by Accounting Standards Update (ASU) No. 2018-07, *Improvements to Nonemployee Share-Based Payment Accounting*, which expands the scope of ASC 718 to include share based payment transactions to non-employees.

The following assumptions are used in valuing options issued using the Black-Scholes option pricing model:

Expected Volatility. The expected volatility of the Company's shares is estimated based on the Company's external valuation.

Expected Term. The expected term of options is estimated using the simplified method which is based on the vesting period and contractual term for each grant, or for each vesting-tranche for awards with graded vesting.

Underlying Common Stock Value. The underlying common stock value of the Company's shares is estimated by a third party valuation expert.

Risk-free Interest Rate. The Company bases the risk-free interest rate on the implied yield available on a U.S. Treasury note with terms equal to the expected term of the underlying grant.

Dividend Yield. The Black-Scholes valuation model calls for a single expected dividend yield as an input. The Company has not paid dividends on Common stock in the past nor does it expect to pay dividends on Common stock in the near future. As such, the Company uses a dividend yield percentage of zero

2. Summary of Significant Accounting Policies (continued)

Income Taxes

The Company uses the liability method of accounting for income taxes, as set forth in ASC 740, *Accounting for Income Taxes*. Under this method, deferred tax assets and liabilities are recognized for the expected future tax consequence of temporary differences between the carrying amounts and the tax basis of assets and liabilities and net operating loss carry forwards, all calculated using presently enacted tax rates (see Note 13).

Management has evaluated the effect of ASC guidance related to uncertain income tax positions and concluded that the Company has no significant financial statement exposure to uncertain income tax positions at December 31, 2022 and 2021. The Company's income tax returns have not been examined by tax authorities through December 31, 2022. The Company is not currently under audit by any tax jurisdiction.

Fair Value Measurements

The Company carries certain liabilities at fair value on a recurring basis. A fair value hierarchy that consists of three levels is used to prioritize the inputs to fair value valuation techniques:

- Level 1 – Inputs are based upon observable or quoted prices for identical instruments traded in active markets.
- Level 2 – Inputs are based upon quoted prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active, and model-based valuation techniques for which all significant assumptions are observable in the market or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3 – Inputs are generally unobservable and typically reflect management's estimates of assumptions that market participants would use in pricing the asset or liability. The fair values are therefore determined using model-based techniques that include option pricing models, discounted cash flow models, and similar techniques.

In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible as well as considers counterparty credit risk in its assessment of fair value.

2. Summary of Significant Accounting Policies (continued)

Recently Adopted Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2016-02, Leases (Topic 842). This ASU requires a lessee to recognize a right-of-use asset and a lease liability under most operating leases in its balance sheet. The ASU is effective for annual and interim periods beginning after December 15, 2021. The Company adopted ASU 2016-02 on January 1, 2022. See Note 15 – Operating Leases.

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*. This standard simplifies the accounting for income taxes through the removal of various exceptions previously provided, as well as providing additional reporting requirements for income taxes. The ASU is effective for the Company on January 1, 2022. The Company has adopted this standard effective January 1, 2022, which did not have a material impact to the financial statements.

In August 2020, the FASB issued ASU No. 2020-06, *Debt – Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity's Own Equity (Subtopic 815-40)*, which simplifies the accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments and contracts on an entity's own equity. This standard will be effective for the Company on January 1, 2024, with early adoption permitted (but no earlier than fiscal years beginning after December 15, 2020). The Company has adopted this standard effective January 1, 2021, which did not have a material impact to the financial statements.

Management does not believe that any other recently issued, but not yet effective, accounting standards could have a material effect on the accompanying financial statements. As new accounting pronouncements are issued, the Company will adopt those that are applicable under the circumstances.

Financial Instruments

The Company's financial instruments are primarily comprised of accounts receivable, accounts payable, accrued liabilities, and long-term debt. For accounts receivable, accounts payable and accrued liabilities, the carrying amount approximates fair value due to the short term maturities of such instruments. The estimated fair value of the Company's long-term debt approximates carrying value.

3. Employee Retention Credit

The CARES Act provides an employee retention credit ("CARES Employee Retention credit"), which is a refundable tax credit against certain employment taxes of up to $5,000 per employee for eligible employers. The tax credit is equal to 50% of qualified wages paid to employees during a quarter, capped at $10,000 of qualified wages per employee through December 31, 2020. Additional relief provisions were passed by the United States government, which extend and slightly expand the qualified wage caps on these credits through September 30, 2021. Based on these additional provisions, the tax credit is now equal to 70% of qualified wages paid to employees during a quarter, and the limit on qualified wages per employee has been increased to $10,000 of qualified wages per quarter. In April 2022, the Company determined it qualified for the tax credit under the CARES Act and recorded a receivable for $229,813 and recognized the amounts as other income on the statement of operations. The Company received full payment for the amount in September 2022.

4. Property and Equipment

Property and equipment consisted of the following at December 31, 2022 and 2021:

	2022	2021
Lab equipment	**$ 1,034,579**	$ 1,016,737
Computer equipment	**30,825**	30,825
Furniture and fixtures	**24,316**	24,316
Leasehold improvements	**28,855**	28,855
Building equipment	**14,932**	14,932
	1,133,507	1,115,665
Less: accumulated depreciation	**(286,549)**	(168,984)
Net property and equipment	**$ 846,958**	$ 946,681

Depreciation expense was $120,651 and $81,866 for the years ended December 31, 2022 and 2021, respectively.

5. Intangible Assets

Intangible assets consisted of the following at December 31:

2022:

	Estimated Useful Life	Gross Amount	Accumulated Amortization	Net Amount
Trademarks	Indefinite	**$ 53,999**	**$ -**	**$ 53,999**
Patents	17 years	**108,198**	**8,140**	**100,058**
License agreement	17 years	**65,510**	**-**	**65,510**
Intangible assets		**$ 227,707**	**$ 8,140**	**$ 219,567**

2021**:**

	Estimated Useful Life	Gross Amount	Accumulated Amortization	Net Amount
Trademarks	Indefinite	$ 50,955	$ -	$ 50,955
Patents	17 years	49,644	2,906	46,738
Intangible assets		$ 100,599	$ 2,906	$ 97,693

During 2022 and 2021, amortization expense related to intangible assets was $5,234 and $2,906, respectively.

Expected amortization expense is as follows for the years ending December 31:

2023	$ 2,920
2024	2,920
2025	2,920
2026	2,920
2027	2,920
Thereafter	85,456
Total	$ 100,058

6. Accrued Expenses

Accrued expenses consisted of the following at December 31, 2022 and 2021:

	2022	2021
Employee payroll and bonuses	**$ 371,010**	$ 138,671
Vacation	**27,082**	43,473
Research and development projects	316,389	149,711
Interest	**223,792**	59,181
Professional fees	**24,502**	58,892
Other	**31,186**	25,557
	$ 993,961	$ 475,485

The Company accrues expenses related to development activities performed by third parties based on an evaluation of services received and efforts expended pursuant to the terms of the contractual arrangements. Payments under some of these contracts depend on research and non-clinical trial milestones. There may be instances in which payments made to the Company's vendors will exceed the level of services provided and result in a prepayment of expense. In accruing service fees, the Company estimates the period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, the Company will adjust the accrual or prepaid expense accordingly. The Company has not experienced any material differences between accrued costs and actual costs incurred since its inception.

7. Convertible Debt

In September 2022, the Company entered into a Convertible Note Purchase Agreement (the Agreement) to issue up to $4,500,000 convertible promissory notes. On the same day, the Company entered into convertible promissory notes (2022 Convertible Notes) with three investors totaling $4,350,000. The 2022 Convertible Notes mature on January 13, 2023 or the occurrence of an Event of Default (as defined) and bear interest at a rate of 8% per annum which shall accrue but is not due and payable until conversion or full repayment of outstanding principal. The principal and interest outstanding under the 2022 Convertible Notes is automatically converted a) upon the closing of a Qualified Financing resulting in gross proceeds to the Company of at least $20 million into securities issued in connection with the Qualified Financing, at a discount of 30% per share; b) upon the closing of a Change of Control event into shares of capital stock of the Company or Series B preferred stock; and c) upon the closing of a Public Company Event, into shares of capital stock being issued to investors equal to two-times (2x) the amount of the outstanding principal and accrued interest then outstanding divided by the public offering price per share. The principal and interest outstanding under the 2022 Convertible Notes is convertible, at the option of the holders, at the maturity date into a new class of Company's Preferred Stock (Series C Preferred) equal to the quotient of the outstanding principal amount plus interest divided by the Capped Price, which is defined as the price per share equal to the Valuation Cap of $30 million divided by the Company Capitalization, as defined in the Agreement.

The Company accounts for the 2022 Convertible Notes under ASC 815. Under 815-15-25, the election can be at the inception of a financial instrument to account for the instrument under the fair value option under ASC 825. The Company has made such election for the 2022 Convertible Notes. Using the fair value option, the convertible promissory note is to be recorded at its initial fair value on the date of issuance, and each balance sheet date thereafter. The Company evaluates the change based on the conversion price at the current market value. When recognized, changes in the estimated fair value of the notes are recognized as a non-cash gain or loss in Other Income (Expense) on the statements of operations. The Company recognized a change in fair value of the 2022 Convertible Notes of $1,250,000 for the year ended December 31, 2022.

Effective January 5, 2021, the Company entered into a Note Purchase Agreement to issue up to $2,000,000 of convertible promissory notes. On the same date, the Company entered into a convertible promissory note (2021 Convertible Note) with one investor for $1,000,000. The 2021 Convertible Note bears interest at a rate of 6% per annum and is due and payable in full on January 5, 2023. The 2021 Convertible Note automatically converts upon a qualified equity financing, as defined in the note agreement to the number of shares equal to all principal and accrued interest divided by the conversion price of $48.00, which is subject to adjustment as defined in the note agreement. The 2021 Convertible Note is also optionally convertible as defined in the note agreement for certain non-qualified financing, a change in control, or upon the maturity date of the 2021 Convertible Note. The Company incurred issuance costs of $15,613 related to the 2021 Convertible Note, which has been recorded as a debt discount and were amortized over the term of the 2021 Convertible Note. The issuance costs were fully amortized at December 31, 2022.

7. Convertible Debt (continued)

The Company evaluated the terms and conditions of the Note Purchase Agreement related to the 2021 Convertible Note in order to assess the accounting considerations under ASC 480 – Distinguishing Liabilities from Equity, and ASC 815 – Derivatives and Hedging. The Company determined the Convertible Note does not meet any of the criteria to be accounted pursuant to an ASC 480 liability. The Company also assessed the embedded features pursuant to the guidance in ASC 815 and determined the embedded features do not meet any of the criteria for bifurcation.

Convertible notes payable consisted of the following at December 31:

	2022	2021
2021 Convertible Note	**$ 1,000,000**	$ 1,000,000
2022 Convertible Notes	**5,600,000**	-
	6,600,000	1,000,000
Debt issuance costs	**-**	(7,981)
	$ 6,600,000	$ 992,019

There was $7,981 and $7,632 amortized related to the debt issuance costs during the years ended December 31, 2022 and 2021, respectively. Interest accrued on the convertible notes was $223,792 and $59,181 at December 31, 2022 and 2021, respectively.

8. Payroll Protection Program Loan

On April 10, 2020 the Company received a loan in the amount of $230,685 under the Payroll Protection Program (PPP Loan). The loan accrued interest at a rate of 1% and had an original maturity date of two years which could be extended to five years by mutual agreement of the Company and the lender.

Under the requirements of the CARES Act, as amended by the PPP Flexibility Act and Consolidated Appropriations Act, 2021, proceeds could only be used for the Company's eligible payroll costs (with salary capped at $100,000 on an annualized basis for each employee), or other eligible costs related to rent, mortgage interest utilities, covered operations expenditures, covered property damage, covered supplier costs, and covered worker protection expenditures, in each case paid during the 24-week period following disbursement. The PPP Loan could be fully forgiven if (i) proceeds are used to pay eligible payroll costs or other eligible costs and (ii) full-time employee headcount and salaries are either maintained during the 24-week period following disbursement or restored by December 31, 2020.

The Company received notification of full forgiveness of the PPP Loan on January 25, 2021 and has recorded the amount in other income on the statement of operations.

9. Stockholders' Equity

Common Stock

At December 31, 2022 and 2021, respectively, per the Company's amended and restated Certificate of Incorporation, the Company was authorized to issue 1,950,000 and 1,400,000 shares of $0.01 par value common stock.

The Company had 147,041 and 146,916 shares of common stock issued and outstanding as of December 31, 2022 and 2021, respectively.

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders and the holders of the Common Stock are entitled to elect one director of the Corporation.

The Company currently has 1,197,842 shares of common stock reserved for future issuance for the potential conversion of the outstanding Preferred Stock and the exercise of stock options and warrants outstanding at December 31, 2022.

Preferred Stock

At December 31, 2022 and 2021, respectively, per the Company's amended and restated Certificate of Incorporation, the Company has authorized 1,437,150 and 978,042 shares of $0.0001 par value preferred stock.

The Series A, Series A-1, and Series B Preferred Stock have the following rights, preferences and privileges:

Conversion

The preferred stock is convertible, at the option of the holder, into common shares based upon a predefined formula. A holder of preferred stock may convert such shares into common shares at any time. For purpose of conversion, the initial conversion price is $16.25 per share (original issue price) for Series A Preferred Stock, $37.50 per share (original issue price) for Series A-1 Preferred Stock, and $43.45 per share (original issue price) for Series B Preferred Stock, and is subject to adjustment as described in the Certificate of Incorporation. Preferred stock will automatically convert into common shares upon the earlier of (a) an initial public offering with gross proceeds in excess of $100,000,000 or (b) the date and time, or the occurrence of an event, specified by vote or written consent of the required preferred stock shareholders, all outstanding Series A, Series A-1, and Series B Preferred Stock shall automatically convert into common shares, at the then effective conversion rate.

9. Stockholders' Equity (continued)

Preferred Stock (continued)

Voting Rights

The holders of the Series A, Series A-1, and Series B Preferred Stock are entitled to vote on any matter presented to the stockholders of the Corporation for their action or consideration at any meeting of stockholders of the Corporation (or by written consent of stockholders in lieu of meeting), each holder of outstanding shares of preferred stock shall be entitled to cast the number of votes equal to the number of whole shares of Common Stock into which the shares of preferred stock held by such holder are convertible as of the record date for determining stockholders entitled to vote on such matter. The holders of the Series A and Series A-1 Preferred Stock are each entitled to elect one director of the Corporation. The holders of the Series B Stock are entitled to elect two members of the Board. Each class of preferred stock can remove from office such directors and to fill any vacancy caused by the resignation, death or removal of such directors under certain circumstances as described in the Certificate of Incorporation.

Dividends

The holders of Series A Preferred Stock are entitled to receive dividends at a rate of 8% per annum of the Series A original issue price of $16.25 per share on each outstanding share of Series A Preferred Stock (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series A Preferred Stock). Dividends accumulate from the original date of issuance of the Series A Preferred Stock, are cumulative and are payable upon declaration of the Board of Directors or liquidation of the Company. At December 31, 2022, cumulative dividends on Series A Preferred Stock were $1,541,575.

The holders of Series A-1 Stock are entitled to receive dividends at a rate of 8% per annum of the Series A-1 original issue price of $37.50 per share on each outstanding share of Series A-1 (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series A-1 Preferred Stock). Dividends are cumulative and are payable upon declaration of the Board of Directors or liquidation of the Company. At December 31, 2022, cumulative dividends on Series A-1 Preferred Stock were $4,332,153.

The holders of Series B Stock are entitled to receive dividends at a rate of 8% per annum of the Series B original issue price of $43.45 per share on each outstanding share of Series B (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series B Preferred Stock). Dividends are cumulative and are payable upon declaration of the Board of Directors or liquidation of the Company. At December 31, 2022, cumulative dividends on Series B Preferred Stock were $3,135,585.

9. Stockholders' Equity (continued)

Preferred Stock (continued)

Liquidation

In the event of any liquidation, dissolution or winding up of the Company, the holders of the preferred stock are entitled to receive, prior to and in preference to the holders of the common shares, an amount equal to the Series A, Series A-1, or Series B Preferred Stock original issue price, plus declared and/or accrued but unpaid dividends. In the event of any such liquidation event, after the payment of all preferential amounts required to be paid to the holders of shares of preferred stock, the remaining assets of the Corporation available for distribution to its stockholders shall be distributed among the holders of the shares of preferred stock and Common Stock, pro rata based on the number of shares held by each such holder, treating for this purpose all such securities as if they had been converted into Common Stock pursuant to the terms of the Certificate of Incorporation immediately prior to such liquidation event.

10. Warrants

The Company issued warrants to purchase 6,745 shares of common stock in 2018 in conjunction with convertible debt financing that have a redemption provision providing the holder the right to have the Company redeem all or any portion of the warrant (or shares it has converted into) at a purchase price equal to the fair market value of the shares as determined by the board of directors or an independent appraiser. As a result of this redemption provision, the warrants have been classified as a liability in the financial statements based on ASC 480 – Distinguishing Liabilities from Equity. These warrants have an exercise price of $3.39 per share a term of 10 years. The warrants are marked to market each reporting period. The fair value is $70,283 and $71,104 at December 31, 2022 and 2021, respectively. At December 31, 2022, the Company estimated the fair value of the warrants using the Black-Scholes option pricing model with the following assumptions: Underlying common stock value of $12.09; Expected term of 5 years; Expected Volatility of 86.0%; Risk Free Interest Rate of 3.01%; and Dividend Yield of 0%. At December 31, 2021, the Company estimated the fair value of the warrants using the Black-Scholes option pricing model with the following assumptions: Underlying common stock value of $12.09; Expected term of 6 years; Expected Volatility of 86.0%; Risk Free Interest Rate of 1.35%; and Dividend Yield of 0%.

The Company also issued warrants in 2016 and 2019 which did not meet the criteria under ASC 480 to be classified as a liability, and instead meet equity classification criteria.

10. Warrants (continued)

The following table summarizes information about warrants outstanding at December 31, 2022:

		Warrants Outstanding			Warrants Exercisable		
Year Granted	Exercise Price	Number of Warrants at 12/31/2022	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number of Warrants at 12/31/2022	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price
2016	$ 0.01	1,615	3.7 years	$ 0.01	1,615	3.7 years	$ 0.01
2018	$ 3.39	6,745	5.3 years	$ 3.39	6,745	5.3 years	$ 3.36
2019	$ 37.50	30,402	3.1 years	$ 37.50	30,402	3.1 years	$ 37.50
		38,762		$ 30.00	38,762		$ 30.00

11. Stock Options

During 2016, the Company established the Azitra Inc 2016 Stock Incentive Plan (the Plan) which provides for the granting of stock options and restricted shares to the Company's employees, officers, directors, advisors and consultants. There are 209,943 shares available for granting under the Plan at December 31, 2022 and 2021. Options vest over varying time frames.

During the year ended December 31, 2022 and 2021, the Company granted 0 and 69,800, respectively, stock options to acquire shares of common stock. The options vest over varying time frames between two and four years, have a life of ten years and an exercise price of $12.09. During the years ended December 31, 2022 and 2021, the Company recognized stock compensation expense of $184,465 and $306,055, respectively, relating to the issuance of service-based stock options. At December 31, 2022, there was $427,784 of unamortized compensation expense that will be amortized over the remaining vesting period. At December 31, 2022, there were 13,120 performance-based options outstanding with a fair value of $109,551. During the year ended December 31, 2022, the Company did not recognize any compensation expense for performance-based options. The Company determined the options qualified as plain vanilla under the provisions of SAB 107 and the simplified method was used to estimate the expected option life.

To determine the estimated fair value of the options granted during 2021, the Company used the Black-Scholes option pricing model with the following assumptions: Underlying common stock value of $12.09; Expected term of 7 years; Expected Volatility of 86.0%; Risk Free Interest Rate of 0.66% - 1.26%; and Dividend Yield of 0%.

11. Stock Options (continued)

The following table summarizes information about options outstanding and exercisable at December 31, 2022:

	Options Outstanding			Options Exercisable		
Exercise Price	Number of Options at 12/31/2022	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number of Options at 12/31/2022	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price
$ 3.39	34,667	3.0 years	$ 3.39	34,667	3.0 years	$ 3.39
$ 6.58	32,631	3.0 years	$ 6.58	25,776	3.0 years	$ 6.58
$ 12.09	114,437	8.3 years	$ 12.09	64,842	8.0 years	$ 12.09
	181,735			125,285		

Total stock option activity for the years ended December 31, 2022 and 2021 is summarized as follows:

	Shares	Weighted Average Exercise Price
Outstanding at December 31, 2020	135,187	$ 7.90
Granted	69,800	12.09
Exercised	(2,500)	3.39
Forfeited	(7,852)	7.28
Outstanding at December 31, 2021	**194,635**	**$ 9.48**
Exercised	**(125)**	**12.09**
Forfeited	**(12,775)**	**9.98**
Outstanding at December 31, 2022	**181,735**	**$ 9.44**

There are 22,252 shares available for future grant under the Plan at December 31, 2022.

12. Fair Value Measurements

The following tables summarize the fair values and levels within the fair value hierarchy in which the fair value measurements fall for assets and liabilities measured on a recurring basis as of:

December 31, 2022

Description	**Level 1**	**Level 2**	**Level 3**	**Total**
Liabilities:				
Common stock warrants	**$ -**	**$ -**	**$ 70,283**	**$ 70,283**
2022 Convertible Notes	**-**	**-**	**5,600,000**	**5,600,000**
Total	**$ -**	**$ -**	**$ 5,670,283**	**$ 5,670,283**

December 31, 2021

Description	**Level 1**	**Level 2**	**Level 3**	**Total**
Liabilities:				
Common stock warrants	$ -	$ -	$ 71,104	$ 71,104

The following table presents the changes in Level 3 instruments measured on a recurring basis for the years ended December 31, 2022 and 2021:

Balance at January 1, 2021	$ 72,093
Change in fair value of warrants	(989)
Balance at December 31, 2021	**71,104**
Change in fair value of warrants	**(821)**
Issuance of 2022 Convertible Notes	**4,350,000**
Change in fair value of 2022 Convertible Notes	**1,250,000**
	$ 5,670,283

Fluctuation in the fair value of the Company's Common stock is the primary driver for the change in the Common Stock Warrant liability valuation during each year. As the fair value of the Common stock increases the value to the holder of the instrument generally increases.

Fluctuations in the various inputs, including the enterprise value, time to liquidity, volatility, and discount rate are the primary drivers for the changes in valuation of the 2022 Convertible Notes each reporting period. As the fair value of the enterprise value, estimated time to liquidity, volatility, and discount rate increase, the value to the holder of the 2022 Convertible Notes generally increases.

13. Income Taxes

Deferred income taxes are provided on temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and those for income tax reporting purposes. Deferred income tax assets / (liabilities) as of December 31, 2022 and 2021 are as follows:

	2022	2021
Deferred tax assets:		
Net operating loss carryforwards	**$ 7,870,665**	$ 6,994,967
Tax credits	**1,729,421**	1,216,246
Depreciation and amortization	**1,189,975**	
Accrued expenses	**81,876**	48,288
Other	**28,057**	25,240
Total deferred tax assets	**10,899,994**	8,284,741
Deferred tax liabilities:		
Depreciation and amortization	**-**	(234,616)
Total deferred tax liabilities	**-**	(234,616)
Valuation allowance	**(10,899,994)**	(8,050,125)
Net deferred tax (liability) asset	**$ -**	$ -

The Company has federal net operating loss carryforwards of approximately $29,192,000 and $25,954,000 for the tax years ending December 31, 2022 and 2021, respectively, of which $1,285,000 will expire in tax years 2036 through 2037 and approximately $27,907,000 which does not expire. The Company has state net operating loss carryforwards of approximately $29,374,000 and $25,947,000 for the tax years ending December 31, 2022 and 2021, respectively, which will expire in tax years 2036 through 2042.

The Company has federal research tax credits of approximately $1,235,000 and $859,000 for the tax years ending December 31, 2022 and 2021, respectively, which expire in tax years 2039 through 2042. The Company has state research tax credits of approximately $350,000 and $249,000 for the tax years ending December 31, 2022 and 2021, respectively, of which $96,000 will expire in tax year 2036, $100,000 will expire in tax year 2037 and the remainder can be carried forward indefinitely. The Company has Canadian research tax credits of approximately $218,000 and $138,000 for the tax years ending December 31, 2022 and 2021, respectively, which expire in tax years 2039 through 2042.

13. Income Taxes (continued)

The U.S. Internal Revenue Code Section 382 imposes an annual limit on the ability of a corporation that undergoes a greater than 50% ownership change to use its net operating loss carry forwards to reduce its tax liability. If in the future the Company undergoes an ownership change exceeding the 50% limitation threshold imposed by Section 382, the Company's net operating loss carryforwards may be significantly limited as to the amount of use in a particular year. In addition, all or a portion of the Company's net operating loss carryforwards incurred before 2018, may expire unutilized.

The realization of deferred tax assets is dependent upon the Company's ability to generate future taxable income during the periods in which the temporary differences become deductible. Based on the Company's recent earnings history and projected future U.S. earnings, management believes that it is more likely than not that its federal and state deferred tax assets will not be fully realized in the foreseeable future. As a result of this assessment, management believes that a full valuation allowance against its net federal and state deferred tax assets is required.

The Company applies the provisions of ASC 740-10 to account for uncertain tax positions. ASC 740-10 addresses the determination of whether tax benefits claimed or expected to be claimed on a tax return should be recorded in the financial statements. Under ASC 740-10, the Company may recognize the tax benefit from an uncertain tax position only if it is more likely that not that the tax position will be sustained on examination by the taxing authorities, based on the technical merits of the position. The Company has determined that it has no significant uncertain tax positions requiring recognition and measurement under ASC 740-10.

The Company is subject to U.S. federal income tax, Connecticut state income tax and Canada branch tax. The Company has not been audited by the IRS, state, or foreign tax authorities in connection with income taxes. The Company's tax years remain open to examination for all federal and state tax matters until its net operating loss carryforwards are utilized and the applicable statute of limitations have expired.

The Company will recognize interest and penalties related to unrecognized tax benefits, if applicable, as a component of income tax expense.

14. Net Loss Per Share

Basic and diluted net loss per share were calculated as follows:

The numerator for basic and diluted net loss per share is as follows:

	For the Year Ended December 31,	
	2022	**2021**
Net loss	**$ 10,680,366**	$ 8,939,675
Dividends on preferred stock	**2,768,984**	2,768,984
Net loss attributable to common shareholders	**$ 13,449,350**	$ 11,708,659

The denominator is as follows:

	For the Year Ended December 31,	
	2022	**2021**
Weighted average common stock outstanding, basic and diluted	**147,041**	145,676
$0.01 warrants	**1,615**	1,615
Total	**148,656**	147,291

Net loss per share, basic and diluted is as follows:

	For the Year Ended December 31,	
	2022	**2021**
Net loss per share, basic and diluted	**$ (90.47)**	$ (79.49)

14. Net Loss Per Share (continued)

The following potential common stock equivalents, presented based on amounts outstanding at each period end, were excluded from the calculation of diluted net loss per share for the periods indicated because including them would have had an anti-dilutive effect:

	December 31,	
	2022	**2021**
Options to purchase shares of common stock	**181,735**	194,635
Warrants outstanding	**37,147**	37,147
	218,882	231,782

15. Commitments and Contingencies

Legal

The Company is subject to legal proceedings or claims which arise in the ordinary course of its business. Although occasional adverse decisions or settlements may occur, the Company believes that the final disposition of such matters should not have a material adverse effect on its financial position, results of operations or liquidity.

License Agreement

Effective January 26, 2022, the Company entered into an Exclusive License Agreement (the Agreement) with an unrelated third party. Under the Agreement, the Company is granted an exclusive license for certain patents and a non-exclusive license for certain know-how. The Agreement continues until the later of the expiration of the last to expire licensed patent or ten years after the first commercial sale of the first licensed therapeutic or non-therapeutic product. The Company may terminate the Agreement at any time by providing at least 30 days written notice to the third party. The Agreement is also terminated upon breach of a material obligation under the agreement or bankruptcy. Upon any termination of the agreement, neither party is relieved of obligations incurred prior to the termination.

During the year ended December 31, 2022, the Company capitalized payments made under this license agreement in the amount of $65,510. These capitalized costs will be amortized over the life of the licensed patents, once issued.

Operating Leases

The Company leases office and lab space in Branford, CT; Groton, CT; and Laval, Quebec. The Company’s leases expire at various dates through May 31, 2027. Most leases are for a fixed term and for a fixed amount. The Company is not a party to any leases that have step rent provisions, escalation clauses, capital improvement funding or payment increases based on any index or rate.

15. Commitments and Contingencies (continued)

Operating Leases (continued)

During 2020, the Company entered into a new lease agreement for the Company's primary office and laboratory space in Branford, CT. The Branford lease requires monthly payments of $13,033 for the first year of the lease, which increases approximately 2% in each of the following years. The Branford lease also requires the Company to pay a pro-rata share of common area maintenance.

During May 2021, the Company entered into a new lease for office and laboratory space in Groton, CT. The Groton lease required monthly payments of $4,234, which was increased to $6,824 in September 2021 upon leasing additional space. The Groton lease is initially for a one-year term, with up to three additional years renewal available.

Future minimum payments under non-cancelable operating leases with initial or remaining terms in excess of one year during each of the next five years follow:

2023	$	329,937
2024		335,988
2025		277,209
2026		204,159
2027		76,324
Total future undiscounted lease payments		1,223,617
Less: interest		(95,337)
Present value of lease liabilities	$	1,128,280

Rent expense for all operating leases was $338,864 for the year ended December 31, 2022. The weighted average lease term for all operating leases is 3.8 years. The weighted average discount rate for all operating leases is 4.25%.

16. Retirement Plan

Effective January 1, 2019, the Company sponsors a 401(k) plan that covers substantially all employees. In order to be eligible to participate, an employee must complete two consecutive months of service and work a minimum of two hundred and fifty hours or work 1,000 hours in their first year of service. Employees may make pre-tax deferrals upon meeting the Plan eligibility requirements. Effective January 1, 2020, the Plan was transitioned to a safe harbor plan in which highly compensated employees are not eligible for matching contributions and non-highly compensated employees earn 100% match on first 3% contributed and 50% on the next 2% contributed. Total employer matching contributions were $23,466 and $31,548 for the years ended December 31, 2022 and 2021, respectively.

17. Concentration of Credit Risk

Financial instruments that potentially subject the Company to credit risk consist principally of cash and accounts receivable.

For the years ended December 31, 2022 and 2021, all grant revenue was from one grantor and three grantors, respectively, and all service revenue was from one customer for both years.

The cash balance identified in the balance sheet is held in an account with a financial institution and insured by the Federal Deposit Insurance Corporation (FDIC) up to $250,000. At times, cash maintained on deposit may be in excess of FDIC limits.

In early March 2020, there was a global outbreak of COVID-19 that has resulted in significant changes in the global economy. While the Company has not experienced any disruptions to its business operations to date, these changes, including a potential economic downturn, and any potential resulting direct or indirect negative impact to the Company cannot be determined, however they could have a prospective material impact to the Company's business, cash flows and liquidity.

18. Related Parties

The Company earned service revenue from an entity who was also an investor in the Company's Series B Preferred Stock financing (see Note 9). Total related party revenue was $284,000 and $110,000 for the years ended December 31, 2022 and 2021, respectively and accounts receivable due from the related party was $175,000 and $125,000 at December 31, 2022 and 2021, respectively. Contract liabilities from the related party were $156,000 and $15,000 at December 31, 2022 and 2021, respectively.

In September 2022 the Company entered into a convertible promissory note totaling $4,350,000 of which $4,000,000 was attributable to an entity who was also an investor in the Company's Series A, A-1, and B Preferred Stock financing. (See Note 7)

19. Subsequent Events

The Company has evaluated events occurring between December 31, 2022 and April 10, 2023, the date the financial statements were available to be issued.

In January 2023, the Company elected to convert the 2021 Convertible Note (see Note 7), including interest accrued but not yet paid of $120,058 at a conversion price of $48.00 into 23,335 shares of its Series B Preferred Stock in accordance with the terms outlined in the Note Purchase Agreement.

In February 2023, the 2022 Convertible Notes were amended to extend the maturity date to March 31, 2023 and to change the conversion price upon a Qualified Financing or Change in Control event to $30 million divided by the number of shares of the Company's common stock issued and outstanding, on a fully diluted basis, immediately prior to the close of the Qualified Financing or Change in Control event.

In March 2023, the Company's Board of Directors and stockholders approved the 2023 Stock Incentive Plan ("2023 Plan"); however, no grants shall be made until the date which the proposed forward stock split and increase in the authorized shares of common stock becomes effective which is expected to occur upon the effectiveness of our registration statement of which this prospectus forms a part. The 2023 Plan allows the Committee to grant up to 2,000,000 shares of Common Stock in the form of incentive and non-statutory stock options, restricted stock awards, restricted stock units, and other stock-based awards to employees, directors, and non-employees. As of March 20, 2023, there were no awards issued under the 2023 Plan.

Upon the effectiveness of the registration statement of which this prospectus forms a part, we will effect a forward stock split at a ratio of 7.1-for-1. These audited financial statements have not been adjusted to give effect to the forward stock split.

2,400,000 Shares of Common Stock

Azitra Inc

PRELIMINARY PROSPECTUS

ThinkEquity

, 2023

Through and including , 2023 (the 25th day after the date of this offering), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

PART II - INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution

The following table sets forth the various expenses to be incurred in connection with the sale and distribution of our common stock being registered hereby, all of which will be borne by us (except any underwriting discounts and commissions and expenses incurred for brokerage, accounting, tax or legal services or any other expenses incurred in disposing of the shares). All amounts are estimated except the SEC registration fee, the FINRA filing fee and the NYSE American filing fee.

SEC Registration Fee	$	2,661
FINRA Filing Fee		5,000
Non-Accountable Expenses to Underwriters		225,000
Initial NYSE American Listing Fee		35,000
Printing and Engraving Expenses		25,000
Accounting Fees and Expenses		200,000
Legal Fees and Expenses		650,000
Transfer Agent's and Registrar's Fees and Expenses		5,000
Miscellaneous Fees		7,339
Total	$	1,155,000

Item 14. Indemnification of Directors and Officers

The following summary is qualified in its entirety by reference to the complete text of any statutes referred to below and the amended and restated certificate of incorporation of Azitra Inc, a Delaware corporation.

Section 145 of the General Corporation Law of the State of Delaware (the "DGCL") permits a Delaware corporation to indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of the corporation) by reason of the fact that the person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by the person in connection with such action, suit or proceeding if the person acted in good faith and in a manner the person reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe the person's conduct was unlawful.

In the case of an action by or in the right of the corporation, Section 145 of the DGCL permits a Delaware corporation to indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action or suit by reason of the fact that the person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees) actually and reasonably incurred by the person in connection with such action, suit or proceeding if the person acted in good faith and in a manner the person reasonably believed to be in or not opposed to the best interests of the corporation and except that no indemnification shall be made in respect of any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or the court in which such action or suit was brought shall determine upon application that, despite the adjudication of liability but in view of all the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses that the Court of Chancery or such other court shall deem proper.

Section 145 of the DGCL also permits a Delaware corporation to purchase and maintain insurance on behalf of any person who is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against any liability asserted against such person and incurred by such person in any such capacity, or arising out of such person's status as such, whether or not the corporation would have the power to indemnify such person against such liability under Section 145 of the DGCL.

Our Amended and Restated Certificate of Incorporation to be adopted following the completion of this offering will state that to the fullest extent permitted by the DGCL our directors shall not be personally liable to us or to our stockholders for monetary damages for breach of fiduciary duty as a director. If the DGCL is amended after the date hereof to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of our directors shall be eliminated or limited to the fullest extent permitted by the DGCL, as so amended.

Our Amended and Restated Certificate of Incorporation to be adopted following the completion of this offering shall require us, to the fullest extent permitted by applicable law, to provide indemnification of (and advancement of expenses to) our directors and officers, and authorizes us, to the fullest extent permitted by applicable law, to provide indemnification of (and advancement of expenses to) to other employees and agents (and any other persons to which the DGCL permits us to provide indemnification) through bylaw provisions, agreements with such directors, officers, employees, agents or other persons, vote of stockholders or disinterested directors or otherwise, subject only to limits created by the DGCL with respect to actions for breach of duty to our corporation, our stockholders and others.

Our Amended and Restated Certificate of Incorporation to be adopted following the completion of this offering shall also provide that we shall, to the maximum extent and in the manner permitted by the DGCL, indemnify each of our directors, officers and all other persons we have the power to indemnify under Section 145 of the DGCL against expenses (including attorneys' fees), judgments, fines, settlements and other amounts actually and reasonably incurred in connection with any proceeding, arising by reason of the fact that such person is or was a director of the Company. We may maintain insurance, at our expense, to protect the Company and any of our directors, officers, employees or agents against any such expense, liability or loss, whether or not we have the power to indemnify such person.

Prior to the closing of this offering, we expect to enter into indemnification agreements with each of our directors and executive officers that may be broader than the specific indemnification provisions contained in the DGCL. These indemnification agreements will require us, among other things, to indemnify our directors and executive officers against liabilities that may arise by reason of their status or service. These indemnification agreements will also require us to advance all expenses incurred by the directors and executive officers in investigating or defending any such action, suit, or proceeding. We believe that these agreements are necessary to attract and retain qualified individuals to serve as directors and executive officers.

Prior to the closing of this offering, we plan to enter into an underwriting agreement, which will provide that the underwriters are obligated, under some circumstances, to indemnify our directors, officers and controlling persons against specified liabilities.

Item 15. Recent Sales of Unregistered Securities

Issuances of capital stock

The following list sets forth information regarding all unregistered securities sold by us over the three year period preceding the date of the prospectus that forms a part of this registration statement.

In September 2020, we conducted the placement of 392,000 shares of our Series B convertible preferred stock, at a price of $43.45 per share, to eight investors. Our Series B convertible preferred stock which will convert into 2,778,251 shares of our common stock upon the consummation of this offering.

In January 2022, we sold to one investor an unsecured convertible promissory note in the principal amount of $1,000,000. In January 2023, the principal amount of the note, along with all accrued interest, was converted into 23,432 shares of our Series B convertible preferred stock.

In September 2022, we conducted the placement of our unsecured convertible promissory notes in the aggregate principal amount of $4.35 million to five investors. The principal amount of the notes, along with all accrued and unpaid interest thereunder, is convertible into shares of our common at the conversion price of 50% of the initial public offering price.

We believe the offers, sales and issuances of the above securities by us were exempt from registration under the Securities Act by virtue of Section 4(a)(2) of the Securities Act and Rule 506 thereunder as transactions not involving a public offering. All of the investors were accredited investors as such term is defined in Rule 501 under the Securities Act. The recipients of the securities in each of these transactions represented their intentions to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were placed upon the stock certificates, notes and warrants issued in these transactions. All recipients had adequate access, through their relationships with us, to information about our Company. The sales of these securities were made without any general solicitation or advertising.

Item 16. Exhibits and Financial Statement Schedules.

(a) Exhibits.

Exhibit No.	Description of Document
1.1**	Form of Underwriting Agreement (including the form of Lock-Up Agreement).
3.1*	Amended and Restated Certificate of Incorporation of the Registrant.
3.2*	Certificate of Amendment to Amended and Restated Certificate of Incorporation of the Registrant.
3.3*	Form of Second Amended and Restated Certificate of Incorporation of the Registrant to be in effect upon completion of the offering.
3.4*	Amended and Restated Bylaws of the Registrant.
3.5*	Form of Second Amended and Restated Bylaws of the Registrant to be in effect upon completion of the offering.
4.1**	Specimen Certificate representing shares of Common Stock.
4.2*	Form of Warrant.
4.3**	Form of Representative's Warrant (included in Exhibit 1.1).
5.1**	Opinion of Greenberg Traurig, LLP.
10.1+*	Form of Indemnity Agreement between the Registrant and each of its directors and executive officers.
10.2+*	Azitra Inc 2016 Stock Incentive Plan.
10.3*	Second Amended and Restated Investors' Rights Agreement dated September 10, 2020 between the Registrant and each of the investors named therein.
10.4+*	Executive Employment Agreement dated April 22, 2021 between the Registrant and Francisco D. Salva.
10.5+*	Azitra Inc 2023 Stock Incentive Plan.
21.1*	List of Subsidiaries of the Registrant.
23.1**	Consent of Greenberg Traurig, LLP (included in Exhibit 5.1).
23.2	Consent of Grassi & Co., CPAs, P.C., Independent Registered Public Accounting Firm.
24.1*	Power of Attorney.
99.1*	Consents of Director Nominees.
107*	Filing Fee Table.

* Previously filed.
** To be filed by amendment.
\+ Indicates management compensatory plan, contract or arrangement.

(b) Financial Statement Schedules.

All schedules have been omitted because they are not required or are not applicable.

Item 17. Undertakings

The undersigned registrant hereby undertakes to provide to the underwriter at the closing specified in the underwriting agreements, certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned registrant undertakes that:

(1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus as filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Branford, State of Connecticut on April 10, 2023.

AZITRA INC

/s/ Francisco D. Salva
Francisco D. Salva
Chief Executive Officer and Director

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Francisco D. Salva Francisco D. Salva	President, Chief Executive Officer and Director *(Principal Executive Officer)*	April 10, 2023
/s/ Norman Staskey Norman Staskey	Chief Financial Officer, Treasurer and Secretary *(Principal Financial and Accounting Officer)*	April 10, 2023
* Travis Whitfill	Director	April 10, 2023
* Andrew McClary	Director	April 10, 2023

By:/s/ Francisco D. Salva*
Francisco D. Salva
Attorney-in Fact

Exhibit 23.2

GRASSI
ADVISORS & ACCOUNTANTS

Consent of Independent Registered Public Accounting Firm

We hereby consent to the inclusion in this Registration Statement on Form S-1 of our report dated February 20, 2023, except for Note 19, as to which the date is April 10, 2023, which includes an explanatory paragraph as to the Company's ability to continue as a going concern, relating to the financial statements of Azitra Inc as of and for the years ended December 31, 2022 and 2021. We also consent to the reference to our firm under the heading "Experts" appearing therein.

/s/ Grassi & Co., CPAs, P.C.
Grassi & Co., CPAs, P.C.

Jericho, New York
April 10, 2023

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