# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# FORM S-1

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

## **AZITRA INC**

(I	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)
(Address, including zip code, and	21 Business Park Drive Branford, CT 06405 (203) 646-6446 I telephone number, including area code,	, of registrant's principal executive offices)
(Name, address, including	Francisco D. Salva President and Chief Executive Of Azitra Inc 21 Business Park Drive Branford, CT 06405 (203) 646-6446 g zip code, and telephone number, include	
Daniel K. Donahue, Esq. Greenberg Traurig, LLP 18565 Jamboree Road, Suite 5 Irvine, California 92612 (949) 732-6557	Copies to:	William N. Haddad, Esq. Arif Soto, Esq. Venable LLP 1270 Avenue of the Americas, 24 <sup>th</sup> Floor New York, New York 10020 (212) 307-5500
Approximate date of commencement of propo	sed sale to the public: As soon as pract	icable after this Registration Statement becomes effective.
If any of the securities being registered on this F of 1933 check the following box. $\Box$	Form are to be offered on a delayed or c	ontinuous basis pursuant to Rule 415 under the Securities Act
If this Form is filed to register additional securit and list the Securities Act registration statement number		2(b) under the Securities Act, please check the following box atement for the same offering. $\Box$
If this Form is a post-effective amendment filed registration statement number of the earlier effective		urities Act, check the following box and list the Securities Act ing. $\Box$
If this Form is a post-effective amendment filed registration statement number of the earlier effective		urities Act, check the following box and list the Securities Act ing. $\Box$
		filer, a non-accelerated filer, smaller reporting company, or an filer," "smaller reporting company," and "emerging growth
Large accelerated filer $\square$		Accelerated filer $\square$
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.  $\Box$ 

	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 DECEMBER , 2022

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 \$\text{ and \$\text{ }}.

We have applied to have our common stock listed on the , under the symbol " ."

Investing in our common stock involves a high degree of risk. See the section titled "<u>Risk Factors</u>" 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 <sup>(1)</sup>	\$	\$
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 allotments, if any.

additional shares of common stock solely to cover over-

The underwriters expect to deliver the shares to purchasers on or about, 2022.

# **ThinkEquity**

The date of this prospectus is

2022

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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, and its consolidated subsidiaries.

#### 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.

On , 2022, we effected a -for-1 forward split of our common stock. All historical share amounts and share price information presented in this prospectus have been proportionally adjusted to reflect the impact of this forward stock split.

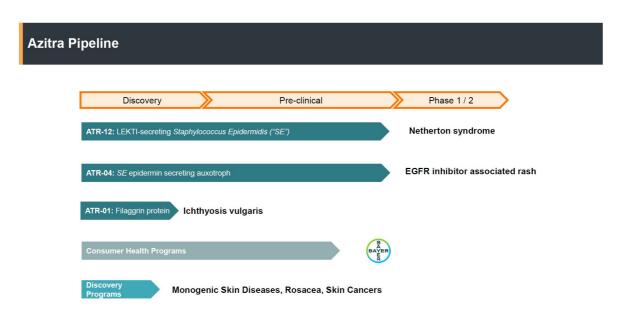
#### **Our Company**

We are a preclinical 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 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 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 United States Food and Drug Administration, or FDA, in 2019. We are planning to submit an investigational new drug application, or IND, for a Phase 1/2 clinical trial of ATR-12 in Netherton syndrome patients in the fourth quarter of 2022. Subject to FDA approval of our IND, we expect to commence our Phase 1/2 clinical trial in the first half of 2023 and report initial results as early as 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 1/2 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 1/2 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 *S. epidermidis* 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 *S. epidermidis* 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.



- Proprietary platform has generated multiple candidates for precision dermatology treatments
- Discovery efforts harness the promise of genomic sequencing by leveraging artificial intelligence and machine learning

We also have established partnerships with teams from Carnegie Mellon University and the Fred Hutchison Cancer Center, or FHCC, 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 FHCC 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. Our collaboration with FHCC 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 *S. epidermidis* strains for oleogel 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. Bayer has an option to acquire the exclusive license rights for period of six month 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. We intend to file an IND for a first-in-human trial of ATR-12 in Netherton syndrome patients. Our IND proposes a combined Phase1b/2a clinical study of ATR-12 in patients with Netherton syndrome, with initial results expected in the second half of 2023. We also plan to conduct a Phase 1/2 trial of our ATR-04 in certain cancer patients undergoing EGFRi therapy. We expect to file an IND for ATR-12 by the end of 2022 and 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 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 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 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. This product candidate represents a potential \$250 million global sales opportunity. 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 TM, but such references should not be construed as any indication that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto.

#### **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 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 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 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, is convertible into shares of our common at \$ per share, which will convert into approximately shares of our common stock upon the consummation of this offering; 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 conversion price of 50% of the initial public offering price, which will convert into approximately offering at an assumed initial public offering price of \$ per share (which is the midpoint of the price range set forth on the cover page of this prospectus).

Except as otherwise indicated, all information in this prospectus concerning our outstanding share of common stock assumes the automatic conversion of the above-described shares of convertible preferred stock and convertible notes, collectively referred to as the Convertible Securities, into a total of approximately shares of our common stock upon the consummation of this offering at an assumed initial public offering price of per share.

#### **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	shares
Common stock to be outstanding after this offering	shares (or shares if the underwriters' option to purchase additional shares is exercised in full) of common stock.
Offering Price	\$ per share.
Over-allotment option	We have granted the underwriters the option to purchase up to an additional 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 \$ million from our sale of common stock in this offering, or approximately \$ million if the underwriters exercise their over-allotment option in full. 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 theunder the symbol " ."
Risk factors	Investing in our common stock involves a high degree of risk. See the section titled " <i>Risk Factors</i> " 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 officers, directors, 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 6 months or 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 shares of our common stock outstanding as of December, 2022 (including the conversion of our shares of convertible preferred stock and convertible promissory notes described above), and excludes:

- shares of our common stock issuable upon exercise of outstanding options, with a weighted average exercise price of \$ per share, granted pursuant to our 2016 Stock Incentive Plan, or the 2016 Plan;
- approximately shares of our common stock issuable upon exercise of outstanding warrants, with a weighted average exercise price of \$ per share
- up to shares issuable pursuant to the underwriters' over-allotment option;
- 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 shares if the over-allotment option is exercised) at an exercise price of \$ per share; and
- shares of our common stock reserved for future grants under our 2016 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 a preclinical 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, 2021 and 2020 is derived from the audited financial statements that are included elsewhere in this prospectus. The financial information as of and for the nine months ended September 30, 2022 and 2021 is derived from our unaudited condensed financial statements that are included elsewhere in this prospectus. The unaudited condensed financial statements were prepared on a basis consistent with our audited financial statements and include, in management's opinion, all adjustments, consisting only of normal recurring adjustments that we consider necessary for a fair presentation of the financial information set forth in those statements. Our historical results are not necessarily indicative of the results that may be expected in the future, and our interim results are not necessarily indicative of the results to be expected for the full year or any other period.

	Years Ended December 31,			Nine Months Ended September 30,		
(in thousands)		2021	2020		2022	2021
					(unaudited)	_
Revenues	\$	110	425	\$	254	-
Net loss	\$	(8,940)	(6,811)	\$	(6,634)	(7,031)

		-	mber 30, 022
(in thousands)	 Actual (unaudited)		Pro Forma as orma (1)  udited)  Adjusted(2)  (unaudited)
Balance Sheet Data:			
Cash and cash equivalents	\$ 5,938	\$	\$
Working capital	\$ 4,701	\$	\$
Total assets	\$ 9,351	\$	\$
Convertible notes payable	\$ 5,348	\$	\$
Convertible preferred stock	\$ (33,695)	\$	\$
Total common stock	\$ 1	\$	\$
Additional paid-in capital	\$ 1,023	\$	\$
Total stockholders' equity (deficit)	\$ (32,243)	\$	\$

- (1) The pro forma column reflects the (i) automatic conversion of all of our outstanding shares of convertible preferred stock at the close of this offering into shares of our common stock and reclassification into common stock, and (ii) automatic conversion of all principal and accrued and unpaid interest under our outstanding convertible promissory notes at the close of this offering into approximately shares of our common stock and additional paid-in capital.
- (2) The pro forma as adjusted column reflects all adjustments included in the pro forma column and gives effect to the sale by us of common stock offered by this prospectus at the public offering price of \$ , less estimated offering expenses of \$ .

#### 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 a preclinical biopharmaceutical company with limited operating history.

We are a preclinical 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 a preclinical 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 preclinical-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 year ended December 31, 2021 and for the nine months ended September 30, 2022, we incurred a net loss of \$8.9 million and \$6.6 million, respectively. As of September 30, 2022, we had an accumulated deficit of \$33.3 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 months 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, 2021 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 September 30, 2022, we had total assets of \$9.4 million and working capital of \$4.7 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 the commencement of our Phase 1/2 clinical trial for ATR-12 and the filing of an IND 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 Phase 1/2 clinical trials of our ATR-12 and ATR-04 product candidates in the first half of 2023 and the first half of 2024, respectively. 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 ongoing Phase 1/2 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 1/2 clinical trial for ATR-12 in the first half of 2023 and file an IND for 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 1/2 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 1/2 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, manufacturer, 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.

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. We have not submitted an IND to the FDA, nor an application to any comparable foreign regulatory authority, for any of our product candidates, which is the means by which drug companies obtain approval to initiate clinical trials in humans in the United States or other countries. As of the date of this prospectus, we plan on submitting our IND for ATR-12 in late 2022 and our IND for ATR-04 by the end of 2023; however, there can be no assurance we will be able to submit the INDs in those timeframes. 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 throug

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 \_\_\_\_\_ under the symbol " ." 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 \_\_\_\_\_ could result in a delisting of our common stock.

If, after listing, we fail to satisfy the continued listing requirements of the \_\_\_\_\_, such as the corporate governance requirements or the minimum closing bid price requirement, the \_\_\_\_ 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 \_\_\_\_\_ minimum bid price requirement or prevent future non-compliance with the \_\_\_\_\_ 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 \_\_\_\_\_\_ 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 eliqible 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 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 assumed offering price of \$ per share, if you purchase shares of common stock in this offering, you will experience immediate and substantial dilution of \$ per share in the net tangible book value of the common stock at September 30, 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 2022, 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 , 2022. 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 consolidated 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, 2021 and 2020, 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 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 consolidated 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 \_\_\_\_\_ shares of our common stock in this offering will be approximately \$ million (or \$ million if the underwriters exercise in full their option to purchase additional shares), assuming an initial public offering price of \$ per share (which is the midpoint of the price range set forth on the cover page of this prospectus), 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 \$8 million to fund clinical trials and product development;
- approximately \$6 million for research and development;
- approximately \$3 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 September 30, 2022:

- on an actual basis;
- on a pro forma basis to give effect to the automatic conversion of all outstanding convertible preferred stock into an aggregate of shares of common stock and the automatic conversion of all convertible promissory notes into an aggregate of stock, which will occur upon the closing of this offering; and
- on a pro forma as adjusted basis to reflect, in addition, our sale of shares of common stock in this offering at the assumed initial public offering price of \$ 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.

You should read the information in this table together with our consolidated 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 September 30, 2022					
(in thousands, except share amounts)		Actual	Pro Forma	Pro Forma As Adjusted		
Cash and cash equivalents	\$	5,938	\$ —	\$		
Convertible notes payable	\$	5,348				
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		<u> </u>		
Series B convertible preferred stock; \$0.0001 par value, 392,000 shares						
authorized, 391,303 issued and outstanding, actual; no shares issued and						
outstanding, pro forma and pro forma as adjusted		16,321	_	_		
Common stock, \$ par value, shares authorized, shares issued and outstanding, actual; shares issued and outstanding, pro				-		
forma; shares issued and outstanding, pro forma as adjusted		1	_	_		
Additional paid-in capital		1,023	_	_		
Accumulated deficit		(33,268)	_	_		
Total stockholders' equity (deficit)		(32,243)				
Total capitalization	\$	1,451	\$ —	<u> </u>		
41						

# **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 September 30, 2022, our pro forma net tangible book value was approximately \$6.8 million, or \$ 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 September 30, 2022, after giving effect to the automatic conversion of all outstanding shares of our preferred stock and convertible notes as of September 30, 2022 into common stock immediately prior to the closing of this offering.

After giving effect to our sale in this offering of shares of our common stock, at the assumed initial public offering price of \$ 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 September 30, 2022 would have been approximately \$ million, or \$ per share of our common stock. This represents an immediate increase in pro forma as adjusted net tangible book value of \$ per share to our existing stockholders and an immediate dilution of \$ per share to investors purchasing shares in this offering.

The following table illustrates this dilution:

Assumed initial public offering price per share	\$
Pro forma net tangible book value per share as of September 30, 2022, before giving effect to	
this offering	\$
Increase in pro forma net tangible book value per share attributable to new investors	
purchasing shares in this offering	
Pro forma as adjusted net tangible book value per share, after giving effect to this offering	\$
Dilution per share to new investors purchasing shares in this offering	\$

Each \$1.00 increase or decrease in the assumed initial public offering price of \$ 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 \$ , and would increase or decrease, as applicable, dilution per share to new investors in this offering by \$ , 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 \$ per share, and the dilution in pro forma net tangible book value per share to new investors in this offering would be \$ 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 the automatic conversion of all outstanding shares of our preferred stock and all outstanding convertible notes, including the \$4.35 million of notes sold in September 2022 into common stock immediately prior to 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 average price per share paid to us or to be paid to us at an assumed initial public offering price of \$ 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 Pu	Shares Purchased			Total Consideration			
	Number	Percent		Amount	Percent		Share	
Existing stockholders		%	\$	-	<del></del> %	\$	_	
New public investors	-	%	\$	-	%	\$	-	
Total		100.0%	\$	_	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 September 30, 2022, after giving effect to the automatic conversion of all outstanding shares of our preferred stock and convertible promissory notes into common stock immediately prior to the closing of this offering, and excludes:

- shares of our common stock issuable upon exercise of outstanding options, with a weighted average exercise price of \$ per share, granted pursuant to our 2016 Stock Incentive Plan, or the 2016 Plan;
- approximately shares of our common stock issuable upon exercise of outstanding warrants, with a weighted average exercise price of \$ per share
- up to shares issuable pursuant to the underwriters' over-allotment option;
- 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 shares if the over-allotment option is exercised) at an exercise price of \$ per share; and
- shares of our common stock reserved for future grants under our 2016 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 a pre-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 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 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 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, is convertible into shares of our common at \$ per share, which will convert into approximately shares of our common stock upon the consummation of this offering; 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 conversion price of 50% of the initial public offering price, which will convert into approximately shares of our common stock upon the consummation of this offering at an assumed initial public offering price of \$ per share (which is the midpoint of the price range set forth on the cover page of this prospectus).

Except as otherwise indicated, all information in this prospectus concerning our outstanding share of common stock assumes the automatic conversion of the above-described shares of convertible preferred stock and convertible promissory notes, collectively referred to as the Convertible Securities, into a total of approximately shares of our common stock upon the consummation of this offering at an assumed initial public offering price of \$ per share.

# **Results of Operations**

We are a preclinical 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 *S. epidermidis* 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, 2021 Compared to Year Ended December 31, 2020

	Years Ended December 31,						
		2021		2020		\$ Change	%Change
Service Revenue	\$	110,000	\$	425,000	\$	(315,000)	(74)%
Total Revenue		110,000		425,000		(315,000)	(74)%
Operating expenses:							
General and administrative		2 051 252		2 220 002	\$	711,359	22%
Research and development		3,951,352		3,239,993	- 1	·	
<u>-</u>		5,380,102		4,075,854	\$	1,304,248	32%
Total operating expenses		9,331,454		7,315,847		2,015,607	54%
		,			_	(	
Loss from operations		(9,221,454)		(6,890,847)	\$	(2,330,607)	34%
Other income (expense):							
Interest income		8,759		33,630	\$	(24,871)	(74)%
Interest expense		(66,968)		(1,666)	\$	(65,302)	3920%
Other income		112,141		92,441	\$	19,700	21%
Forgiveness of payroll protection Program loan		232,506		-	\$	232,506	100%
Other expense		(4,659)		(44,705)	\$	40,046	(90)%
Total other income (expense)		281,779		79,700	\$	202,079	254%
Net loss before income taxes		(9.020.675)		(6,811,147)	\$	(2,128,528)	31%
Net ioss before income taxes		(8,939,675)		(0,011,147)	Ф	(2,120,320)	3170
Income tax benefit (expense)		-		-			
Net loss	\$	(8,939,675)	\$	(6,811,147)	\$	(2,128,528)	31%
		(-,,,,		(-,-=-,,		( ) (0,000)	

#### Service Revenue

We generated \$110,000 of service revenue under the Bayer JDA during fiscal 2021 compared to service revenue of \$425,000 under the JDA in fiscal 2020. The decrease of \$315,000 in service revenue is attributable to a decreased amount of reimbursable development costs in 2021.

# General and Administrative

General and administrative costs during fiscal 2021 increased by \$711,359, or 22%, to \$3,951,352 from the prior year period. The increase was primarily related to an increase of \$540,000 in payroll and related costs attributable to the payment of separation benefits to our former chief executive officer, recruiting expenses for our new chief executive officer, the realization of full year salaries for new hires in the fourth quarter of 2020, an increase of \$150,000 in rent expense primarily related to the addition of our facility in Groton, Connecticut and \$21,000 net increase of other overhead expenses.

# Research and Development

During fiscal 2021, research and development expenses increased by \$1,304,248, or 32%, to \$5,380,102 from the prior year period. The increase was primarily related to an increase of \$812,000 in clinical trial start-up expenses attributable to the setup of a clinical trial for ATR-04, an increase of \$250,000 in payroll and related costs attributable to additional personnel hired for our manufacturing operations, and a net increase of \$242,000 in other research and development related costs attributable to our efforts in moving our Netherton program forward.

# Other Income (Expense)

Our other income (expense) consists of refundable research and development credits, forgiveness of the payroll protection loan, valuation of warrants, amortization of debt issuance costs and interest expense on the placement of the \$1 million unsecured promissory note in January 2021. During fiscal 2021, other income (expense) increased by \$202,079, or 254%, compared to fiscal 2020. The increase was primarily related to an increase of \$233,000 attributable to the forgiveness of the payroll protection loan, an increase of \$19,000 attributable to refundable research and development credits from the State of Connecticut and Revenue Quebec, an increase of \$65,000 attributable to the interest expense on the placement of the \$1 million unsecured promissory note, a decrease of \$25,000 attributable to the lower cash balance maintained on which interest is earned, a decrease of \$36,000 attributable to the valuation of the warrants associated with the 2018 convertible note and a net increase of \$4,000 attributable to foreign currency gains and losses.

# Nine Months Ended September 30, 2022 Compared to Nine Months Ended September 30, 2021

	Periods ended September 30,							
		2022		2021		\$ Change	%Change	
Service Revenue	\$	253,500	\$	-	\$	253,500	100%	
Total Revenue		253,500		-		253,500	100%	
Operating expenses:								
General and administrative		2,583,809		2,979,797	\$	(395,988)	(13)%	
Research and development		4,425,195		4,228,777	\$	196,418	5%	
Total operating expenses		7,009,004		7,208,574		(199,570)	(9)%	
Loss from operations		(6,755,504)		(7,208,574)	\$	(453,070)	(6)%	
2000 From operations		(0,755,504)		(7,200,574)	Ψ	(433,070)	(0)/0	
Other income (expense):								
Interest income		4,056		8,072	\$	(4,016)	(50)%	
Interest expense		(66,781)		(49,876)	\$	(16,905)	34%	
Employee Retention Credit		229,813		-	\$	229,813	100%	
Forgiveness of Payroll Protection Program loan		-		232,506	\$	(232,506)	(100)%	
Other expense		(45,365)		(13,478)	\$	(31,887)	237%	
Total other income (expense)		121,723		177,224	\$	(55,501)	(31)%	
Net loss before income taxes		(6,633,781)		(7,031,350)	\$	397,569	(6)%	
				,		ĺ	( )	
Income tax benefit (expense)		-		<u>-</u>				
Net loss	\$	(6,633,781)	\$	(7,031,350)	\$	397,569	(6)%	

#### Service Revenue

We generated \$253,500 of service revenue under the Bayer JDA during the first nine months of fiscal 2022 compared to service revenue of \$0 under the JDA for the comparable period in fiscal 2021. The increase of \$253,500 in service revenue is attributable to an increased amount of reimbursable development costs in 2022.

#### General and Administrative

General and administrative costs during the first nine months of fiscal 2022 decreased by \$395,588, or 13%, to \$2,583,809 from the prior year period. The decrease was primarily related to a decrease of \$337,000 in payroll and related costs attributable to the end of separation benefits paid to our former chief executive officer and a \$58,000 net decrease of other overhead expenses.

# Research and Development

During the first nine months of fiscal 2022, research and development expenses increased by \$196,418, or 5%, to \$4,425,195 from the prior year period. The increase was primarily related to net increase of \$843,000 in other research and development related costs attributable to our efforts in moving our ATR-12 product candidate forward. This was offset by a decrease of \$647,000 in net clinical related costs attributable to the decision to pursue a more promising microbial strain for the ATR-04 program and push the expected clinical trial start to the first half of 2024.

# Other Income (Expense)

Our other income (expense) consists of refundable research and development credits, forgiveness of the payroll protection loan, the employee retention credit, valuation of warrants, amortization of debt issuance costs and interest expense on the placement two unsecured promissory notes. During the first nine months of fiscal 2022, other income (expense) decreased by \$55,501, or 31%, from the prior year period. The decrease was primarily related to an increase of \$17,000 attributable to the interest expense on the placement of two convertible unsecured promissory notes, an increase of \$16,000 attributable to Connecticut state tax expense, a loss on sale of equipment of \$8,000, a net increase of \$11,000 attributable to foreign currency gains and losses and a \$3,000 net increase of other income and expense items.

#### **Liquidity and Financial Condition**

#### Overview

As of September 30, 2022, we had total assets of 9.4 million and working capital of \$4.7 million. As of September 30, 2022, our liquidity included \$6.0 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 the commencement of our Phase 1/2 clinical trial for ATR-12 and the filing of an IND 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, 2021 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.

# **Cash Flows**

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

# Year Ended December 31, 2021 Compared to Year Ended December 31, 2020

	Years Ended December 31,				
	 2021		2020		
Cash Used in Operating Activities	\$ (8,067,359)	\$	(6,540,698)		
Cash Used in Investing Activities	\$ (652,275)	\$	(541,036)		
Cash provided by Financing Activities	\$ 992,862	\$	16,551,750		
Net Increase (Decrease) in Cash and Cash Equivalents	\$ (7,726,772)	\$	9,470,016		

*Operating Activities*. 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. During the year ended December 31, 2020, operating activities used \$6.5 million of cash primarily driven by our net loss of \$6.8 million offset by non-cash items of \$0.3 million.

*Investing Activities.* During the year ended December 31, 2021, investing activities used \$0.652 million of cash primarily driven by \$0.203 million of trademark and patent costs and \$0.446 million for the purchase of furniture and equipment. During the year ended December 31, 2020, investing activities used \$0.541 million of cash primarily driven by \$0.323 million of trademark and patent costs and \$0.218 million for the purchase of furniture and equipment.

*Financing Activities*. During the year ended December 31, 2021, financing activities provided \$0.993 million in cash primarily driven by the issuance of a \$1 million convertible promissory note. During the year ended December 31, 2020, financing activities provided \$16.5 million in cash primarily driven by the issuance of a \$16.4 million issuance of shares of our Series B convertible preferred stock.

# Nine Months Ended September 30, 2022 Compared to Nine Months Ended September 30, 2021

	Periods Ended September 30,			
	 2022			
Cash Used in Operating Activities	\$ (6,217,480)	\$	(6,113,222)	
Cash Used in Investing Activities	\$ (239,970)	\$	(448,587)	
Cash provided by Financing Activities	\$ 4,351,510	\$	984,387	
Net Increase (Decrease) in Cash and Cash Equivalents	\$ (2,105,940)	\$	(5,577,422)	

*Operating Activities*. During the period ended September 30, 2022, operating activities used \$6.2 million of cash primarily driven by our net loss of \$6.6 million offset by non-cash items of \$0.4 million. During the period ended September 30, 2021, operating activities used \$6.1 million of cash primarily driven by our net loss of \$7.0 million offset by non-cash items of \$0.9 million.

*Investing Activities*. During the period ended September 30, 2022, investing activities used \$0.24 million of cash primarily driven by \$0.221 million of trademark and patent costs and \$0.019 million for the purchase of furniture and equipment. During the period ended September 30, 2021, investing activities used \$0.449 million of cash primarily driven by \$0.16 million of trademark and patent costs and \$0.289 million for the purchase of furniture and equipment.

Financing Activities. During the period ended September 30, 2022, financing activities provided \$4.4 million in cash primarily driven by the issuance of a \$4.4 million convertible promissory note. During the period ended September 30, 2021, financing activities provided \$.984 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 consolidated 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, 2021 and 2020, 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 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 consolidated 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-intime 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 consolidated 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 June 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 and \$12.09 per share as of September 2020.

#### **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 consolidated financial statements found elsewhere in this prospectus for a description of recent accounting pronouncements applicable to our consolidated financial statements.

#### 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

#### **BUSINESS**

#### Overview

We are a preclinical 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 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.

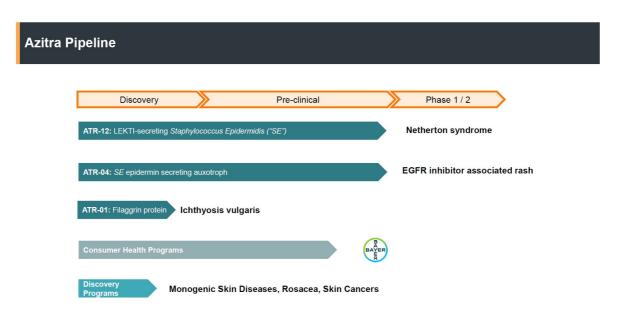
We are a pioneer in genetically engineering bacteria for therapeutic use in dermatology. Our goal is to leverage our platforms and internal microbial library bacterial strains to create new therapeutics that are either engineered living organisms or engineered proteins or peptides to treat skin diseases. 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. We are planning to submit an investigational new drug application, or IND, for a Phase 1/2 clinical trial of ATR-12 in Netherton syndrome patients in the fourth quarter of 2022, Subject to FDA approval of our IND, we expect to commence our Phase 1/2 clinical trial in the first half of 2023 and report initial results as early as 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 1/2 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 1/2 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 *S. epidermidis* 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 *S. epidermidis* 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 Hutchison Cancer Center, or FHCC, 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 FHCC 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 FHCC 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.



- Proprietary platform has generated multiple candidates for precision dermatology treatments
- Discovery efforts harness the promise of genomic sequencing by leveraging artificial intelligence and machine learning

# **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 Phase 1/2 trials in the next 12 months, including a Phase 1/2 trial of our ATR-12 in Netherton syndrome patients and a Phase 1/2 trial of our ATR-04 in certain cancer patients undergoing EGFRi therapy. We expect to file an IND for ATR-12 by the end of 2022 and 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.
- Management team. We are led by Francisco 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 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 X. Representative Species in Azitra Microbial Library

Staphylococcus epidermidis
Escherichia coli
Staphylococcus aureus
Bacillus subtilis
Corynebacteria
Saccharomyces cerevisiae
Candida albicans
Finegoldia magna
Gardnerella vaginalis
Haemophilus influenzae
Haemophilus parainfluenzae
Haemophilus parainfluenzae

Helicobacter pylori
Kelbsiella oxytoca
Klebsiella pneumoniae
Kluyveromyes lactis
Kocuria rhizophila
Micrococcus leteus
Moraxella catarrhalis
Morganella morganii
Mucor circinelloides
Staphylococcus haemolyticus
Staphylococcus hominis
Staphylococcus lugdunensis
Bacilus sterarothermophilus

Streptococcus pneumoniae
Enterobacter cloacae
Salmonella oslo
Deinococcus radiodurans
Enterococcus faecalis
Morazella catarrhalis
Streptococcus miltis group
Streptococcus mitis/oralis
Streptococcus pneumoniae
Streptococcus pyogenes
Streptomyces ambofaciens
Thermoaerobacter marianensis
Thermus thermophilus
Pseudomonas aeruginosa

Vibrio cholerae
Yersinia enterocolitica
Citrobacter freundii
Enterobacter aerogenes
Enterobacter cloacae
Proteus mirabilis
Salmonella Senftenberg
Serratia marcescens
Shigella sonnei
Neisseria gonorrhoeae
Enterococcus faecium
Salmonella typhimurium
Acinetobacter baumannii

# **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 Microbial 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 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 Hutchison Cancer Center orFHCC, 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.

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, FHCC'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, FHCC 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 FHCC 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. The topical application of ATR-12 is 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 proinflammatory 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 cure and 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, 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. 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 Dalanine 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 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 SE351to 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. 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<sup>9</sup> 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 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. We intend to file an investigational new drug application, or IND, for a first-in-human trial of ATR-12 in Netherton syndrome patients by the end of 2022. Our IND proposes a combined Phase1b/2a clinical study of ATR-12 in patients with Netherton syndrome, with initial results expected in the second half of 2023.

# 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 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 drivers 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-36 $\gamma$  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-36 $\gamma$  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.

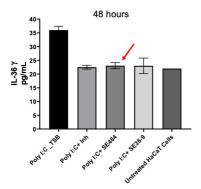
We believe that ATR-04 has the potential to address current limitations to treatment of EGFRi-associated rash:

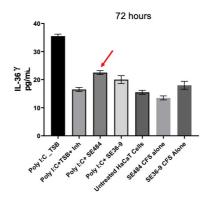
- **Reduced antibiotic use.** From our surveys of clinicians and key opinion leaders, practitioners are reluctant to prescribe systemic antibiotics to patients undergoing EGFRi therapy. These patients can often be prescribed antibiotics for more than 12 months and suffer from antibiotic-related adverse 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.

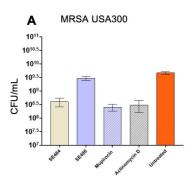
We have demonstrated that cell free supernatant derived from SE484, the strain from which ATR-04 is derived, reduces IL-36 $\gamma$  protein levels *in vitro*.





Plans for continued development of SE484 next include testing of the strain in vivo using a mouse model of EGFRi driven rash induced by afatinib. We will also investigate the effect of the live biotherapeutic product as well as the supernatant upon IL-8, IL-23 and  $TNF\alpha$ .

We have also shown that ATR-04 leads to *in vitro* inhibition of known virulent strains USA300, which is resistant to methicillin, and MSSA, which is sensitive to methicillin.



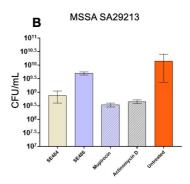
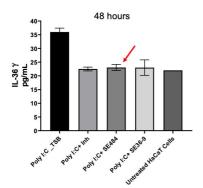
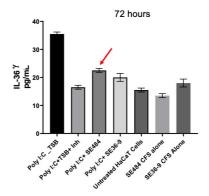


Figure X. Epidermin-expressing SE484 kills S. aureus as well as mupirocin on in vitro agar plates.





We are proposing an initial study of SE484 in the ATR-04 formulation in patients. It is contemplated to be a Phase 1b/2a 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 1/2 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. It has the potential 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. Daily topical application of a human filaggrin unit with a cell penetrating peptide for five days resulted in a dose dependent rapid improvement in TEWL, suggesting improved skin barrier. Thus, topical delivery of a recombinant hFLG unit coupled with a cell penetrating peptide potentially can improve/accelerate the repair of damaged human skin barrier.

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<sup>2</sup>). Daily treatment with mFlg significantly improved TEWL in FT mice compared to vehicle. Histological analysis of the epidermis of the mouse tail sections showed tendency for improved stratum corneum thickness with mFlg treatment. Thus, treatment of damaged mouse skin with recombinant mFlg combined to a cell penetrating peptide improved damaged mouse skin barrier.

# **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 *S. epidermidis* strains for oleogel 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. Bayer has an option to acquire the exclusive license rights for period of six month 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.

#### 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

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 FHCC. Pursuant to our agreement with FHCC, we obtained an exclusive worldwide license under certain patents related to SyMPL technologies developed and owned by FHCC 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 FHCC and also the U.S. government. The patent rights licensed to us by FHCC 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. If issued, these two families will expire in 2037 and 2040, respectively.

In consideration of the license granted to us under the FHCC license agreement, we paid FHCC a nominal upfront payment. In addition, we are required to pay FHCC certain development and commercial milestone payments and running royalties on net sales of the licensed products between 1% and 1.25%, depending on the level of net sales. The FHCC agreement also requires us to reimburse FHCC for the cost of the prosecution and maintenance of the licensed patents.

Pursuant to the FHCC 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 FHCC 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 FHCC license agreement at will at any time upon prior written notice to FHCC. FHCC has the right to terminate the FHCC 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 FHCC 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;
- 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 I* 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 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.
- *Phase II* 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 II clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more costly Phase III clinical trials.
- Phase III clinical trials proceed if the Phase II clinical trials demonstrate that a dose range of the product candidate is potentially effective and has an acceptable safety profile. Phase III 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 III 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 III 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 IV 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 IV clinical trial requirement or to request a change in the product labeling. Failure to exhibit due diligence with regard to conducting Phase IV 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 IV 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 IV 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 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 marketing authorization that all aspects relating to its quality, safety and efficacy must be kept under rev

## **Conditional Approval**

In specific circumstances, EU legislation (Article 14(7) Regulation (EC) No. 726/2004 and Regulation (EC) No. 507/2006 on Conditional Marketing Aurhorisations 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 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 and Directors**

The following table sets forth certain information regarding individuals who are expected to serve as our executive officers and directors upon the closing 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	Director				
Andrew McClary, MD	37	Independent Director				
Barbara Ryan	63	Independent Director Nominee				
John Schroer	57	Independent Director Nominee				

## Information about our Executive Officers and Directors

Francisco 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, 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 in its financial accounting and reporting practice. 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 its 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. 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 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 of directors.

## **Family Relationships**

There are no family relationships among any of our officers or directors.

#### **Involvement in Certain Legal Proceedings**

To the best of our knowledge, none of our directors or executive officers 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. Our Board currently consists of five members, three of whom qualify as independent under the \_\_\_\_\_ rules. Neither Mr. Salva nor Mr. Whitfill are considered to be independent due to their roles as present or, in the case of Mr. Whitfill, former 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 Nasdaq. 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**

Our audit committee consists of	, with	serving as chair of the audit committee. Our Board has determined that e	each
member meets the independence requirements of	the Sarbanes-Oxley A	ct, Rule 10A-3 under the Exchange Act and the applicable listing standards of	the t
Each member of our audit committee car	read and understand	fundamental financial statements in accordance with the audit commi	ittee
requirements. In arriving at this determination, the	Board has examined	each audit committee member's scope of experience and the nature of their p	prior
and/or current employment.			
Our Board has determined that	qualifies as an aud	it committee financial expert within the meaning of SEC regulations and meets	s the
financial sophistication requirements of the	Listing Rules. Both	our independent registered public accounting firm and management periodic	ally
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 \_\_\_\_\_ rules and regulations. We intend to comply with future requirements to the extent they become applicable to us.

Compensation Compe	ommittee
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Our compensation committee consists of , with serving as chair serving as chair of the compensation committee. 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 \_\_\_\_\_, 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 \_\_\_\_\_ rules and regulations. We intend to comply with future requirements to the extent they become applicable to us.

## **Nominating and Corporate Governance Committee**

Our nominating and corporate governance committee consists of , with serving as Chairperson. The composition of our nominating and corporate governance committee meets the requirements for independence under the \_\_\_\_\_ Stock Market 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 \_\_\_\_\_ Stock Market.

## **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, 2021 and 2020. In reviewing the table, please note that:

- Francisco Salva was appointed to serve as our president and chief executive officer in April 2021;
- Richard Andrews served as our president and chief executive officer throughout 2020 and until April 2021;
- Jeanne Bertonis served as our chief operating officer throughout 2020 and 2021 and until April 2022; and
- Norman Staskey was appointed to serve as our chief financial officer in October 2022.

						Option	All Other npensation	
	Year	S	alary (\$)	Во	onus (\$)	ards \$ (1)	(2)	Total
Francisco Salva,	2021	\$	281,615	\$		\$ 793,104	\$ 19,125	\$ 1,093,844
Pres. and CEO	2020	\$	_	\$	_	\$ _	\$ _	\$ _
Richard Andrews,	2021	\$	110,238	\$	31,322	\$ _	\$ 351,360	\$ 492,120
Pres. and CEO	2020	\$	330,000	\$	70,000	\$ 373,267	\$ 120	\$ 773,387
Jeanne Bertonis,	2021	\$	303,714	\$	_	\$ _	\$ 185	\$ 303,899
COO	2020	\$	272,500	\$	55,000	\$ _	\$ 24,673	\$ 352,173

<sup>(1)</sup> 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, 2021 and 2020, 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 10 to our audited financial statements.

<sup>(2)</sup> All other compensation includes commuter benefits, vacation payouts, relocation reimbursements, 401K match contributions, and life insurance premiums, plus a separation benefit payment to Mr. Andrews in 2021 in the amount of \$330,714.

## **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 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 65,600 shares of our common stock at an exercise price of \$12.09 per share under the 2016 Plan. The options vest and become exercisable as follows. 80% of the options, or options to purchase 52,480 common shares, are subject to time-based vesting, with options to purchase 13,120 shares (25%) vesting on the first anniversary of the grant and options to purchase 39,360 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.

#### Richard Andrews

Mr. Andrews served as our president and chief executive officer from August 2017 to April 2021 pursuant to an executive employment agreement dated August 3, 2017. Mr. Andrews was paid a base salary of \$330,000 and \$330,714 during 2020 and 2021, respectively, and was eligible to receive a bonus of up to 30% of his base salary based on performance parameters set by our Board. Mr. Andrew's executive employment agreement entitled him to reimbursement of medical and dental insurance and to participate in other benefits, at our expense, made available to other executive officers. Mr. Andrews' employment ended in April 2021 and pursuant to the separation provisions of the agreement he is entitled to receive the continuation of his base salary and health benefits for a period of 12 months from the date of separation. We paid Mr. Andrews a total of \$342,613 in separation benefits during 2021 and 5,592 during 2022.

We granted Mr. Andrews options to purchase shares of our common stock in 2020. These options are exercisable for a period of the earlier of five years following the separation date or the expiration date of the applicable option.

## 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 \$272,500 in 2020 and \$303,714 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.

## 2016 Stock Incentive Plan

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 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 shares of our common stock at an average exercise price of \$ per share.

## **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, 2021 and 2020, 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 shares, or approximately %, of our outstanding common stock. 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 \$150,000 payment upon execution of the JDA. Pursuant to the JDA, Bayer is responsible for reimbursing us for our development costs, and in 2020 Bayer has paid us \$565,000 for our development costs through September 2022. 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 shares of common stock issued and outstanding prior to the offering, including shares issued and outstanding as of the date of this prospectus, and approximately shares issuable upon the conversion of our convertible preferred stock and convertible promissory notes outstanding as of the date 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 <sup>(1)</sup>	Percentage Owned After Offering <sup>(2)</sup>
Francisco Salva (1)			
Norman Staskey			
Travis Whitfill <sup>(2)</sup>			
Andrew McClary <sup>(3)</sup>			
Barbara Ryan	_		
John Schroer	_		
Directors, executive officers and director nominees, as a group (6 persons)			

\* Less than 1%.

Name and Address of Five Percent Stockholders	Number of Shares	Percentage Owned Prior to Offering	Percentage Owned After Offering
Bios Equity Entities <sup>(4)</sup>			
Bayer Health Care, LLC <sup>(5)</sup>			
Connecticut Innovations, Inc. <sup>(6)</sup>			

- (1) Includes common shares issuable upon exercise of presently exercisable options.
- (2) Includes shares issuable upon exercise of presently exercisable options.
- (3) Includes shares issuable upon exercise of presently exercisable options.
- (4) Consists of (i) shares of common stock issuable to Bios Fund I, LP upon conversion of our convertible preferred stock following the close of this offering, (ii) 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 exercise of warrants, (iii) shares of common stock issuable to Bios Fund II, LP upon conversion of our convertible preferred stock following the close of this offering and upon exercise of warrants, (iv) shares of common stock issuable to Bios Fund III, LP upon conversion of our convertible preferred stock and convertible promissory notes following the close of this offering, (v) 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) shares of common stock issuable to Bios Fund II QP, LP upon conversion of our convertible preferred following the close of this offering, (vii) shares of common stock issuable to Bios Fund III QP, LP upon conversion of our convertible preferred stock and convertible promissory notes following the close of this offering, (viii) 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 upon exercise of warrants, (ix) shares of common stock issuable to Bios Fund III NT,

preferred stock following the close of this offering and upon exercise of warrants, (ix) shares of common stock issuable to Bios Fund II NT, LP upon conversion of our conversion of our convertible preferred stock and 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 that is managed and controlled by Mr. Kreis, is the general partner 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 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 shares of common stock is suable upon conversion of our convertible preferred stock following the close of this offering. The address for Bayer HealthCare, LLC is
- (6) Consists of shares of common stock issuable upon conversion of our convertible preferred stock convertible promissory notes following the close of this offering and exercise of warrants. The address for Connecticut Innovations, Inc. is

## **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 shares of common stock, \$ par value per share, and shares of undesignated preferred stock, \$ par value per share.

Assuming the automatic conversion of all shares of our convertible preferred stock and all of our convertible promissory notes outstanding as of the date of this prospectus, which conversion will occur immediately upon the closing of this offering, there are shares of our common stock outstanding and no shares of our preferred stock outstanding as of the date of this prospectus.

As of the date of this prospectus, we had 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 1,437,151 shares of convertible preferred stock outstanding, including 205,385 shares of Series A convertible preferred stock, 380,657 shares of Series A-1 convertible preferred stock and 391,303 shares Series B convertible preferred stock. Immediately upon the completion of this offering, all outstanding shares of our convertible preferred stock will convert into a total of 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 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 shares of our common stock, at a per share exercise price equal to \$

   The warrants expire on
   The warrants expire on
- Warrants issued in connection with our February 2019 placement of Series A-1 convertible preferred shares to purchase up to an aggregate of shares of our common stock, at a per share exercise price equal to \$ . The warrants expire on .
- Warrants to be issued to ThinkEquity and its designees at the close of this offering to purchase shares of our common stock equal to % of the shares of common stock sold in this offering. This warrant is exercisable at \$ per share ( % of the price of the common stock sold in this offering), expiring five years from the date of this prospectus.

## 2016 Stock Incentive Plan

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 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 shares of our common stock at an average exercise price of \$ per share.

#### **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 shares of our common stock, including shares of our common stock issued upon conversion of our outstanding our convertible preferred stock and unsecured convertible notes and shares of our common stock issuable upon exercise of warrants issued to the parties in connection with our 2018 placement of our unsecured 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 (or 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 . The transfer agent and registrar's address is .

## **National Securities Exchange Listing**

We have applied to have our shares of common stock listed on the \_\_\_\_\_ under the symbol " ."

## 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 shares of common stock will be outstanding, assuming the automatic conversion of all outstanding Series A preferred stock into shares of common stock in connection with the completion of this offering. All 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 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 180 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**

We, our executive officers and directors and the holders of our common stock outstanding on the date of this prospectus have entered into lock-up agreements or otherwise agreed that we and they will not, subject to limited exceptions, (i) offer, pledge, announce the intention to sell, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase or otherwise dispose of, directly or indirectly, or file with the SEC a registration statement under the Securities Act relating to, any shares of our common stock outstanding as of the date of this prospectus, or publicly disclose the intention to make any offer, sale, pledge, disposition or filing, or (ii) enter into any swap or other arrangement that transfers all or a portion of the economic consequences associated with the ownership of any shares of common stock (regardless of whether any of these transactions are to be settled by the delivery of shares of common stock, in cash or otherwise), in each case without the prior written consent of the underwriter for a period of 12 months after the date of this prospectus.

All of the shares common stock issuable upon conversion of our Series A preferred stock upon the closing of this offering are subject to lock-up agreements whereby the holder of those shares 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. Notwithstanding the lock-up agreements, we have agreed to register for resale shares of common stock expected to be issued upon conversion of our Series A preferred stock and shares of common stock underlying certain warrants upon request.

## **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 2018 Plan. 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:

	Number of
Underwriter	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 overallotments, 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 \$ and the total net proceeds, before expenses, to us will be \$ .

# 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.

		Total Without	Total With
		Over- Allotment	Over- Allotment
	Per Share	Option	Option
Initial public offering price	\$	<u>\$</u>	\$
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 \$ .

### Representative's Warrants

We have agreed to issue to the representative or its designees warrants to purchase up to a total of (or 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 officers and directors 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 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 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 overallotment option. If the underwriters sell more securities than could be covered by exercise of the overallotment 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 \_\_\_\_\_\_\_, in the overthe-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 \_\_\_\_\_ 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. 11971"); 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. 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, 2021 and 2020 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 <a href="https://www.sec.gov">www.sec.gov</a>.

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 <a href="https://www.azitrainc.com">www.azitrainc.com</a>. 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**

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### 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, 2021 and 2020, and the related statements of operations, convertible preferred stock and stockholders' deficit, 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, 2021 and 2020, 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.

Grassif Co, CPAs, P.C.

We have served as the Company's auditor since 2022.

Jericho, New York December 15, 2022

# AZITRA INC Balance Sheets

	December 31,			
		2021		2020
Assets				
Current assets:	Φ.	0.044.060	Φ.	45 554 004
Cash Accounts receivable	\$	8,044,262	\$	15,771,034
Tax credits receivable		160,867		123,294
		173,311		405,056
Prepaid expenses The large state of the stat		110,289		274,241
Total current assets		8,488,729		16,573,625
Property and equipment, net		946,681		582,411
Other assets				
Other assets		48,201		47,282
Intangible assets, net		97,693		41,083
Deferred patent costs		620,029		473,406
Total other assets		765,923		561,771
Total assets	\$	10,201,333	\$	17,717,807
	Ψ	10,201,333	Ψ	17,717,007
Liabilities, convertible preferred stock, and stockholders' deficit				
Current liabilities:	ď	717 000	ď	417 270
Accounts payable	\$	717,800	\$	417,370
Income tax payable Accrued expenses		1,302 475,485		10,133 433,758
Contract liabilities		15,000		455,750
Payroll protection program loan		13,000		141,278
Total current liabilities		1,209,587		1,002,539
Warrant liability		71,104		72,093
Convertible notes payable, net		992,019		72,033
Payroll Protection Program loan, net of current portion		332,013		89,407
Total liabilities	_	2,272,710	_	1,164,039
Total habilities		2,2/2,/10		1,104,033
Convertible preferred stock:				
Series A convertible preferred stock; \$0.0001 par value; 205,385 shares authorized at December 31, 2021 and 2020; 205,385 shares issued and outstanding at December 31, 2021 and 2020; liquidation				
value of \$3,337,506 as of December 31, 2021 and 2020		3,272,944		3,272,944
Series A-1 convertible preferred stock; \$0.0001 par value; 380,657 shares authorized at December 31, 2021 and 2020; 380,657 shares issued and outstanding at December 31, 2021 and 2020; liquidation		14400 500		14400 500
value of \$14,274,638 as of December 31, 2021 and 2020 Series B convertible preferred stock; \$0.0001 par value; 392,000 shares authorized at December 31,		14,100,533		14,100,533
2021 and 2020; 391,303 shares issued and outstanding at December 31, 2021 and 2020; liquidation value of \$17,000,159 as of December 31, 2021 and 2020		16,321,065		16,321,065
. a.a.c 5. 41, 5000,100 as 61 December 61, 2021 and 2020		10,021,000		10,021,000
Stockholders' equity:				
Common stock; \$0.01 par value; 1,400,000 authorized at December 31, 2021 and 2020; 146,916 and				
144,416 shares issued and outstanding at December 31, 2021 and 2020, respectively		1,469		1,444
Additional paid-in capital		866,798		552,293
Accumulated deficit		(26,634,186)		(17,694,511)
Total stockholders' deficit		(25,765,919)		(17,140,774)
Total liabilities, convertible preferred stock, and stockholders' deficit	\$	10,201,333	\$	17,717,807
See accompanying notes				
F-2				

# AZITRA INC Statements of Operations

		Years ended December 31,			
		2021		2020	
Service Revenue	\$	110,000	\$	425,000	
Total Revenue		110,000		425,000	
Operating expenses:					
General and administrative		3,951,352		3,239,993	
Research and development		5,380,102		4,075,854	
Total operating expenses		9,331,454		7,315,847	
Loss from operations		(9,221,454)		(6,890,847)	
Other income (expense):					
Interest income		8,759		33,630	
Interest expense		(66,968)		(1,666)	
Other income		112,141		92,441	
Forgiveness of Payroll Protection Program loan		232,506		-	
Other expense		(4,659)		(44,705)	
Total other income (expense)		281,779		79,700	
Net loss before income taxes		(8,939,675)		(6,811,147)	
Income tax benefit (expense)		<u>-</u>		<u>-</u>	
Net loss	\$	(8,939,675)	\$	(6,811,147)	
Net loss per share, basic and diluted	\$	(60.69)	\$	(46.67)	
	·	()	•	( )	
Weighted average common stock outstanding, basic and diluted		147,291		145,954	
See accompanying notes					
F-3					

# Azitra Inc Statements of Convertible Preferred Stock and Stockholders' Deficit For the Years ended December 31, 2021 and 2020

						Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
205,385	\$3,272,944	380,657	\$14,100,533	-	\$ -	142,760	\$ 1,444 -	\$ 289,150 263,143	\$ (10,883,364)	\$ (10,592,770) 263,143
-	-		-	391,303	16,321,065	-	-	-	-	-
-	-	-	-	-	-	1,656	-	-	- (6 911 147)	(6,811,147)
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)
-	-	-	-	-	-	2,500	25	306,055 8,450	-	306,055 8,475
205,385	\$3,272,944	380,657	<u>-</u> \$14,100,533	391,303	\$16,321,065	146,916	<u>-</u> \$ 1,469	\$ 866,798	(8,939,675) \$ (26,634,186)	(8,939,675) \$ (25,765,919)
	Prefers Shares 205,385	205,385 \$3,272,944	Preferred Stock         Prefer           Shares         Amount         Shares           205,385         \$ 3,272,944         380,657           -         -         -           205,385         3,272,944         380,657           -         -         -           -         -         -           -         -         -           -         -         -           -         -         -           -         -         -           -         -         -           -         -         -           -         -         -	Preferred Stock         Preferred Stock           Shares         Amount         Shares         Amount           205,385         \$3,272,944         380,657         \$14,100,533           -         -         -         -           205,385         3,272,944         380,657         14,100,533           -         -         -         -           -         -         -         -           -         -         -         -           -         -         -         -           -         -         -         -           -         -         -         -           -         -         -         -           -         -         -         -           -         -         -         -           -         -         -         -           -         -         -         -           -         -         -         -           -         -         -         -           -         -         -         -           -         -         -         -           -         -         -	Preferred Stock         Preferred	Preferred Stock         Preferred Stock         Preferred Stock         Shares         Amount         Shares         Amount           205,385         \$3,272,944         380,657         \$14,100,533         -         \$391,303         16,321,065           -         -         -         -         -         -         -           205,385         3,272,944         380,657         14,100,533         391,303         16,321,065           -         -         -         -         -         -           -         -         -         -         -         -           205,385         3,272,944         380,657         14,100,533         391,303         16,321,065           -         -         -         -         -         -         -           -         -         -         -         -         -         -         -	Preferred Stock         Preferred Stock         Preferred Stock         Commo           Shares         Amount         Shares         Amount         Shares         Amount         Shares           205,385         \$3,272,944         380,657         \$14,100,533         -         \$         -         142,760           -         -         -         391,303         16,321,065         -         1,656           -         -         -         -         -         144,416           -         -         -         -         -         2,500           -         -         -         -         -         2,500	Preferred Stock         Preferred Stock         Commore Stock         Shares         Amount         Shares         Amount         Shares         Amount         Shares         Amount         Shares         Amount         Shares         Amount         142,760         \$ 1,444           - <td>Series A Convertible Preferred Stock         Series B Convertible Preferred Stock         Series B Convertible Preferred Stock         Commotive Raid-In Capital           Shares         Amount         Shares         <t< td=""><td>Series A ∪ vertible Prefer ∪ Stock         Series B ∪ vertible Prefer ∪ Stock         Commo∪ Shares         Paid-In Capital Deficit           Shares         Amount         Shares         All (10,883,364)         Common Shares         Common Shares         Common Shares</td></t<></td>	Series A Convertible Preferred Stock         Series B Convertible Preferred Stock         Series B Convertible Preferred Stock         Commotive Raid-In Capital           Shares         Amount         Shares <t< td=""><td>Series A ∪ vertible Prefer ∪ Stock         Series B ∪ vertible Prefer ∪ Stock         Commo∪ Shares         Paid-In Capital Deficit           Shares         Amount         Shares         All (10,883,364)         Common Shares         Common Shares         Common Shares</td></t<>	Series A ∪ vertible Prefer ∪ Stock         Series B ∪ vertible Prefer ∪ Stock         Commo∪ Shares         Paid-In Capital Deficit           Shares         Amount         Shares         All (10,883,364)         Common Shares         Common Shares         Common Shares

See accompanying notes

# AZITRA INC Statements of Cash Flows

Years Ended December 31,

		2021		2020
Cash flows from operating activities:				
Net loss	\$	(8,939,675)	\$	(6,811,147)
Adjustments to reconcile net loss to net cash used by operating activities:	Ψ	(0,555,075)	Ψ	(0,011,147)
Depreciation and amortization		84,772		57,034
Amortization of debt discount		7,632		57,054
Accrued interest on convertible notes		59,181		_
Stock-based compensation		306,055		263,143
Change in fair value of warrant liability		(989)		35,837
Forgiveness of Payroll Protection Program loan		(230,685)		-
Changes in operating assets and liabilities:		( / /		
Accounts receivable		(37,573)		194,417
Prepaid expenses		163,952		33,389
Other assets		(919)		(390)
Tax credits receivable		231,745		47,211
Accounts payable and accrued expenses		282,976		(33,332)
Income tax payable		(8,831)		(5,452)
Contract liabilities		15,000		(321,408)
Net cash used by operating activities		(8,067,359)		(6,540,698)
Cash flows from investing activities:				
Purchases of property and equipment		(446,136)		(217,687)
Capitalization of deferred patent costs		(196,267)		(316,779)
Capitalization of trademark costs				(6,570)
-		(9,872)		
Net cash used by investing activities		(652,275)		(541,036)
Cash flows from financing activities:  Proceeds from convertible notes, net of issuance costs		004 207		
Proceeds from convertible notes, net of issuance costs  Proceeds from exercise of stock options		984,387		-
Proceeds from Payroll Protection Program loan		8,475		230,685
Proceeds from preferred stock issuance, net of closing costs		-		
•				16,321,065
Net cash provided by financing activities		992,862		16,551,750
Net (decrease) increase in cash and cash equivalents		(7,726,772)		9,470,016
Cash and cash equivalents at the beginning of the year		15,771,034		6,301,018
Cash and cash equivalents at the end of the year	\$	8,044,262	\$	15,771,034

### 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 2020 and 2021. 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, 2021, the Company has an accumulated deficit of \$26.6 million, a loss from operations of \$9.2 million and used \$8.1 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 still in their pre-clinical phase and therefore does not yet have product revenue. In 2021, the Company issued convertible notes resulting in net cash proceeds of \$1.0 million (see Note 6). 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 October 31, 2023 (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

The Company classifies as cash amounts on deposit in banks.

#### **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, 2021 or 2020. Accounts receivable are written off when deemed uncollectible. Recoveries of accounts receivable previously written off are recorded when received.

### **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.

# **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 2021 or 2020.

### **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, 2021 and 2020.

# **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.

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.

### 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.

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 \$5,380,102 and \$4,075,854 during the years ended 2021 and 2020, respectively.

At December 31, 2021 and 2020, the Company has a state tax credit receivable of \$71,396 and \$261,065, respectively, for pending refunds related to the selling of research and development tax credits back to the State of Connecticut. At December 31, 2021 and 2020, the Company has a federal state tax credit receivable of \$0 and \$81,934, respectively. At December 31, 2021 and 2020, the Company has \$89,855 and \$46,930, respectively for pending refunds related to Canadian Scientific Research and Experimental Development credits. At December 31, 2021 and 2020, the Company has also recorded \$12,060 and \$15,127, 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.

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

### **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 12).

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, 2021 and 2020. The Company's income tax returns have not been examined by tax authorities through December 31, 2021. 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.

### **Recent Accounting Pronouncements**

In February 2016, the FASB issued ASU No. 2016-02, *Leases*. ASU 2016-02 requires lessees to present right-of-use assets and lease liabilities on the balance sheet for all leases with terms longer than 12 months. The guidance is to be applied using a modified retrospective approach at the beginning of the earliest comparative period in the financial statements and is effective for years beginning after December 15, 2021. Early adoption is permitted. The Company has adopted this standard effective January 1, 2022.

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 is currently evaluating the potential impact this standard may have on its financial statements upon adoption.

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.

# **Financial Instruments**

The Company's financial instruments are primarily comprised of accounts receivable, accounts payable, accounts 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. Property and Equipment

Property and equipment consisted of the following at December 31, 2021 and 2020:

	2021	2020
Lab equipment	\$ 1,016,737	\$ 595,352
Computer equipment	30,825	27,661
Furniture and fixtures	24,316	15,325
Leasehold improvements	28,855	27,030
Building equipment	14,932	4,445
	 1,115,665	 669,813
Less: accumulated depreciation	(168,984)	(87,402)
Net property and equipment	\$ 946,681	\$ 582,411

Depreciation expense was \$81,866 and \$57,034 for the years ended December 31, 2021 and 2020, respectively.

# 4. Intangible Assets

Intangible assets consisted of the following at December 31:

2021:

	Estimated Useful Life	Gı	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

2020:

	Estimated Useful Life	 Gross Amount Accumulated Amortization		Net Amount	
	-	 _			_
Trademarks	Indefinite	\$ 41,083	\$	_	\$ 41,083
Intangible Assets		\$ 41,083	\$	_	\$ 41,083

During 2021 and 2020, amortization expense related to intangible assets was \$2,906 and \$0, respectively.

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

2022	\$ 2,920
2023 2024	2,920
2024	2,920
2025 2026	2,920
2026	2,920
Thereafter	32,138
Total	\$ 46,738

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### 5. Accrued Expenses

Accrued expenses consisted of the following at December 31, 2021 and 2020:

	2021	2020
Employee bonuses	\$ 138,671	\$ 337,800
Vacation	43,473	52,275
Research and development projects	149,711	16,097
Interest	59,181	1,666
Professional fees	58,892	25,920
Other	25,557	-
	\$ 475,485	\$ 433,758

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.

### 6. Convertible Debt

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 (the Convertible Note) with one investor for \$1,000,000. The Convertible Note bears interest at a rate of 6% per annum and is due and payable in full on January 5, 2023. The 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 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 Convertible Note. The Company incurred issuance costs of \$15,613 related to the Convertible Note, which has been recorded as a debt discount and will be amortized over the term of the Convertible Note. There was \$7,632 amortized during the year ended December 31, 2021. Interest accrued on the Convertible Note was \$59,181 at December 31, 2021. The balance outstanding on the Convertible note was \$1,000,000 at December 31, 2021.

The Company evaluated the terms and conditions of the Note Purchase Agreement 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.

# 7. 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.

### 8. Stockholders' Equity

#### **Common Stock**

At December 31, 2021 and 2020, per the Company's amended and restated Certificate of Incorporation, the Company was authorized to issue 1,400,000 shares of \$0.01 par value common stock.

The Company had 146,916 and 144,416 shares of common stock issued and outstanding as of December 31, 2021 and 2020, respectively. During 2016, the Company issued 4,416 restricted common shares to an employee for services to be provided. Of these shares, 1,656 were vested during 2020, and resulting the non-cash compensation expense related to the vesting of shares was determined to not be material to the financial statements.

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 1,210,742 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, 2021.

#### Preferred Stock

At December 31, 2021 and 2020, per the Company's amended and restated Certificate of Incorporation, the Company has authorized 978,042 shares of \$0.0001 par value preferred stock.

On September 10, 2020, the Company executed a Series B Preferred Stock Purchase Agreement offering and the Company issued 391,303 shares of Series B preferred stock for cash proceeds of \$17,000,159. In connection with the issuance of the Series B preferred stock, the Company incurred issuance costs of \$679,094, which were netted against the proceeds resulting from the transaction.

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.

### 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, 2021, cumulative dividends on Series A Preferred Stock were \$1,274,575.

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, 2021, cumulative dividends on Series A-1 Preferred Stock were \$3,190,182.

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, 2021, cumulative dividends on Series B Preferred Stock were \$1,775,572.

# 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.

#### 9. 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 \$71,104 and \$72,093 at December 31, 2021 and 2020, respectively. 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%. At December 31, 2020, 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 7 years; Expected Volatility of 86.0%; Risk Free Interest Rate of 0.65%; 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.

The following table summarizes information about warrants outstanding at December 31, 2021:

			<b>Warrants Outstanding</b>			W	Warrants Exercisable			
Year Granted		xercise Price	Number of Warrants at 12/31/2021	Weighted Average Remaining Contractual Life	Av Ex	eighted verage kercise Price	Number of Warrants at 12/31/2021	Weighted Average Remaining Contractual Life	Av Ex	eighted verage sercise Price
rear Graineu		Price	12/31/2021	Life		rice	12/31/2021	Life	1	rice
2016	\$	0.01	1,615	4.7 years	\$	0.01	1,615	4.7 years	\$	0.01
2016 2018	\$ \$	0.01 3.39	1,615 6,745	4.7 years 6.2 years	\$ \$	0.01 3.39	1,615 6,745	4.7 years 6.2 years	\$ \$	0.01 3.36
	\$ \$ \$		,	3				3	\$ \$ \$	

### 10. 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 and 157,440 shares available for granting under the Plan at December 31, 2021 and 2020, respectively. Options vest over varying time frames.

During the year ended December 31, 2021 and 2020, the Company granted 69,800 and 54,637, 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, 2021 and 2020, the Company recognized stock compensation expense of \$306,055 and \$263,143, respectively, relating to the issuance of service-based stock options. At December 31, 2021, there was \$728,895 of unamortized compensation expense that will be amortized over the remaining vesting period. At December 31, 2021, there were 13,120 performance-based options outstanding with a fair value of \$118,132. During the year ended December 31, 2021, 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%.

To determine the estimated fair value of the options granted during 2020, 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 0.64%; and Dividend Yield of 0%.

The following table summarizes information about options outstanding and exercisable at December 31, 2021:

			<b>Options Outstanding</b>			Options Exercisable			
							Weighted		
				_			Average		
		Number of Options at	Weighted Average Remaining		Weighted rage Exercise	Number of Options at	Remaining Contractual		eighted verage
Ex	ercise Price	12/31/2021	Contractual Life	Avei	Price	12/31/2021	Life		cise Price
\$	3.39	36,067	4.0 years	\$	3.39	35,542	4.0 years	\$	3.39
\$	6.58	35,131	4.0 years	\$	6.58	21,605	4.0 years	\$	6.58
\$	12.09	123,437	9.3 years	\$	12.09	48,721	9.0 years	\$	12.09

Total stock option activity for the years ended December 31, 2021 and 2020 is summarized as follows:

	Shares	Weighted Average Exercise Price
Outstanding at December 31, 2019	85,050	\$ 5.13
Granted	54,637	12.09
Forfeited	(4,500)	6.58
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

There are 9,352 shares available for future grant under the Plan at December 31, 2021.

# 11. 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, 2021 Description	Level 1	Level 2	Level 3	Total
Liabilities:				
Common stock warrants	<u> </u>	<u> </u>	<b>\$</b> 71,104	<b>\$</b> 71,104
December 31, 2020				
Description	Level 1	Level 2	Level 3	Total
Liabilities:				
Common stock warrants	<u>\$</u>	<u>\$ -</u>	\$ 72,093	\$ 72,093

The following table presents the changes in Level 3 instruments measured on a recurring basis for the years ended December 31, 2021 and 2020:

	Common Sto	ock Warrants
Balance at January 1, 2020	\$	36,256
Change in fair value of warrants		35,837
Balance at December 31, 2020		72,093
Change in fair value of warrants		(989)
Balance at December 31, 2021	\$	71,104

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.

## 12. 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, 2021 and 2020 are as follows:

		2021		2020
Deferred tax assets:	·			
Net operating loss carryforwards	\$	6,994,967	\$	4,433,551
Tax credits		1,216,246		699,408
Accrued expenses		48,288		102,136
Other		25,240		16,764
Total deferred tax assets		8,284,741		5,251,859
Deferred tax liabilities				
Depreciation and amortization		(234,616)		(56,891)
Total deferred tax liabilities		(234,616)		(56,891)
Valuation allowance		(8,050,125)		(5,194,968)
Net deferred tax (liability) asset	\$	_	\$	_

The Company has federal net operating loss carryforwards of approximately \$25,954,000 and \$16,542,000 for the tax years ending December 31, 2021 and 2020, respectively, of which \$1,285,000 will expire in tax years 2036 through 2037 and approximately \$24,704,000 which does not expire. The Company has state net operating loss carryforwards of approximately \$25,947,000 and \$16,448,000 for the tax years ending December 31, 2021 and 2020, respectively, which will expire in tax years 2036 through 2041.

The Company has federal research tax credits of approximately \$859,000 and \$529,000 for the tax years ending December 31, 2021 and 2020, respectively, which expire in tax years 2040 through 2041. The Company has state research tax credits of approximately \$249,000 and \$154,000 for the tax years ending December 31, 2021 and 2020, respectively, of which \$5,000 will expire in tax year 2031, \$96,000 will expire in tax year 2036 and the remainder can be carried forward indefinitely. The Company has Canadian research tax credits of approximately \$138,000 and \$71,000 for the tax years ending December 31, 2021 and 2020, respectively, which expire in tax years 2039 through 2041.

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.

### 13. 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,			
	 2021	2020		
Net loss	\$ 8,939,675	\$ 6,8	11,147	
The denominator is as follows:	E. d. V. E.L	ID l 24		
	 For the Year Ended December 31,			
	 2021	2020		
Weighted average common stock outstanding, basic and diluted	145,676	1,	44,339	
\$0.01 warrants	1,615	1	1,615	
Total	 147,291	1.	45,954	
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Net loss per share, basic and diluted is as follows:

	F01	For the Year Ended December 31,			
	202	21		2020	
Net loss per share, basic and diluted	\$	(60.69)	\$	(46.6	57)

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	December 31,		
	2021	2020		
Options to purchase shares of common stock	194,635	135,187		
Warrants outstanding	37,147	37,147		
	231,782	172,334		

## 14. 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.

# **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.

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.

Rent expense for the years ended December 31, 2021 and 2020 was \$371,355 and \$218,007, respectively.

Future minimum payments under the lease agreements are expected to be as follows for the year ended December 31:

2022	\$ 435,249
2023	385,130
2024	358,667
2025	268,317
2026	225,412
Thereafter	56,631
Total	\$ 1,729,406

#### 15. 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 \$31,548 and \$35,782 for the years ended December 31, 2021 and 2020, respectively.

### 16. Concentration of Credit Risk

Financial instruments that potentially subject the Company to credit risk consist principally of cash and accounts receivable.

All grant revenue for the years ended December 31, 2021 and 2020 was from three grantors.

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.

### 17. Related Parties

During 2020, the Company earned service revenue from an entity who was also an investor in the Company's Series B Preferred Stock financing (see Note 8). Total related party revenue was \$110,000 and \$425,000 for the years ended December 31, 2021 and 2020, respectively and accounts receivable due from the related party was \$125,000 and \$100,000 at December 31, 2021 and 2020, respectively. Contract liabilities from the related party was \$15,000 at December 31, 2021.

# 18. Subsequent Events

The Company has evaluated events occurring between December 31, 2021 and December 15, 2022, the date the financial statements were available to be issued.

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.

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.

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.

In September 2022, the Company amended its Articles of Incorporation to increase the number of authorized shares. As a result of the amendment the Company is authorized to issue 1,950,000 shares of Common Stock and 1,437,151 shares of Preferred Stock.

During November 2022, the Company amended its Joint Development Agreement with a related party development partner (See Note 17). The amendment changes the option for the development partner to obtain an exclusive royalty-bearing license to add postbiotics derived from the selected strains. The amendment also adds additional development activities with a total anticipated revenue of \$720,000.

# Azitra Inc Balance Sheets Unaudited

	Se	ptember 30, 2022	I	December 31, 2021
Assets	·		-	
Current assets:				
Cash	\$	5,938,322	\$	8,044,262
Accounts receivable		85,695		160,867
Tax credits receivable		124,441		173,311
Prepaid expenses		105,356		110,289
Total current assets		6,253,814		8,488,729
Property and equipment, net		867,541		946,681
Other assets				
Other assets		88,057		48,201
Operating lease right-of-use asset		1,206,032		-
Intangible assets, net		198,121		97,693
Deferred patent costs		737,273		620,029
Total other assets		2,229,483		765,923
Total assets	\$	9,350,838	\$	10,201,333
Liabilities, convertible preferred stock, and stockholders' deficit				
Current liabilities:				
Accounts payable	\$	449,570	\$	717,800
Current operating lease liability		287,664		-
Income tax payable		1,302		1,302
Accrued expenses		802,729		475,485
Contract liabilities		11,500		15,000
Total current liabilities		1,552,765		1,209,587
Long-term operating lease liability		927,985		-
Warrant liability		70,684		71,104
Convertible notes payable, net		5,347,914		992,019
Total liabilities		7,899,348		2,272,710
Convertible preferred stock:				
Series A convertible preferred stock; \$0.0001 par value; 205,385 shares authorized				
at September 30, 2022 and December 31, 2021; 205,385 shares issued and				
outstanding at September 30, 2022 and December 31, 2021; liquidation value of				
\$3,337,506 at September 30, 2022 and December 31, 2021, Inquidation value of		3,272,944		3,272,944
Series A-1 convertible preferred stock; \$0.0001 par value; 380,657 shares		5,272,544		5,272,544
authorized at September 30, 2022 and December 31, 2021; 380,657 shares issued				
and outstanding at September 30, 2022 and December 31, 2021; liquidation value of				
\$14,274,638 as of September 30, 2022 and December 31, 2021		14,100,533		14,100,533
Series B convertible preferred stock; \$0.0001 par value; 851,108 and 392,000 shares				
authorized at September 30, 2022 and December 31, 2021, respectively; 391,303				
shares issued and outstanding at September 30, 2022 and December 31, 2021;				
liquidation value of \$17,000,159 as of September 30, 2022 and December 31, 2021		16,321,065		16,321,065
Stockholders' equity:				
Common stock; \$0.01 par value; 1,950,000 and 1,400,000 shares authorized at				
September 30, 2022 and December 31, 2021, respectively; 147,041 and 146,916				
shares issued and outstanding at September 30, 2022 and December 31, 2021,				
respectively		1,470		1,469
Additional paid-in capital		1,023,445		866,798
Accumulated deficit		(33,267,967)		(26,634,186)
Total stockholders' deficit		(32,243,052)		(25,765,919)
Total liabilities, convertible preferred stock, and stockholders' deficit	\$	9,350,838	\$	10,201,333
rotal maomities, convertible preferred stock, and stockholders deficit	Ψ	3,330,030	Ψ	10,201,333
The accompanying notes are an integral part of these condensed financial statements.				
T 00				
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# Azitra Inc Statements of Operations Unaudited

	Nine months ende			d September 30,		
		2022		2021		
Service revenue	\$	253,500	\$	-		
Total revenue		253,500		-		
Operating expenses:						
General and administrative		2,583,809		2,979,797		
Research and development		4,425,195		4,228,777		
Total operating expenses		7,009,004		7,208,574		
Loss from operations		(6,755,504)		(7,208,574)		
Other income (expense):						
Interest income		4,056		8,072		
Interest expense		(66,781)		(49,876)		
Employee retention credit		229,813		-		
Forgiveness of Payroll Protection Program loan		-		232,506		
Other expense		(45,365)		(13,478)		
Total other income (expense)		121,723		177,224		
Net loss before income taxes		(6,633,781)		(7,031,350)		
Income tax benefit (expense)		<u>-</u>		-		
Net loss	\$	(6,633,781)	\$	(7,031,350)		
Net loss per share, basic and diluted	\$	(44.63)	\$	(48.15)		
Weighted average common stock outstanding,						
basic and diluted		148,645		146,031		
	\$	-				
The accompanying notes are an integral part of these condensed financial statements.						
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# Azitra Inc Statements of Convertible Preferred Stock and Stockholders' Deficit For the Nine Months Ended September 30, 2022 and 2021 Unaudited

		Convertible red Stock		Convertible red Stock	Series B Convertible Preferred Stock Commo		Additional Paid-In Stock Capital		Accumulated Deficit	Total Stockholders' Deficit	
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
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	-	-	-	-	-	-	-	-	245,897		245,897
Net loss	-	-	-	-	-	-	-	-	-	(7,031,350)	(7,031,350)
Balance, September 30, 2021	205,385	3,272,944	380,657	14,100,533	391,303	16,321,065	144,416	1,444	798,190	(24,725,861)	(23,926,227)
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	-	-	-	-	-	-	-	-	155,138	-	155,138
Exercise of stock options	-	-	-	-	-	-	125	1	1,509	-	1,510
Net loss										(6,633,781)	(6,633,781)
Balance, September 30, 2022	205,385	\$3,272,944	380,657	\$14,100,533	391,303	\$16,321,065	147,041	\$ 1,470	\$ 1,023,445	\$ (33,267,967)	\$ (32,243,052)

 $\label{thm:companying} \textit{ notes are an integral part of these condensed financial statements.}$ 

# Azitra Inc Statements of Cash Flows Unaudited

# Nine Months Ended September 30,

		ocptem	ioci ou,	
		2022		2021
Cash flows from operating activities:				
Net loss	\$	(6,633,781)	\$	(7,031,350
Adjustments to reconcile net loss to net cash used by operating activities:		(-,, - ,	,	( ) ,
Depreciation and amortization		93,515		58,428
Amortization of debt discount		5,895		5,664
Amortization of right-of-use assets		212,470		-
Accrued interest on convertible notes		60,877		44,057
Stock-based compensation		155,138		245,897
Forgiveness of Payroll Protection Program loan		-		(230,685)
Change in fair value of warrant liability		(420)		(709)
Loss on disposal of property and equipment		7,923		-
Changes in operating assets and liabilities:		,,,,,		
Accounts receivable		75,172		107,609
Prepaid expenses		4,933		162,505
Other assets		(39,856)		(899)
Tax credits receivable		48,871		258,091
Accounts payable and accrued expenses		(1,864)		278,170
Operating lease liability		(202,853)		=70,170
Income tax payable		(=0=,000)		(10,000)
Contract liabilities		(3,500)		(10,000)
Net cash used by operating activities		(6,217,480)		(6,113,222)
Tet cash used by operating activities		(0,217,400)		(0,113,222)
Cash flows from investing activities:				
Purchases of property and equipment		(23,198)		(284,816)
Proceeds from sale of property and equipment		4,250		(204,010)
Capitalization of deferred patent costs		(117,244)		(107,608)
Capitalization of licenses		(57,372)		(107,000)
Capitalization of necesses  Capitalization of patent and trademark costs		(46,406)		(E6 162)
				(56,163)
Net cash used by investing activities		(239,970)		(448,587)
Cash flows from financing activities:				
Proceeds from convertible notes, net of issuance costs		4,350,000		984,387
Proceeds from exercise of stock options		1,510		-
Net cash provided by financing activities		4,351,510		984,387
The cash provided by intakening activities		7,551,510	-	304,307
Net change in cash and cash equivalents		(2,105,940)		(5,577,422)
The change in cash and cash equivalents		(=,100,0.0)		(3,377, 122)
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	\$	5,938,322	\$	10,193,612
Supplemental disclosure of cash flow information:				
Non-cash transactions:				
Obtaining a right-of-use asset in exchange for lease liability	\$	1,418,502	\$	-
· ·				
The accompanying notes are an integral part of these condensed financial statements	i <b>.</b>			

#### 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.

#### **Going Concern Matters**

The unaudited condensed 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 nine months ended September 30, 2022, the Company has an accumulated deficit of \$33.3 million, a loss from operations of \$6.7 million and used \$6.2 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 still in their pre-clinical phase and therefore does not yet have product revenue. 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 for twelve months from 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 ("U.S. GAAP").

#### **Unaudited Interim Financial Information**

The unaudited interim financial statements and related notes have been prepared in accordance with U.S. GAAP for interim financial information, within the rules and regulations of the United States Securities and Exchange Commission (the "SEC"). Certain information and disclosures normally included in the annual financial statements prepared in accordance with U.S. GAAP have been condensed or omitted pursuant to such rules and regulations. The unaudited interim financial statements have been prepared on a basis consistent with the audited financial statements and in the opinion of management, reflect all adjustments, consisting of only normal recurring adjustments, necessary for the fair presentation of the results for the interim periods presented and of the financial condition as of the date of the interim balance sheet. The financial data and the other information disclosed in these notes to the interim financial statements related to the nine-month periods are unaudited. Unaudited interim results are not necessarily indicative of the results for the full fiscal year. These unaudited interim financial statements should be read in conjunction with the financial statements of the Company for the year ended December 31, 2021 and notes thereto that are included in the Company's Registration Statement.

#### **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

The Company classifies as cash amounts on deposit in banks.

#### **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.

#### 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 September 30, 2022 and December 31, 2021. Accounts receivable are written off when deemed uncollectible. Recoveries of accounts receivable previously written off are recorded when received.

#### **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 September 30, 2022, the Company had operating right-of-use assets with a net value of \$1,206,032 and current and long-term operating lease liabilities of \$287,664 and \$927,985, 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 during the nine months ended September 30, 2022 or **2021**.

#### **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 nine months ended September 30, 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.

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 debt should be accounted for in accordance with ASC 480 – Distinguishing Liabilities from Equity. If the debt does not meet the criteria of an ASC 480 liability, the note's conversion features require bifurcation in accordance with ASC 815 – Derivatives and Hedging. If the Company determines the embedded conversion feature requires bifurcation in accordance with ASC 815, the Company also considers if it can elect the fair value option. If the fair value option is elected, the Company records the note at its initial fair value with any subsequent changes in fair value option for the 2022 Convertible Notes and will record the notes at their initial fair values with any subsequent changes in fair value recorded in earnings.

#### 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.

#### 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 and 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.

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 related to labor, materials and supplies. Research and development costs incurred were \$4,425,195 and \$4,228,777 during the nine month period ended September 30, 2022 and 2021, respectively.

At September 30, 2022 and December 31, 2021, the Company has a state tax credit receivable of \$71,396 for pending refunds related to the selling of research and development tax credits back to the State of Connecticut. At September 30, 2022 and December 31, 2021, the Company has \$45,398 and \$89,855, respectively for pending refunds related to Canadian Scientific Research and Experimental Development (SRED) credits. At September 30, 2022 and December 31, 2021, the Company has also recorded \$7,647 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.

# 2. Summary of Significant Accounting Policies (continued)

#### **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.

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

#### **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.

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 September 30, 2022 and December 31, 2021. The Company's income tax returns have not been examined by tax authorities through December 31, 2021.

#### **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.

#### **Recent 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 14 – 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 is currently evaluating the potential impact this standard may have on its financial statements upon adoption.

#### **Recent Accounting Pronouncements (continued)**

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 September 30, 2022 and December 31, 2021:

	September 30, 2022	December 31, 2021		
Lab equipment	\$ 1,024,016	\$	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	
	 1,122,944		1,115,665	
Less: accumulated depreciation	(255,403)		(168,984)	
Net property and equipment	\$ 867,541	\$	946,681	

Depreciation expense was \$90,165 and \$56,246 for the nine months ended September 30, 2022 and 2021, respectively.

# 5. Intangible Assets

Intangible assets consisted of the following at:

September 30, 2022:

	Estimated Useful Life	 Gross Amount	Accumulated Amortization	Net Amount		
Trademarks	Indefinite	\$ 53,999	\$ -	\$	53,999	
Patents	17 years	93,006	6,256		86,750	
License agreement	17 years	57,372			57,372	
Intangible Assets		\$ 204,377	\$ 6,256	\$	198,121	

December 31, 2021:

	Estimated Useful Life	G	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 the nine months ended September 30, 2022 and 2021, amortization expense related to intangible assets was \$3,350 and \$2,182, respectively.

# 6. Accrued Expenses

Accrued expenses consisted of the following at:

	September 30, 2022	<b>December 31, 2021</b>		
Employee bonuses	\$ 265,941	\$	138,671	
Employee payroll	37,533		-	
Vacation	54,165		43,473	
Research and development projects	246,525		149,711	
Interest	120,058		59,181	
Professional fees	73,349		58,892	
Other	5,158		25,557	
	\$ 802,729	\$	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.

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 will be amortized over the term of the 2021 Convertible Note.

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:

	September 30, 2022		December 31, 2021
2021 Convertible Note	\$ 1,000,000	\$	1,000,000
2022 Convertible Notes	4,350,000		-
	5,350,000		1,000,000
Debt issuance costs	(2,086)		(7,981)
	\$ 5,347,914	\$	992,019
		-	

There was \$5,895 and \$5,664 amortized related to the debt issuance costs during the nine months ended September 30, 2022 and 2021, respectively. Interest accrued on the convertible notes was \$120,058 and \$59,181 at September 30, 2022 and December 31, 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 for the nine months ended September 30, 2021.

#### 9. Stockholders' Equity

#### Common Stock

At September 30, 2022 and December 31, 2021, per the Company's amended and restated Certificate of Incorporation, the Company was authorized to issue 1,950,000 and 1,400,000 shares, respectively, of \$0.01 par value common stock.

The Company had 147,041 and 146,916 shares of common stock issued and outstanding as of September 30, 2022 and December 31, 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 1,199,742 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 September 30, 2022.

# **Preferred Stock**

At September 30, 2022 and December 31, 2021, per the Company's amended and restated Certificate of Incorporation, the Company has authorized 1,437,150 and 978,042 shares, respectively, 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.

#### 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 September 30, 2022, cumulative dividends on Series A Preferred Stock were \$1,474,825.

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 September 30, 2022, cumulative dividends on Series A-1 Preferred Stock were \$4,046,660.

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 September 30, 2022, cumulative dividends on Series B Preferred Stock were \$2,795,582.

# 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 \$70,684 and \$71,104 at September 30, 2022 and December 31, 2021, respectively. At September 30, 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 5.54 years; Expected Volatility of 86.0%; Risk Free Interest Rate of 4.06%; 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 6.29 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.

The following table summarizes information about warrants outstanding at September 30, 2022:

			Wa	rrants Outstand	ing		Wa	rrants Exercisal	ole	
				Weighted		-		Weighted		,
				Average	W	eighted		Average	W	eighted
			Number of	Remaining	Α	verage	Number of	Remaining	A	verage
	]	Exercise	Warrants at	Contractual		xercise	Warrants at	Contractual		ercise
 Year Granted		Price	9 /30/2022	Life		Price	9 /30/2022	Life	]	Price
2016	\$	0.01	1,615	4.0 years	\$	0.01	1,615	4.0 years	\$	0.01
2018	\$	3.39	6,745	5.5 years	\$	3.39	6,745	5.5 years	\$	3.36
2019	\$	37.50	30,402	3.4 years	\$	37.50	30,402	3.4 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 September 30, 2022 and December 31, 2021. Options vest over varying time frames.

During the nine months ended September 30, 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 nine months ended September 30, 2022 and 2021, the Company recognized stock compensation expense of \$155,138 and \$245,897, respectively, relating to the issuance of service-based stock options. At September 30, 2022, there was \$501,485 of unamortized compensation expense that will be amortized over the remaining vesting period. At September 30, 2022 and 2021, there were 13,120 performance-based options outstanding with a fair value of \$118,132. During the nine months ended September 30, 2022 and 2021, 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 the nine months ended September 30, 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% to 1.26%; and Dividend Yield of 0%.

The following table summarizes information about options outstanding and exercisable at September 30, 2022:

			<b>Options Outstanding</b>	Options Exercisable					
							Weighted		
		Number of Options at	Weighted Average Remaining		Weighted rage Exercise	Number of Options at	Average Remaining		eighted verage
Exe	rcise Price	9/30/2022	Contractual Life	7110	Price	9/30/2022	Contractual Life		cise Price
\$	3.39	36,067	3.3 years	\$	3.39	36,009	3.3 years	\$	3.39
\$	6.58	33,131	3.3 years	\$	6.58	25,023	3.3 years	\$	6.58
\$	12.09	114,437	8.5 years	\$	12.09	60,440	8.3 years	\$	12.09

Total stock option activity for the nine months ended September 30, 2022 is summarized as follows:

		Weighted Average
	Shares	Exercise Price
Outstanding at December 31, 2021	194,635	\$ 9.48
Granted	-	-
Exercised	(125)	12.09
Forfeited	(10,875)	12.09
Outstanding at September 30, 2022	183,635	\$ 9.46

There are 20,352 shares available for future grant under the Plan at September 30, 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:

# September 30, 2022

September 30, 2022				
Description	Level 1	Level 2	Level 3	Total
Liabilities:	 		 	
Common stock warrants	\$ -	\$ -	\$ 70,684	\$ 70,684
2022 Convertible Notes	-	-	4,350,000	4,350,000
Total	\$ -	\$ _	\$ 4,420,684	\$ 4,420,684
December 31, 2021				
Description	 Level 1	 Level 2	 Level 3	 Total
Liabilities:				
Common stock warrants	\$ 	\$ 	\$ 71,104	\$ 71,104
	F-39			

The following table presents the changes in Level 3 instruments measured on a recurring basis for the period ended September 30, 2022:

	Common Stock Warrants					
Balance at December 31, 2021	\$ 71,104					
Change in fair value of warrants	(420)					
Issuance of 2022 Convertible Notes	4,350,000					
Balance at September 30, 2022	\$ 4,420,684					

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. 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:

	F	For the Nine Months Ended September 30,		
		2022		2021
Net loss	\$	6,633,781	\$	7,031,350

The denominator is as follows:

	For the Nine Months En	For the Nine Months Ended September 30,	
	2022	2021	
Weighted average common stock outstanding, basic and diluted	147,030	144,416	
\$0.01 warrants	1,615	1,615	
Total	148,645	146,031	

Net loss per share, basic and diluted is as follows:

	For the Nine M	For the Nine Months Ended September 30,		
	2022		2021	
Net loss per share, basic and diluted	\$ (4	4.63) \$	(48.15)	

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:

		September 3	September 30,	
		2022	2021	
Options to purchase shares of common stock		183,635	197,135	
Warrants outstanding		37,147	37,147	
		220,782	234,282	
	F-40			

#### 14. 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 nine months ended September 30, 2022, the Company capitalized payments made under this license agreement in the amount of \$57,372. 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.

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	\$ 332,832
2024	338,752
2025	301,637
2026	228,531
2027	121,665
Total future undiscounted lease payments	1,323,417
Less: interest	(107,768)
Present value of lease liabilities	\$ 1,215,649

Rent expense for all operating leases was \$254,148 for the nine months ended September 30, 2022. The weighted average lease term for all operating leases is 4.1 years. The weighted average discount rate for all operating leases is 4.25%.

#### 15. 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 \$18,945 and \$21,598 for the nine months ended September 30, 2022 and 2021, respectively.

#### 16. Concentration of Credit Risk

Financial instruments that potentially subject the Company to credit risk consist principally of cash and accounts receivable.

All service revenue for the nine months ended September 30, 2022 was from one customer.

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.

# 17. Related Parties

Total related party revenue was \$253,500 and \$0 for the nine months ended September 30, 2022 and 2021, respectively and accounts receivable due from the related party was \$86,841 and \$125,000 at September 30, 2022 and December 31, 2021, respectively. Contract liabilities from the related party was \$11,500 and \$15,000 at September 30, 2022 and December 31, 2021, respectively.

# 18. Subsequent Events

The Company has evaluated events subsequent to the balance sheet date through December 15, 2022, the date these condensed financial statements were available to be issued.

During November 2022, the Company amended its Joint Development Agreement with a related party development partner (See Note 17). The amendment changes the option for the development partner to obtain an exclusive royalty-bearing license to add postbiotics derived from the selected strains. The amendment also adds additional development activities with a total anticipated revenue of \$720,000.

# **Shares of Common Stock**



# **Azitra Inc**

PRELIMINARY PROSPECTUS

# **ThinkEquity**

, 2022

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 \_\_\_\_\_\_ filing fee.

SEC Registration Fee	\$ *
FINRA Filing Fee	*
Non-Accountable Expenses to Underwriters	*
Initial Listing Fee	*
Printing and Engraving Expenses	*
Accounting Fees and Expenses	*
Legal Fees and Expenses	*
Transfer Agent's and Registrar's Fees and Expenses	*
Miscellaneous Fees	*
Total	\$ *

<sup>\*</sup> To be filed by amendment.

#### 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 shares of our common stock upon the consummation of this offering.

In January placement, we sold to one investor an unsecured convertible promissory note in the principal amount of \$1,000,000. The principal amount of the note, along is convertible into shares of our common at \$ per share, which will convert into approximately shares of our common stock upon the consummation of this offering.

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. Certificate of Amendment to Amended and Restated Certificate of Incorporation of the Registrant. 3.2 3.3\* Form of Second Amended and Restated Certificate of Incorporation of the Registrant to be in effect upon completion of the offering, Amended and Restated Bylaws of the Registrant. 3.4 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. Form of Warrant. 4.2 4.3\* Form of Representative's Warrant (included in Exhibit 1.1). 5.1\* Opinion of Greenberg Traurig, LLP. Form of Indemnity Agreement between the Registrant and each of its directors and executive officers. 10.1 +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 10.4 +Executive Employment Agreement dated April 22, 2021 between the Registrant and Francisco Salva. 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 (included on signature page to this registration statement). 99.1\* Consents of Director Nominees. 107\* Filing Fee Table.

- 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 December [●], 2022.

#### AZITRA INC

Francisco Salva Chief Executive Officer and Director (Principal Executive Officer)

# POWER OF ATTORNEY

Each person whose signature appears below constitutes and appoints Francisco Salva, his true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this registration statement, any subsequent registration statements pursuant to Rule 462 of the Securities Act of 1933, as amended, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof. This power of attorney may be executed in counterparts.

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
Francisco Salva	President,  Chief Executive Officer and Director (Principal Executive Officer)	December [●], 2022
Norman Staskey	Chief Financial Officer,  Treasurer and Secretary (Principal Financial and Accounting Officer)	December [•], 2022
Travis Whitfill	Director	December [●], 2022
Andrew McClary	Director	December [●], 2022
	II-4	

# **Delaware**

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY THE ATTACHED IS A TRUE AND CORRECT COPY OF THE RESTATED CERTIFICATE OF "AZITRA INC", FILED IN THIS OFFICE ON THE NINTH DAY OF SEPTEMBER, A. D. 2020, AT 1:04 O'CLOCK P. M.

# AMENDED AND RESTATED CERTIFICATE OF INCORPORATION

# AZITRA INC

# a Delaware Corporation

(Pursuant to Sections 228, 242 and 245 of the General Corporation Law of the State of Delaware)

Azitra Inc, a corporation organized and existing under and by virtue of the provisions of the General Corporation Law of the State of Delaware (the "General Corporation Law"), does hereby certify as follows:

FIRST: The name of the corporation is Azitra Inc (the "**Corporation**") and that the Corporation was originally incorporated pursuant to the General Corporation Law on January 2, 2014. The Corporation last amended and restated its Certificate of Incorporation and filed an Amended and Restated Certificate of Incorporation with the Secretary of State of the State of Delaware on February 22, 2019.

SECOND: The Amended and Restated Certificate of Incorporation of the Corporation in the form attached hereto as <u>Exhibit A</u> has been duly adopted in accordance with the provisions of Sections 228, 242 and 245 of the General Corporation Law by the directors and stockholders of the Corporation.

THIRD: The Amended and Restated Certificate of Incorporation so adopted reads in full as set forth in  $Exhibit\ A$  attached hereto and is hereby incorporated herein by this reference.

IN WITNESS WHEREOF, the Corporation has caused this Certificate to be signed by its Chief Executive Officer this 9th day of September, 2020.

By: /s/ Richard Andrews

Name: Richard Andrews
Title: Chief Executive Officer

#### **EXHIBIT A**

# AMENDED AND RESTATED CERTIFICATE OF INCORPORATION OF

# AZITRA INC a Delaware Corporation

**FIRST:** The name of this corporation is Azitra Inc (the "Corporation").

**SECOND:** The address of the registered office of the Corporation in the State of Delaware is 251 Little Falls Drive, in the City of Wilmington, County of New Castle, Delaware 19808. The Corporation's registered agent at such address is Corporation Service Company.

**THIRD:** The nature of the business or purposes to be conducted or promoted is to engage in any lawful act or activity for which corporations may be organized under the General Corporation Law.

**FOURTH:** The total number of shares that the Corporation is authorized to issue is (i) 1,400,000 shares of Common Stock, \$0.01 par value per share ("Common Stock") and (ii) 978,042 shares of Preferred Stock, \$0.0001 par value per share ("Preferred Stock").

The following is a statement of the designations and the powers, privileges and rights, and the qualifications, limitations or restrictions thereof in respect of each class of capital stock of the Corporation.

#### A. COMMON STOCK

- 1. <u>General</u>. The voting, dividend and liquidation rights of the holders of the Common Stock are subject to and qualified by the rights, powers and preferences of the holders of the Preferred Stock set forth herein.
- 2. <u>Voting</u>. The holders of the Common Stock are entitled to one vote for each share of Common Stock held at all meetings of stockholders (and written actions in lieu of meetings); <u>provided</u>, <u>however</u>, that, except as otherwise required by law, holders of Common Stock, as such, shall not be entitled to vote on any amendment to this Amended and Restated Certificate of Incorporation (the "Certificate of Incorporation") that relates solely to the terms of one or more outstanding series of Preferred Stock if the holders of such affected series are entitled, either separately or together with the holders of one or more other such series, to vote thereon pursuant to the Certificate of Incorporation or pursuant to the General Corporation Law. There shall be no cumulative voting. The number of authorized shares of Common Stock may be increased or decreased (but not below the number of shares thereof then outstanding) by (in addition to any vote of the holders of one or more series of Preferred Stock that may be required by the terms of the Certificate of Incorporation) the affirmative vote of the holders of shares of capital stock of the Corporation representing a majority of the votes represented by all outstanding shares of capital stock of the Corporation entitled to vote, irrespective of the provisions of Section 242(b)(2) of the General Corporation Law.

#### B. PREFERRED STOCK

205,385 shares of the authorized and unissued Preferred Stock of the Corporation are hereby designated "Series A Preferred Stock," 380,657 shares of the authorized and unissued Preferred Stock of the Corporation are hereby designated "Series A-1 Preferred Stock," and 392,000 shares of the authorized and unissued Preferred Stock of the Corporation are hereby designated "Series B Preferred Stock," with the following rights, preferences, powers, privileges and restrictions, qualifications and limitations. Unless otherwise indicated, references to "sections" or "subsections" in this Part B of this Article Fourth.

1. <u>Dividends</u>. The holders of the Preferred Stock shall be entitled to receive dividends at the applicable Dividend Rate (as defined below), payable out of funds legally available therefor, prior and in preference to any declaration or payment of any dividend (other than dividends payable solely in Common Stock) on the Common Stock. Such dividends shall accrue from day to day, from and after the original date of the issuance of the applicable shares of Preferred Stock, and be cumulative (the "Accruing Dividends"); provided, however, that except as set forth in the remainder of this Section 1, such Accruing Dividends shall be payable only when, as, and if declared by the Board of Directors of the Corporation (the "Board") and the Corporation shall be under no obligation to pay such Accruing Dividends. The "Dividend Rate" shall mean (a) with respect to the Series A Preferred Stock, eight percent (8%) per annum of the Series A Original Issue Price (as defined below) for each share of Series A Preferred Stock (as adjusted for any stock dividends, stock splits, stock combinations, recapitalizations or similar events with respect to such shares), (b) with respect to the Series A-1 Preferred Stock, eight percent (8%) per annum of the Series A-1 Original Issue Price (as defined below) for each share of Series A-1 Preferred Stock (as adjusted for any stock dividends, stock splits, stock combinations, recapitalizations or similar events with respect to such shares) and (c) with respect to the Series B Preferred Stock, eight percent (8%) per annum of the Series B Original Issue Price (as defined below) for each share of Series B Preferred Stock (as adjusted for any stock dividends, stock splits, stock combinations, recapitalizations or similar events with respect to such shares). The Corporation shall not declare, pay or set aside any dividends on shares of any other class or series of capital stock of the Corporation (other than dividends on shares of Common Stock payable in shares of Common Stock) unless (in addition to the obtaining of any consents required elsewhere in the Certificate of Incorporation) the holders of the Preferred Stock then outstanding shall first receive, or simultaneously receive, both (i) the amount of the aggregate Accruing Dividends on each outstanding share of Preferred Stock not previously paid and (ii) a dividend on each outstanding share of Preferred Stock in an amount at least equal to that dividend per share of Preferred Stock as would equal the product of (A) the dividend payable on each share of such class or series determined as if all shares of such class or series had been converted into Common Stock and (B) the number of shares of Common Stock issuable upon conversion of a share of such series of Preferred Stock, in each case calculated on the record date for determination of holders entitled to receive such dividend. The Requisite Holders (as defined below) can waive any dividend preference that such holders shall be entitled to receive under this Section 1. The term "Series A Original Issue Price" shall mean \$16.25 per share, 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. The term "Series A-1 Original Issue Price" shall mean \$37.50 per share, 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. The term "Series B Original Issue Price" shall mean \$43.4450 per share, 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. The Series A Original Issue Price, the Series A-1 Original Issue Price and the Series B Original Issue Price are each sometimes referred to herein as the "Original Issue Price" for the applicable specified series.

# 2. Liquidation, Dissolution or Winding Up; Certain Mergers, Consolidations and Asset Sales

2.1 <u>Preferential Payments to Holders of Preferred Stock.</u> In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Corporation or Deemed Liquidation Event (as defined below), the holders of shares of Preferred Stock then outstanding shall be entitled to be paid, on a pan passu basis, out of the assets of the Corporation available for distribution to its stockholders before any payment shall be made to the holders of Common Stock by reason of their ownership thereof, an amount per share equal to the greater of (a) one (1) times the Original Issue Price of such applicable series of Preferred Stock, plus any dividends declared and/or accrued but unpaid thereon, or (b) such amount per share as would have been payable had all shares of the applicable series of Preferred Stock been converted into Common Stock pursuant to <u>Section 4</u> immediately prior to such liquidation, dissolution or winding up or Deemed Liquidation Event. If upon any such liquidation, dissolution or winding up of the Corporation or Deemed Liquidation Event, the assets of the Corporation available for distribution to its stockholders shall be insufficient to pay the holders of shares of Preferred Stock the full amount to which they shall be entitled under this <u>Subsection 2.1</u>, the holders of shares of Preferred Stock shall share ratably in any distribution of the assets available for distribution in proportion to the respective amounts which would otherwise be payable in respect of the shares held by them upon such distribution if all amounts payable on or with respect to such shares were paid in full.

2.2 <u>Distribution of Remaining Assets</u>. In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Corporation or Deemed Liquidation Event, after full payment of all amounts required to be paid to the holders of Preferred Stock pursuant to <u>Subsection 2.1</u>, 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 shares of Preferred Stock as if they had been converted to Common Stock pursuant to the terms of the Certificate of Incorporation immediately prior to such liquidation, dissolution or winding up of the Corporation or Deemed Liquidation Event. The aggregate amount which a holder of a share of Preferred Stock is entitled to receive under <u>Subsections 2.1</u> and <u>2.2</u> is hereinafter referred to as the "**Preferred Liquidation Amount**."

# 2.3 Deemed Liquidation Events.

2.3.1 <u>Definition</u>. Each of the following events shall be considered a "Deemed Liquidation Event" unless the holders of at least 75% of the outstanding shares of Preferred Stock, voting together as a single class on an as-converted basis (the "**Requisite Holders**"), elect otherwise by written notice sent to the Corporation at least ten (10) days prior to the effective date of any such event:

- (a) a merger or consolidation in which
  - (i) the Corporation is a constituent party or
- (ii) a subsidiary of the Corporation is a constituent party and the Corporation issues shares of its capital stock pursuant to such merger or consolidation,

except any such merger or consolidation involving the Corporation or a subsidiary in which the shares of capital stock of the Corporation outstanding immediately prior to such merger or consolidation continue to represent, or are converted into or exchanged for shares of capital stock that represent, immediately following such merger or consolidation, at least a majority, by voting power, of the capital stock of (1) the surviving or resulting corporation; or (2) if the surviving or resulting corporation is a wholly owned subsidiary of another corporation immediately following such merger or consolidation, the parent corporation of such surviving or resulting corporation; or

(b) the sale, lease, transfer, exclusive license or other disposition, in a single transaction or series of related transactions, by the Corporation or any subsidiary of the Corporation of all or substantially all the assets of the Corporation and its subsidiaries taken as a whole or the sale or disposition (whether by merger, consolidation or otherwise) of one or more subsidiaries of the Corporation if substantially all of the assets of the Corporation and its subsidiaries taken as a whole are held by such subsidiary or subsidiaries, except where such sale, lease, transfer, exclusive license or other disposition is to a wholly owned subsidiary of the Corporation.

#### 2.3.2 Effecting a Deemed Liquidation Event.

(a) The Corporation shall not have the power to effect a Deemed Liquidation Event referred to in <u>Subsection 2.3.1(a)(i)</u> unless the consideration payable to the stockholders of the Corporation and/or the Corporation in such Deemed Liquidation Event shall be allocated among the holders of capital stock of the Corporation in accordance with Subsections 2.1 and 2.2.

(b) In the event of a Deemed Liquidation Event referred to in <u>Subsection 2.3.1(a)(ii)</u> or <u>2.3.1(b)</u>, if the Corporation does not effect a dissolution of the Corporation under the General Corporation Law within ninety (90) days after such Deemed Liquidation Event, then (i) the Corporation shall send a written notice to each holder of Preferred Stock no later than the ninetieth (90th) day after the Deemed Liquidation Event advising such holders of their right (and the requirements to be met to secure such right) pursuant to the terms of the following clause; (ii) to require the redemption of such shares of Preferred Stock, and (iii) if the Requisite Holders so request in a written instrument delivered to the Corporation not later than one hundred twenty (120) days after such Deemed Liquidation Event, the Corporation shall use the consideration received by the Corporation for such Deemed Liquidation Event (net of any retained liabilities associated with the assets sold or technology licensed, as determined in good faith by the Board), together with any other assets of the Corporation available for distribution to its stockholders, all to the extent permitted by Delaware law governing distributions to stockholders (the "Available Proceeds"), on the one hundred fiftieth (150th) day after such Deemed Liquidation Event, to redeem all outstanding shares of Preferred Stock at a price per share equal to the Preferred Liquidation Amount. Notwithstanding the foregoing, in the event of a redemption pursuant to the preceding sentence, if the Available Proceeds are not sufficient to redeem all outstanding shares of Preferred Stock, the Corporation shall ratably redeem each holder's shares of Preferred Stock to the fullest extent of such Available Proceeds, based on the respective amounts which would otherwise be payable in respect of the shares to be redeemed if the Available Proceeds were sufficient to redeem all such shares, and shall redeem the remaining shares as soon as it may lawfully do so under Delaware law governing distributions to stockholders. Prior to the distribution or redemption provided for in this Subsection 2.3.2(b), the Corporation shall not expend or dissipate the consideration received for such Deemed Liquidation Event, except to discharge expenses incurred in connection with such Deemed Liquidation Event or in the ordinary course of business.

2.3.3 <u>Amount Deemed Paid or Distributed</u>. Subject to <u>Subsection 2.3.4</u>, the amount deemed paid or distributed to the holders of capital stock of the Corporation upon any Deemed Liquidation Event or redemption shall be the cash or the value of the property, rights or securities paid or distributed to such holders by the Corporation or the acquiring person, firm or other entity. Subject to <u>Subsection 2.3.4</u>, the value of such property, rights or securities shall be determined in good faith by the Board.

2.3.4 <u>Allocation of Escrow and Contingent Consideration</u>. In the event of a Deemed Liquidation Event pursuant to <u>Subsection 2.3.1</u>, if any portion of the consideration payable to the Corporation or the stockholders of the Corporation is payable only upon satisfaction of contingencies (whether upon the occurrence of any event, the passage of time or otherwise (including, without limitation, any deferred purchase price payments, installment payments, payments made in respect of any promissory note issued in such transaction, payments from escrow, purchase price adjustment payments or payments in respect of "earnouts" or holdbacks)) (the "**Additional Consideration**"), the definitive agreement(s) with respect to such Deemed Liquidation Event shall provide that (a) the portion of such consideration that is not Additional Consideration (such portion, the "**Initial Consideration**") shall be allocated among the holders of capital stock of the Corporation in accordance with <u>Subsections 2.1</u> and <u>2.2</u> as if the Initial Consideration were the only consideration payable in connection with such Deemed Liquidation Event; and (b) any Additional Consideration which becomes payable upon satisfaction of such contingencies shall be allocated among the holders of capital stock of the Corporation in accordance with <u>Subsections 2.1</u> and <u>2.2</u> after taking into account the previous payment of the Initial Consideration as part of the same transaction. For the purposes of this <u>Subsection 2.3.4</u>, consideration placed into escrow or retained as a holdback to be available for satisfaction or indemnification or similar obligations in connection with such Deemed Liquidation Event shall be deemed to be Initial Consideration.

# 3. Voting.

3.1 General. In addition to any special class or series voting rights provided by law or by the other provisions of the Certificate of Incorporation, 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 and shall be entitled to vote, together with the holders of Common Stock, with respect to any question upon which holders of Common Stock have the right to vote. Except as provided by law or by the other provisions of the Certificate of Incorporation, holders of Preferred Stock shall vote together with the holders of Common Stock as a single class and on an as-converted to Common Stock basis.

3.2 Election of Directors. The holders of record of the shares of Series B Preferred Stock shall be entitled, by vote of the holders of a majority of the then outstanding shares of Series B Preferred Stock, exclusively and as a separate class, to elect two (2) members of the Board (each, a "Series B Preferred Director" and, collectively, the "Series B Preferred Directors") at each meeting or pursuant to each consent of the Corporation's stockholders for the election of directors, and to remove from office any Series B Preferred Director and to fill any vacancy caused by the resignation, death or removal of any Series B Preferred Director. The holders of record of the shares of Series A-1 Preferred Stock shall be entitled, by vote of the holders of a majority of the then outstanding shares of Series A-1 Preferred Stock, exclusively and as a separate class, to elect one (1) member of the Board (the "Series A-1 Preferred Director") at each meeting or pursuant to each consent of the Corporation's stockholders for the election of directors, and to remove from office the Series A-1 Preferred Director and to fill any vacancy caused by the resignation, death or removal of the Series A-1 Preferred Director. The holders of record of the shares of Series A Preferred Stock shall be entitled, by vote of the holders of a majority of the then outstanding shares of Series A Preferred Stock, exclusively and as a separate class, to elect one (1) member of the Board (the "Series A Preferred Director" and, together with the Series B Preferred Directors and Series A-1 Preferred Director, the "Preferred Directors") at each meeting or pursuant to each consent of the Corporation's stockholders for the election of directors, and to remove from office the Series A Preferred Director and to fill any vacancy caused by the resignation, death or removal of the Series A Preferred Director. The holders of record of the shares of Common Stock shall be entitled, by vote of the holders of a majority of the then outstanding shares of Common Stock, exclusively and as a separate class, to elect one (1) member of the Board at each meeting or pursuant to each consent of the Company's stockholders for the election of directors, and to remove from office such director and to fill any vacancy caused by the resignation, death or removal of such director. The holders of record of the shares of Common Stock and Preferred Stock, voting together as a single class, shall be entitled, by vote of the holders of a majority of the then outstanding shares of Common Stock (calculated on an as-ifconverted to Common Stock basis), to elect all remaining members of the Board at each meeting or pursuant to each consent of the Corporation's stockholders for the election of directors, and to remove from office such director(s) and to fill any vacancy caused by the resignation, death or removal of such director(s). If the holders of shares of Preferred Stock (or class or series thereof) and/or Common Stock, as the case may be, fail to elect a sufficient number of directors to fill all directorships for which they are entitled to elect directors pursuant to this Subsection 3.2, then any directorship not so filled shall remain vacant until such time as the holders of the Preferred Stock (or class or series thereof) and/or Common Stock, as the case may be, elect a person to fill such directorship by vote or written consent in lieu of a meeting; and no such directorship may be filled by stockholders of the Corporation other than by the stockholders of the Corporation that are entitled to elect a person to fill such directorship, voting exclusively and as a separate class. At any meeting held for the purpose of electing a director, the presence in person or by proxy of the holders of a majority of the outstanding shares of the class or series entitled to elect such director shall constitute a quorum for the purpose of electing such director. Except as otherwise provided in this <u>Subsection</u> 3.2, a vacancy in any directorship filled by the holders of any class or series shall be filled only by vote or written consent in lieu of a meeting of the holders of such class or series or by any remaining director or directors elected by the holders of such class or series pursuant to this Subsection 3.2; provided, however, for administrative convenience, the initial Series B Preferred Directors may also be appointed by the Board in connection with the approval of the initial issuance of Series B Preferred Stock without a separate action by the holders of Series B Preferred Stock.

3.3 <u>Preferred Stock Protective Provisions</u>. At any time when shares of Preferred Stock are outstanding, the Corporation shall not, either directly or indirectly by amendment, merger, consolidation or otherwise, do any of the following, or cause or permit any subsidiary of the Company to do any of the following (as any of the following shall be reasonably applied to such subsidiary), without (in addition to any other vote required by law, the Bylaws of the Corporation or the Certificate of Incorporation) the written consent or affirmative vote of the Requisite Holders, given in writing or by vote at a meeting, consenting or voting (as the case may be) separately as a class, and any such act or transaction entered into without such consent or vote shall be null and void ab initio, and of no force or effect.

3.3.1 alter any provision of the certificate of incorporation or the bylaws if it would adversely alter the rights, preferences, privileges or powers of or restrictions of the Preferred Stock or any series thereof;

- 3.3.2 increase or decrease the authorized number of shares of Preferred Stock or any series thereof;
- 3.3.3 authorize or create (by reclassification or otherwise) any new class or series of shares having rights, preferences or privileges with respect to dividends or liquidation senior to or on parity with the Series A Preferred Stock, Series A-1 Preferred Stock or Series B Preferred Stock or having voting rights other than those granted to the Preferred Stock generally; or
- 3.3.4 liquidate, dissolve or wind-up the business and affairs of the Corporation, effect any merger or consolidation or any other Deemed Liquidation Event, or consent to any of the foregoing;
  - 3.3.5 increase the authorized number of directors constituting the Board;
- 3.3.6 encumber or grant a security interest in all or substantially all of the assets of the Company in connection with any indebtedness of the Company;
- 3.3.7 acquire a material amount of assets through a merger or purchase of all or substantially all of the assets or capital stock of another entity;

3.3.8 declare or pay any dividend or distribution, or approve any repurchase with respect to the Preferred Stock (except as otherwise provided in this Certificate of Incorporation) or the Common Stock (other than for employee buybacks or distributions occurring upon a liquidity event), excluding in each case redemption of shares of capital stock or other equity securities held by Connecticut Innovations, Incorporated (together with any permitted transferee, "CII") after CU's exercise of its put rights as set forth in that certain Connecticut Presence Agreement between the Corporation and CII, dated as of April 13, 2018;

stock or option plan;

- 3.3.9 increase the number of shares authorized for issuance under any existing stock or option plan or create any new
- 3.3.10 make any changes to the senior management team;
- 3.3.11 authorize indebtedness for borrowed money greater than \$200,000;
- 3.3.12 enter into any agreement with a third party licensing the Corporation's material technology to such party;
- 3.3.13 enter into a material joint venture; or
- 3.3.14 enter into any transaction between the Corporation and any director, founder, officer or other management employee or affiliate or family member of any such individual.
- 3.4 Series B Preferred Stock Protective Provisions. At any time when at least 97,825 shares of Series B 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 B Preferred Stock) are outstanding, the Corporation shall not, either directly or indirectly by amendment, merger, consolidation or otherwise, do any of the following, or cause or permit any subsidiary of the Company to do any of the following (as any of the following shall be reasonably applied to such subsidiary) without (in addition to any other vote required by law or this Amended and Restated Certificate of Incorporation) the written consent or affirmative vote of the holders of at least a majority of the then-outstanding shares of Series B Preferred Stock, given in writing or by vote at a meeting, consenting or voting (as the case may be) separately as a class, and any such act or transaction entered into without such consent or vote shall be null and void ab initio, and of no force or effect:
- 3.4.1 liquidate, dissolve or wind-up the business and affairs of the Corporation, effect any merger or consolidation or any other Deemed Liquidation Event, or consent to any of the foregoing, if such transaction provides an enterprise value for the Corporation that is less than \$150 million.
- 3.4.2 amend, alter or repeal any provision of the Certificate of Incorporation or the Bylaws of the Corporation in a manner that adversely affects the powers, preferences or rights of the Series B Preferred Stock;
- 3.4.3 purchase or redeem (or permit any subsidiary to purchase or redeem) or pay or declare any dividend or make any distribution on, any shares of capital stock of the Corporation other than (i) redemptions of or dividends or distributions on any series of Preferred Stock as expressly authorized herein, (ii) repurchases of stock from former employees, officers, directors, consultants or other persons who performed services for the Corporation or any subsidiary in connection with the cessation of such employment or service at the lower of the original purchase price or the thencurrent fair market value thereof, (iii) redemption of shares of capital stock or other equity securities held by CII after CII's exercise of its put rights as set forth in that certain Connecticut Presence Agreement between the Corporation and CII, dated as of April 13, 2018, or (iv) as approved by the Board, including the approval of the Series B Preferred Directors;

3.4.4 create, or authorize the creation of, or issue, or authorize the issuance of any debt security or create any lien or security interest (except for purchase money liens or statutory liens of landlords, mechanics, materialmen, workmen, warehousemen and other similar persons arising or incurred in the ordinary course of business) or incur other indebtedness for borrowed money, including but not limited to obligations and contingent obligations under guarantees, or permit any subsidiary to take any such action with respect to any debt security lien, security interest or other indebtedness for borrowed money, if the aggregate indebtedness of the Corporation and its subsidiaries for borrowed money following such action would exceed \$500,000, unless such debt security has received the prior approval of the Board;

3.4.5 create, or hold capital stock in, any subsidiary that is not wholly owned (either directly or through one or more other subsidiaries) by the Corporation, or permit any subsidiary to create, or authorize the creation of, or issue or obligate itself to issue, any shares of any class or series of capital stock, or sell, transfer or otherwise dispose of any capital stock of any direct or indirect subsidiary of the Corporation, or permit any direct or indirect subsidiary to sell, lease, transfer, exclusively license or otherwise dispose (in a single transaction or series of related transactions) of all or substantially all of the assets of such subsidiary; or

3.4.6 increase or decrease the authorized number of directors constituting the Board.

#### 4. Optional Conversion.

The holders of the Preferred Stock shall have conversion rights as follows (the "Conversion Rights"):

#### 4.1 Right to Convert.

4.1.1 <u>Conversion Ratio</u>. Each share of Preferred Stock shall be convertible, at the option of the holder thereof, at any time and from time to time, and without the payment of additional consideration by the holder thereof, into such number of fully paid and non-assessable shares of Common Stock as is determined by dividing the applicable Original Issue Price by the applicable Conversion Price (as defined below) in effect at the time of conversion. The applicable "Conversion Price" for each series of Preferred Stock shall initially be equal to the Original Issue Price for each such series of Preferred Stock. Such initial applicable Conversion Price, and the rate at which shares of Preferred Stock may be converted into shares of Common Stock, shall be subject to adjustment as provided in this <u>Section 4</u>.

4.1.2 <u>Termination of Conversion Rights</u>. In the event of a liquidation, dissolution or winding up of the Corporation or a Deemed Liquidation Event, the Conversion Rights shall terminate at the close of business on the last full day preceding the date fixed for the payment of any such amounts distributable on such event to the holders of Preferred Stock; provided that the foregoing termination of Conversion Rights shall not affect the amount(s) otherwise paid or payable in accordance with <u>Subsection 2.1</u> to holders of Preferred Stock pursuant to such liquidation, dissolution or winding up of the Corporation or a Deemed Liquidation Event.

4.2 <u>Fractional Shares</u>. No fractional shares of Common Stock shall be issued upon conversion of the Preferred Stock. In lieu of any fractional shares to which the holder would otherwise be entitled, the Corporation shall pay cash equal to such fraction multiplied by the fair market value of a share of Common Stock as determined in good faith by the Board. Whether or not fractional shares would be issuable upon such conversion shall be determined on the basis of the total number of shares of Preferred Stock the holder is at the time converting into Common Stock and the aggregate number of shares of Common Stock issuable upon such conversion.

# 4.3 Mechanics of Conversion.

4.3.1 Notice of Conversion. In order for a holder of Preferred Stock to voluntarily convert shares of Preferred Stock into shares of Common Stock, such holder shall (a) provide written notice to the Corporation's transfer agent at the office of the transfer agent for the Preferred Stock (or at the principal office of the Corporation if the Corporation serves as its own transfer agent) that such holder elects to convert all or any number of such holder's shares of Preferred Stock and, if applicable, any event on which such conversion is contingent and (b) if such holder's shares are certificated, surrender the certificate or certificates for such shares of Preferred Stock (or, if such registered holder alleges that such certificate has been lost, stolen or destroyed, a lost certificate affidavit and agreement reasonably acceptable to the Corporation to indemnify the Corporation against any claim that may be made against the Corporation on account of the alleged loss, theft or destruction of such certificate), at the office of the transfer agent for the Preferred Stock (or at the principal office of the Corporation if the Corporation serves as its own transfer agent). Such notice shall state such holder's name or the names of the nominees in which such holder wishes the shares of Common Stock to be issued. If required by the Corporation, any certificates surrendered for conversion shall be endorsed or accompanied by a written instrument or instruments of transfer, in form satisfactory to the Corporation, duly executed by the registered holder or his, her or its attorney duly authorized in writing. The close of business on the date of receipt by the transfer agent (or by the Corporation if the Corporation serves as its own transfer agent) of such notice and, if applicable, certificates (or lost certificate affidavit and agreement) shall be the time of conversion (the "Conversion Time"), and the shares of Common Stock issuable upon conversion of the specified shares shall be deemed to be outstanding of record as of such date. The Corporation shall, as soon as practicable after the Conversion Time (i) issue and deliver to such holder of Preferred Stock, or to his, her or its nominees, a certificate or certificates for the number of full shares of Common Stock issuable upon such conversion in accordance with the provisions hereof and a certificate for the number (if any) of the shares of the applicable series of Preferred Stock represented by the surrendered certificate that were not converted into Common Stock, (ii) pay in cash such amount as provided in Subsection 4.2 in lieu of any fraction of a share of Common Stock otherwise issuable upon such conversion and (iii) pay all declared but unpaid dividends on the shares of Preferred Stock converted.

4.3.2 Reservation of Shares. The Corporation shall at all times when any shares of the Preferred Stock shall be outstanding, reserve and keep available out of its authorized but unissued capital stock, for the purpose of effecting the conversion of the Preferred Stock, such number of its duly authorized shares of Common Stock as shall from time to time be sufficient to effect the conversion of all outstanding Preferred Stock; and if at any time the number of authorized but unissued shares of Common Stock shall not be sufficient to effect the conversion of all then outstanding shares of the Preferred Stock, the Corporation shall take such corporate action as may be necessary to increase its authorized but unissued shares of Common Stock to such number of shares as shall be sufficient for such purposes, including, without limitation, engaging in best efforts to obtain the requisite stockholder approval of any necessary amendment to the Certificate of Incorporation. Before taking any action which would cause an adjustment reducing the applicable Conversion Price for any series of Preferred Stock below the then par value of the shares of Common Stock issuable upon conversion of such series, the Corporation will take any corporate action which may, in the opinion of its counsel, be necessary in order that the Corporation may validly and legally issue fully paid and non-assessable shares of Common Stock at such adjusted Conversion Price.

4.3.3 Effect of Conversion. All shares of Preferred Stock which shall have been surrendered for conversion as herein provided shall no longer be deemed to be outstanding and all rights with respect to such shares shall immediately cease and terminate at the Conversion Time, except only the right of the holders thereof to receive shares of Common Stock in exchange therefor, to receive payment in lieu of any fraction of a share otherwise issuable upon such conversion as provided in <u>Subsection 4.2</u> and to receive payment of any dividends declared but unpaid thereon. Any shares of Preferred Stock so converted shall be retired and cancelled and may not be reissued as shares of such series, and the Corporation may thereafter take such appropriate action (without the need for stockholder action) as may be necessary to reduce the authorized number of shares of Preferred Stock accordingly.

4.3.4 <u>No Further Adjustment</u>. Upon any such conversion, no adjustment to the Conversion Price of the applicable series of Preferred Stock shall be made for any declared but unpaid dividends on the Preferred Stock surrendered for conversion or on the Common Stock delivered upon conversion.

4.3.5 <u>Taxes</u>. The Corporation shall pay any and all issue and other similar taxes that may be payable in respect of any issuance or delivery of shares of Common Stock upon conversion of shares of Preferred Stock pursuant to this Section 4. The Corporation shall not, however, be required to pay any tax which may be payable in respect of any transfer involved in the issuance and delivery of shares of Common Stock in a name other than that in which the shares of Preferred Stock so converted were registered, and no such issuance or delivery shall be made unless and until the person or entity requesting such issuance has paid to the Corporation the amount of any such tax or has established, to the satisfaction of the Corporation, that such tax has been paid.

### 4.4 Adjustments to Conversion Price for Diluting Issues.

- 4.4.1 <u>Special Definitions</u>. For purposes of this Article Fourth, the following definitions shall apply:
- (a) "Option" shall mean rights, options or warrants to subscribe for, purchase or otherwise acquire Common Stock or

Convertible Securities.

- (b) "Series B Original Issue Date" shall mean the date on which the first share of Series B Preferred Stock was issued.
- (c) "Convertible Securities" shall mean any evidences of indebtedness, shares or other securities directly or indirectly convertible into or exchangeable for Common Stock, but excluding Options.
- (d) "Additional Shares of Common Stock" shall mean all shares of Common Stock issued (or, pursuant to <u>Subsection 4.4.3</u> below, deemed to be issued) by the Corporation after the Series B Original Issue Date, other than (1) the following shares of Common Stock and (2) shares of Common Stock deemed issued pursuant to the following Options and Convertible Securities (clauses (1) and (2), collectively, "Exempted Securities"):
- (i) shares of Common Stock, Options or Convertible Securities issued upon conversion of or as a dividend or distribution on Preferred Stock;
- (ii) shares of Common Stock, Options or Convertible Securities issued by reason of a dividend, stock split, split-up or other distribution on shares of Common Stock that is covered by <u>Subsection 4.5</u>, <u>4.6</u>, <u>4.7</u> or <u>4.8</u>;
- (iii) shares of Common Stock or Options issued to employees or directors of, or consultants or advisors to, the Corporation or any of its subsidiaries pursuant to a plan, agreement or arrangement approved by the Board, including the approval of at least three (3) Preferred Directors;
- (iv) shares of Common Stock or Convertible Securities actually issued upon the exercise of Options or shares of Common Stock actually issued upon the conversion or exchange of Convertible Securities, in each case provided such issuance is pursuant to the terms of such Option or Convertible Security;
- (v) shares of Common Stock, Options or Convertible Securities issued to banks, equipment lessors or other financial institutions, or to real property lessors, pursuant to a debt financing, equipment leasing or real property leasing transaction approved by the Board, including the approval of at least three (3) Preferred Directors;
- (vi) shares of Common Stock, Options or Convertible Securities issued to suppliers or third party service providers in connection with the provision of goods or services pursuant to transactions approved by the Board, including the approval of at least three (3) Preferred Directors;
- (vii) shares of Common Stock, Options or Convertible Securities issued pursuant to the acquisition of another corporation by the Corporation by (a) merger, (b) purchase of substantially all of such entity's assets, (c) purchase of all of such entity's equity securities or (d) other reorganization, or pursuant to a joint venture agreement, provided that such issuances are approved by the Board, including the approval of at least three (3) Preferred Directors;

(viii) shares of Common Stock issued in connection with a public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended;

(ix) shares of Common Stock, Options or Convertible Securities issued in connection with sponsored research, collaboration, technology license, development, OEM, marketing or other similar agreements or strategic partnerships approved by the Board, including the approval of at least three (3) Preferred Directors; or

(x) shares of Series B Preferred Stock issued in connection with or arising out of that certain Series B Preferred Stock Purchase Agreement, dated September 10, 2020, by and among the Corporation and the investors listed on Exhibit A thereto.

4.4.2 <u>No Adjustment of Conversion Price</u>. No adjustment in the applicable Conversion Price of any series of Preferred Stock shall be made as the result of the issuance or deemed issuance of Additional Shares of Common Stock if the Corporation receives written notice from the Requisite Holders agreeing that no such adjustment shall be made as the result of the issuance or deemed issuance of such Additional Shares of Common Stock.

### 4.4.3 <u>Deemed Issue of Additional Shares of Common Stock.</u>

(a) If the Corporation, at any time or from time to time after the Series B Original Issue Date, shall issue any Options or Convertible Securities (excluding Options or Convertible Securities which are themselves Exempted Securities) or shall fix a record date for the determination of holders of any class of securities entitled to receive any such Options or Convertible Securities, then the maximum number of shares of Common Stock (as set forth in the instrument relating thereto, assuming the satisfaction of any conditions to exercisability, convertibility or exchangeability but without regard to any provision contained therein for a subsequent adjustment of such number) issuable upon the exercise of such Options or, in the case of Convertible Securities and Options therefor, the conversion or exchange of such Convertible Securities, shall be deemed to be Additional Shares of Common Stock issued as of the time of such issue or, in case such a record date shall have been fixed, as of the close of business on such record date.

(b) If the terms of any Option or Convertible Security, the issuance of which resulted in an adjustment to the applicable Conversion Price for any series of Preferred Stock, pursuant to the terms of Subsection 4.4.4, are revised as a result of an amendment to such terms or any other adjustment pursuant to the provisions of such Option or Convertible Security (but excluding automatic adjustments to such terms pursuant to anti-dilution or similar provisions of such Option or Convertible Security) to provide for either (1) any increase or decrease in the number of shares of Common Stock issuable upon the exercise, conversion and/or exchange of any such Option or Convertible Security or (2) any increase or decrease in the consideration payable to the Corporation upon such exercise, conversion and/or exchange, then, effective upon such increase or decrease becoming effective, such Conversion Price computed upon the original issue of such Option or Convertible Security (or upon the occurrence of a record date with respect thereto) shall be readjusted to the Conversion Price as would have been obtained had such revised terms been in effect upon the original date of issuance of such Option or Convertible Security. Notwithstanding the foregoing, no readjustment pursuant to this clause (b) shall have the effect of increasing an applicable Conversion Price to an amount which exceeds the lower of (i) the Conversion Price in effect immediately prior to the original adjustment made as a result of the issuance of such Option or Convertible Security, or (ii) the Conversion Price that would have resulted from any issuances of Additional Shares of Common Stock (other than deemed issuances of Additional Shares of Common Stock as a result of the issuance of such Option or Convertible Security) between the original adjustment date and such readjustment date.

(c) If the terms of any Option or Convertible Security (excluding Options or Convertible Securities which are themselves Exempted Securities), the issuance of which did not result in an adjustment to the applicable Conversion Price for any series of Preferred Stock pursuant to the terms of Subsection 4.4.4 (either because the consideration per share (determined pursuant to Subsection 4.4.5) of the Additional Shares of Common Stock subject thereto was equal to or greater than the Conversion Price, as applicable, then in effect, or because such Option or Convertible Security was issued before the Series B Original Issue Date), are revised after the Series B Original Issue Date as a result of an amendment to such terms or any other adjustment pursuant to the provisions of such Option or Convertible Security (but excluding automatic adjustments to such terms pursuant to anti-dilution or similar provisions of such Option or Convertible Security) to provide for either (1) any increase in the number of shares of Common Stock issuable upon the exercise, conversion or exchange of any such Option or Convertible Security or (2) any decrease in the consideration payable to the Corporation upon such exercise, conversion or exchange, then such Option or Convertible Security, as so amended or adjusted, and the Additional Shares of Common Stock subject thereto (determined in the manner provided in Subsection 4.4.3(a) shall be deemed to have been issued effective upon such increase or decrease becoming effective.

(d) Upon the expiration or termination of any unexercised Option or unconverted or unexchanged Convertible Security (or portion thereof) which resulted (either upon its original issuance or upon a revision of its terms) in an adjustment to the applicable Conversion Price for any series of Preferred Stock pursuant to the terms of <u>Subsection 4.4.4</u>, the applicable Conversion Price shall be readjusted to the Conversion Price as would have obtained had such Option or Convertible Security (or portion thereof) never been issued.

(e) If the number of shares of Common Stock issuable upon the exercise, conversion and/or exchange of any Option or Convertible Security, or the consideration payable to the Corporation upon such exercise, conversion and/or exchange, is calculable at the time such Option or Convertible Security is issued or amended but is subject to adjustment based upon subsequent events, any adjustment to any Conversion Price provided for in this Subsection 4.4.3 shall be effected at the time of such issuance or amendment based on such number of shares or amount of consideration without regard to any provisions for subsequent adjustments (and any subsequent adjustments shall be treated as provided in clauses (b) and (c) of this Subsection 4.4.3). If the number of shares of Common Stock issuable upon the exercise, conversion and/or exchange of any Option or Convertible Security, or the consideration payable to the Corporation upon such exercise, conversion and/or exchange, cannot be calculated at all at the time such Option or Convertible Security is issued or amended, any adjustment to a Conversion Price that would result under the terms of this Subsection 4.4.3 at the time of such issuance or amendment shall instead be effected at the time such number of shares and/or amount of consideration is first calculable (even if subject to subsequent adjustments), assuming for purposes of calculating such adjustment to such Conversion Price that such issuance or amendment took place at the time such calculation can first be made.

4.4.4 <u>Adjustment of Conversion Price Upon Issuance of Additional Shares of Common Stock</u>. In the event the Corporation shall at any time after the Series B Original Issue Date issue Additional Shares of Common Stock (including Additional Shares of Common Stock deemed to be issued pursuant to <u>Subsection 4.4.3</u>), without consideration or for a consideration per share less than any applicable Conversion Price for any series of Preferred Stock in effect immediately prior to such issue, then such applicable Conversion Price shall be reduced, concurrently with such issue, to a price (calculated to the nearest one-hundredth of a cent) determined in accordance with the following formula:

$$CP_2 = CP_1 * (A + B) = (A + C).$$

For purposes of the foregoing formula, the following definitions shall apply:

(a) " $CP_2$ " shall mean the applicable Conversion Price in effect immediately after such issue of Additional Shares of

Common Stock

(b) "CP<sub>1</sub>" shall mean the applicable Conversion Price in effect immediately prior to such issue of Additional Shares of

Common Stock;

(c) "A" shall mean the number of shares of Common Stock outstanding immediately prior to such issue of Additional Shares of Common Stock (treating for this purpose as outstanding all shares of Common Stock issuable upon exercise of Options outstanding immediately prior to such issue or upon conversion or exchange of Convertible Securities (including the Preferred Stock) outstanding (assuming exercise of any outstanding Options therefor) immediately prior to such issue);

(d) "B" shall mean the number of shares of Common Stock that would have been issued if such Additional Shares of Common Stock had been issued at a price per share equal to CPI (determined by dividing the aggregate consideration received by the Corporation in respect of such issue by CPI); and

(e) "C" shall mean the number of such Additional Shares of Common Stock issued in such transaction.

4.4.5 <u>Determination of Consideration</u>. For purposes of this Subsection 4.4 the consideration received by the Corporation for the issue of any Additional Shares of Common Stock shall be computed as follows:

### (a) <u>Cash and Property</u>: Such consideration shall:

- (i) insofar as it consists of cash, be computed at the aggregate amount of cash received by the Corporation, excluding amounts paid or payable for accrued interest;
- (ii) insofar as it consists of property other than cash, be computed at the fair market value thereof at the time of such issue, as determined in good faith by the Board; and
- (iii) in the event Additional Shares of Common Stock are issued together with other shares or securities or other assets of the Corporation for consideration which covers both, be the proportion of such consideration so received, computed as provided in clauses (i) and (ii) above, as determined in good faith by the Board.
- (b) Options and Convertible Securities. The consideration per share received by the Corporation for Additional Shares of Common Stock deemed to have been issued pursuant to Subsection 4.4.3 relating to Options and Convertible Securities, shall be determined by dividing:
- (i) the total amount, if any, received or receivable by the Corporation as consideration for the issue of such Options or Convertible Securities, plus the minimum aggregate amount of additional consideration (as set forth in the instruments relating thereto, without regard to any provision contained therein for a subsequent adjustment of such consideration) payable to the Corporation upon the exercise of such Options or the conversion or exchange of such Convertible Securities, or in the case of Options for Convertible Securities, the exercise of such Options for Convertible Securities and the conversion or exchange of such Convertible Securities, by
- (ii) the maximum number of shares of Common Stock (as set forth in the instruments relating thereto, without regard to any provision contained therein for a subsequent adjustment of such number) issuable upon the exercise of such Options or the conversion or exchange of such Convertible Securities, or in the case of Options for Convertible Securities, the exercise of such Options for Convertible Securities and the conversion or exchange of such Convertible Securities.
- 4.4.6 <u>Multiple Closing Dates</u>. In the event the Corporation shall issue on more than one date Additional Shares of Common Stock that are a part of one transaction or a series of related transactions and that would result in an adjustment to the applicable Conversion Price, pursuant to the terms of <u>Subsection 4.4.4</u>, then, upon the final such issuance, the applicable Conversion Price shall be readjusted to give effect to all such issuances as if they occurred on the date of the first such issuance (and without giving effect to any additional adjustments as a result of any such subsequent issuances within such period).
- 4.5 <u>Adjustment for Stock Splits and Combinations</u>. If the Corporation shall at any time or from time to time after the Series B Original Issue Date effect a subdivision of the outstanding Common Stock, the applicable Conversion Price for each series of Preferred Stock in effect immediately before that subdivision shall be proportionately decreased so that the number of shares of Common Stock issuable on conversion of each share of such series shall be increased in proportion to such increase in the aggregate number of shares of Common Stock outstanding. If the Corporation shall at any time or from time to time after the Series B Original Issue Date combine the outstanding shares of Common Stock, the applicable Conversion Price for each series of Preferred Stock in effect immediately before the combination shall be proportionately increased so that the number of shares of Common Stock issuable on conversion of each share of such series shall be decreased in proportion to such decrease in the aggregate number of shares of Common Stock outstanding. Any adjustment under this subsection shall become effective at the close of business on the date the subdivision or combination becomes effective.

4.6 <u>Adjustment for Certain Dividends and Distributions</u>. In the event the Corporation at any time or from time to time after the Series B Original Issue Date shall make or issue, or fix a record date for the determination of holders of Common Stock entitled to receive, a dividend or other distribution payable on the Common Stock in additional shares of Common Stock, then and in each such event the applicable Conversion Price for each series of Preferred Stock in effect immediately before such event shall be decreased as of the time of such issuance or, in the event such a record date shall have been fixed, as of the close of business on such record date, by multiplying such applicable Conversion Price then in effect by a fraction:

(1) the numerator of which shall be the total number of shares of Common Stock issued and outstanding immediately prior to the time of such issuance or the close of business on such record date, and

(2) the denominator of which shall be the total number of shares of Common Stock issued and outstanding immediately prior to the time of such issuance or the close of business on such record date plus the number of shares of Common Stock issuable in payment of such dividend or distribution.

Notwithstanding the foregoing (a) if such record date shall have been fixed and such dividend is not fully paid or if such distribution is not fully made on the date fixed therefor, the applicable Conversion Price shall be recomputed accordingly as of the close of business on such record date and thereafter the applicable Conversion Price shall be adjusted pursuant to this subsection as of the time of actual payment of such dividends or distributions; and (b) that no such adjustment shall be made if the holders of such series of Preferred Stock simultaneously receive a dividend or other distribution of shares of Common Stock in a number equal to the number of shares of Common Stock as they would have received if all outstanding shares of Preferred Stock had been converted into Common Stock on the date of such event.

4.7 <u>Adjustments for Other Dividends and Distributions</u>. In the event the Corporation at any time or from time to time after the Series B Original Issue Date shall make or issue, or fix a record date for the determination of holders of Common Stock entitled to receive, a dividend or other distribution payable in securities of the Corporation (other than a distribution of shares of Common Stock in respect of outstanding shares of Common Stock) or in other property and the provisions of <u>Section 1</u> do not apply to such dividend or distribution, then and in each such event the holders of Preferred Stock shall receive, simultaneously with the distribution to the holders of Common Stock, a dividend or other distribution of such securities or other property in an amount equal to the amount of such securities or other property as they would have received if all outstanding shares of Preferred Stock had been converted into Common Stock on the date of such event.

4.8 Adjustment for Merger or Reorganization, etc. Subject to the provisions of Subsection 2.3, if there shall occur any reorganization, recapitalization, reclassification, consolidation or merger involving the Corporation in which the Common Stock (but not the Preferred Stock) is converted into or exchanged for securities, cash or other property (other than a transaction covered by Subsections 4.4, 4.6 or 4.7, then, following any such reorganization, recapitalization, reclassification, consolidation or merger, each share of Preferred Stock shall thereafter be convertible in lieu of the Common Stock into which it was convertible prior to such event into the kind and amount of securities, cash or other property which a holder of the number of shares of Common Stock of the Corporation issuable upon conversion of one share of Preferred Stock immediately prior to such reorganization, recapitalization, reclassification, consolidation or merger would have been entitled to receive pursuant to such transaction; and, in such case, appropriate adjustment (as determined in good faith by the Board) shall be made in the application of the provisions in this Section 4 with respect to the rights and interests thereafter of the holders of the Preferred Stock, to the end that the provisions set forth in this Section 4 (including provisions with respect to changes in and other adjustments of the applicable Conversion Price of such series of Preferred Stock) shall thereafter be applicable, as nearly as reasonably may be, in relation to any securities or other property thereafter deliverable upon the conversion of the Preferred Stock. For the avoidance of doubt, nothing in this Subsection 4.8 shall be construed as preventing the holders of Preferred Stock from seeking any appraisal rights under the General Corporation Law in connection with a merger triggering an adjustment hereunder, nor shall this Subsection 4.8 be deemed conclusive evidence of the fair value of the shares of Preferred Stock in any such appraisal proceeding.

4.9 <u>Certificate as to Adjustments</u>. Upon the occurrence of each adjustment or readjustment of the applicable Conversion Price of a series of Preferred Stock pursuant to this <u>Section 4</u>, the Corporation at its expense shall, as promptly as reasonably practicable but in any event not later than ten (10) days thereafter, compute such adjustment or readjustment in accordance with the terms hereof and furnish to each holder of Preferred Stock a certificate setting forth such adjustment or readjustment (including the kind and amount of securities, cash or other property into which the Preferred Stock is convertible) and showing in detail the facts upon which such adjustment or readjustment is based. The Corporation shall, as promptly as reasonably practicable after the written request at any time of any holder of Preferred Stock (but in any event not later than ten (10) days thereafter), furnish or cause to be furnished to such holder a certificate setting forth (i) the Conversion Price of such series of Preferred Stock then in effect, and (ii) the number of shares of Common Stock and the amount, if any, of other securities, cash or property which then would be received upon the conversion of Preferred Stock.

### 4.10 Notice of Record Date. In the event:

(a) the Corporation shall take a record of the holders of its Common Stock (or other capital stock or securities at the time issuable upon conversion of the Preferred Stock) for the purpose of entitling or enabling them to receive any dividend or other distribution, or to receive any right to subscribe for or purchase any shares of capital stock of any class or any other securities, or to receive any other security; or

(b) of any capital reorganization of the Corporation, any reclassification of the Common Stock of the Corporation, or any Deemed Liquidation Event; or

(c) of the voluntary or involuntary dissolution, liquidation or winding-up of the Corporation, then, and in each such case, the Corporation will send or cause to be sent to the holders of the Preferred Stock a notice specifying, as the case may be, (i) the record date for such dividend, distribution or right, or (ii) the effective date on which such reorganization, reclassification, consolidation, merger, transfer, dissolution, liquidation or winding-up is proposed to take place, and the time, if any is to be fixed, as of which the holders of record of Common Stock (or such other capital stock or securities at the time issuable upon the conversion of the Preferred Stock) shall be entitled to exchange their shares of Common Stock (or such other capital stock or securities) for securities or other property deliverable upon such reorganization, reclassification, consolidation, merger, transfer, dissolution, liquidation or winding-up, and the amount per share and character of such exchange applicable to the Preferred Stock and the Common Stock. Such notice shall be sent at least ten (10) days prior to the record date or effective date for the event specified in such notice.

### 5. Mandatory Conversion.

5.1 <u>Preferred Stock Conversion Trigger Events</u>. Upon the earlier of (a) the closing of the sale of shares of Common Stock to the public in a firmly underwritten public offering with gross offering proceeds in excess of \$100,000,000 pursuant to an effective registration statement under the Securities Act of 1933, as amended (a "Qualified IPO") or (b) the date and time, or the occurrence of an event, specified by vote or written consent of the Requisite Holders (the time of such closing or the date and time specified or the time of the event specified in such vote or written consent is referred to herein as the "Preferred Mandatory Conversion Time"), then (i) all outstanding shares of Preferred Stock shall automatically be converted into shares of Common Stock, at the then effective conversion rate as calculated pursuant to <u>Subsection 4.1.1</u> and (ii) such shares may not be reissued by the Corporation.

5.2 <u>Series B Conversion Trigger Events</u>. Upon the date and time, or the occurrence of an event, specified by vote or written consent of the holders of a majority of the then-outstanding shares of Series B Preferred Stock (the date and time specified or the time of the event specified in such vote or written consent is referred to herein as the "Series B Mandatory Conversion Time"), then (i) all outstanding shares of Series B Preferred Stock shall automatically be converted into shares of Common Stock, at the then effective conversion rate as calculated pursuant to <u>Subsection 4.1.1</u> and (ii) such shares may not be reissued by the Corporation.

5.3 <u>Series A-1 and Series A Conversion Trigger Events</u>. Upon the date and time, or the occurrence of an event, specified by vote or written consent of the holders of a majority of the then-outstanding shares of Series A-1 Preferred Stock and Series A Preferred Stock, voting together as a single class on an as-converted basis (the date and time specified or the time of the event specified in such vote or written consent is referred to herein as the "Series A Mandatory Conversion Time," and the Preferred Mandatory Conversion Time, Series B Mandatory Conversion Time and Series A Mandatory Conversion Time are each sometimes referred to herein as the "Mandatory Conversion Time" for the applicable conversion time), then (i) all outstanding shares of Series A-1 Preferred Stock and Series A Preferred Stock shall automatically be converted into shares of Common Stock, at the then effective conversion rate as calculated pursuant to <u>Subsection 4.1.1</u> and (ii) such shares may not be reissued by the Corporation.

5.4 Procedural Requirements. All holders of record of shares of the applicable series of Preferred Stock being converted pursuant to Subsection 5.1, 5.2, or 5.3 shall be sent written notice of the applicable Mandatory Conversion Time and the place designated for such mandatory conversion of all such shares of Preferred Stock pursuant to this Section 5. Such notice need not be sent in advance of the occurrence of the Mandatory Conversion Time. Upon receipt of such notice, each holder of shares of Preferred Stock in certificated form that are being converted pursuant to this Section 5 shall surrender his, her or its certificate or certificates for all such shares (or, if such holder alleges that such certificate has been lost, stolen or destroyed, a lost certificate affidavit and agreement reasonably acceptable to the Corporation to indemnify the Corporation against any claim that may be made against the Corporation on account of the alleged loss, theft or destruction of such certificate) to the Corporation at the place designated in such notice. If so required by the Corporation, any certificates surrendered for conversion shall be endorsed or accompanied by written instrument or instruments of transfer, in form satisfactory to the Corporation, duly executed by the registered holder or by his, her or its attorney duly authorized in writing. All rights with respect to the Preferred Stock converted pursuant to Subsection 5.1, 5.2 or 5.3 (as applicable), including the rights, if any, to receive notices and vote (other than as a holder of Common Stock), will terminate at the applicable Mandatory Conversion Time (notwithstanding the failure of the holder or holders thereof to surrender any certificates at or prior to such time), except only the rights of the holders thereof, upon surrender of any certificate or certificates of such holders (or lost certificate affidavit and agreement) therefor, to receive the items provided for in the next sentence of this Subsection 5.4. As soon as practicable after the applicable Mandatory Conversion Time and, if applicable, the surrender of any certificate or certificates (or lost certificate affidavit and agreement) for Preferred Stock, the Corporation shall (a) issue and deliver to such holder, or to his, her or its nominees, a certificate or certificates for the number of full shares of Common Stock issuable on such conversion in accordance with the provisions hereof and (b) pay cash as provided in Subsection 4.2 in lieu of any fraction of a share of Common Stock otherwise issuable upon such conversion and the payment of any declared but unpaid dividends on the shares of Preferred Stock converted. Such converted Preferred Stock shall be retired and cancelled and may not be reissued as shares of such series, and the Corporation may thereafter take such appropriate action (without the need for stockholder action) as may be necessary to reduce the authorized number of shares of Preferred Stock (including with respect to any converted series of Preferred Stock) accordingly.

6. <u>Redeemed or Otherwise Acquired Shares</u>. Any shares of Preferred Stock that are redeemed or otherwise acquired by the Corporation or any of its subsidiaries shall be automatically and immediately cancelled and retired and shall not be reissued, sold or transferred. Neither the Corporation nor any of its subsidiaries may exercise any voting or other rights granted to the holders of Preferred Stock following redemption.

- 7. <u>Waiver</u>. Any of the rights, powers, preferences and other terms of the Preferred Stock set forth herein may be waived on behalf of all holders of Preferred Stock by the affirmative written consent or vote of the Requisite Holders; <u>provided</u>, <u>however</u>, that if any proposed waiver would waive the rights of one or more series of Preferred Stock so as to effect such series adversely, but shall not so affect the entire class of Preferred Stock, then the holders of a majority of the shares of such series of Preferred Stock so affected must also consent to such waiver.
- 8. <u>Notices</u>. Any notice required or permitted by the provisions of this Article Fourth to be given to a holder of shares of Preferred Stock shall be mailed, postage prepaid, to the post office address last shown on the records of the Corporation, or given by electronic communication in compliance with the provisions of the General Corporation Law, and shall be deemed sent upon such mailing or electronic transmission.

**FIFTH:** Subject to any additional vote required by the Certificate of Incorporation or Bylaws, in furtherance and not in limitation of the powers conferred by statute, the Board is expressly authorized to make, repeal, alter, amend and rescind any or all of the Bylaws of the Corporation. Each director shall be entitled to one vote on each matter presented to the Board; <u>provided</u>, <u>however</u>, that so long as the holders of Series B Preferred Stock are entitled to elect a Series B Preferred Director, the affirmative vote of the Series B Preferred Directors shall be required for the authorization by the Board of any of the matters set forth in <u>Section 5.8</u> of the Second Amended and Restated Investors' Rights Agreement, dated as of September 10, 2020, by and among the Corporation and the other parties thereto, as such agreement may be amended from time to time.

**SIXTH:** Subject to any additional vote required by the Certificate of Incorporation, the number of directors of the Corporation shall be determined in the manner set forth in the Bylaws of the Corporation.

**SEVENTH:** Elections of directors need not be by written ballot unless the Bylaws of the Corporation shall so provide.

**EIGHTH:** Meetings of stockholders may be held within or without the State of Delaware, as the Bylaws of the Corporation may provide. The books of the Corporation may be kept outside the State of Delaware at such place or places as may be designated from time to time by the Board or in the Bylaws of the Corporation.

**NINTH:** To the fullest extent permitted by law, a director of the Corporation shall not be personally liable to the Corporation or its stockholders for monetary damages for breach of fiduciary duty as a director. If the General Corporation Law or any other law of the State of Delaware is amended after approval by the stockholders of this Article Ninth to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of a director of the Corporation shall be eliminated or limited to the fullest extent permitted by the General Corporation Law as so amended.

Any repeal or modification of the foregoing provisions of this Article Ninth by the stockholders of the Corporation shall not adversely affect any right or protection of a director of the Corporation existing at the time of, or increase the liability of any director of the Corporation with respect to any acts or omissions of such director occurring prior to, such repeal or modification.

**TENTH:** The following indemnification provisions shall apply to the persons enumerated below.

- 1. Right to Indemnification of Directors and Officers. The Corporation shall indemnify and hold harmless, to the fullest extent permitted by applicable law as it presently exists or may hereafter be amended, any person (an "Indemnified Person") who was or is made or is threatened to be made a party or is otherwise involved in any action, suit or proceeding, whether civil, criminal, administrative or investigative (a "Proceeding"), by reason of the fact that such person, or a person for whom such person is the legal representative, is or was a director or officer of the Corporation or, while a director or officer of the Corporation, is or was serving at the request of the Corporation as a director, officer, employee or agent of another corporation or of a partnership, joint venture, limited liability company, trust, enterprise or nonprofit entity, including service with respect to employee benefit plans, against all liability and loss suffered and expenses (including attorneys' fees) reasonably incurred by such Indemnified Person in such Proceeding. Notwithstanding the preceding sentence, except as otherwise provided in Section 3 of this Article Tenth, the Corporation shall be required to indemnify an Indemnified Person in connection with a Proceeding (or part thereof) commenced by such Indemnified Person only if the commencement of such Proceeding (or part thereof) by the Indemnified Person was authorized in advance by the Board.
- 2. <u>Prepayment of Expenses of Directors and Officers</u>. The Corporation shall pay the expenses (including attorneys' fees) incurred by an Indemnified Person in defending any Proceeding in advance of its final disposition, provided, however, that, to the extent required by law, such payment of expenses in advance of the final disposition of the Proceeding shall be made only upon receipt of an undertaking by the Indemnified Person to repay all amounts advanced if it should be ultimately determined that the Indemnified Person is not entitled to be indemnified under this Article Tenth or otherwise.
- 3. <u>Claims by Directors and Officers</u>. If a claim for indemnification or advancement of expenses under this Article Tenth is not paid in full within thirty (30) days after a written claim therefor by the Indemnified Person has been received by the Corporation, the Indemnified Person may file suit to recover the unpaid amount of such claim and, if successful in whole or in part, shall be entitled to be paid the expense of prosecuting such claim. In any such action the Corporation shall have the burden of proving that the Indemnified Person is not entitled to the requested indemnification or advancement of expenses under applicable law.
- 4. <u>Indemnification of Employees and Agents</u>. The Corporation may indemnify and advance expenses to any person who was or is made or is threatened to be made or is otherwise involved in any Proceeding by reason of the fact that such person, or a person for whom such person is the legal representative, is or was an employee or agent of the Corporation or, while an employee or agent of the Corporation, is or was serving at the request of the Corporation as a director, officer, employee or agent of another corporation or of a partnership, joint venture, limited liability company, trust, enterprise or nonprofit entity, including service with respect to employee benefit plans, against all liability and loss suffered and expenses (including attorneys' fees) reasonably incurred by such person in connection with such Proceeding. The ultimate determination of entitlement to indemnification of persons who are non-director or officer employees or agents shall be made in such manner as is determined by the Board in its sole discretion. Notwithstanding the foregoing sentence, the Corporation shall not be required to indemnify a person in connection with a Proceeding initiated by such person if the Proceeding was not authorized in advance by the Board.

- 5. <u>Advancement of Expenses of Employees and Agents</u>. The Corporation may pay the expenses (including attorneys' fees) incurred by an employee or agent in defending any Proceeding in advance of its final disposition on such terms and conditions as may be determined by the Board.
- 6. Non-Exclusivity of Rights. The rights conferred on any person by this Article Tenth shall not be exclusive of any other rights which such person may have or hereafter acquire under any statute, provision of the Certificate of Incorporation, the Bylaws of the Corporation, or any agreement, or pursuant to any vote of stockholders or disinterested directors or otherwise.
- 7. Other Indemnification. The Corporation's obligation, if any, to indemnify any person who was or is serving at its request as a director, officer or employee of another corporation, partnership, limited liability company, joint venture, trust, organization or other enterprise shall be reduced by any amount such person may collect as indemnification from such other corporation, partnership, limited liability company, joint venture, trust, organization or other enterprise.
- 8. <u>Insurance</u>. The Board may, to the full extent permitted by applicable law as it presently exists, or may hereafter be amended from time to time, authorize an appropriate officer or officers to purchase and maintain at the Corporation's expense insurance: (a) to indemnify the Corporation for any obligation which it incurs as a result of the indemnification of directors, officers and employees under the provisions of this Article Tenth; and (b) to indemnify or insure directors, officers and employees against liability in instances in which they may not otherwise be indemnified by the Corporation under the provisions of this Article Tenth.
- 9. <u>Amendment or Repeal</u>. Any repeal or modification of the foregoing provisions of this Article Tenth shall not adversely affect any right or protection hereunder of any person in respect of any act or omission occurring prior to the time of such repeal or modification. The rights provided hereunder shall inure to the benefit of any Indemnified Person and such person's heirs, executors and administrators.

**ELEVENTH:** The Corporation renounces, to the fullest extent permitted by law, any interest or expectancy of the Corporation in, or in being offered an opportunity to participate in, any Excluded Opportunity. An "**Excluded Opportunity**" is any matter, transaction or interest that is presented to, or acquired, created or developed by, or which otherwise comes into the possession of (i) any director of the Corporation who is not an employee of the Corporation or any of its subsidiaries, or (ii) any holder of Preferred Stock or any partner, member, director, stockholder, employee or agent of any such holder, other than someone who is an employee of the Corporation or any of its subsidiaries (collectively, "**Covered Persons**"), unless such matter, transaction or interest is presented to, or acquired, created or developed by, or otherwise comes into the possession of, a Covered Person expressly and solely in such Covered Person's capacity as a director of the Corporation.

**TWELFTH:** Unless the Corporation consents in writing to the selection of an alternative forum, the Court of Chancery in the State of Delaware shall be the sole and exclusive forum for any stockholder (including a beneficial owner) to bring (i) any derivative action or proceeding brought on behalf of the Corporation, (ii) any action asserting a claim of breach of fiduciary duty owed by any director, officer or other employee of the Corporation to the Corporation or the Corporation's stockholders, (iii) any action asserting a claim against the Corporation, its directors, officers or employees arising pursuant to any provision of the Delaware General Corporation Law or the Corporation's certificate of incorporation or bylaws or (iv) any action asserting a claim against the Corporation, its directors, officers or employees governed by the internal affairs doctrine, except for, as to each of (i) through (iv) above, any claim as to which the Court of Chancery determines that there is an indispensable party not subject to the jurisdiction of the Court of Chancery (and the indispensable party does not consent to the personal jurisdiction of the Court of Chancery within ten (10) days following such determination), which is vested in the exclusive jurisdiction of a court or forum other than the Court of Chancery, or for which the Court of Chancery does not have subject matter jurisdiction. If any provision or provisions of this Article Twelfth shall be held to be invalid, illegal or unenforceable as applied to any person or entity or circumstance for any reason whatsoever, then, to the fullest extent permitted by law, the validity, legality and enforceability of such provisions in any other circumstance and of the remaining provisions of this Article Twelfth (including, without limitation, each portion of any sentence of this Article Twelfth containing any such provision held to be invalid, illegal or unenforceable) and the application of such provision to other persons or entities and circumstances shall not in any way

**THIRTEENTH:** The Board is expressly authorized and empowered to make, alter, amend or repeal the Bylaws of the Corporation in any manner not inconsistent with the laws of the State of Delaware.

### **Delaware**

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY THE ATTACHED IS A TRUE AND CORRECT COPY OF THE CERTIFICATE OF AMENDMENT OF "AZITRA INC", FILED IN THIS OFFICE ON THE TWENTIETH DAY OF SEPTEMBER, A.D. 2022, AT 6:14 O'CLOCK P.M.

# CERTIFICATE OF AMENDMENT TO THE AMENDED AND RESTATED CERTIFICATE OF INCORPORATION OF AZITRA INC

(Pursuant to Section 242 of the General Corporation Law of the State of Delaware)

Azitra Inc, a corporation organized and existing under and by virtue of the provisions of the General Corporation Law of the State of Delaware (the "General Corporation Law"), does hereby certify as follows.

- 1. The name of the corporation (hereinafter, the "Corporation") is Azitra Inc.
- 2. The Amended and Restated Certificate of Incorporation of the Corporation was filed with the Secretary of State of the State of Delaware on September 9, 2020 (the "Certificate").
- 3. The Board of Directors of the Corporation duly adopted resolutions proposing to amend certain provisions of the Certificate, declaring said amendment to be advisable and in the best interests of this corporation and its stockholders, and authorizing the appropriate officers of this corporation to solicit the consent of the stockholders therefor.
  - 4. The Article Fourth of the Certificate is hereby amended and restated in its entirety to read as follows:
  - **"FOURTH:** The total number of shares of shares that the Corporation is authorized to issue is (i) 1,950,000 shares of Common Stock, \$0.01 par value per share ("**Common Stock**") and (ii) 1,437,151 shares of Preferred Stock, \$0.0001 par value per shares ("**Preferred Stock**")."
  - 5. Part B of the Article Fourth of the Certificate is hereby amended and restated in its entirety to read as follows:
  - "205,385 shares of the authorized and unissued Preferred Stock of the Corporation are hereby designated "Series A Preferred Stock," 380,657 shares of the authorized and unissued Preferred Stock of the Corporation are hereby designated "Series A-1 Preferred Stock," and 851,108 shares of the authorized and unissued Preferred Stock of the Corporation are hereby designated "Series B Preferred Stock, with the following rights, preferences, powers, privileges and restrictions, qualifications and limitations. Unless otherwise indicated, references to "sections" or "subsections" in this Part B of this Article Fourth refer to sections and subsections of Part B of this Article Fourth."
- 6. That the foregoing amendments were approved by the holders of the requisite number of shares of this corporation in accordance with Section 228 of the General Corporation Law.

[Remainder of Page Intentionally Left Blank; Signature Page Follows]

**IN WITNESS WHEREOF**, this Certificate of Amendment to the Amended and Restated Certificate of Incorporation has been executed by a duly authorized officer of this corporation as of September 16, 2022.

# **AZITRA INC**

By: /s/ Francisco D. Salva

Francisco D. Salva, President

[Signature Page to Certificate of Amendment]

# AMENDED AND RESTATED BYLAWS OF

# **AZITRA INC**

Adopted March 17, 2017

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### AMENDED AND RESTATED BYLAWS OF AZITRA INC

### ARTICLE I — MEETINGS OF STOCKHOLDERS

- 1.1 *Place of Meetings*. Meetings of stockholders of Azitra Inc (the "*Company*") shall be held at any place, within or outside the State of Delaware, determined by the Company's board of directors (the "*Board*"). The Board may, in its sole discretion, determine that a meeting of stockholders shall not be held at any place, but may instead be held solely by means of remote communication as authorized by Section 211(a)(2) of the Delaware General Corporation Law (the "*DGCL*"). In the absence of any such designation or determination, stockholders' meetings shall be held at the Company's principal executive office.
- 1.2 *Annual Meeting.* An annual meeting of stockholders may be held for the election of directors at such date and time as may be designated by resolution of the Board from time to time. Any other proper business may be transacted at the annual meeting. The Company shall not be required to hold an annual meeting of stockholders, *provided* that (i) the stockholders are permitted to act by written consent under the Company's certificate of incorporation and these bylaws, (ii) the stockholders take action by written consent to elect directors and (iii) the stockholders unanimously consent to such action or, if such consent is less than unanimous, all of the directorships to which directors could be elected at an annual meeting held at the effective time of such action are vacant and are filled by such action.
- 1.3 *Special Meeting.* A special meeting of the stockholders may be called at any time by the Board, Chairperson of the Board or President or by one or more stockholders holding shares in the aggregate entitled to cast greater than 25% of the votes at that meeting.

If any person(s) other than the Board calls a special meeting, the request shall:

- (i) be in writing;
- (ii) specify the time of such meeting and the general nature of the business proposed to be transacted; and
- (iii) be delivered personally or sent by registered mail or by facsimile transmission to the Chairperson of the Board, the President or the Secretary of the Company.

The officer(s) receiving the request shall cause notice to be promptly given to the stockholders entitled to vote at such meeting, in accordance with these bylaws, that a meeting will be held at the time requested by the person or persons calling the meeting. No business may be transacted at such special meeting other than the business specified in such notice to stockholders. Nothing contained in this paragraph of this **section 1.3** shall be construed as limiting, fixing, or affecting the time when a meeting of stockholders called by action of the Board may be held.

1.4 *Notice of Stockholders' Meetings.* Whenever stockholders are required or permitted to take any action at a meeting, a written notice of the meeting shall be given which shall state the place, if any, date and hour of the meeting, the means of remote communication, if any, by which stockholders and proxy holders may be deemed to be present in person and vote at such meeting, and, in the case of a special meeting, the purpose or purposes for which the meeting is called. Except as otherwise provided in the DGCL, the certificate of incorporation or these bylaws, the written notice of any meeting of stockholders shall be given not less than 10 nor more than 60 days before the date of the meeting to each stockholder entitled to vote at such meeting.

1.5 **Quorum.** Except as otherwise provided by law, the certificate of incorporation or these bylaws, at each meeting of stockholders the presence in person or by proxy of the holders of shares of stock having a majority of the votes which could be cast by the holders of all outstanding shares of stock entitled to vote at the meeting shall be necessary and sufficient to constitute a quorum. Where a separate vote by a class or series or classes or series is required, a majority of the outstanding shares of such class or series or classes or series, present in person or represented by proxy, shall constitute a quorum entitled to take action with respect to that vote on that matter, except as otherwise provided by law, the certificate of incorporation or these bylaws.

If, however, such quorum is not present or represented at any meeting of the stockholders, then either (i) the chairperson of the meeting, or (ii) the stockholders entitled to vote at the meeting, present in person or represented by proxy, shall have the power to adjourn the meeting from time to time, in the manner provided in **section 1.6**, until a quorum is present or represented.

- 1.6 *Adjourned Meeting; Notice.* Any meeting of stockholders, annual or special, may adjourn from time to time to reconvene at the same or some other place, and notice need not be given of the adjourned meeting if the time, place, if any, thereof, and the means of remote communications, if any, by which stockholders and proxy holders may be deemed to be present in person and vote at such adjourned meeting are announced at the meeting at which the adjournment is taken. At the adjourned meeting, the Company may transact any business which might have been transacted at the original meeting. If the adjournment is for more than 30 days, or if after the adjournment a new record date is fixed for the adjourned meeting, a notice of the adjourned meeting shall be given to each stockholder of record entitled to vote at the meeting.
- 1.7 *Conduct of Business.* Meetings of stockholders shall be presided over by the Chairperson of the Board, if any, or in his or her absence by the Vice Chairperson of the Board, if any, or in the absence of the foregoing persons by the Chief Executive Officer, or in the absence of the foregoing persons by the President, or in the absence of the foregoing persons by a Chairperson designated by the Board, or in the absence of such designation by a chairperson chosen at the meeting. The Secretary shall act as secretary of the meeting, but in his or her absence the chairperson of the meeting may appoint any person to act as secretary of the meeting. The chairperson of any meeting of stockholders shall determine the order of business and the procedure at the meeting, including such regulation of the manner of voting and the conduct of business.
- 1.8 *Voting.* The stockholders entitled to vote at any meeting of stockholders shall be determined in accordance with the provisions of **section 1.10** of these bylaws, subject to Section 217 (relating to voting rights of fiduciaries, pledgors and joint owners of stock) and Section 218 (relating to voting trusts and other voting agreements) of the DGCL.

Except as may be otherwise provided in the certificate of incorporation, each stockholder entitled to vote at any meeting of stockholders shall be entitled to one vote for each share of capital stock held by such stockholder which has voting power upon the matter in question. Voting at meetings of stockholders need not be by written ballot and, unless otherwise required by law, need not be conducted by inspectors of election unless so determined by the holders of shares of stock having a majority of the votes which could be cast by the holders of all outstanding shares of stock entitled to vote thereon which are present in person or by proxy at such meeting. If authorized by the Board, such requirement of a written ballot shall be satisfied by a ballot submitted by electronic transmission (as defined in **section 7.2** of these bylaws), *provided* that any such electronic transmission must either set forth or be submitted with information from which it can be determined that the electronic transmission was authorized by the stockholder or proxy holder.

Except as otherwise required by law, the certificate of incorporation or these bylaws, in all matters other than the election of directors, the affirmative vote of a majority of the voting power of the shares present in person or represented by proxy at the meeting and entitled to vote on the subject matter shall be the act of the stockholders. Except as otherwise required by law, the certificate of incorporation or these bylaws, directors shall be elected by a plurality of the voting power of the shares present in person or represented by proxy at the meeting and entitled to vote on the election of directors. Where a separate vote by a class or series or classes or series is required, in all matters other than the election of directors, the affirmative vote of the majority of shares of such class or series or classes or series present in person or represented by proxy at the meeting shall be the act of such class or series or classes or series, except as otherwise provided by law, the certificate of incorporation or these bylaws.

1.9 Stockholder Action by Written Consent Without a Meeting. Unless otherwise provided in the certificate of incorporation, any action required by the DGCL to be taken at any annual or special meeting of stockholders of a corporation, or any action which may be taken at any annual or special meeting of such stockholders, may be taken without a meeting, without prior notice, and without a vote, if a consent or consents in writing, setting forth the action so taken, shall be signed by the holders of outstanding stock having not less than the minimum number of votes that would be necessary to authorize or take such action at a meeting at which all shares entitled to vote thereon were present and voted.

An electronic transmission (as defined in **section 7.2**) consenting to an action to be taken and transmitted by a stockholder or proxy holder, or by a person or persons authorized to act for a stockholder or proxy holder, shall be deemed to be written, signed and dated for purposes of this section, *provided* that any such electronic transmission sets forth or is delivered with information from which the Company can determine (i) that the electronic transmission was transmitted by the stockholder or proxy holder or by a person or persons authorized to act for the stockholder or proxy holder and (ii) the date on which such stockholder or proxy holder or authorized person or persons transmitted such electronic transmission.

In the event that the Board shall have instructed the officers of the Company to solicit the vote or written consent of the stockholders of the Company, an electronic transmission of a stockholder written consent given pursuant to such solicitation may be delivered to the Secretary or the President of the Company or to a person designated by the Secretary or the President. The Secretary or the President of the Company or a designee of the Secretary or the President shall cause any such written consent by electronic transmission to be reproduced in paper form and inserted into the corporate records.

The Company shall provide prompt notice of the taking of a corporate action without a meeting by less than unanimous written consent to those stockholders who have not consented in writing and who, if the action had been taken at a meeting, would have been entitled to notice of the meeting if the record date for such meeting had been the date that written consents signed by a sufficient number of holders to take the action were delivered to the Company as provided in Section 228 of the DGCL. In the event that the action which is consented to is such as would have required the filing of a certificate under any provision of the DGCL, if such action had been voted on by stockholders at a meeting thereof, the certificate filed under such provision shall state, in lieu of any statement required by such provision concerning any vote of stockholders, that written consent has been given in accordance with Section 228 of the DGCL.

- 1.10 *Record Date for Stockholder Notice; Voting; Giving Consents.* In order that the Company may determine the stockholders entitled to notice of or to vote at any meeting of stockholders or any adjournment thereof, or entitled to express consent to corporate action in writing without a meeting, or entitled to receive payment of any dividend or other distribution or allotment of any rights, or entitled to exercise any rights in respect of any change, conversion or exchange of stock or for the purpose of any other lawful action, the Board may fix a record date, which record date shall not precede the date upon which the resolution fixing the record date is adopted by the Board and which record date:
- (i) in the case of determination of stockholders entitled to notice of or to vote at any meeting of stockholders or adjournment thereof, shall, unless otherwise required by law, not be more than sixty nor less than ten days before the date of such meeting;
- (ii) in the case of determination of stockholders entitled to express consent to corporate action in writing without a meeting, shall not be more than ten days after the date upon which the resolution fixing the record date is adopted by the Board; and
  - (iii) in the case of determination of stockholders for any other action, shall not be more than 60 days prior to such other action.

If no record date is fixed by the Board:

- (i) the record date for determining stockholders entitled to notice of or to vote at a meeting of stockholders shall be at the close of business on the day next preceding the day on which notice is given, or, if notice is waived, at the close of business on the day next preceding the day on which the meeting is held;
- (ii) the record date for determining stockholders entitled to express consent to corporate action in writing without a meeting when no prior action of the Board is required by law, shall be the first date on which a signed written consent setting forth the action taken or proposed to be taken is delivered to the Company in accordance with applicable law, or, if prior action by the Board is required by law, shall be at the close of business on the day on which the Board adopts the resolution taking such prior action; and
- (iii) the record date for determining stockholders for any other purpose shall be at the close of business on the day on which the Board adopts the resolution relating thereto.

A determination of stockholders of record entitled to notice of or to vote at a meeting of stockholders shall apply to any adjournment of the meeting, *provided* that the Board may fix a new record date for the adjourned meeting.

- 1.11 *Proxies.* Each stockholder entitled to vote at a meeting of stockholders or to express consent or dissent to corporate action in writing without a meeting may authorize another person or persons to act for such stockholder by proxy authorized by an instrument in writing or by a transmission permitted by law filed in accordance with the procedure established for the meeting, but no such proxy shall be voted or acted upon after three years from its date, unless the proxy provides for a longer period. The revocability of a proxy that states on its face that it is irrevocable shall be governed by the provisions of Section 212 of the DGCL.
- 1.12 List of Stockholders Entitled to Vote. The officer who has charge of the stock ledger of the Company shall prepare and make, at least ten days before every meeting of stockholders, a complete list of the stockholders entitled to vote at the meeting, arranged in alphabetical order, and showing the address of each stockholder and the number of shares registered in the name of each stockholder. The Company shall not be required to include electronic mail addresses or other electronic contact information on such list. Such list shall be open to the examination of any stockholder, for any purpose germane to the meeting for a period of at least ten days prior to the meeting: (i) on a reasonably accessible electronic network, provided that the information required to gain access to such list is provided with the notice of the meeting, or (ii) during ordinary business hours, at the Company's principal place of business. In the event that the Company determines to make the list available on an electronic network, the Company may take reasonable steps to ensure that such information is available only to stockholders of the Company. If the meeting is to be held at a place, then the list shall be produced and kept at the time and place of the meeting during the whole time thereof, and may be inspected by any stockholder who is present. If the meeting is to be held solely by means of remote communication, then the list shall also be open to the examination of any stockholder during the whole time of the meeting on a reasonably accessible electronic network, and the information required to access such list shall be provided with the notice of the meeting.

## ARTICLE II — DIRECTORS

- 2.1 *Powers.* The business and affairs of the Company shall be managed by or under the direction of the Board, except as may be otherwise provided in the DGCL or the certificate of incorporation.
- 2.2 *Number of Directors*. The Board shall consist of one or more members, each of whom shall be a natural person. Unless the certificate of incorporation fixes the number of directors, the number of directors shall be determined from time to time by resolution of the Board. No reduction of the authorized number of directors shall have the effect of removing any director before that director's term of office expires.
- 2.3 *Election, Qualification and Term of Office of Directors.* Except as provided in **section 2.4** of these bylaws, and subject to **sections 1.2** and **1.9** of these bylaws, directors shall be elected at each annual meeting of stockholders. Directors need not be stockholders unless so required by the certificate of incorporation or these bylaws. The certificate of incorporation or these bylaws may prescribe other qualifications for directors. Each director shall hold office until such director's successor is elected and qualified or until such director's earlier death, resignation or removal.

2.4 *Resignation and Vacancies*. Any director may resign at any time upon notice given in writing or by electronic transmission to the Company. A resignation is effective when the resignation is delivered unless the resignation specifies a later effective date or an effective date determined upon the happening of an event or events. A resignation which is conditioned upon the director failing to receive a specified vote for reelection as a director may provide that it is irrevocable. Unless otherwise provided in the certificate of incorporation or these bylaws, when one or more directors resign from the Board, effective at a future date, a majority of the directors then in office, including those who have so resigned, shall have power to fill such vacancy or vacancies, the vote thereon to take effect when such resignation or resignations shall become effective.

Unless otherwise provided in the certificate of incorporation or these bylaws:

- (i) Vacancies and newly created directorships resulting from any increase in the authorized number of directors elected by all of the stockholders having the right to vote as a single class may be filled by a majority of the directors then in office, although less than a quorum, or by a sole remaining director.
- (ii) Whenever the holders of any class or classes of stock or series thereof are entitled to elect one or more directors by the provisions of the certificate of incorporation, vacancies and newly created directorships of such class or classes or series may be filled by a majority of the directors elected by such class or classes or series thereof then in office, or by a sole remaining director so elected.

If at any time, by reason of death or resignation or other cause, the Company should have no directors in office, then any officer or any stockholder or an executor, administrator, trustee or guardian of a stockholder, or other fiduciary entrusted with like responsibility for the person or estate of a stockholder, may call a special meeting of stockholders in accordance with the provisions of the certificate of incorporation or these bylaws, or may apply to the Court of Chancery for a decree summarily ordering an election as provided in Section 211 of the DGCL.

If, at the time of filling any vacancy or any newly created directorship, the directors then in office constitute less than a majority of the whole Board (as constituted immediately prior to any such increase), the Court of Chancery may, upon application of any stockholder or stockholders holding more than 25% of the voting stock at the time outstanding having the right to vote for such directors, summarily order an election to be held to fill any such vacancies or newly created directorships, or to replace the directors chosen by the directors then in office as aforesaid, which election shall be governed by the provisions of Section 211 of the DGCL as far as applicable.

A director elected to fill a vacancy shall be elected for the unexpired term of his or her predecessor in office and until such director's successor is elected and qualified, or until such director's earlier death, resignation or removal.

2.5 *Place of Meetings; Meetings by Telephone.* The Board may hold meetings, both regular and special, either within or outside the State of Delaware.

Unless otherwise restricted by the certificate of incorporation or these bylaws, members of the Board, or any committee designated by the Board, may participate in a meeting of the Board, or any committee, by means of conference telephone or other communications equipment by means of which all persons participating in the meeting can hear each other, and such participation in a meeting shall constitute presence in person at the meeting.

- 2.6 *Conduct of Business.* Meetings of the Board shall be presided over by the Chairperson of the Board, if any, or in his or her absence by the Vice Chairperson of the Board, if any, or in the absence of the foregoing persons by a chairperson designated by the Board, or in the absence of such designation by a chairperson chosen at the meeting. The Secretary shall act as secretary of the meeting, but in his or her absence the chairperson of the meeting may appoint any person to act as secretary of the meeting.
- 2.7 *Regular Meetings*. Regular meetings of the Board may be held without notice at such time and at such place as shall from time to time be determined by the Board.
- 2.8 *Special Meetings; Notice.* Special meetings of the Board for any purpose or purposes may be called at any time by the Chairperson of the Board, the President or any two directors.

Notice of the time and place of special meetings shall be:

- (i) delivered personally by hand, by courier or by telephone;
- (ii) sent by United States first-class mail, postage prepaid;
- (iii) sent by facsimile; or
- (iv) sent by electronic mail,

directed to each director at that director's address, telephone number, facsimile number or electronic mail address, as the case may be, as shown on the Company's records.

If the notice is (i) delivered personally by hand, by courier or by telephone, (ii) sent by facsimile or (iii) sent by electronic mail, it shall be delivered or sent at least 48 hours before the time of the holding of the meeting. If the notice is sent by United States mail, it shall be deposited in the United States mail at least four days before the time of the holding of the meeting. Any oral notice may be communicated to the director. The notice need not specify the place of the meeting (if the meeting is to be held at the Company's principal executive office) nor the purpose of the meeting.

2.9 **Quorum; Voting.** At all meetings of the Board, a majority of the total number of acting directors shall constitute a quorum for the transaction of business. If a quorum is not present at any meeting of the Board, then the directors present thereat may adjourn the meeting from time to time, without notice other than announcement at the meeting, until a quorum is present. A meeting at which a quorum is initially present may continue to transact business notwithstanding the withdrawal of directors, if any action taken is approved by at least a majority of the required quorum for that meeting.

The vote of a majority of the directors present at any meeting at which a quorum is present shall be the act of the Board, except as may be otherwise specifically provided by statute, the certificate of incorporation or these bylaws.

If the certificate of incorporation provides that one or more directors shall have more or less than one vote per director on any matter, every reference in these bylaws to a majority or other proportion of the directors (including, without limitation, for the purpose of determining whether a quorum is present at any meeting of the Board) shall refer to a majority or other proportion of the votes of the directors.

- 2.10 *Board Action by Written Consent Without a Meeting.* Unless otherwise restricted by the certificate of incorporation or these bylaws, any action required or permitted to be taken at any meeting of the Board, or of any committee thereof, may be taken without a meeting if all members of the Board or committee, as the case may be, consent thereto in writing or by electronic transmission and the writing or writings or electronic transmission or transmissions are filed with the minutes of proceedings of the Board or committee. Such filing shall be in paper form if the minutes are maintained in paper form and shall be in electronic form if the minutes are maintained in electronic form.
- 2.11 *Fees and Compensation of Directors*. Unless otherwise restricted by the certificate of incorporation or these bylaws, the Board shall have the authority to fix the compensation of directors.
- 2.12 *Removal of Directors.* Unless otherwise restricted by statute, the certificate of incorporation or these bylaws, any director or the entire Board may be removed, with or without cause, by the holders of a majority of the shares then entitled to vote at an election of directors.

No reduction of the authorized number of directors shall have the effect of removing any director prior to the expiration of such director's term of office.

2.13 *Stockholder Agreements.* Nothing herein shall be deemed to prohibit or limit the ability of 2 or more stockholders of the Company to enter into agreements regarding the exercise of voting rights, including without limitation, the election and/or removal directors.

### ARTICLE III — COMMITTEES

- 3.1 *Committees of Directors.* The Board may designate one or more committees, each committee to consist of one or more of the directors of the Company. The Board may designate one or more directors as alternate members of any committee, who may replace any absent or disqualified member at any meeting of the committee. In the absence or disqualification of a member of a committee, the member or members thereof present at any meeting and not disqualified from voting, whether or not such member or members constitute a quorum, may unanimously appoint another member of the Board to act at the meeting in the place of any such absent or disqualified member. Any such committee, to the extent provided in the resolution of the Board or in these bylaws, shall have and may exercise all the powers and authority of the Board in the management of the business and affairs of the Company, and may authorize the seal of the Company to be affixed to all papers that may require it; but no such committee shall have the power or authority to (i) approve or adopt, or recommend to the stockholders, any action or matter (other than the election or removal of directors) expressly required by the DGCL to be submitted to stockholders for approval, or (ii) adopt, amend or repeal any bylaw of the Company.
  - 3.2 Committee Minutes. Each committee shall keep regular minutes of its meetings and report the same to the Board when required.
- 3.3 *Meetings and Actions of Committees.* Meetings and actions of committees shall be governed by, and held and taken in accordance with, the provisions of:
  - (i) **section 2.5** (Place of Meetings; Meetings by Telephone);
  - (ii) section 2.7 (Regular Meetings);
  - (iii) **section 2.8** (Special Meetings; Notice);
  - (iv) section 2.9 (Quorum; Voting);
  - (v) section 2.10 (Board Action by Written Consent Without a Meeting); and
  - (vi) section 7.5 (Waiver of Notice)

with such changes in the context of those bylaws as are necessary to substitute the committee and its members for the Board and its members. *However*:

- (i) the time of regular meetings of committees may be determined either by resolution of the Board or by resolution of the committee;
- (ii) special meetings of committees may also be called by resolution of the Board; and
- (iii) notice of special meetings of committees shall also be given to all alternate members, who shall have the right to attend all meetings of the committee. The Board may adopt rules for the government of any committee not inconsistent with the provisions of these bylaws.

Any provision in the certificate of incorporation providing that one or more directors shall have more or less than one vote per director on any matter shall apply to voting in any committee or subcommittee, unless otherwise provided in the certificate of incorporation or these bylaws.

3.4 *Subcommittees.* Unless otherwise provided in the certificate of incorporation, these bylaws or the resolutions of the Board designating the committee, a committee may create one or more subcommittees, each subcommittee to consist of one or more members of the committee, and delegate to a subcommittee any or all of the powers and authority of the committee.

### ARTICLE IV — OFFICERS

- 4.1 *Officers.* The officers of the Company shall be a President and a Secretary. The Company may also have, at the discretion of the Board, a Chairperson of the Board, a Chief Executive Officer, one or more Vice Presidents, a Chief Financial Officer, a Treasurer, one or more Assistant Treasurers, one or more Assistant Secretaries, and any such other officers as may be appointed in accordance with the provisions of these bylaws. Any number of offices may be held by the same person.
- 4.2 **Appointment of Officers.** The Board shall appoint the officers of the Company, except such officers as may be appointed in accordance with the provisions of **section 4.3** of these bylaws.
- 4.3 *Subordinate Officers*. The Board may appoint, or empower the Chief Executive Officer or, in the absence of a Chief Executive Officer, the President, to appoint, such other officers and agents as the business of the Company may require. Each of such officers and agents shall hold office for such period, have such authority, and perform such duties as are provided in these bylaws or as the Board may from time to time determine.
- 4.4 *Removal and Resignation of Officers*. Any officer may be removed, either with or without cause, by an affirmative vote of the majority of the Board at any regular or special meeting of the Board or, except in the case of an officer chosen by the Board, by any officer upon whom such power of removal may be conferred by the Board.

Any officer may resign at any time by giving written notice to the Company. Any resignation shall take effect at the date of the receipt of that notice or at any later time specified in that notice. Unless otherwise specified in the notice of resignation, the acceptance of the resignation shall not be necessary to make it effective. Any resignation is without prejudice to the rights, if any, of the Company under any contract to which the officer is a party.

- 4.5 Vacancies in Offices. Any vacancy occurring in any office of the Company shall be filled by the Board or as provided in section 4.3.
- 4.6 *Representation of Shares of Other Corporations.* Unless otherwise directed by the Board, the President or any other person authorized by the Board or the President is authorized to vote, represent and exercise on behalf of the Company all rights incident to any and all shares of any other corporation or corporations standing in the name of the Company. The authority granted herein may be exercised either by such person directly or by any other person authorized to do so by proxy or power of attorney duly executed by such person having the authority.

4.7 **Authority and Duties of Officers.** Except as otherwise provided in these bylaws, the officers of the Company shall have such powers and duties in the management of the Company as may be designated from time to time by the Board and, to the extent not so provided, as generally pertain to their respective offices, subject to the control of the Board.

### ARTICLE V — INDEMNIFICATION

- 5.1 *Indemnification of Directors and Officers in Third Party Proceedings.* Subject to the other provisions of this Article V, the Company shall indemnify, to the fullest extent permitted by the DGCL, as now or hereinafter in effect, 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 (a "*Proceeding*") (other than an action by or in the right of the Company) by reason of the fact that such person is or was a director or officer of the Company, or is or was a director or officer of the Company serving at the request of the Company 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 such person in connection with such Proceeding if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the Company, and, with respect to any criminal action or proceeding, had no reasonable cause to believe such person's conduct was unlawful. The termination of any Proceeding by judgment, order, settlement, conviction, or upon a plea of *nolo contendere* or its equivalent, shall not, of itself, create a presumption that the person did not act in good faith and in a manner which such person reasonably believed to be in or not opposed to the best interests of the Company, and, with respect to any criminal action or proceeding, had reasonable cause to believe that such person's conduct was unlawful.
- 5.2 *Indemnification of Directors and Officers in Actions by or in the Right of the Company.* Subject to the other provisions of this Article V, the Company shall indemnify, to the fullest extent permitted by the DGCL, as now or hereinafter in effect, 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 or in the right of the Company to procure a judgment in its favor by reason of the fact that such person is or was a director or officer of the Company serving at the request of the Company 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 such person in connection with the defense or settlement of such action or suit if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the Company; 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 Company 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 which the Court of Chancery or such other court shall deem proper.

- 5.3 *Successful Defense*. To the extent that a present or former director or officer of the Company has been successful on the merits or otherwise in defense of any action, suit or proceeding described in **section 5.1** or **section 5.2**, or in defense of any claim, issue or matter therein, such person shall be indemnified against expenses (including attorneys' fees) actually and reasonably incurred by such person in connection therewith.
- 5.4 *Indemnification of Others.* Subject to the other provisions of this **Article V**, the Company shall have power to indemnify its employees and agents to the extent not prohibited by the DGCL or other applicable law. The Board shall have the power to delegate to such person or persons the determination of whether employees or agents shall be indemnified.
- 5.5 **Advanced Payment of Expenses.** Expenses (including attorneys' fees) incurred by an officer or director of the Company in defending any Proceeding shall be paid by the Company in advance of the final disposition of such Proceeding upon receipt of a written request therefor (together with documentation reasonably evidencing such expenses) and an undertaking by or on behalf of the person to repay such amounts if it shall ultimately be determined that the person is not entitled to be indemnified under this **Article V** or the DGCL. Such expenses (including attorneys' fees) incurred by former directors and officers or other employees and agents may be so paid upon such terms and conditions, if any, as the Company deems appropriate. The right to advancement of expenses shall not apply to any claim for which indemnity is excluded pursuant to these bylaws.

Notwithstanding the foregoing, unless otherwise determined pursuant to **section 5.8**, no advance shall be made by the Company to an officer of the Company (except by reason of the fact that such officer is or was a director of the Company, in which event this paragraph shall not apply) in any Proceeding if a determination is reasonably and promptly made (i) by a majority vote of the directors who are not parties to such Proceeding, even though less than a quorum, or (ii) by a committee of such directors designated by majority vote of such directors, even though less than a quorum, or (iii) if there are no such directors, or if such directors so direct, by independent legal counsel in a written opinion, that facts known to the decision-making party at the time such determination is made demonstrate clearly and convincingly that such person acted in bad faith or in a manner that such person did not believe to be in or not opposed to the best interests of the Company.

- 5.6 *Limitation on Indemnification*. Subject to the requirements in **section 5.3** and the DGCL, the Company shall not be obligated to indemnify any person pursuant to this **Article V** in connection with any Proceeding (or any part of any Proceeding):
- (i) for which payment has actually been made to or on behalf of such person under any statute, insurance policy, indemnity provision, vote or otherwise, except with respect to any excess beyond the amount paid;
- (ii) for an accounting or disgorgement of profits pursuant to Section 16(b) of the Securities Exchange Act of 1934, as amended, or similar provisions of federal, state or local statutory law or common law, if such person is held liable therefor (including pursuant to any settlement arrangements);

- (iii) for any reimbursement of the Company by such person of any bonus or other incentive-based or equity-based compensation or of any profits realized by such person from the sale of securities of the Company, as required in each case under the Securities Exchange Act of 1934, as amended (including any such reimbursements that arise from an accounting restatement of the Company pursuant to Section 304 of the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act"), or the payment to the Company of profits arising from the purchase and sale by such person of securities in violation of Section 306 of the Sarbanes-Oxley Act), if such person is held liable therefor (including pursuant to any settlement arrangements);
- (iv) initiated by such person, including any Proceeding (or any part of any Proceeding) initiated by such person against the Company or its directors, officers, employees, agents or other indemnitees, unless (a) the Board authorized the Proceeding (or the relevant part of the Proceeding) prior to its initiation, (b) the Company provides the indemnification, in its sole discretion, pursuant to the powers vested in the Company under applicable law, (c) otherwise required to be made under **section 5.7** or (d) otherwise required by applicable law; or
  - (v) if prohibited by applicable law.
- 5.7 **Determination; Claim.** If a claim for indemnification or advancement of expenses under this **Article V** is not paid in full within 90 days after receipt by the Company of the written request therefor, the claimant shall be entitled to an adjudication by a court of competent jurisdiction of his or her entitlement to such indemnification or advancement of expenses. The Company shall indemnify such person against any and all expenses that are incurred by such person in connection with any action for indemnification or advancement of expenses from the Company under this **Article V**, to the extent such person is successful in such action, and to the extent not prohibited by law, In any such suit, the Company shall, to the fullest extent not prohibited by law, have the burden of proving that the claimant is not entitled to the requested indemnification or advancement of expenses.
- 5.8 *Non-Exclusivity of Rights*. The indemnification and advancement of expenses provided by, or granted pursuant to, this **Article V** shall not be deemed exclusive of any other rights to which those seeking indemnification or advancement of expenses may be entitled under the certificate of incorporation or any statute, bylaw, agreement, vote of stockholders or disinterested directors or otherwise, both as to action in such person's official capacity and as to action in another capacity while holding such office. The Company is specifically authorized to enter into individual contracts with any or all of its directors, officers, employees or agents respecting indemnification and advancement of expenses, to the fullest extent not prohibited by the DGCL or other applicable law.

- 5.9 *Insurance*. The Company may purchase and maintain insurance on behalf of any person who is or was a director, officer, employee or agent of the Company, or is or was serving at the request of the Company 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 Company would have the power to indemnify such person against such liability under the provisions of the DGCL.
- 5.10 *Survival*. The rights to indemnification and advancement of expenses conferred by this **Article V** shall continue as to a person who has ceased to be a director, officer, employee or agent and shall inure to the benefit of the heirs, executors and administrators of such a person.
- 5.11 *Effect of Repeal or Modification.* Any amendment, alteration or repeal of this **Article V** shall not adversely affect any right or protection hereunder of any person in respect of any act or omission occurring prior to such amendment, alteration or repeal.
- 5.12 *Certain Definitions.* For purposes of this **Article V**, references to the "*Company*" shall include, in addition to the resulting corporation, any constituent corporation (including any constituent of a constituent) absorbed in a consolidation or merger which, if its separate existence had continued, would have had power and authority to indemnify its directors, officers, employees or agents, so that any person who is or was a director, officer, employee or agent of such constituent corporation, or is or was serving at the request of such constituent corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, shall stand in the same position under the provisions of this **Article V** with respect to the resulting or surviving corporation as such person would have with respect to such constituent corporation if its separate existence had continued. For purposes of this **Article V**, references to "other enterprises" shall include employee benefit plans; references to "fines" shall include any excise taxes assessed on a person with respect to an employee benefit plan; and references to "serving at the request of the Company" shall include any service as a director, officer, employee or agent of the Company which imposes duties on, or involves services by, such director, officer, employee or agent with respect to an employee benefit plan, its participants or beneficiaries; and a person who acted in good faith and in a manner "not opposed to the best interests of the Company" as referred to in this **Article V**.

### ARTICLE VI — STOCK

6.1 Stock Certificates; Partly Paid Shares. The shares of the Company shall be represented by certificates, provided that the Board may provide by resolution or resolutions that some or all of any or all classes or series of its stock shall be uncertificated shares. Any such resolution shall not apply to shares represented by a certificate until such certificate is surrendered to the Company. Every holder of stock represented by certificates shall be entitled to have a certificate signed by, or in the name of the Company by the Chairperson of the Board or Vice-Chairperson of the Board, or the President or a Vice-President, and by the Treasurer or an Assistant Treasurer, or the Secretary or an Assistant Secretary of the Company representing the number of shares registered in certificate form. Any or all of the signatures on the certificate may be a facsimile. In case any officer, transfer agent or registrar who has signed or whose facsimile signature has been placed upon a certificate has ceased to be such officer, transfer agent or registrar before such certificate is issued, it may be issued by the Company with the same effect as if such person were such officer, transfer agent or registrar at the date of issue. The Company shall not have power to issue a certificate in bearer form.

The Company may issue the whole or any part of its shares as partly paid and subject to call for the remainder of the consideration to be paid therefor. Upon the face or back of each stock certificate issued to represent any such partly paid shares, or upon the books and records of the Company in the case of uncertificated partly paid shares, the total amount of the consideration to be paid therefor and the amount paid thereon shall be stated. Upon the declaration of any dividend on fully paid shares, the Company shall declare a dividend upon partly paid shares of the same class, but only upon the basis of the percentage of the consideration actually paid thereon.

- 6.2 Special Designation on Certificates. If the Company is authorized to issue more than one class of stock or more than one series of any class, then the powers, the designations, the preferences, and the relative, participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights shall be set forth in full or summarized on the face or back of the certificate that the Company shall issue to represent such class or series of stock; provided that, except as otherwise provided in Section 202 of the DGCL, in lieu of the foregoing requirements there may be set forth on the face or back of the certificate that the Company shall issue to represent such class or series of stock, a statement that the Company will furnish without charge to each stockholder who so requests the powers, designations, preferences and/or rights. Within a reasonable time after the issuance or transfer of uncertificated stock, the Company shall send to the registered owner thereof a written notice containing the information required to be set forth or stated on certificates pursuant to this section 6.2 or Sections 156, 202(a) or 218(a) of the DGCL or with respect to this section 6.2 a statement that the Company will furnish without charge to each stockholder who so requests the powers, designations, preferences and relative, participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights. Except as otherwise expressly provided by law, the rights and obligations of the holders of uncertificated stock and the rights and obligations of the holders of certificates representing stock of the same class and series shall be identical.
- 6.3 **Lost Certificates.** Except as provided in this **section 6.3**, no new certificates for shares shall be issued to replace a previously issued certificate unless the latter is surrendered to the Company and cancelled at the same time. The Company may issue a new certificate of stock or uncertificated shares in the place of any certificate theretofore issued by it, alleged to have been lost, stolen or destroyed, and the Company may require the owner of the lost, stolen or destroyed certificate, or such owner's legal representative, to give the Company a bond sufficient to indemnify it against any claim that may be made against it on account of the alleged loss, theft or destruction of any such certificate or the issuance of such new certificate or uncertificated shares.
- 6.4 *Dividends*. The Board, subject to any restrictions contained in the certificate of incorporation or applicable law, may declare and pay dividends upon the shares of the Company's capital stock. Dividends may be paid in cash, in property, or in shares of the Company's capital stock, subject to the provisions of the certificate of incorporation.

The Board may set apart out of any of the funds of the Company available for dividends a reserve or reserves for any proper purpose and may abolish any such reserve.

6.5 *Stock Transfer Agreements*. The Company shall have power to enter into and perform any agreement with any number of stockholders of any one or more classes of stock of the Company to restrict the transfer of shares of stock of the Company of any one or more classes owned by such stockholders in any manner not prohibited by the DGCL.

### 6.6 *Registered Stockholders*. The Company:

- (i) shall be entitled to recognize the exclusive right of a person registered on its books as the owner of shares to receive dividends and to vote as such owner;
  - (ii) shall be entitled to hold liable for calls and assessments the person registered on its books as the owner of shares; and
- (iii) shall not be bound to recognize any equitable or other claim to or interest in such share or shares on the part of another person, whether or not it shall have express or other notice thereof, except as otherwise provided by the laws of Delaware.
- 6.7 *Transfers*. Transfers of record of shares of stock of the Company shall be made only upon its books by the holders thereof, in person or by an attorney duly authorized, and, if such stock is certificated, upon the surrender of a certificate or certificates for a like number of shares, properly endorsed or accompanied by proper evidence of succession, assignation or authority to transfer.

## ARTICLE VII — MANNER OF GIVING NOTICE AND WAIVER

- 7.1 *Notice of Stockholder Meetings.* Notice of any meeting of stockholders, if mailed, is given when deposited in the United States mail, postage prepaid, directed to the stockholder at such stockholder's address as it appears on the Company's records. An affidavit of the Secretary or an Assistant Secretary of the Company or of the transfer agent or other agent of the Company that the notice has been given shall, in the absence of fraud, be *prima facie* evidence of the facts stated therein.
- 7.2 *Notice by Electronic Transmission.* Without limiting the manner by which notice otherwise may be given effectively to stockholders pursuant to the DGCL, the certificate of incorporation or these bylaws, any notice to stockholders given by the Company under any provision of the DGCL, the certificate of incorporation or these bylaws shall be effective if given by a form of electronic transmission consented to by the stockholder to whom the notice is given. Any such consent shall be deemed revoked if:
- (i) the Company is unable to deliver by electronic transmission two consecutive notices given by the Company in accordance with such consent; and
- (ii) such inability becomes known to the Secretary or an Assistant Secretary of the Company or to the transfer agent, or other person responsible for the giving of notice.

However, the inadvertent failure to treat such inability as a revocation shall not invalidate any meeting or other action.

Any notice given pursuant to the preceding paragraph shall be deemed given:

- (i) if by facsimile telecommunication, when directed to a number at which the stockholder has consented to receive notice;
- (ii) if by electronic mail, when directed to an electronic mail address at which the stockholder has consented to receive notice;
- (iii) if by a posting on an electronic network together with separate notice to the stockholder of such specific posting, upon the later of (A) such posting and (B) the giving of such separate notice; and
  - (iv) if by any other form of electronic transmission, when directed to the stockholder.

An affidavit of the Secretary or an Assistant Secretary or of the transfer agent or other agent of the Company that the notice has been given by a form of electronic transmission shall, in the absence of fraud, be *prima facie* evidence of the facts stated therein.

An "*electronic transmission*" means any form of communication, not directly involving the physical transmission of paper, that creates a record that may be retained, retrieved, and reviewed by a recipient thereof, and that may be directly reproduced in paper form by such a recipient through an automated process.

Notice by a form of electronic transmission shall not apply to Sections 164, 296, 311, 312 or 324 of the DGCL.

- 7.3 *Notice to Stockholders Sharing an Address.* Except as otherwise prohibited under the DGCL, without limiting the manner by which notice otherwise may be given effectively to stockholders, any notice to stockholders given by the Company under the provisions of the DGCL, the certificate of incorporation or these bylaws shall be effective if given by a single written notice to stockholders who share an address if consented to by the stockholders at that address to whom such notice is given. Any such consent shall be revocable by the stockholder by written notice to the Company. Any stockholder who fails to object in writing to the Company, within 60 days of having been given written notice by the Company of its intention to send the single notice, shall be deemed to have consented to receiving such single written notice.
- 7.4 *Notice to Person with Whom Communication is Unlawful.* Whenever notice is required to be given, under the DGCL, the certificate of incorporation or these bylaws, to any person with whom communication is unlawful, the giving of such notice to such person shall not be required and there shall be no duty to apply to any governmental authority or agency for a license or permit to give such notice to such person. Any action or meeting which shall be taken or held without notice to any such person with whom communication is unlawful shall have the same force and effect as if such notice had been duly given. In the event that the action taken by the Company is such as to require the filing of a certificate under the DGCL, the certificate shall state, if such is the fact and if notice is required, that notice was given to all persons entitled to receive notice except such persons with whom communication is unlawful.

7.5 *Waiver of Notice*. Whenever notice is required to be given under any provision of the DGCL, the certificate of incorporation or these bylaws, a written waiver, signed by the person entitled to notice, or a waiver by electronic transmission by the person entitled to notice, whether before or after the time of the event for which notice is to be given, shall be deemed equivalent to notice. Attendance of a person at a meeting shall constitute a waiver of notice of such meeting, except when the person attends a meeting for the express purpose of objecting at the beginning of the meeting, to the transaction of any business because the meeting is not lawfully called or convened. Neither the business to be transacted at, nor the purpose of, any regular or special meeting of the stockholders need be specified in any written waiver of notice or any waiver by electronic transmission unless so required by the certificate of incorporation or these bylaws.

### ARTICLE VIII — GENERAL MATTERS

- 8.1 Fiscal Year. The fiscal year of the Company shall be fixed by resolution of the Board and may be changed by the Board.
- 8.2 *Seal*. The Company may adopt a corporate seal, which shall be in such form as may be approved from time to time by the Board. The Company may use the corporate seal by causing it or a facsimile thereof to be impressed or affixed or in any other manner reproduced.
- 8.3 *Annual Report.* The Company shall cause an annual report to be sent to the stockholders of the Company to the extent required by applicable law. If and so long as there are fewer than 100 holders of record of the Company's shares, the requirement of sending an annual report to the stockholders of the Company is expressly waived (to the extent permitted under applicable law).
- 8.4 *Construction; Definitions*. Unless the context requires otherwise, the general provisions, rules of construction, and definitions in the DGCL shall govern the construction of these bylaws. Without limiting the generality of this provision, the singular number includes the plural, the plural number includes the singular, and the term "*person*" includes both a corporation and a natural person.

#### ARTICLE IX — AMENDMENTS

Except as otherwise provided in the Company's certificate of incorporation, these bylaws may be altered, amended or repealed, or new bylaws may be adopted, by the holders of shares of stock having a majority of the votes which could be cast by the holders of all outstanding shares of stock entitled to vote thereon or by the Board, when such power is conferred upon the Board by the certificate of incorporation. If the power to adopt, amend or repeal bylaws is conferred upon the Board by the Company's certificate of incorporation, it shall not divest or limit the power of the stockholders to adopt, amend or repeal bylaws.

THESE SECURITIES HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT"), OR ANY STATE SECURITIES LAWS AND MAY NOT BE TRANSFERRED OR OTHERWISE DISPOSED OF UNLESS THEY HAVE BEEN REGISTERED UNDER SUCH ACT AND ALL SUCH APPLICABLE LAWS OR AN EXEMPTION FROM SUCH REGISTRATION IS AVAILABLE.

### **AZITRA INC**

1.2221111110			
[Form of]			
WARRANT TO PURCHASE COMMON STOCK			
This Warrant is issued to or its registered assigns (" <i>Holder</i> ") by <b>AZITRA INC</b> , a Delaware corporation (the " <i>Company</i> "), pursuant to that certain Series A-1 Preferred Stock and Warrant Purchase Agreement, dated as of February 22, 2019 (the " <i>Purchase Agreement</i> ").			
1. <u>Purchase of Common Stock.</u> Subject to the terms and conditions hereinafter set forth, for value received, the Holder is entitled, upon surrender of this Warrant at the principal office of the Company (or at such other place as the Company shall notify the Holder in writing), to purchase from the Company up to () shares of the Company's common stock, par value \$0.01 per share (the " <i>Common Stock</i> ") (subject to adjustment as described herein) at the Exercise Price (as defined below).			
2. <u>Definitions.</u> Capitalized terms not otherwise defined herein shall have the same definitions as stated in the Purchase Agreement.			
(a) <u>Exercise Price</u> . The exercise price for each share of Common Stock issuable hereunder shall be \$37.50 (as adjusted from time to time in accordance with the terms hereof, the " <i>Exercise Price</i> ").			
(b) Exercise Period. This Warrant shall be exercisable, in whole or in part, during the term commencing on the date hereof and ending on the expiration of this Warrant pursuant to Section 14 hereof.			
3. <u>Method of Exercise</u> . While this Warrant remains outstanding and exercisable in accordance with Section 2 above, the Holder may exercise, in whole or in part, the purchase rights evidenced hereby. Such exercise shall be effected by:			
(a) the surrender of the Warrant, together with a notice of exercise to the Chief Executive Officer of the Company (or other officer of the Company performing similar functions) at its principal offices substantially in the form attached hereto as <a href="Exhibit 1"><u>Exhibit 1</u></a> ; and			
(b) subject to Section 4 below, the payment to the Company, in cash, of an amount equal to the aggregate applicable Exercise Price for the number of shares of Common Stock being purchased.			

4. <u>Net Exercise</u>. In lieu of exercising this Warrant in exchange for cash as described in Section 3(b) above, the Holder may elect to receive a number of shares of Common Stock equal to the value of this Warrant (or the portion thereof being canceled), as determined below, in which event the Company shall issue to the holder hereof a number of shares of Common Stock computed using the following formula:

$$X = \frac{Y(A - B)}{A}$$

Where

- X -- The number of shares of Common Stock to be issued to the Holder.
- Y -- The number of shares of Common Stock purchasable under this Warrant or, if only a portion of this Warrant is being exercised, the portion of the Warrant being exercised (at the date of such calculation).
- A -- The fair market value of one share of Common Stock.
- B -- The applicable Exercise Price (as adjusted to the date of such calculations).

For purposes of Rule 144, it is intended, understood and acknowledged that the shares of Common Stock issued hereunder upon exercise of this Warrant pursuant to this Section 4 shall be deemed to have been acquired at the time this Warrant was issued. Moreover, it is intended, understood and acknowledged that the holding period for the shares of Common Stock issued hereunder upon exercise of this Warrant pursuant to this Section 4 shall be deemed, for both federal tax and Rule 144 purposes, to have commenced on the date this Warrant was issued.

- 5. Fair Market Value. For purposes of Section 4, the fair market value of a share of Common Stock is defined as follows:
- (a) if the exercise is in connection with an initial public offering of the Common Stock, and if the Company's registration statement relating to such offering has been declared effective by the Securities and Exchange Commission, then the fair market value shall be the initial "Price to Public" specified in the final prospectus with respect to the offering;
- (b) if the exercise is in connection with a Sale of the Company (as defined in the Voting Agreement, defined below), then the fair market value shall be the value received for one share of Common Stock pursuant to such transaction;
- (c) if the exercise occurs after, and not in connection with, the Company's initial public offering, and (i) if traded on a securities exchange or the Nasdaq Stock Market, then the value shall be deemed to be the average of the closing prices of the securities on such exchange or market over the thirty (30) day period ending three (3) days prior to the date of delivery of the notice of exercise; or (ii) if actively traded over-the-counter, then the value shall be deemed to be the average of the closing bid prices over the thirty (30) day period ending three (3) days prior to the date of delivery of the notice of exercise; or

- (d) if none of the above apply, then the value shall be the fair market value thereof, as determined in good faith by the board of directors of the Company taking into account the Company's most recently obtained written report from an independent valuation firm for purposes of obtaining safe harbor coverage under Section 409A of the Internal Revenue Code of 1986, as amended, and the regulations thereunder.
- 6. <u>Certificates for Common Stock</u>. Upon the exercise of the purchase rights evidenced by this Warrant, one or more certificates for the number of shares of Common Stock so purchased shall be issued as soon as practicable thereafter, and in any event within five (5) days of the delivery of the exercise notice and payment therefor. In case the Holder shall exercise this Warrant with respect to fewer than all of the shares of Common Stock that may be purchased under this Warrant, the Company shall execute a new warrant in the form of this Warrant for the balance of such shares and deliver such new warrant to the Holder. The Person in whose name any certificate or certificates for shares of Common Stock purchased under this Warrant are to be issued upon the exercise of this Warrant shall be deemed to have become the holder of record of such shares on the date on which this Warrant was surrendered and payment of the Exercise Price was made, irrespective of the date of delivery of such certificate or certificates.
- 7. <u>Issuance of Common Stock</u>. The Company hereby agrees that at all times there shall be reserved for issuance and delivery upon exercise of this Warrant, free from preemptive rights, such number of shares of Common Stock from time to time issuable upon exercise of this Warrant. The Company covenants that the shares of Common Stock, when issued pursuant to the exercise of this Warrant, will be duly and validly issued, fully paid and nonassessable and free from all taxes, liens, and charges with respect to the issuance thereof.
- 8. <u>Adjustment of Exercise Price and Number of Shares of Common Stock</u>. The number of and kind of securities purchasable upon exercise of this Warrant and the Exercise Price shall be subject to adjustment from time to time as follows:
- (a) <u>Subdivisions, Combinations and Other Issuances</u>. If the Company shall at any time prior to the expiration of this Warrant subdivide the shares of Common Stock, by split-up or otherwise, or combine its shares of Common Stock, or issue additional shares of Common Stock as a dividend, the number of shares of Common Stock issuable on the exercise of this Warrant shall forthwith be proportionately increased and the Exercise Price shall be proportionately decreased in the case of a subdivision, as of the effective date of such subdivision (or, if the Company shall take a record of holders of Common Stock for purposes of such subdivision), or dividend, as of the date of such dividend (or, if the Company shall take a record of holders of Common Stock for purposes of such dividend, as at such record date, if earlier than the date of such dividend), or proportionately decreased and the Exercise Price shall be proportionately increased in the case of a combination, as of the effective date of such combination (or, if the Company shall take a record of holders of Common Stock for purposes of such combination, as at such record date, if earlier than the effective date of such combination).

- (b) <u>Reclassification, Reorganization and Consolidation</u>. In the event of any reclassification, capital reorganization, or change in the equity securities of the Company (other than as a result of a subdivision, combination, or dividend provided for in Section 8(a) above), then the Holder shall have the right at any time prior to the expiration of this Warrant to purchase the kind and amount of shares and other securities and property receivable in connection with such reclassification, reorganization, or change by a holder of the same number of shares of Common Stock as were purchasable by the Holder immediately prior to such reclassification, reorganization, or change. In any such case appropriate provisions shall be made with respect to the rights and interest of the Holder so that the provisions hereof shall thereafter be applicable with respect to any shares or other securities and property deliverable upon exercise hereof, and appropriate adjustments shall be made to the applicable Exercise Price per share of Common Stock payable hereunder, provided the aggregate applicable Exercise Price shall remain the same.
- (c) <u>Notice of Adjustment</u>. When any adjustment is required to be made in the number or kind of equity securities purchasable upon exercise of this Warrant, or in the applicable Exercise Price, the Company shall promptly notify the Holder of such event and of the number of shares of Common Stock or other securities or property thereafter purchasable upon exercise of this Warrant.
- (d) Other Action Affecting Common Stock. In the event that the Company shall make a distribution in respect of shares of Common Stock that is not elsewhere described in this Section 8, the Holder shall be entitled, upon exercise of this Warrant, to receive from the Company its pro rata share of any such distribution such that the Holder receives, upon exercise of this Warrant, the same type and amount of property which such Holder would have received if such Holder had exercised this Warrant immediately prior to such distribution or the date the Company shall take a record of the holders of its equity securities for purposes of such distribution, as applicable, and, from and after the date of such distribution, the Company shall hold and set aside (or cause to be held and set aside in a commercially reasonable manner) an amount of such property equal to the Holder's pro rata portion thereof for distribution to the Holder pursuant hereto.
- 9. <u>No Fractional Shares or Scrip</u>. No fractional shares or scrip representing fractional shares shall be issued upon the exercise of this Warrant, but in lieu of such fractional shares the Company shall make a cash payment therefor on the basis of the fair market value thereof then in effect.

# 10. Restrictive Legend.

The shares of Common Stock issuable upon exercise of this Warrant (unless registered under the Securities Act) shall be stamped or imprinted with a legend in substantially the following form:

THE SECURITIES REPRESENTED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933 (THE "<u>SECURITIES ACT</u>") AND MAY NOT BE TRANSFERRED OR OTHERWISE DISPOSED OF UNLESS THEY HAVE BEEN REGISTERED UNDER SUCH ACT AND ALL SUCH APPLICABLE LAWS.

11. Warrant Transferable. Subject to compliance with the terms and conditions of this Section 11, the Purchase Agreement and the other Transaction Agreements, this Warrant and all rights hereunder are transferable to Permitted Transferees, in whole or in part, without charge to the holder hereof (except for transfer taxes), upon surrender of this Warrant properly endorsed or accompanied by a written instruction of transfer substantially in the form attached hereto as Exhibit 2; provided that the transferee consents in writing to be bound by the terms hereunder. With respect to any offer, sale or other disposition of this Warrant prior to registration of such Warrant, the holder hereof agrees to give written notice to the Company prior thereto, describing briefly the manner thereof and indicating whether or not under the Securities Act certificates for this Warrant require any restrictive legend as to applicable restrictions on transferability in order to ensure compliance with such law. Upon receiving such written notice and the written consent of the proposed transferee agreeing to be bound by the terms hereunder, the Company, as promptly as practicable, shall notify the Holder that it may sell or otherwise dispose of this Warrant, all in accordance with the terms of the notice delivered to the Company. Each certificate representing this Warrant transferred in accordance with this Section 11 shall bear a legend as to the applicable restrictions on transferability in order to ensure compliance with such laws, unless such legend is not required in order to ensure compliance with such laws. The Company may issue stop transfer instructions to its transfer agent in connection with such restrictions. As used herein, the term "Permitted Transferee" means, as to any proposed transfer of this Warrant by any Holder to (a) if the Holder is a natural person, his/her ancestors, descendants, siblings, or spouse, any executor or administrator of his/her estate, or to a custodian, trustee (including a trustee of a voting trust), executor, or other fiduciary primarily for the account of such Holder or his/her ancestors, descendants, siblings, or spouse, whether step, in-law or adopted, and, in the case of any such trust or fiduciary, a transfer of the Warrant thereto solely for bona fide estate planning purposes, either during his/her lifetime or on death by will or intestacy; (b) if the Holder is a partnership (including, without limitation, a limited partnership) or limited liability company, a partner or retired partner, or member or retired member, or any Affiliate of such Holder; (c) the Company, if effected pursuant to any redemption or repurchase right; (d) any Person in connection with a Sale of the Company; (e) (i) any Affiliate of a Holder (other than any investment portfolio company of such Holder that is an Affiliate), (ii) any successor of such Holder by consolidation, merger or transfer of assets of such Purchaser, (iii) the then existing members, shareholders, Affiliates or other investors in the Purchaser in connection with the dissolution or winding-up of such Holder, or (iv) any Person in connection with any consolidation or reorganization of the Holder directly or indirectly with or into one or more other investment vehicles; or (f) solely with respect to CII (as defined in the Purchase Agreement) or any Permitted CII Transferee (as defined in the Purchase Agreement), transfers by or among CII and Permitted CII Transferees.

12. <u>Rights of Stockholders</u>. Except as expressly set forth in Section 8 or Section 14 hereof, no holder of this Warrant shall be entitled, as a Warrant holder, to vote or receive dividends or be deemed the holder of shares of Common Stock or any other securities of the Company which may at any time be issuable on the exercise hereof for any purpose, nor shall anything contained herein be construed to confer upon the holder of this Warrant, as such, any of the rights of a stockholder of the Company or any right to vote for the election of directors or upon any matter submitted to stockholders at any meeting thereof, or to give or withhold consent to any corporate action (whether upon any recapitalization, issuance of equity securities, reclassification of equity securities, change of par value, consolidation, merger, conveyance, or otherwise) or to receive notice of meetings, or to receive dividends or subscription rights until the Warrant shall have been exercised.

- 13. [Reserved].
- 14. Expiration of Warrant; Notice of Certain Events Terminating This Warrant.
  - (a) This Warrant shall expire and shall no longer be exercisable upon the earliest to occur of:
    - (i) 5:00 p.m. (Eastern time) on February 22, 2026;
- (ii) the consummation of a Sale of the Company; provided that the Company shall have provided notice to the Holder of such Sale of the Company pursuant to Section 14(b) below.
- (b) The Company shall provide at least ten (10) days prior written notice to the Holder of any event set forth in Section 14(a)(ii). In addition, in the event of any taking by the Company of a record of holders of any class of securities for the purpose of determining the holders thereof who or which are entitled to receive any dividend or other distribution, the Company shall provide notice thereof to the Holder, at least seven (7) days prior thereto, of the date on which any record is to be taken for the purpose of such dividend or distribution.
- 15. Notices. All notices and other communications required or permitted hereunder shall be in writing and shall be (i) mailed by first-class, registered or certified mail, postage prepaid, (ii) delivered either by hand or by messenger or commercial overnight delivery service, or (iii) sent via computer mail or other electronic means followed by a copy mailed by first class mail, postage prepaid, addressed: (a) if to the Holder, at the Holder's address as set forth in the Purchase Agreement, or at such other address as the Holder shall have furnished to the Company in writing; and (b) if to the Company, at 400 Farmington Ave, Farmington, CT 06032, e-mail address: andrews@azitrainc.com, Attention: Chief Executive Officer, or at such other address as the Company shall have furnished to the Holder in writing, with a copy to Shipman & Goodwin LLP, One Constitution Plaza, Hartford, CT 06103, Attention: James C. Schulwolf, Esq., e-mail address: jschulwolf@goodwin.com. Any notice or other communications so addressed and mailed, postage prepaid, by registered or certified mail (in each case, with return receipt requested) shall be deemed to be given two (2) days after so mailed. Any notice so addressed and otherwise delivered shall be deemed to be given when actually received by the addressee.
- 16. <u>Governing Law</u>. This Warrant and all actions arising out of or in connection with this Warrant shall be governed by and construed in accordance with the laws of the State of Delaware, without regard to the conflicts of law provisions of the State of Delaware or of any other state.
- 17. <u>Rights and Obligations Survive Exercise of Warrant</u>. Unless otherwise provided herein, the rights and obligations of the Company and of the holder of this Warrant shall survive the exercise of this Warrant.

- 18. Counterparts; Facsimile and Electronic Signatures. This Warrant may be executed in any number of counterparts, and each such counterpart hereof shall be deemed to be an original instrument, but all such counterparts together shall constitute but one agreement (notwithstanding that all of the parties are not signatories to the original or the same counterpart, or that signature pages from different counterparts are combined), and it shall not be necessary when making proof of this Warrant or any counterpart thereof to account for any other counterpart, and the signature of any party to any counterpart shall be deemed to be a signature to and may be appended to any other counterpart. For purposes of this this Warrant, a document (or signature page thereto) signed and transmitted by facsimile machine or other electronic means is to be treated as an original document. The signature of any party on any such document, for purposes hereof and thereof, is to be considered as an original signature, and the document transmitted is to be considered to have the same binding effect as an original signature on an original document. At the request of any party, any facsimile or other electronic signature is to be reexecuted in original form by the parties which executed the facsimile or other electronic signature. No party may raise the use of a facsimile machine or other electronic means, or the fact that any signature was transmitted through the use of a facsimile machine or other electronic means, as a defense to the enforcement of this Warrant.
- 19. <u>Amendments</u>. Except as otherwise expressly set forth in this Warrant, any term of this Warrant may be amended or waived (either retroactively or prospectively) only with the written consent of the Company and the Holder. Any amendment effected in accordance with this Section 19 shall be binding upon Holder and the Company.
- 20. <u>No Waiver</u>. No waiver of any provision or consent to any action shall constitute a waiver of any other provision or consent to any other action, whether or not similar. No waiver or consent shall constitute a continuing waiver or consent or commit a party to provide a waiver in the future except to the extent specifically set forth in writing.
- 21. <u>No Impairment</u>. The Company shall not by any action, including, without limitation, through any reorganization, transfer of assets, consolidation, merger, dissolution, issuance or sale of securities or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms of this Warrant, but will at all times carry out of all such terms and take all such actions as may be necessary or appropriate to protect the rights of the Holder against impairment.
- 22. <u>Voting Agreement</u>. Upon exercise of this Warrant, in whole or in part, and prior to receipt of any Common Stock in connection therewith, the Holder shall execute an Adoption Agreement to that certain Second Amended and Restated Voting Agreement, dated as of February 22, 2019, by and among the Company and the Investors and Key Holders party thereto (as may be amended from time to time, the "*Voting Agreement*"), agreeing to be bound by and subject to the terms of the Voting Agreement as a Stockholder and shall be deemed a Stockholder for all purposes under the Voting Agreement.

[Signature page follows]

IN WITNESS WHEREOF, the parties hereto have caused this Wa officers as of the date first written above.	rrant to be duly executed and delivered by their proper and duly authorized
	AZITRA INC.
	By: Name: Richard Andrews Title: President and Chief Executive Officer  By:
	By: Name: Title:
[SICNATURE DACE TO WADDANT]	

# EXHIBIT 1

# NOTICE OF EXERCISE

TO: Azitra Inc 400 Farmington Ave, Farmington, CT 06032 Attention: Chief Executive Officer

(Title)

1. The undersigned hereby elects to purchase shares of Common Stock, par value $\$0.01$ p to the terms of the attached Warrant.	er share, of Azitra Inc, a Delaware corporation, pursuant			
2. [Method of Exercise (Please check the applicable blank):				
The undersigned elects to exercise the attached Warrant by means of a cash payment, and tenders herewith payment in full for the purchase price of the shares being purchased, together with all applicable transfer taxes, if any.				
The undersigned elects to exercise the attached Warrant by means of the	net exercise provisions of Section 4 of the Warrant.]			
3. Please issue a certificate or certificates representing said shares in the name of the under	rsigned or in such other name as is specified below:			
(Name)				
(Address)				
	(Signature)			
	(Name)			

(Title)

# EXHIBIT 2

FORM OF TRANSFER (To be signed only upon transfer of Warrant)

attached Warrant to purchase	rsigned hereby sells, assigns and transfers unto shares of Common Stock, par value \$0.01 per share of AZITRA I Attorney to transfer such right on the books of	NC, a Delaware corporation, to which the
Dated:		
	(Signature must conform in all respe face of the Warrant)	cts to name of Holder as specified on the
	Address:	
Signed in the presence of:		

#### **AZITRA INC**

### INDEMNIFICATION AGREEMENT

**THIS INDEMNIFICATION AGREEMENT** ("*Agreement*") is entered into as of [•], 2022 by and between **Azitra Inc**, a Delaware corporation (the "*Company*"), and [•] ("*Indemnitee*").

- A. The Company desires to attract and retain the services of highly qualified individuals, such as Indemnitee, to serve the Company and its related entities.
- B. In order to induce Indemnitee to continue to provide services to the Company, the Company wishes to provide for the indemnification of and the advancement of expenses to, Indemnitee to the maximum extent permitted by law.
- C. The Company and Indemnitee recognize the continued difficulty in obtaining liability insurance for the Company's directors, officers, employees, agents and fiduciaries, the significant increases in the cost of such insurance and the general reductions in the coverage of such insurance.
- D. Indemnitee does not regard the protection available under the Company's certificate of incorporation, bylaws and insurance as adequate in the present circumstances, and may not be willing to serve as an officer or director without adequate protection, and the Company desires Indemnitee to serve in such capacity.
- E. The Company and Indemnitee further recognize the substantial increase in corporate litigation in general, subjecting directors, officers, employees, agents and fiduciaries to expensive litigation risks at the same time as the availability and coverage of liability insurance has been severely limited.
- F. In view of the considerations set forth above, the Company desires that Indemnitee shall be indemnified and advanced expenses by the Company as set forth in this Agreement.
- G. Indemnitee may have certain rights to indemnification and/or insurance provided by one or more other entities and/or organizations, which Indemnitee and the Company intend to be secondary to the primary obligation of the Company to indemnify Indemnitee as provided herein, with the Company's acknowledgement and agreement to the foregoing being a material condition to Indemnitee's willingness to serve as an officer or director of the Company.

The parties agree as follows:

## 1. DEFINITIONS.

- (a) "Affiliate" means, with respect to a Person, any Person that directly, or indirectly through one or more intermediaries, controls, is controlled by or is under common control with such first Person. "Control" and, with correlative meanings, the terms "controlled by" and "under common control with" means: (i) the power to direct the management or policies of a Person, whether through ownership of voting securities or by contract relating to voting rights or corporate governance, resolution, regulation or otherwise, or (ii) to own fifty percent (50%) or more of the outstanding voting securities or other ownership interest of such Person.
  - (b) Board of Directors" means the board of directors of the Company.

- (c) "Change in Control" means, and will be deemed to have occurred if, on or after the date of this Agreement, (i) any "person" (as such term is used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended), other than a trustee or other fiduciary holding securities under an employee benefit plan of the Company acting in such capacity or a corporation owned directly or indirectly by the stockholders of the Company in substantially the same proportions as their ownership of stock of the Company, becomes the "beneficial owner" (as defined in Rule 13d-3 under said Act), directly or indirectly, of securities of the Company representing more than 30% of the total voting power represented by the Company's then outstanding Voting Securities (as defined below), (ii) during any period of two consecutive years, individuals who at the beginning of such period constitute the Board of Directors and any new director whose election by the Board of Directors or nomination for election by the Company's stockholders was approved by a vote of at least two-thirds of the directors then still in office who either were directors at the beginning of the period or whose election or nomination for election was previously so approved, cease for any reason to constitute a majority thereof, or (iii) the stockholders of the Company approve a merger or consolidation of the Company with any other corporation or business entity other than a merger or consolidation that would result in the Voting Securities of the Company outstanding immediately prior thereto continuing to represent (either by remaining outstanding or by being converted into Voting Securities of the Surviving entity) at least 80% of the total voting power represented by the Voting Securities of the Company or such surviving entity outstanding immediately after such merger or consolidation, or (iv) the stockholders of the Company approve a plan of complete liquidation of the Company's assets.
- **(d)** "Claim" means any threatened, pending or completed action, suit, proceeding or alternative dispute resolution mechanism, or any hearing, inquiry or investigation that Indemnitee in good faith believes might lead to the institution of any such action, suit, proceeding or alternative dispute resolution mechanism, whether civil, criminal, administrative, investigative or other and whether brought in the right of or by the Company or otherwise, in each case, by reason of the fact of a Covered Event.
- **(e)** References to the "*Company*" include, in addition to Azitra Inc, any constituent corporation or other business entity (including any Affiliate of a constituent) absorbed in a consolidation or merger to which Azitra Inc (or any of its wholly owned subsidiaries) is a party, that, if its separate existence had continued, would have had power and authority to indemnify its directors, officers, managers, employees, agents or fiduciaries, so that if Indemnitee is or was a director, officer, manager, employee, agent or fiduciary of such constituent corporation, or is or was serving at the request of such constituent corporation as a director, officer, manager, employee, agent or fiduciary of another corporation, partnership, joint venture, employee benefit plan, trust or other enterprise, Indemnitee will stand in the same position under the provisions of this Agreement with respect to the resulting or surviving corporation as Indemnitee would have with respect to such constituent corporation if its separate existence had continued.
- **(f)** "Covered Event" means any event or occurrence (i) related to or by reason of the fact that Indemnitee is or was a director, officer, employee, agent or fiduciary of the Company, or any subsidiary of the Company or (ii) related to or by reason of the fact that Indemnitee is or was serving at the request of the Company as a director, officer, employee, agent or fiduciary of another corporation, partnership, joint venture, trust or other enterprise, or by reason of any action or inaction on the part of Indemnitee while serving in either capacity.
- **(g)** "Expenses" means any and all expenses (including attorneys' fees and all other costs, expenses and obligations incurred in connection with investigating, defending, being a witness in or participating in (including on appeal), or preparing to defend, to be a witness in or to participate in, any action, suit, proceeding, alternative dispute resolution mechanism, hearing, inquiry or investigation), judgments, fines, penalties and amounts paid in settlement (if such settlement is approved in advance by the Company, which approval will not be unreasonably withheld), actually and reasonably incurred, of any Claim and any federal, state, local or foreign taxes imposed on the Indemnitee as a result of the actual or deemed receipt of any payments under this Agreement.
  - **(h)** "*Expense Advance*" means a payment to Indemnitee of Expenses in advance of a Claim.
- **(i)** "Independent Legal Counsel" means an attorney or firm of attorneys, who will not have otherwise performed services for the Company or Indemnitee within the last three years (other than with respect to matters concerning the rights of Indemnitee under this Agreement, or of other indemnitees under similar indemnity agreements).
- (j) References to "other enterprises" include employee benefit plans; references to "fines" include any excise taxes assessed on Indemnitee with respect to an employee benefit plan; and references to "serving at the request of the Company" include any service as a director, officer, employee, agent or fiduciary of the Company, which role imposes duties on, or involves services by, such director, officer, employee, agent or fiduciary with respect to an employee benefit plan, its participants or its beneficiaries; and if Indemnitee acted in good faith and in a manner Indemnitee reasonably believed to be in the interest of the participants and beneficiaries of an employee benefit plan, Indemnitee will be deemed to have acted in a manner "not opposed to the best interests of the Company" as referred to in this Agreement.

- **(k)** "Person" means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, incorporated association, joint venture or similar entity or organization, including a government or political subdivision, department or agency of a government.
- (I) "Reviewing Party" means any person or body appointed by the Board of Directors in accordance with applicable law to review the Company's obligations hereunder and under applicable law, which may include (i) the directors who are not parties to the action, suit or proceeding in question ("Disinterested Directors"), even if less than a quorum, (ii) a committee of Disinterested Directors designated by a vote of the majority of the Disinterested Directors, even if less than a quorum, (iii), Independent Legal Counsel in a written opinion, if there are no such Disinterested Directors, or if such Disinterested Directors so direct or (iv) the stockholders of the Company.
  - (m) "Section" refers to a section of this Agreement unless otherwise indicated.
  - (m) "Voting Securities" means any securities of the Company that vote generally in the election of directors.

# 2. INDEMNIFICATION.

- **(a) Indemnification of Expenses.** Subject to the provisions of Section 2(b) below, the Company shall indemnify Indemnitee for Expenses to the fullest extent permitted by law if Indemnitee was or is or becomes a party to or witness or other participant in, or is threatened to be made a party to or witness or other participant in, any Claim, including all interest, assessments and other charges paid or payable in connection with or in respect of such Expenses.
- **(b) Review of Indemnification Obligations.** Notwithstanding the foregoing, upon written request for indemnification pursuant to Section 4(b), a determination with respect to Indemnitee's entitlement thereto shall be made by a Reviewing Party selected pursuant to Section 2(d). In the event any Reviewing Party will have determined (in a written opinion, in any case in which Independent Legal Counsel is the Reviewing Party) that Indemnitee is not entitled to be indemnified hereunder under applicable law, (i) the Company shall have no further obligation under Section 2(a) to make any payments to Indemnitee not made prior to such determination by such Reviewing Party, and (ii) the Company shall be entitled to be reimbursed by Indemnitee (who hereby agrees to reimburse the Company) for all Expenses theretofore paid in indemnifying Indemnitee; *provided, however*, that if Indemnitee has commenced or thereafter commences legal proceedings in the Delaware Court (as defined below) to secure a determination that Indemnitee is entitled to be indemnified hereunder under applicable law, any determination made by any Reviewing Party that Indemnitee is not entitled to be indemnified hereunder under applicable law will not be binding and Indemnitee shall not be required to reimburse the Company for any Expenses theretofore paid in indemnifying Indemnitee until a final judicial determination is made with respect thereto (as to which all rights of appeal therefrom have been exhausted or lapsed). Indemnitee's obligation to reimburse the Company for any Expenses will be unsecured and no interest will be charged thereon.
- **(c) Indemnitee Rights on Unfavorable Determination; Binding Effect.** If any Reviewing Party determines that Indemnitee is not entitled to be indemnified hereunder in whole or in part under applicable law, Indemnitee shall have the right to commence litigation seeking a determination by the Delaware Court or challenging any such determination by such Reviewing Party or any aspect thereof, including the legal or factual bases therefor, and, subject to the provisions of Section 15, the Company hereby consents to service of process and to appear in any such proceeding. Absent such litigation, any determination by any Reviewing Party will be conclusive and binding on the Company and Indemnitee.

(d) Selection of Reviewing Party; Change in Control. If there has not been a Change in Control, any Reviewing Party will be selected by the Board of Directors and approved by the Indemnitee (which approval will not be unreasonably withheld). If the Board of Directors chooses to utilize an Independent Legal Counsel as the Reviewing Party, the Independent Legal Counsel will be chosen by the Company and approved by the Indemnitee (which approval will not be unreasonably withheld). If there has been a Change in Control (other than a Change in Control that has been approved by a majority of the Board of Directors who were directors immediately prior to such Change in Control), any Reviewing Party with respect to all matters thereafter arising concerning the rights of Indemnitee to indemnification of Expenses under this Agreement or any other agreement or under the Company's certificate of incorporation or bylaws as now or hereafter in effect, or under any other applicable law, if desired by Indemnitee, will be Independent Legal Counsel selected by Indemnitee and approved by the Company (which approval shall not be unreasonably withheld). Such counsel, among other things, will render its written opinion to the Company and Indemnitee as to whether and to what extent Indemnitee would be entitled to be indemnified hereunder under applicable law and the Company agrees to abide by such opinion. The Company agrees to pay the reasonable fees of the Independent Legal Counsel referred to above and to indemnify fully such counsel against any and all expenses (including reasonable attorneys' fees), claims, liabilities and damages arising out of or relating to this Agreement or its engagement pursuant hereto. Notwithstanding any other provision of this Agreement, the Company shall not be required to pay Expenses of more than one Independent Legal Counsel in connection with all matters concerning a single Indemnitee, and such Independent Legal Counsel shall be the Independent Legal Counsel for any or all other Indemnitees unless (i) the Company otherwise determines or (ii) any Indemnitee shall provide a written statement setting forth in detail a reasonable objection to such Independent Legal Counsel representing other Indemnitees.

**(e) Mandatory Payment of Expenses.** Notwithstanding any other provision of this Agreement other than Section 10 hereof, to the extent that Indemnitee has been successful on the merits or otherwise, including, without limitation, the dismissal of an action without prejudice, in defense of any Claim, Company shall indemnify Indemnitee against all Expenses incurred by Indemnitee in connection therewith.

#### 3. EXPENSE ADVANCES.

- **(a) Obligation to Make Expense Advances.** The Company will make Expense Advances to Indemnitee [within 20 days of receipt of a written undertaking by or on behalf of the Indemnitee to repay such amounts if it is ultimately determined that the Indemnitee is not entitled to be indemnified therefor by the Company.
- **(b) Form of Undertaking.** Any written undertaking by the Indemnitee to repay any Expense Advances hereunder will be unsecured, and no interest shall be charged thereon.

#### 4. PROCEDURES FOR INDEMNIFICATION AND EXPENSE ADVANCES.

- **(a) Timing of Payments.** All payments of Expenses (including without limitation Expense Advances) by the Company to the Indemnitee pursuant to this Agreement will be made to the fullest extent permitted by law as soon as practicable after written demand by Indemnitee therefor is presented to the Company, but in no event later than 30 days after such written demand by Indemnitee is presented to the Company, except in the case of Expense Advances, which will be made no later than 20 days after such written demand by Indemnitee is presented to the Company.
- **(b) Notice/Cooperation by Indemnitee.** Indemnitee shall, as a condition precedent to Indemnitee's right to be indemnified or Indemnitee's right to receive Expense Advances under this Agreement, give the Company notice in writing as soon as practicable of any Claim made against Indemnitee for which indemnification will or could be sought under this Agreement. Notice to the Company will be directed to the President or Chief Executive Officer of the Company at the address shown on the signature page of this Agreement (or such other address as the Company shall designate in writing to Indemnitee). In addition, Indemnitee will give the Company such information and cooperation as it may reasonably require and as shall be within Indemnitee's power. The failure by Indemnitee to timely notify the Company of any Claim will not relieve the Company from any liability hereunder unless, and only to the extent that, such failure results in forfeiture by the Company of substantial defenses, rights, or insurance coverage.

(c) Timing of Indemnification Determination. The Company will use its reasonable best efforts to cause any determination by a Reviewing Party to be made as promptly as practicable. If the Reviewing Party shall not have made a determination within 60 days after the later of (A) receipt by the Company of written notice from Indemnitee advising the Company of the final disposition of the applicable Claim and (B) the selection of an Independent Counsel, if such determination is to be made by Independent Counsel, then Indemnitee shall be deemed to have satisfied the applicable standard of conduct absent (i) a misstatement by Indemnitee of a material fact, or an omission of a material fact necessary to make Indemnitee's statement not materially misleading, in connection with the request for indemnification, or (ii) a prohibition of such indemnification under applicable law; provided, however, that such 60-day period may be extended for a reasonable time, not to exceed (1) an additional 30 days, if the Reviewing Party in good faith requires such additional time to obtain or evaluate documentation and/or information relating thereto or (2) an additional 75 days, if the Reviewing Party will be the stockholders of the Company.

(d) No Presumptions; Burden of Proof. For purposes of this Agreement, the termination of any Claim by judgment, order, settlement (whether with or without court approval) or conviction, or upon a plea of *nolo contendere*, or its equivalent, will not create a presumption that Indemnitee did not meet any particular standard of conduct or have any particular belief or that a court has determined that indemnification is not permitted by this Agreement or applicable law. In addition, neither the failure of any Reviewing Party to have made a determination as to whether Indemnitee has met any particular standard of conduct or had any particular belief, nor an actual determination by any Reviewing Party that Indemnitee has not met such standard of conduct or did not have such belief, prior to the commencement of legal proceedings by Indemnitee to secure a judicial determination that Indemnitee should be indemnified under this Agreement or applicable law, shall be a defense to Indemnitee's claim or create a presumption that Indemnitee has not met any particular standard of conduct or did not have any particular belief. In connection with any determination by any Reviewing Party or otherwise as to whether the Indemnitee is entitled to be indemnified hereunder, the burden of proof will be on the Company to establish that Indemnitee is not so entitled.

**(e) Notice to Insurers.** If, at the time of the receipt by the Company of a notice of a Claim pursuant to Section (b) hereof, the Company has liability insurance in effect that may cover such Claim, the Company shall give prompt notice of the commencement of such Claim to the insurers in accordance with the procedures set forth in the respective policies. The Company shall thereafter take all necessary or desirable action to cause such insurers to pay, on behalf of the Indemnitee, all amounts payable as a result of such Claim in accordance with the terms of such policies; provided, however, that nothing in this subsection (e) shall relieve the Company of its obligations hereunder (or allow the Company to delay in its performance of its obligations hereunder) to provide indemnification for or make any Expense Advances with respect to the Expenses of any Claim, between the time that it so notifies its insurers and the time that its insurers actually pay any such amounts payable as a result of any such Claim to the Company.

(f) Selection of Counsel. In the event the Company shall be obligated hereunder to provide indemnification for or make any Expense Advances with respect to the Expenses of any Claim, the Company, if appropriate, shall be entitled to assume the defense of such Claim with counsel which shall be selected by the Company and approved by Indemnitee (which approval shall not be unreasonably withheld) upon the delivery to Indemnitee of written notice of the Company's election to do so. After delivery of such notice, approval of such counsel by Indemnitee and the retention of such counsel by the Company, the Company will not be liable to Indemnitee under this Agreement for any fees or expenses of separate counsel subsequently employed by or on behalf of Indemnitee with respect to the same Claim; provided, however, that (i) Indemnitee shall have the right to employ Indemnitee's separate counsel in any such Claim at Indemnitee's expense and (ii) if (A) the employment of separate counsel by Indemnitee has been previously authorized by the Company, (B) Indemnitee shall have reasonably concluded that there may be a conflict of interest between the Company and Indemnitee in the conduct of any such defense, or (C) the Company shall not continue to retain such counsel to defend such Claim, then the fees and expenses of Indemnitee's separate counsel will be Expenses for which Indemnitee may receive indemnification or Expense Advances hereunder. The Company shall not be liable to Indemnitee under this Agreement for any amounts paid in settlement of any threatened or pending Claim effected without the Company's prior written consent. The Company shall not, without the prior written consent of the Indemnitee, effect any settlement of any threatened or pending Claim which the Indemnitee is or could have been a party unless such settlement solely involves the payment of money and includes a complete and unconditional release of the Indemnitee from all liability on any claims that are the subject matter of such Claim. Neither the Company nor Indemnitee shall unreasonably withhold its consent to any proposed settlement; provided that Indemnitee may withhold consent to any settlement that does not provide a complete and unconditional release of Indemnitee.

#### 5. ADDITIONAL INDEMNIFICATION RIGHTS: NONEXCLUSIVITY.

- (a) Scope. The Company hereby agrees to indemnify the Indemnitee to the fullest extent permitted by law, notwithstanding that such indemnification is not specifically authorized by the other provisions of this Agreement, the Company's certificate of incorporation, the Company's bylaws or by statute. In the event of any change after the date of this Agreement in any applicable law, statute or rule that expands the right of a Delaware corporation to indemnify a member of its board of directors or an officer, employee, agent or fiduciary, it is the intent of the parties hereto that Indemnitee shall enjoy by this Agreement the greater benefits afforded by such change. In the event of any change in any applicable law, statute or rule that narrows the right of a Delaware corporation to indemnify a member of its board of directors or an officer, employee, agent or fiduciary, such change, to the extent not otherwise required by such law, statute or rule to be applied to this Agreement, will have no effect on this Agreement or the parties' rights and obligations hereunder except as set forth in Section 10(a) hereof.
- **(b) Nonexclusivity.** The indemnification and the payment of Expense Advances provided by this Agreement will be in addition to any rights to which Indemnitee may be entitled under the Company's certificate of incorporation, its bylaws, any other agreement, any vote of stockholders or disinterested directors, the Delaware General Corporation Law, or otherwise. The indemnification and the payment of Expense Advances provided under this Agreement will continue as to Indemnitee for any action taken or not taken while serving in an indemnified capacity even though subsequent thereto Indemnitee may have ceased to serve in such capacity.
- (c) Company Obligations Primary. The Company hereby acknowledges that Indemnitee may have certain rights to indemnification, advancement of expenses and/or insurance provided by one or more other entities and/or organizations (collectively, the "Secondary Indemnitors"). The Company hereby agrees that (i) it is the indemnitor of first resort (i.e., its obligations to Indemnitee are primary and any obligation of the Secondary Indemnitors to advance expenses or to provide indemnification for the same Expenses or liabilities incurred by Indemnitee are secondary), (ii) it will be required to advance the full amount of Expenses incurred by Indemnitee and will be liable for the full amount of all Expenses, judgments, penalties, fines and amounts paid in settlement to the extent legally permitted and as required by the certificate of incorporation or bylaws of the Company (or any agreement between the Company and Indemnitee), without regard to any rights Indemnitee may have against the Secondary Indemnitors and (iii) it irrevocably waives relinquishes and releases the Secondary Indemnitors from any and all claims against the Secondary Indemnitors for contribution, subrogation or any other recovery of any kind in respect thereof. The Company further agrees that no advancement or payment by the Secondary Indemnitors on behalf of Indemnitee with respect to any claim for which Indemnitee has sought indemnification from the Company will affect the foregoing and the Secondary Indemnitors will have a right of contribution and/or be subrogated to the extent of such advancement or payment to all of the rights of recovery of Indemnitee against the Company. The Company and Indemnitee agree that the Secondary Indemnitors are express third party beneficiaries of the terms hereof.
- **6. NO DUPLICATION OF PAYMENTS.** Subject to Section 5(c) above, the Company will not be liable under this Agreement to make any payment in connection with any Claim made against Indemnitee to the extent Indemnitee has otherwise actually received payment (under any insurance policy, provision of the Company's certificate of incorporation, bylaws or otherwise) of the amounts otherwise payable under this Agreement.
- **7. PARTIAL INDEMNIFICATION.** If Indemnitee is entitled under any provision of this Agreement to indemnification by the Company for some or a portion of Expenses incurred in connection with any Claim, but not, however, for all of the total amount thereof, the Company will indemnify Indemnitee for the portion of such Expenses to which Indemnitee is entitled.
- **8. MUTUAL ACKNOWLEDGMENT.** Both the Company and Indemnitee acknowledge that in certain instances, federal law or applicable public policy may prohibit the Company from indemnifying its directors, officers, employees, agents or fiduciaries under this Agreement or otherwise. Indemnitee understands and acknowledges that the Company has undertaken or may be required in the future to undertake with the Securities and Exchange Commission to submit the question of indemnification to a court in certain circumstances for a determination of the Company's right under public policy to indemnify Indemnitee.

**9. LIABILITY INSURANCE.** The Company shall obtain and maintain during the term of this Agreement liability insurance applicable to directors, officers or fiduciaries in an amount determined by the Board of Directors; *provided, however*, that nothing in this Section 9 shall relieve the Company of its obligations hereunder (or allow the Company to delay in its performance of its obligations hereunder) to provide indemnification for or make any Expense Advances with respect to the Expenses of any Claim. To the extent the Company maintains liability insurance applicable to directors, officers or fiduciaries, Indemnitee shall be covered by such policies in such a manner as to provide Indemnitee the same rights and benefits as are provided to the most favorably insured of the Company's directors, if Indemnitee is a director; or of the Company's officers, if Indemnitee is not a director of the Company but is an officer. The Company shall promptly notify Indemnitee of any expiration, lapse, non-renewal or denial of coverage under any such policy.

### 10. EXCEPTIONS.

- **(a) Excluded Action or Omissions.** The Company will not indemnify Indemnitee for Expenses resulting from acts, omissions or transactions for which Indemnitee is prohibited from receiving indemnification under this Agreement or applicable law; *provided*, *however*, that notwithstanding any limitation set forth in this subsection (a) regarding the Company's obligation to provide indemnification, Indemnitee will be entitled under Section 3 to receive Expense Advances hereunder with respect to any such Claim unless and until the Delaware Court will have made a final judicial determination (as to which all rights of appeal therefrom have been exhausted or lapsed) that Indemnitee has engaged in acts, omissions or transactions for which Indemnitee is prohibited from receiving indemnification under this Agreement or applicable law.
- **(b)** Claims Initiated by Indemnitee. The Company will not indemnify or make Expense Advances to Indemnitee with respect to Claims initiated or brought voluntarily by Indemnitee and not by way of defense, counterclaim or cross claim, except (i) with respect to actions or proceedings brought to establish or enforce a right to indemnification under this Agreement or any other agreement or insurance policy or under the Company's certificate of incorporation or bylaws now or hereafter in effect relating to Claims, (ii) in specific cases if the Board of Directors has approved the initiation or bringing of such Claim, or (iii) as otherwise required under Section 145 of the Delaware General Corporation Law (relating to indemnification of officers, directors, employees and agents; and insurance), regardless of whether Indemnitee ultimately is determined to be entitled to such indemnification or insurance recovery, as the case may be.
- (c) Lack of Good Faith. The Company will not indemnify Indemnitee for any Expenses incurred by the Indemnitee with respect to any action in which the Indemnitee has been finally adjudged by the Delaware Court (i) to have acted in bad faith; (ii) to not have acted in a manner Indemnitee reasonably believed to be in the best interests of the Company; or (iii) with respect to criminal actions or proceedings, to have had reasonable cause to believe Indemnitee's conduct was unlawful.
- **(d) Claims Under Section 16(b).** The Company will not indemnify Indemnitee for Expenses and the payment of profits arising from the purchase and sale by Indemnitee of securities in violation of Section 16(b) of the Securities Exchange Act of 1934, as amended, or any similar successor statute; *provided, however*, that notwithstanding any limitation set forth in this subsection (d) regarding the Company's obligation to provide indemnification, Indemnitee shall be entitled under Section 3 to receive Expense Advances hereunder with respect to any such Claim unless and until the Delaware Court will have made a final judicial determination (as to which all rights of appeal therefrom have been exhausted or lapsed) that Indemnitee has violated said statute.
- **(e) Clawback Under Sarbanes-Oxley Act.** The Company will not indemnify Indemnitee in connection with any Claim for reimbursement of the Company by Indemnitee of any bonus or other incentive-based or equity-based compensation or of any profits realized by Indemnitee from the sale of securities of the Company, as required in each case under the Securities Exchange Act of 1934, as amended (including any such reimbursements that arise from an accounting restatement of the Company pursuant to Section 304 of the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act"), or the payment to the Company of profits arising from the purchase and sale by Indemnitee of securities in violation of Section 306 of the Sarbanes-Oxley Act), if Indemnitee is held liable therefor (including pursuant to any settlement).

- 11. COUNTERPARTS. This Agreement may be executed in one or more counterparts, each of which will be an original, but all of which together will constitute one instrument.
- 12. BINDING EFFECT; SUCCESSORS AND ASSIGNS. This Agreement will be binding upon and inure to the benefit of and be enforceable by the parties hereto and their respective successors, assigns (including any direct or indirect successor by purchase, merger, consolidation or otherwise to all or substantially all of the business or assets of the Company), spouses, heirs and personal and legal representatives. The Company shall require and cause any successor (whether direct or indirect, and whether by purchase, merger, consolidation or otherwise) to all, substantially all, or a substantial part, of the business or assets of the Company, by written agreement in form and substance satisfactory to Indemnitee, expressly to assume and agree to perform this Agreement in the same manner and to the same extent that the Company would be required to perform if no such succession had taken place. This Agreement will continue in effect regardless of whether Indemnitee continues to serve as a director, officer, employee, agent or fiduciary (as applicable) of the Company or of any other enterprise at the Company's request, but only with respect to Claims.
- 13. EXPENSES INCURRED IN ACTION RELATING TO ENFORCEMENT OR INTERPRETATION. In the event that any action is instituted by Indemnitee under this Agreement or under any liability insurance policies maintained by the Company to enforce or interpret any of the terms hereof or thereof, Indemnitee shall be entitled to be indemnified for all Expenses incurred by Indemnitee with respect to such action (including without limitation reasonable attorneys' fees), regardless of whether Indemnitee is ultimately successful in such action, unless as a part of such action the Delaware Court makes a final judicial determination (as to which all rights of appeal therefrom have been exhausted or lapsed) that each of the material assertions made by Indemnitee as a basis for such action was not made in good faith or was frivolous; *provided*, *however*, that until such final judicial determination is made, Indemnitee shall be entitled under Section 3 to receive payment of Expense Advances hereunder with respect to such action. In the event of an action instituted by or in the name of the Company under this Agreement to enforce or interpret any of the terms of this Agreement, Indemnitee shall be entitled to be indemnified for all Expenses incurred by Indemnitee in defense of such action (including without limitation costs and expenses incurred with respect to Indemnitee's counterclaims and cross-claims made in such action), unless as a part of such action the Delaware Court makes a final judicial determination (as to which all rights of appeal therefrom have been exhausted or lapsed) that each of the material defenses asserted by Indemnitee in such action was made in bad faith or was frivolous; *provided*, *however*, that until such final judicial determination is made, Indemnitee shall be entitled under Section 3 to receive payment of Expense Advances hereunder with respect to such action.
- **14. NOTICES.** All notices required or permitted hereunder shall be in writing and shall be deemed effectively given: (a) upon personal delivery to the party to be notified, (b) when sent by confirmed electronic mail or facsimile if sent during normal business hours of the recipient; if not, then on the next business day, (c) five days after having been sent by registered or certified mail, return receipt requested, postage prepaid, or (d) one day after deposit with a nationally recognized overnight courier, specifying next day delivery, with written verification of receipt. Addresses for notice to either party are as shown on the signature page of this Agreement or as subsequently modified by written notice.
- **15. CONSENT TO JURISDICTION.** The Company and Indemnitee each hereby irrevocably consent to the jurisdiction of the courts of the State of Delaware for all purposes in connection with any claim or cause of action contemplated by Section 16 below and agree that any such claim or cause of action will be commenced, prosecuted and continued only in the Court of Chancery of the State of Delaware (the "*Delaware Court*"), which will be the exclusive and only proper forum for adjudicating such a claim or cause of action.
- **16. CHOICE OF LAW.** This Agreement, and all claims or causes of action (whether in contract, tort or statute) that may be based upon, arise out of or relate to this Agreement, or the negotiation, execution or performance of this Agreement (including any claim or cause of action based upon, arising out of or related to any representation or warranty made in or in connection with this Agreement or as an inducement to enter into this Agreement), will be governed by and enforced in accordance with the internal laws of the State of Delaware, including its statutes of limitations, without regard to any borrowing statute that would result in the application of the statute of limitations of any other jurisdiction.

- **17. SEVERABILITY.** In the event one or more of the provisions of this Agreement should, for any reason, be held to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability will not affect any other provisions of this Agreement, and this Agreement will be construed as if such invalid, illegal or unenforceable provision had never been contained herein.
- **18. SUBROGATION.** Subject to Section 5(c) above, in the event of payment under this Agreement, the Company shall be subrogated to the extent of such payment to all of the rights of recovery of Indemnitee, who shall execute all documents required and shall do all acts that may be necessary to secure such rights and to enable the Company effectively to bring suit to enforce such rights.
- **19. AMENDMENT, TERMINATION AND WAIVER.** No amendment, modification, termination or cancellation of this Agreement will be effective unless it is in writing signed by both the parties hereto. No waiver of any of the provisions of this Agreement will be deemed to be or will constitute a waiver of any other provisions hereof (whether or not similar), nor will such waiver constitute a continuing waiver.
- **20. INTEGRATION; ENTIRE AGREEMENT.** This Agreement sets forth the entire understanding between the parties hereto and supersedes and merges all previous written and oral negotiations, commitments, understandings and agreements between the parties relating to the subject matter contained in this Agreement.
- **21. HEADINGS.** The section and subsection headings contained in this Agreement are for reference purposes only and will not affect in any way the meaning or interpretation of this Agreement.
- **22. NO CONSTRUCTION AS EMPLOYMENT AGREEMENT.** Nothing contained in this Agreement will be construed as giving Indemnitee any right to be retained in the employ of the Company or any of its subsidiaries or affiliated entities.

The parties have executed this Indemnification Agreement as of the date first above written.

AZITRA INC, a Delaware corporation	
By:	
Address:	
	Agreed to and accepted by:
	INDEMNITEE:
	Signature of Indemnitee
	Print or Type Name of Indemnitee
	Address:
	9

#### **AZITRA INC**

#### 2016 STOCK INCENTIVE PLAN

Date Adopted by Board: April 21, 2016 Date Approved by Stockholders: April 21, 2016

Effective Date: April 21, 2016

As amended: October 24, 2017

#### **SECTION 1. PURPOSE OF THIS PLAN**

- 1.1 *Eligible Award Recipients*. The individuals eligible to receive Awards under the Azitra Inc 2016 Stock Incentive Plan (the "*Incentive Plan*") are the key Employees, Directors and Consultants who are responsible for or contribute to the management, growth and success of Azitra Inc, a Delaware corporation (the "*Company*"), and its Affiliates.
- 1.2 General Purpose. The Company, by means of the Incentive Plan, seeks to retain and attract Eligible Individuals who contribute to the Company's success by their ability, ingenuity and industry, and to enable such individuals to participate in the long-term success and growth of the Company by giving them a proprietary interest in the Company through the granting of the following Awards: (i) Incentive Stock Options, (ii) Non-Qualified Stock Options, and (iii) Restricted Shares.

#### **SECTION 2. DEFINITIONS**

As used in this Incentive Plan, the following terms shall have the meanings set forth below unless the context requires otherwise:

- 2.1 "Affiliate" means any Parent Corporation or Subsidiary Corporation, whether now existing or hereafter established.
- 2.2 "Award" shall mean the grant of a Stock Option or Restricted Shares pursuant to this Incentive Plan.
- 2.3 "Award Agreement" shall mean the written agreement evidencing the terms and conditions of a grant of one or more Awards under this Incentive Plan to an Eligible Individual. Each Award Agreement shall be subject to the terms and conditions of the Incentive Plan and need not be identical.
  - 2.4 "Award Date" shall mean the date on which an Award is granted to an Eligible Individual.
- 2.5 "Award Term" shall mean the maximum period during which a Participant may exercise, purchase, or otherwise benefit from an Award granted under this Incentive Plan.
  - 2.6 "Board" shall mean the Board of Directors of the Company, as the same may be constituted from time to time.

- 2.7 "Cause" shall mean termination of a Participant's service with the Company or an Affiliate as a result of the occurrence of one or more of the following events, except as otherwise expressly provided in the applicable Award Agreement: misconduct, negligence, dishonesty, violence or threat of violence (including any violation of federal securities laws) that is injurious to the Company or any of its Affiliates; disclosure of trade secrets, client information or other confidential information; breach of the provisions of an agreement, covenant or other obligation with the Company or an Affiliate, including without limitation an employment agreement or a non-disclosure or confidentiality agreement; material mismanagement in the performance of his or her duties; willful failure to execute or comply with the major policies of the Company or an Affiliate or his stated duties; any other willful misconduct which is materially injurious to the financial condition or business reputation of the Company or any of its Affiliates; material breach of a written policy of the Company or an Affiliate or the laws or rules of any governmental or regulatory body applicable to the Company or an Affiliate; and conviction of, or plea of nolo contendere to, any felony or another crime involving dishonesty or moral turpitude or which could reflect negatively upon the Company or an Affiliate or otherwise impair or impede its operations. If Participant is a party to an employment or service agreement with the Company or its Affiliates and such agreement provides for a definition of Cause, the definition therein contained shall constitute "Cause" for purposes of this Incentive Plan in addition to the above definition. The determination of a Participant's termination for "Cause" shall be made in the sole and absolute discretion of the Board.
- 2.8 "Change of Control" shall mean the occurrence of (i) a sale, lease or other disposition of all or substantially all of the assets of the Company, (ii) a merger or consolidation in which the Company is not the surviving corporation (except for a merger or consolidation with an entity controlled by the stockholders of the Company), (iii) a reverse merger in which the Company is the surviving corporation but the Shares of Common Stock outstanding immediately preceding the merger are converted by virtue of the merger into other property, whether in the form of securities, cash or otherwise or (iv) the adoption of a plan of dissolution or liquidation of the Company.
  - 2.9 "Code" shall mean the Internal Revenue Code of 1986, as amended from time to time (or any successor to such legislation).
- 2.10 "*Committee*" shall mean the one or more Persons appointed by the Board and to which some or all of the Board's authority to administer the Incentive Plan has been delegated in accordance with the provisions of <u>subsection 3.1</u> hereof. If no Committee has been appointed, the Board shall be deemed the Committee.
- 2.11 "*Common Stock*" shall mean the authorized shares of common stock of the Company, \$0.01 par value per share, as may be adjusted by the Board from time to time. Any adjustment to the par value of a share shall be incorporated herein without any need to otherwise amend the Incentive Plan.
  - 2.12 "Company" shall mean Azitra Inc, a corporation organized under the laws of the State of Delaware, and any successor thereto.

- 2.13 "*Consultant*" shall mean any Person, including an advisor, (i) engaged by the Company or any Affiliate to render consulting or advisory services and who is compensated for such services or who provides *bona fide* services to the Company or any Affiliate pursuant to a written agreement; or (ii) who is a member of the board of directors of any Affiliate. However, the term "Consultant" shall not include either Directors who are not compensated by the Company for their services as Directors or Directors who are merely paid a director's fee by the Company for their services as Directors.
- 2.14 "Continuous Service" means that Participant's service with the Company or any Affiliate, whether as an Employee, Director or Consultant, is not interrupted or terminated. The Participant's Continuous Service shall not be deemed to have terminated merely because of a change in the capacity in which Participant renders service to the Company or any Affiliate as an Employee, Consultant or Director or a change in the entity for which Participant renders such service, provided that there is no interruption or termination of Participant's Continuous Service. For example, a change in status from an Employee of the Company to a Consultant of an Affiliate or a Director will not constitute an interruption of Continuous Service. Notwithstanding the foregoing, with respect to an Incentive Stock Option, an Employee's Continuous Service shall be deemed to have terminated in the event of a change in capacity from an Employee to a Consultant or non-Employee Director. The Plan Administrator, in its sole discretion, may determine whether Continuous Service shall be considered interrupted in the case of any leave of absence approved by the Company, including sick leave, military leave or any other personal leave.
  - 2.15 "Director" shall mean a member of the Board, whether an Employee or non-Employee Director.
- 2.16 "*Disability*" shall mean the Participant's permanent and total inability to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment which can be expected to result in death or which can be expected to last for a continuous period of not less than 12 months. The determination of a Participant's "Disability" shall be made in the sole and absolute discretion of the Plan Administrator.
  - 2.17 "Effective Date" shall mean April 21, 2016.
  - 2.18 "Eliqible Individual" shall mean an Employee, Consultant or Director eligible to receive an Award under Section 5 of this Incentive Plan.
- 2.19 "*Employee*" shall mean the common-law employee of the Company or any Affiliate. Mere service as a Director or payment of a director's fee by the Company or any Affiliate shall not be sufficient to constitute "employment" by the Company or an Affiliate.
- 2.20 "Exercise Agreement" shall mean the written agreement delivered by Participant to the Plan Administrator to evidence such Participant's exercise of his rights provided under the applicable Award Agreement.
- 2.21 "Exercise Date" shall mean the date set out in the Exercise Agreement on which Participant exercises his rights provided under the applicable Award Agreement.

- 2.22 "Exercise Price" shall mean the consideration required, as determined by the Plan Administrator and set out in the Award Agreement, to be remitted upon exercise of an Award.
- 2.23 "*Expiration Date*" shall mean October 5, 2027 or in the event the Incentive Plan is subsequently amended to make any change described in clause (ii) of <u>subsection 12.1</u>, the date which is ten (10) years from the date on which such amendment is approved by the Board, or if earlier, the date on which such amendment is approved by the stockholders of the Company.
- 2.24 "*Fair Market Value*" shall mean, with respect to the Shares, the value established, in good faith, by the Board as of any date. Fair Market Value shall be determined in accordance with applicable guidance and regulations promulgated under Section 409A of the Code (or any successor provision thereto).
  - 2.25 "Incentive Plan" shall mean this Azitra Inc 2016 Stock Incentive Plan, as amended from time to time.
- 2.26 "*Incentive Stock Option*" shall mean any option to purchase Shares awarded pursuant to <u>Section 6</u> of this Incentive Plan that qualifies as an "incentive stock option" pursuant to Section 422 of the Code.
- 2.27 "*Non-Qualified Stock Option*" shall mean any option to purchase Shares awarded pursuant to <u>Section 6</u> of this Incentive Plan that does not qualify as an Incentive Stock Option (including, without limitation, any option to purchase Shares originally designated, or intended to qualify, as an Incentive Stock Option but that does not, for any reason whatsoever, qualify as an Incentive Stock Option).
- 2.28 "Parent Corporation" shall mean any entity (other than the Company) in an unbroken chain of entities ending with the Company, provided each entity in the unbroken chain (other than the Company) owns, at the time of the determination, ownership interests possessing fifty percent (50%) or more of the total combined voting power of all classes of ownership interests in one of the other entities in such chain; provided, however, that with respect to an Award of an Incentive Stock Option, the term "Parent Corporation" shall refer solely to an entity that is taxed under federal income tax laws as a corporation.
  - 2.29 "Participant" shall mean any Eligible Individual who has been granted and holds an Award granted pursuant to this Incentive Plan.
- 2.30 "Person" shall mean an individual, partnership, joint venture, corporation, limited liability company, trust, estate or other entity or organization.
- 2.31 "*Plan Administrator*" shall mean the Committee appointed by the Board to administer the Incentive Plan pursuant to <u>subsection 3.1</u> hereof, or if no Committee has been appointed or is then serving, the Board.
- 2.32 "*Purchase Price*" shall mean the consideration required, as determined by the Plan Administrator and set out in the Award Agreement, to be remitted upon grant of an Award of Restricted Shares.

- 2.33 "*Restricted Shares*" shall mean any Shares granted pursuant to <u>Section 7</u> of this Incentive Plan that are subject to transferability restrictions and/or a substantial risk of forfeiture.
- 2.34 "*Restriction Period*" shall mean the period during which Restricted Shares issued pursuant to <u>Section 7</u> hereof are subject to a substantial risk of forfeiture.
  - 2.35 "Securities Act" shall mean the Securities Act of 1933, as amended from time to time (or any successor to such legislation).
- 2.36 "*Shares*" shall mean shares of the Common Stock and any shares of capital stock or other securities hereafter issued or issuable upon, in respect of or in substitution or exchange for shares of Common Stock.
  - 2.37 "Stock Option" shall mean any Incentive Stock Option or Non-Qualified Stock Option.
- 2.38 "Subsidiary Corporation" shall mean any entity (other than the Company) in an unbroken chain of entities beginning with the Company, provided each entity (other than the last entity) in the unbroken chain owns, at the time of the determination, ownership interests possessing fifty percent (50%) or more of the total combined voting power of all classes of ownership interests in one of the other entities in such chain; provided, however, that with respect to an Award of an Incentive Stock Option, the term "Subsidiary Corporation" shall refer solely to an entity that is taxed under federal income tax laws as a corporation.
- 2.39 "*Ten Percent Shareholder*" shall mean an individual who, at the time a Stock Option is granted pursuant to <u>Section 6</u> hereof, owns (or is deemed to own pursuant to Section 424(d) of the Code) stock possessing more than ten percent (10%) of the total combined voting power of all classes of stock of the Company or any Affiliate.
- 2.40 "*Termination Date*" shall mean the date on which a Participant's Continuous Service with the Company (or any Affiliate) terminates due to retirement, death, Disability, voluntary termination, with or without Cause, or otherwise.

### SECTION 3. ADMINISTRATION OF THE PLAN

3.1 *Administration of Incentive Plan*. The Incentive Plan shall be administered by the Plan Administrator. If a Committee is appointed by the Board to serve as Plan Administrator, the Committee shall consist of at least one member of the Board. In the event of a vacancy, the Board shall appoint another individual to serve. All members of the Committee will serve at the pleasure of the Board and shall be authorized to act with respect to all functions delegated to the Committee. Any Committee to which the Board's authority has been delegated will act by a majority of its members (or by unanimous vote if the Committee is comprised of less than three (3) members). To the extent a Committee appointed hereunder shall cease or no longer be authorized to act hereunder, the functions delegated to the Committee shall revert to the Board.

- 3.2 *Powers of the Plan Administrator*. The Plan Administrator shall have the power, in its sole and absolute discretion, but subject to and within the limitations of the express provisions of the Incentive Plan:
  - (a) To determine from time to time which Eligible Individuals under the Incentive Plan shall be granted Awards under the Incentive Plan; when and how each Award shall be granted; what type or combination of types of Awards shall be granted; the provisions of each Award granted (which need not be identical), including the time or times when an Award may be exercised; the number of Shares with respect to which an Award shall be granted to each Eligible Individual; the Exercise Price or the Purchase Price for Shares under an Award; the terms, performance criteria or other conditions, vesting periods or any restrictions for an Award and any restrictions on Shares acquired pursuant to an Award; and any other terms and conditions of an Award that the Plan Administrator deems appropriate and as are not inconsistent with the terms of this Incentive Plan;
  - (b) To determine whether, to what extent, and under what circumstances, to allow alternative payment options to exercise Awards or pay withholding taxes imposed upon the grant, exercise or vesting of any Award, and the terms and conditions of such payment options;
  - (c) To rely upon Employees of the Company or an Affiliate for such clerical and recordkeeping duties as may be necessary in connection with the administration of this Incentive Plan;
    - (d) To accelerate or defer (with the consent of the subject Participant) the vesting of any rights under an Award;
  - (e) To establish, amend and revoke rules and regulations as it may deem appropriate for the conduct of meetings and the proper administration of the Incentive Plan;
    - (f) To delegate to one or more Persons the right to act on its behalf in such matters as authorized by the Plan Administrator;
    - (g) To construe and interpret the Incentive Plan and Award Agreements issued hereunder;
  - (h) To take such actions as are deemed necessary or advisable by the Plan Administrator to qualify the Incentive Plan for exemption from the registration requirements of federal and state securities laws, to prepare, file and execute all applications, agreements, certificates and other documents with respect to the Incentive Plan, the grant of any Award hereunder, or the exercise of any Award hereunder with the appropriate federal and state agencies, and to take any and all other actions that are deemed necessary or advisable by the Plan Administrator to comply with applicable federal and state securities laws;

- (i) To cancel or revoke any Award issued hereunder if the issuance of such Award would violate any applicable federal or state securities laws:
- (j) To amend the Incentive Plan or an Award Agreement to the extent provided under <u>Section 12</u> hereof. The Plan Administrator, in the exercise of this power, may correct any defect, omission or inconsistency in the Incentive Plan or in any Award Agreement, in a manner and to the extent it shall deem necessary or expedient to make the Incentive Plan fully effective; and
- (k) To take any and all other actions that are deemed necessary or advisable by the Plan Administrator for the administration of the Incentive Plan.
- 3.3 *Effect of Plan Administrator's Decision.* All determinations, interpretations and constructions made by the Plan Administrator in good faith shall not be subject to review by any Person and shall be final, binding and conclusive on all Persons. Any member of the Board or Committee acting as Plan Administrator and any officer or Employee of the Company or any Affiliate acting at the direction of the Plan Administrator shall not be personally liable for any action or determination taken or made in good faith with respect to the Incentive Plan, and shall, to the extent provided in <u>subsection 13.6</u> hereof, be fully indemnified by the Company with respect to any such action or determination.

### SECTION 4. SHARES SUBJECT TO PLAN AND RELATED ADJUSTMENTS

- 4.1 *Share Reserve.* Except as otherwise provided in this Section 4, the maximum number of Shares that may be issued with respect to Awards granted pursuant to this Plan shall not exceed 209,943 Shares; provided, however, that the maximum number of Shares that may be issued upon exercise of Incentive Stock Options granted pursuant to this Plan shall not exceed 209,943 Shares. The Shares issued pursuant to this Plan may be authorized but unissued Shares or may be Shares issued pursuant to this Plan that have been reacquired by the Company.
- 4.2 *Cancellation, Expiration, or Forfeiture of Awards.* To the extent that any Award granted pursuant to this Plan shall be forfeited, expire or be cancelled, in whole or in part, then the number of Shares subject to the Plan pursuant to <u>subsection 4.1</u> shall be increased by the portion of the Awards or stock options so forfeited, expired or cancelled, and such forfeited, expired or cancelled Shares may be awarded pursuant to the provisions of this Plan.
- 4.3 *Payment in Shares*. If Shares are permitted to be delivered to the Company in full or partial payment of the Exercise Price, Purchase Price or the applicable withholding taxes imposed on any Award granted pursuant to this Plan then the number of Shares available for future Awards granted pursuant to this Plan shall be reduced only by the net number of Shares issued under the applicable award.
- 4.4 **Repurchases of Shares.** If Shares issued in connection with any Award granted pursuant to this Plan shall be repurchased by the Company, in whole or in part, then the number of Shares subject to the Plan pursuant to <u>subsection 4.1</u> shall be increased by the portion of the Shares repurchased by the Company, and such repurchased Shares may again be awarded pursuant to the provisions of this Plan.

4.5 *Issuance of Share Certificates*. Prior to the issuance of Common Stock hereunder, whether upon grant, exercise, or purchase pursuant to the applicable Award, Participant shall submit the consideration, if any, required under the applicable Award Agreement, payment or other provision for any applicable tax withholding obligations, and all documents to be executed and delivered by Participant to the Company in accordance with the provisions of this Plan and the applicable Award Agreement or as may otherwise be required by the Company or the Plan Administrator, including, without limitation, an executed counterpart to an applicable stockholder's agreement and, with respect to Restricted Shares, a stock power, endorsed in blank, relating to the Shares covered by such Award. The Company will evidence the issuance of Shares hereunder by any means appropriate, including, without limitation, book- entry registration or issuance of a duly executed Share certificate in the name of Participant, provided that stock certificates evidencing Restricted Shares granted pursuant to this Plan shall be held in the custody by the Company or its duly authorized delegate until the restrictions thereon have lapsed. If certificates are issued, a separate certificate or certificates will be issued for Shares issued in connection with each type of Award granted to the Participant.

#### **SECTION 5. ELIGIBILITY**

- 5.1 *Individuals Eligible to Participate*. The Plan Administrator shall determine, within the limitations of the Incentive Plan, the Employees, Consultants or Directors of the Company or any Affiliate to whom Awards may be granted. In making such determination, as well as the determination of the type of Award and terms of such Award, the Plan Administrator may consider the position and responsibilities of the Eligible Individual, the importance of such individual to the Company, the duties of such individual, the past, present and potential contributions of such individual to the growth and success of the Company and such other factors as the Plan Administrator may deem relevant in connection with accomplishing the purposes of this Incentive Plan.
- 5.2 *Evidence of Participation*. Each Award granted to an Eligible Individual shall be evidenced by an Award Agreement, in such form as prescribed by the Plan Administrator and containing such terms and provisions as are not inconsistent with this Incentive Plan. The provisions of separate Award Agreements need not be identical, but each Award Agreement shall include (through incorporation of the provisions hereof by reference in the Award Agreement or otherwise) the substance of the terms of the Incentive Plan. Each Award will be deemed to have been granted as of the date on which the Plan Administrator has completed the action declaring the Award, which date shall be specified by the Plan Administrator in the applicable Award Agreement, notwithstanding any delay which may elapse in the delivery and execution of such Award Agreement.

#### **SECTION 6. STOCK OPTIONS**

6.1 **Grant of Stock Options.** The Plan Administrator may, in its sole and absolute discretion, may grant Stock Options, whether alone or in addition to other Awards granted pursuant to this Incentive Plan, to any Eligible Individual. Each Eligible Individual so selected shall be offered a Stock Option to purchase the number of Shares determined by the Plan Administrator and set forth in an Award Agreement; provided, however only Employees of the Company (or any Affiliate) may be granted Incentive Stock Options. The Plan Administrator shall specify in the Award Agreement the number of Shares subject to the Award, whether such Stock Option is an Incentive Stock Option or Non-Qualified Stock Option and such other terms or conditions as the Plan Administrator shall, in its sole and absolute discretion, determine appropriate and which are not inconsistent with the terms of the Incentive Plan.

- 6.2 *Award Term.* No Stock Option shall be exercisable after the expiration of the Award Term determined by the Plan Administrator and set out in Participant's Award Agreement. Notwithstanding any provision herein to the contrary, the Award Term of any Incentive Stock Option granted under this Incentive Plan shall not exceed ten (10) years from the Award Date, or, in the case of an Incentive Stock Option granted to a Ten Percent Shareholder, five (5) years from the Award Date.
- 6.3 *Exercise Price*. The Exercise Price of each Stock Option granted under this Section 6 shall be established by the Plan Administrator or shall be determined by a method established by the Plan Administrator as of the Award Date. Notwithstanding the foregoing, the Exercise Price of any Stock Option shall not be less than 100% of the Fair Market Value of a Share on the Award Date (or if greater, the par value of such Common Stock), or, in the case of an Incentive Stock Option granted to a Ten Percent Shareholder, 110% of the Fair Market Value of a Share on the Award Date.
- 6.4 *Vesting of Stock Options*. Each Stock Option granted pursuant to this Plan may only be exercised to the extent that Participant is vested in such Stock Option. Except as otherwise provided under <u>subsection 11.2</u> herein, each Stock Option shall vest separately in accordance with the vesting schedule determined by the Plan Administrator and set out in the applicable Award Agreement. Notwithstanding the foregoing, the Plan Administrator may accelerate the vesting schedule of any outstanding Stock Option to the extent the Plan Administrator determines, in its sole and absolute discretion, that such acceleration is not inconsistent with the purposes of this Plan.
- 6.5 *Time and Manner of Exercise*. Except to the extent otherwise provided in the applicable Award Agreement, each Stock Option may be exercised, in whole or in part, by submitting to the Plan Administrator an Exercise Agreement in the form prescribed by the Plan Administrator and duly executed by Participant (or, following Participant's Disability or death, his legal representative, estate or heirs, as the case may be). Except as otherwise permitted by the Plan Administrator and expressly provided in the applicable Award Agreement, the Exercise Price and applicable tax withholding shall be paid in full at the time of exercise in a manner permitted under Section 9 herein.
  - (a) <u>Voluntary Termination of Service</u>. Unless otherwise provided in the applicable Award Agreement, in the event Participant's Continuous Service terminates (other than upon Participant's death or Disability, or for Cause), Participant may thereafter exercise the vested portion of his Stock Option (to the extent that Participant was entitled to exercise such Stock Option as of the Termination Date) but only within such period of time ending on the earlier of (i) the date ninety (90) days following Participant's Termination Date or (ii) the expiration of the Award Term under <u>subsection 6.2</u>. If, after termination, Participant does not exercise Participant's Stock Option within the time specified herein, the Stock Option shall terminate and will no longer be exercisable.

- (b) <u>Death of Participant</u>. Unless otherwise provided in the applicable Award Agreement, in the event Participant's Continuous Service terminates by reason of such Participant's death (or Participant dies within the ninety (90) day period following Participant's Termination Date), Participant's estate or heirs may thereafter exercise Participant's Stock Option (to the extent that Participant was entitled to exercise such Stock Option as of the Termination Date) but only within such period of time ending on the earlier of (i) the first anniversary of the Participant's death or (ii) the expiration of the Award Term under <u>subsection 6.2</u>. If, after the Participant's death, Participant's estate or heirs have not exercised Participant's Stock Option within the time specified herein, the Stock Option shall terminate and will no longer be exercisable.
- (c) <u>Disability of Participant</u>. Unless otherwise provided in the applicable Award Agreement, in the event Participant's Continuous Service terminates by reason of such Participant's Disability, Participant, or his legal representative, may thereafter exercise Participant's Stock Option (to the extent that Participant was entitled to exercise such Stock Option as of the Termination Date) but only within such period of time ending on the earlier of (i) the first anniversary of the Participant's Termination Date or (ii) the expiration of the Award Term under <u>subsection</u> 6.2. If, after termination, Participant, or his legal representative, has not exercised Participant's Stock Option within the time specified herein, the Stock Option shall terminate and will no longer be exercisable.
- (d) <u>Termination For Cause</u>. Unless otherwise provided in the applicable Award Agreement, in the event Participant's Continuous Service terminates for Cause, all Stock Options held by such Participant, whether or not vested, shall immediately terminate and will no longer be exercisable.
- (e) <u>Discretion of Plan Administrator</u>. The Plan Administrator shall have the sole discretion, exercisable at any time, to extend the time during which a Stock Option is to remain exercisable following Participant's Termination Date from the period otherwise in effect for that Stock Option and set forth in the Award Agreement to such greater period of time as the Plan Administrator shall deem appropriate; provided, however, that the period in which the Stock Option is exercisable shall not be extended to a date beyond the expiration of the Award Term under <u>subsection 6.2</u> or, if later, thirty (30) days following the date on which the exercise of the Stock Option would no longer violate applicable securities laws. If the Plan Administrator extends the time during which an Incentive Stock Option will remain exercisable, then such extension shall be treated as the grant of a new Option as of the date of the extension.

- (f) <u>Payment Upon Subsequent Exercise</u>. Notwithstanding any provision to the contrary herein, upon notice of intent to exercise of any one or more Stock Options on or after Participant's Termination Date in accordance with this <u>subsection 6.5</u>, the Company may, as soon as administratively feasible, in lieu of the issuance of Shares, remit to Participant (or his legal representative, estate, or heirs, as the case may be) a payment, in such manner as the Company may deem appropriate, equal to the Fair Market Value of the Shares that would otherwise be issued under the applicable Stock Option(s), less the aggregate Exercise Price and less applicable withholding taxes; provided, however, that such payment shall not be made unless (i) the Company has sufficient capital and liquidity, as determined by the Board, in its sole and absolute discretion, to make such cash payment and (ii) the Plan Administrator has received from Participant all necessary assignments, endorsements, instruments or such other evidences of title as may be reasonably required by the Plan Administrator.
- (g) <u>Lapsed and Cancelled Stock Options</u>. Nothing contained in this Incentive Plan will be deemed to extend the term of a Stock Option or to revive any Stock Option that has previously lapsed or been cancelled, terminated or surrendered.

### 6.6 Transferability of Option.

- (a) <u>Rights to Transfer</u>. A Stock Option shall be transferable to the extent provided in the Award Agreement; provided, however, that an Incentive Stock Option shall not be transferable except by will or by the laws of descent and distribution and shall be exercisable during the lifetime of Participant only by Participant. If the Award Agreement does not provide for transferability, then the Stock Option shall not be transferable except by will or by the laws of descent and distribution, and shall be exercisable during the lifetime of Participant only by Participant.
- (b) <u>Evidence of Rights</u>. The transferee of a Stock Option shall not be permitted to exercise the Stock Option unless and until such transferee has provided the Plan Administrator a copy of the will and/or such other evidence as the Plan Administrator determines necessary to establish the validity of the transfer.

# 6.7 Restrictions for Incentive Stock Options.

- (a) <u>Shareholder Approval of Plan</u>. To the extent shareholder approval of this Incentive Plan is required by Section 422 of the Code, no Eligible Individual shall be granted an Incentive Stock Option unless this Incentive Plan is approved by the stockholders of the Company within twelve (12) months before or after the date this Incentive Plan is initially adopted (or, if applicable, amended pursuant to clause (ii) of <u>subsection 12.1</u>) by the Board.
- (b) <u>Fair Market Value Restrictions</u>. To the extent that the aggregate Fair Market Value (determined on the Award Date) of Common Stock with respect to which Incentive Stock Options are exercisable for the first time by any Participant during any calendar year (under all plans of the Company and its Affiliates) exceeds one hundred thousand dollars (\$100,000), the Stock Options or portions thereof that exceed such limit (according to the order in which they were granted) shall be treated as Non-Qualified Stock Options.
- (c) <u>Termination of Authority to Issue Incentive Stock Options</u>. Notwithstanding any provision of this Incentive Plan to the contrary, no Incentive Stock Option shall be granted to any Employee after the Expiration Date.

- (d) <u>Qualification of Incentive Stock Option</u>. To the extent that a Stock Option designated as an Incentive Stock Option does not qualify as an Incentive Stock Option (whether because of its provisions, the failure of the stockholders of the Company to timely approve this Incentive Plan, or the time or manner of its exercise or otherwise) such Stock Option or the portion thereof that does not qualify as an Incentive Stock Option shall be deemed to constitute a Non-Qualified Stock Option under this Incentive Plan.
- (e) <u>Failure to Qualify</u>. Notwithstanding any provision herein to the contrary, none of the Plan Administrator, the Company, any Affiliates, or the directors, officers or Employees of the foregoing shall have any liability to any Participant or any other Person if a Stock Option designated as an Incentive Stock Option fails to qualify as such at any time.

### **SECTION 7. RESTRICTED SHARES**

- 7.1 **Grants of Restricted Shares.** The Plan Administrator may, in its sole and absolute discretion, grant Restricted Shares, whether alone or in addition to other Awards granted pursuant to this Plan, to any Eligible Individual. Each Eligible Individual granted Restricted Shares shall execute an Award Agreement setting forth the terms and conditions of such Restricted Shares, including, without limitation, the Purchase Price, if any, the Restriction Period, and conditions of forfeiture, whether based on performance standards, period of service or otherwise.
- 7.2 **Payment for Restricted Shares.** Upon Participant's acceptance of an applicable Award Agreement for Restricted Shares, Participant shall pay to the Company the Purchase Price, if any, for the Restricted Shares. Such Purchase Price may be paid in any manner permitted under <u>Section 9</u> herein and set forth in the applicable Award Agreement. The Purchase Price, if any, shall be determined by the Plan Administrator, in its sole and absolute discretion, and set forth in the applicable Award Agreement.

# 7.3 Terms of Restricted Shares.

- (a) <u>Forfeiture of Restricted Shares</u>. Subject to <u>subsection 7.3(b)</u> herein, and except as otherwise provided in the applicable Award Agreement, all Restricted Shares shall be forfeited and returned to the Company and all rights of Participant with respect to such Restricted Shares shall terminate unless Participant satisfies the requirements of the Award Agreement, which may include requirements for continuation of service, performance, and such other terms and conditions as the Plan Administrator shall, in its sole and absolute discretion, determine applicable with respect to the Restricted Shares.
- (b) <u>Waiver of Forfeiture Period</u>. Notwithstanding anything contained in this <u>Section 7</u> to the contrary, the Plan Administrator may, in its sole and absolute discretion, waive the Restriction Period and any other conditions set forth in the applicable Award Agreement under appropriate circumstances (which may include the death or Disability of Participant, or a material change in circumstances arising after the Award Date) and impose such terms and conditions (including forfeiture of a proportionate number of the Restricted Shares) as the Plan Administrator shall deem appropriate.

7.4 Tax Elections. Each Participant who has been granted an Award of Restricted Shares shall have the opportunity to file with the Internal Revenue Service an election under Section 83(b) of the Code (an "83(b) Election") to recognize taxable income for the taxable year in which the Award was granted equal to the Fair Market Value of such Restricted Shares on the Award Date (less the Purchase Price, if any). A Participant who makes an 83(b) Election with respect to Restricted Shares shall be treated as the owner of such Shares for federal income tax purposes and, on or before January 31 of each calendar year, shall receive a Form 1099 showing the amount of dividends or distributions paid during such year with respect to such Restricted Shares, if any. A Participant who does not make an 83(b) Election with respect to Restricted Shares shall not be treated as the owner of such Shares for federal income tax purposes until the expiration of the Restriction Period and, on or before January 31 of each calendar year during the Restriction Period, shall, if an Employee, receive a Form W-2 or, if a non- Employee, receive a Form 1099, as the case may be, showing the amount of dividends or distributions paid during such year with respect to such Restricted Shares and applicable withholding amounts, if any. Notwithstanding the foregoing, a Participant's making or failure to make an 83(b) Election shall not affect the Participant becoming a shareholder of record, for state law purposes, pursuant to subsection 4.5.

#### **SECTION 8. SHAREHOLDER RIGHTS**

- 8.1 **Rights Upon Grant of Award.** No Person shall have any rights as a stockholder of the Company with respect to any Shares of Common Stock subject to an Award unless and until such Person becomes the holder of record of such Shares pursuant to <u>subsection 4.5</u> hereof, and except as otherwise permitted by <u>subsection 11.1</u>, no adjustment will be made for dividends or other distributions in respect of such Shares for which the record date is prior to the date on which such Person has become the holder of record. For these purposes, a Participant who receives a grant of Restricted Shares shall become a holder of record as of the Award Date or, if later, the date on which the applicable Purchase Price is paid and shall thereafter be entitled to the voting and dividend or distribution rights appurtenant to such Shares.
- 8.2 *Rights Following Termination of Continuous Service*. Following termination of a Participant's Continuous Services for any reason, the Shares of Common Stock obtained by the Participant in connection with the grant, exercise or vesting of an Award issued pursuant to this Incentive Plan, whether held by Participant or Participant's legal representative, estate or heirs, shall be subject to repurchase by the Company in accordance with the terms of any applicable stockholders' agreement and such other conditions as set forth in the applicable Award Agreement.

#### **SECTION 9. PAYMENT UNDER AWARDS**

- 9.1 *Consideration for Shares.* Except as otherwise provided in this Incentive Plan, consideration for Shares purchased under Awards may be submitted only in such amounts and at such intervals of time as specified in the applicable Award Agreement:
  - (a) by payment to the Company of the amount of such consideration by cash, wire transfer, certified check or bank draft;

- (b) by execution of a promissory note, to be submitted with a stock power, endorsed in blank relating to the Shares held as collateral for such note:
- (c) by "cashless exercise," pursuant to which the Company withholds from the Shares that would otherwise be issued upon exercise of an Award that number of Shares with a Fair Market Value equal to the Exercise Price for the Award with respect to which such election was made;
- (d) through the delivery of unrestricted Shares having a Fair Market Value equal to the Exercise Price and owned by Participant for more than six (6) months (or such shorter or longer period of time as is necessary to avoid a charge to earnings on the Company's financial statements);
  - (e) any combination of one or more methods described herein; or
  - (f) any other consideration deemed acceptable by the Plan Administrator, in its sole and absolute discretion.

Notwithstanding any provision herein to the contrary, a Participant shall not be permitted to exercise an Incentive Stock Option pursuant to paragraphs (c) - (f) above unless the Award Agreement specifically permits such method of exercise on the Award Date.

- 9.2 *Withholding Requirements*. The amount, as determined by the Plan Administrator, of any federal, state or local tax required to be withheld by the Company due to the grant, exercise, or vesting of an Award must be submitted in such amounts and at such time as specified in the applicable Award Agreement.
  - (a) by payment to the Company of the amount of such withholding obligation by cash, wire transfer, certified check or bank draft;
  - (b) through either the retention by the Company of a number of Shares out of the Shares being acquired through the Award or the delivery of unrestricted Shares owned by Participant for more than six (6) months (or such shorter or longer period as is necessary to avoid a charge to earnings on the Company's financial statements) and having a Fair Market Value equal to the minimum withholding obligation; or
  - (c) pursuant to a written agreement between the Participant and the Company authorizing the Company to withhold from such Participant's regular wages the amount of such withholding obligation.

If Participant elects to use and the Plan Administrator permits either method described in <u>subsection 9.2(b)</u> herein in full or partial satisfaction of any withholding tax liability resulting from the grant, exercise or vesting of an Award hereunder, the Company shall remit a cash payment or an amount equal to the Fair Market Value of the Shares so withheld or delivered, as the case may be, to the appropriate taxing authorities.

# SECTION 10. COMPLIANCE WITH SECURITIES AND OTHER LAWS

10.1 Securities Laws. Notwithstanding any other provision of this Incentive Plan, the Company shall not be obligated to sell or issue any Shares pursuant to any Award granted under this Incentive Plan unless (a) the Shares have been registered under applicable federal securities law, or the issuance of such Shares is exempt from registration, (b) the prior approval of such sale or issuance has been obtained from any state regulatory body having jurisdiction to the extent necessary to comply with applicable state securities laws, and (c) if the Shares have been listed on any exchange, the Shares have been duly listed on such exchange in accordance with the procedures specified thereunder. As a condition to the issuance or transfer of any Award or any security issuable in connection with such Award, the Company may require an opinion of counsel, satisfactory to the Company, to the effect that such issuance and/or transfer will not be in violation of the Securities Act or any other applicable securities laws and may place such legends on any agreement, instrument or certificate evidencing such Award or Shares, issue stop transfer orders with respect thereto and require such agreements or undertakings as the Company may deem necessary or advisable to assure compliance with applicable laws or regulations. The Company shall not be liable for damages due to delay in the issuance, delivery or transfer of any Award or any security issuable in connection with such Award or any agreement, instrument or certificate evidencing such Award or Shares for any reason whatsoever. The Company is under no obligation to take any action or incur any expense to perfect any exemption from such registration or qualification or to list any Share issuable in connection with such Award or any Share issuable in connection with such Award or any Share issuable in connection with such Award or any Share issuable in connection with such Award or any Share issuable in connection with such Award or any Share issuable in connection with such Awar

10.2 *Investment Assurances*. The Company may require a Participant, as a condition of exercising or acquiring Common Stock under any Award, (i) to give written assurances satisfactory to the Company as to Participant's knowledge and experience in financial and business matters and/or to employ a purchaser representative reasonably satisfactory to the Company who is knowledgeable and experienced in financial and business matters and that he is capable of evaluating, alone or together with the purchaser representative, the merits and risks of exercising the Award; and (ii) to give written assurances satisfactory to the Company stating that Participant is acquiring Common Stock subject to the Award for Participant's own account and not with any present intention of selling or otherwise distributing the Common Stock. The foregoing requirements, and any assurances given pursuant to such requirements, shall be inoperative if (1) the issuance of the Shares upon the exercise or grant of an Award has been registered under a then currently effective registration statement under then applicable securities laws or (2) as to any particular requirement, a determination is made by counsel for the Company that such requirement need not be met in the circumstances under the then applicable securities laws.

10.3 **Prohibition on Deferred Compensation.** Notwithstanding any provision herein to the contrary, the Company intends that no Award granted hereunder will constitute a deferral of compensation under a "nonqualified deferred compensation plan", as such term is defined under Section 409A(d)(1) of the Code (or a successor provision thereto), either in form or operation. If any provision of this Incentive Plan or any Award is ambiguous, such provision shall be construed in a manner necessary to achieve the intent of the foregoing provision.

#### SECTION 11. ADJUSTMENTS UPON CHANGES IN SHARES

- 11.1 *Capitalization Adjustments*. If any change is made in the Common Stock subject to the Incentive Plan, or subject to any Award, without the receipt of consideration by the Company (through merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, stock split, liquidating dividend, combination of Shares, exchange of Shares, change in corporate structure or other transaction not involving the receipt of consideration by the Company), the Incentive Plan will be appropriately adjusted in the class(es) and maximum number of Shares available for issuance under the Incentive Plan pursuant to <u>subsection 4.1</u> and the outstanding Awards will be appropriately adjusted in the class(es) and number of securities and price per Share of Common Stock subject to such outstanding Awards. The Plan Administrator shall make such adjustments, and its determination shall be final, binding and conclusive. (The conversion of any convertible securities of the Company shall not be treated as a transaction "without receipt of consideration" by the Company).
- 11.2 *Change of Control.* In the event of a Change of Control, unless the Plan Administrator determines otherwise, then with respect to Awards held by Participants whose Continuous Service has not terminated:
  - (a) <u>Notice and Acceleration</u>. (i) the Company shall provide each Participant written notice of such Change of Control, (ii) all outstanding Stock Options of such Participant shall automatically accelerate and become fully exercisable, and (iii) the restrictions and conditions on all outstanding Restricted Stock held by such Participant shall immediately lapse.
  - (b) <u>Assumption of Grants</u>. Upon a Change of Control where the Company is not the surviving corporation (or survives only as a subsidiary of another corporation), unless the Plan Administrator determines otherwise, all outstanding Stock Options that are not exercised shall be assumed by, or replaced with comparable options or rights, by the surviving corporation.
  - (c) <u>Other Alternatives</u>. Notwithstanding the foregoing, in the event of a Change of Control, the Plan Administrator may take one or both of the following actions: the Plan Administrator may (i) require that Participants surrender their outstanding Stock Options in exchange for a payment by the Company, in cash or Common Stock as determined by the Plan Administrator, in an amount equal to the amount by which the then Fair Market Value of the shares of Common Stock subject to the Participant's unexercised Stock Options exceeds the Exercise Price of the Stock Options, or (ii) after giving Participants an opportunity to exercise their outstanding Stock Options, terminate any or all unexercised Stock Options at such time as the Plan Administrator deems appropriate. Such surrender or termination shall take place as of the date of the Change of Control or such other date as the Plan Administrator may specify.

### SECTION 12. AMENDMENT AND TERMINATION

- 12.1 Amendment of Incentive Plan. Notwithstanding anything contained in this Incentive Plan to the contrary, all provisions of this Incentive Plan may at any time, or from time to time, be modified or amended by the Board; provided, however, that no amendment or modification shall be made to the Incentive Plan that would (i) impair the rights of any Participant with respect to an outstanding Award issued to such Participant, unless a majority of the Participants impaired by the amendment or modification consent to such change in writing or (ii) increase the number of Shares subject to issuance upon the exercise of Incentive Stock Options (other than in accordance with an adjustment pursuant to subsection 11.1 hereof), change the class of Employees eligible to receive Incentive Stock Options pursuant to this Incentive Plan, or change the identity of the granting company or the Shares issued upon exercise of Incentive Stock Options, unless such amendment is approved by the stockholders of the Company within twelve (12) months before or after such amendment. In addition, the Plan Administrator shall be authorized to the same extent as the Board to correct any defect, omission or inconsistency in the Incentive Plan in a manner and to the extent it shall deem necessary or expedient to make the Incentive Plan fully effective.
- 12.2 **Amendment of Award.** The Plan Administrator may amend, modify or terminate any outstanding Award at any time prior to payment or exercise in any manner not inconsistent with the terms of this Incentive Plan; provided, however, that a Participant's rights under the Award shall not be impaired by such amendment unless (i) the Plan Administrator requests the consent of such Participant and (ii) the Participant consents in writing.
- 12.3 *Termination of Incentive Plan.* The Board may suspend or terminate this Plan at any time, and such suspension or termination may be retroactive or prospective; provided that the termination of this Plan shall not impair or affect any Award previously granted hereunder and the rights of the holder thereof shall remain in effect until the Award has been exercised in its entirety or has expired or otherwise has been terminated by the terms of such Award. Absent any action by the Board to terminate or suspend the Incentive Plan, the Incentive Plan shall automatically terminate on the Expiration Date.

### **SECTION 13. GENERAL PROVISIONS**

- 13.1 *General Assets*. The proceeds to be received by the Company upon exercise of any Award or purchase of Shares pursuant to any Award will constitute general assets of the Company and may be used for any proper purposes.
- 13.2 *No Assignment or Alienation.* Any attempted assignment, transfer, pledge, hypothecation or other disposition of an Award or the Shares issued in connection with an Award contrary to the provisions of this Incentive Plan or the applicable Award Agreement, or the levy of any execution, attachment or similar process upon an Award or Shares issued in connection with an Award shall be null and void and without effect.
- 13.3 *No Limit on Other Compensation Arrangements*. Nothing contained in this Incentive Plan shall prevent the Company from adopting or continuing in effect other compensation arrangements, and such arrangements may be either generally applicable or applicable only in specific cases.

- 13.4 *Tax Withholding*. The Plan Administrator shall notify each Participant of any tax withholding obligations arising as a result of the grant, exercise or vesting of an Award. As a condition to a Participant's exercise of an Award, and the issuance of Shares, Participant must satisfy the applicable withholding obligation as may be required by law in a manner permitted under <u>Section 9.2</u> hereof.
- 13.5 *No Right to Employment or Continuation of Relationship.* Nothing in this Incentive Plan or in any Award Agreement, nor the grant of any Award, shall confer upon or be construed as giving any Participant any right to remain in the employ of the Company or an Affiliate or to continue as a Consultant or non-Employee Director. Further, the Company or an Affiliate may at any time dismiss a Participant from employment or terminate the relationship of any Consultant or non-Employee Director with the Company or any Affiliate, free from any liability or any claim pursuant to this Incentive Plan, unless otherwise expressly provided in this Incentive Plan or in any Award Agreement. No Consultant, Director or Employee of the Company or any Affiliate shall have any claim to be granted an Award, and there is no obligation for uniformity of treatment of any Consultant, Director or Employee of the Company or any Affiliate, or of any Participants.
- 13.6 *Indemnification of Plan Administrator*. The Company shall indemnify each present and future member of the Committee or the Board acting in its capacity as Plan Administrator, as well as any officer or Employee acting at the direction of the Plan Administrator or its authorized delegate, for all expenses (including the amount of judgments and the amount of approved settlements made with a view to the curtailment of costs of litigation, other than amounts paid to the Company itself) reasonably incurred by him in connection with or arising out of any action, suit, or proceeding in which he may be involved by reason of his performance or non-performance of services in connection with the administration of this Incentive Plan, whether or not he continues in such position at the time of incurring such expenses; provided, however, that such indemnity shall not include any expenses incurred by such individual (a) in respect of matters as to which he shall be finally adjudged in any such action, suit, or proceeding to have been guilty of gross negligence or willful misconduct in the performance of his duties hereunder or (b) in respect of any matter in which any settlement is effected in an amount in excess of the amount approved by the Company on the advice of its legal counsel. The foregoing right of indemnification shall inure to the benefit of the heirs, executors, or administrators of the estate of each such member of the Committee or the Board, as well as any Employee acting at the direction of the Plan Administrator or its authorized delegate, and shall be in addition to all other rights to which such member, officer or Employee shall be entitled as a matter of law, contract, or otherwise.
- 13.7 *No Limitation Upon the Rights of the Company*. The grant of an Award pursuant to this Incentive Plan shall not affect in any way the right or power of the Company to make adjustments, reclassifications, or changes of its capital or business structure; to merge, convert or consolidate; to dissolve or liquidate; or sell or transfer all or any part of its business or assets.

13.8 *No Fractional Shares*. No fractional Shares shall be issued or delivered pursuant to this Incentive Plan. If an Award vests or becomes exercisable with respect to a fractional Share, such installment will instead be rounded to the next highest whole number of Shares, except for the final installment, which will be for the balance of the total Shares subject to the Award. If the final installment results in a fractional Share, the Plan Administrator shall determine, in its sole discretion, whether cash, other securities or other property shall be paid or transferred in lieu of any such fractional Shares or whether such fractional Shares or any rights thereto shall be cancelled, terminated or otherwise eliminated.

13.9 **GOVERNING LAW.** TO THE EXTENT NOT OTHERWISE PREEMPTED BY FEDERAL LAW, THE VALIDITY, CONSTRUCTION AND EFFECT OF THIS PLAN AND ANY RULES AND REGULATIONS RELATING TO THIS PLAN SHALL BE DETERMINED IN ACCORDANCE WITH THE LAWS OF THE STATE OF DELAWARE, WITHOUT GIVING EFFECT TO THE CONFLICT OF LAWS PRINCIPLES THEREOF.

- 13.10 Qualification of Incentive Plan. This Incentive Plan is not intended to be, and shall not be, qualified under Section 401(a) of the Code.
- 13.11 *Severability*. If any provision of this Incentive Plan or any Award is, or becomes, or is deemed to be, invalid, illegal or unenforceable in any jurisdiction or as to any individual or Award, or would cause this Incentive Plan or any Award to fail to comply under any law deemed applicable by the Plan Administrator, such provision shall be construed or deemed amended to conform to applicable law, or if it cannot be construed or deemed amended without, in the sole determination of the Plan Administrator, materially altering the intent of this Incentive Plan or the Award, such provision shall be stricken as to such jurisdiction, individual or Award and the remainder of this Incentive Plan and any such Award shall remain in full force and effect.
- 13.12 *Headings*. Headings are given throughout this Incentive Plan solely as a convenience to facilitate reference. Such headings shall not be deemed in any way material or relevant to the construction or interpretation of this Incentive Plan or any provision thereof.
- 13.13 *Gender and Number*. In construing the Incentive Plan, any masculine terminology herein shall also include the feminine, and the definition of any term herein in the singular shall also include the plural, except when otherwise indicated by the context.
- 13.14 *Effective Date*. Except as otherwise expressly provided to the contrary, this Incentive Plan shall be effective as of the 21st day of April 2016.

THIS CONCLUDES THE 2016 STOCK INCENTIVE PLAN

#### SECOND AMENDED AND RESTATED INVESTORS' RIGHTS AGREEMENT

THIS SECOND AMENDED AND RESTATED INVESTORS' RIGHTS AGREEMENT (this "**Agreement**") is made as of September 10, 2020 by and among Azitra Inc, a Delaware corporation (the "**Company**"), each of the investors from time to time listed on <u>Schedule A</u> hereto (each, an "**Investor**" and collectively, the "**Investors**") and each Person that becomes a party to this Agreement in accordance with <u>Section 6.9</u> hereof.

#### RECITALS

- A. Certain of the Investors (the "Existing Investors") hold shares of the Company's Preferred Stock and possess registration rights, information rights, rights of first offer and other rights pursuant to that certain Amended and Restated Investors' Rights Agreement, dated as of February 22, 2019, by and among the Company and such Existing Investors (the "**Prior Agreement**").
- B. Pursuant to Subsection 6.6 of the Prior Agreement, the Existing Investors, as holders of at least 66.67% of the outstanding shares of the Company's Series A Preferred Stock and Series A-1 Preferred Stock, taken together, and together with the Company (collectively, the "**Required Parties**") desire to amend and restate the Prior Agreement in its entirety and to accept the rights created pursuant to this Agreement in lieu of the rights granted to them under the Prior Agreement.
- C. Concurrently with the execution of this Agreement, the Company and certain of the Investors are entering into a Series B Preferred Stock Purchase Agreement (the "Purchase Agreement") providing for the sale of shares of Series B Preferred Stock of the Company to such Investors on the terms and conditions set forth therein.
- C. As an inducement for such Investors to enter into the Purchase Agreement, the parties signatory hereto desire to amend and restate the Prior Agreement in its entirety as set forth in this Agreement.
- **NOW, THEREFORE**, the Required Parties hereby agree that the Prior Agreement shall be amended and restated as set forth herein, and the parties to this Agreement further agree as follows:
  - 1. <u>Definitions</u>. For purposes of this Agreement:
- 1.1 "Affiliate" means, with respect to any specified Person, any other Person who, directly or indirectly, controls, is controlled by, or is under common control with such Person, including without limitation any general partner, managing member, officer, director or trustee of such Person, or any venture capital fund or registered investment company now or hereafter existing that is controlled by one (1) or more general partners, managing members or investment advisers of, or shares the same management company or investment adviser with, such Person; <u>provided</u>, <u>however</u>, that CII and Permitted CII Affiliates shall be deemed to be Affiliates of each other.
  - 1.2 "Bayer" means Bayer HealthCare LLC.

- 1.3 "Bios Partners" means, collectively, Bios Fund I, LP, a Delaware limited partnership, Bios Fund I QP, LP, a Delaware limited partnership, Bios Fund II, LP, a Delaware limited partnership, Bios Fund III NT, LP, a Delaware limited partnership, Bios Fund III QP, LP, a Delaware limited partnership, and Bios Fund III NT, LP, a Delaware limited partnership, and Bios Fund III NT, LP, a Delaware limited partnership.
  - 1.4 "Board" means the board of directors of the Company.
- 1.5 "Certificate of Incorporation" means the Company's Amended and Restated Certificate of Incorporation, as amended from time to time.
  - 1.6 "CII" means Connecticut Innovations, Incorporated.
  - 1.7 "Common Stock" means shares of the Company's common stock, par value \$0.01 per share.
- 1.8 "Competitor" means a Person engaged, directly or indirectly (including through any partnership, limited liability company, corporation, joint venture or similar arrangement (whether now existing or formed hereafter)), in the research, development, manufacture or sale of novel therapeutics or consumer health products to treat adverse skin conditions and disease, but shall not include any financial investment firm or collective investment vehicle that, together with its Affiliates, holds less than twenty percent (20%) of the outstanding equity of any Competitor and does not, nor do any of its Affiliates, have a right to designate any members of the board of directors of any Competitor; provided, however, that "Competitor" shall not include (i) Bios Partners or any of their respective Affiliates), (ii) CII or any Permitted CII Transferees or (iii) Bayer.
- 1.9 "Damages" means any loss, damage, claim or liability (joint or several) to which a party hereto may become subject under the Securities Act, the Exchange Act, or other federal or state law, insofar as such loss, damage, claim or liability (or any action in respect thereof) arises out of or is based upon: (i) any untrue statement or alleged untrue statement of a material fact contained in any registration statement of the Company, including any preliminary prospectus or final prospectus contained therein or any amendments or supplements thereto; (ii) an omission or alleged omission to state therein a material fact required to be stated therein, or necessary to make the statements therein not misleading; or (iii) any violation or alleged violation by the indemnifying party (or any of its agents or Affiliates) of the Securities Act, the Exchange Act, any state securities law, or any rule or regulation promulgated under the Securities Act, the Exchange Act, or any state securities law.
- 1.10 "**Derivative Securities**" means any securities or rights convertible into, or exercisable or exchangeable for (in each case, directly or indirectly), Common Stock, including options and warrants.
  - 1.11 "Exchange Act" means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

- 1.12 "Excluded Registration" means (i) a registration relating to the sale of or grant of securities to employees of the Company or a subsidiary pursuant to a stock option, stock purchase, equity incentive or similar plan; (ii) a registration relating to an SEC Rule 145 transaction; (iii) a registration on any form that does not include substantially the same information as would be required to be included in a registration statement covering the sale of the Registrable Securities; or (iv) a registration in which the only Common Stock being registered is Common Stock issuable upon conversion of debt securities that are also being registered.
- 1.13 "FOIA Party" means a Person that, in the determination of the Board, may be subject to, and thereby required to disclose non-public information furnished by or relating to the Company under, the Freedom of Information Act, 5 U.S.C. 552 ("FOIA"), any state public records access law, any state or other jurisdiction's laws similar in intent or effect to FOIA, or any other similar statutory or regulatory requirement; provided, however that "FOIA Party" shall not include CII or any Permitted CII Transferees.
- 1.14 **"Form S-1"** means such form under the Securities Act as in effect on the date hereof or any successor registration form under the Securities Act subsequently adopted by the SEC.
- 1.15 "**Form S-3**" means such form under the Securities Act as in effect on the date hereof or any registration form under the Securities Act subsequently adopted by the SEC that permits forward incorporation of substantial information by reference to other documents filed by the Company with the SEC.
  - 1.16 "GAAP" means generally accepted accounting principles in the United States as in effect from time to time.
  - 1.17 "Holder" means any holder of Registrable Securities who is a party to this Agreement.
- 1.18 "**Immediate Family Member**" means a child, stepchild, grandchild, parent, stepparent, grandparent, spouse, sibling, mother-in-law, father-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law, including, adoptive relationships, of a natural person referred to herein.
  - 1.19 "Initiating Holders" means, collectively, Holders who properly initiate a registration request under this Agreement.
  - 1.20 "**IPO**" means the Company's first underwritten public offering of its Common Stock under the Securities Act.
- 1.21 "Major Investor" means (i) any Investor that, individually or together with such Investor's Affiliates, holds at least 23,000 shares of Registrable Securities (as adjusted for any stock split, stock dividend, combination, or other recapitalization or reclassification effected after the date hereof) and (ii) The Thiel Foundation. The Thiel Foundation shall remain a Major Investor until the earlier to occur of (A) such time that all other Persons who or which were Major Investors (for this purpose, as defined in the Prior Agreement), as of immediately following the consummation of the transactions contemplated by the Prior Agreement on February 22, 2019, are no longer Major Investors and (B) The Thiel Foundation no longer owns any equity securities of the Company.

- 1.22 "New Securities" means, collectively, all shares of capital stock or other equity securities of the Company, whether or not currently authorized, as well as rights, options, or warrants to purchase such shares or equity securities, or securities of any type whatsoever that are, or may become, convertible or exchangeable into or exercisable for such shares or equity securities.
- 1.23 "**Permitted CII Transferee**" means any of (i) CII, (ii) any governmental or quasi-governmental agency of the State of Connecticut, governmental unit of the State of Connecticut or statutorily created entity of the State of Connecticut; (iii) any corporation, limited liability company, partnership or other entity controlled by CII or (iv) any other Person that directly, or indirectly through one (1) or more intermediaries, controls, or is controlled by, or is under common control with, CII created for the purpose of managing and/or making investments in portfolio companies based in Connecticut including, without limitation, Connecticut Emerging Enterprises, L.P. or (v) any successor or replacement agency of the State of Connecticut (or other entity) for CII.
  - 1.24 "Person" means any individual, corporation, partnership, trust, limited liability company, association or other entity.
  - 1.25 "Preferred Directors" means, collectively, the Series A Director, Series A-1 Director and Series B Directors.
- 1.26 "**Preferred Stock**" means, collectively, shares of the Series A Preferred Stock, Series A-1 Preferred Stock and Series B Preferred Stock.
- 1.27 "**Registrable Securities**" means (i) the Common Stock issuable or issued upon conversion of the Preferred Stock; (ii) any Common Stock, or any Common Stock issued or issuable (directly or indirectly) upon conversion and/or exercise of any other securities of the Company, acquired by the Investors after the date hereof; and (iii) any Common Stock issued as (or issuable upon the conversion or exercise of any warrant, right, or other security that is issued as) a dividend or other distribution with respect to, or in exchange for or in replacement of, the shares referenced in clauses (i) and (ii) above; excluding in all cases, however, any Registrable Securities sold by a Person in a transaction in which the applicable rights under this Agreement are not assigned pursuant to Subsection 6.1 and excluding for purposes of Section 2 any shares for which registration rights have terminated pursuant to Subsection 2.13 of this Agreement.
- 1.28 **"Registrable Securities then outstanding**" means the number of shares determined by adding the number of shares of outstanding Common Stock that are Registrable Securities and the number of shares of Common Stock issuable (directly or indirectly) pursuant to then exercisable and/or convertible securities that are Registrable Securities.
- 1.29 "**Restricted Securities**" means the securities of the Company required to be notated with the legend set forth in <u>Subsection 2.12(b)</u> hereof.

- 1.30 "Qualified IPO" means a sale of shares of Common Stock to the public in an underwritten public offering, under the Securities Act, with gross offering proceeds in excess of \$100,000,000.
  - 1.31 "SEC" means the Securities and Exchange Commission.
  - 1.32 "SEC Rule 144" means Rule 144 promulgated by the SEC under the Securities Act.
  - 1.33 "SEC Rule 145" means Rule 145 promulgated by the SEC under the Securities Act.
  - 1.34 "Securities Act" means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.
- 1.35 "**Selling Expenses**" means all underwriting discounts, selling commissions, and stock transfer taxes applicable to the sale of Registrable Securities, and fees and disbursements of counsel for any Holder, except for the fees and disbursements of the Selling Holder Counsel borne and paid by the Company as provided in <u>Subsection 2.6</u>.
- 1.36 "**Series A Director**" means any director of the Company that the holders of record of the Series A Preferred Stock are entitled to elect, exclusively and as a separate class, pursuant to the Certificate of Incorporation.
  - 1.37 "Series A Preferred Stock" means shares of the Company's Series A Preferred Stock, par value \$0.0001 per share.
- 1.38 "**Series A-1 Director**" means any director of the Company that the holders of record of the Series A-1 Preferred Stock are entitled to elect, exclusively and as a separate class, pursuant to the Certificate of Incorporation.
  - 1.39 "Series A-1 Preferred Stock" means shares of the Company's Series A-1 Preferred Stock, par value \$0.0001 per share.
- 1.40 "Series B Director" means any director of the Company that the holders of record of the Series B Preferred Stock are entitled to elect, exclusively and as a separate class, pursuant to the Certificate of Incorporation.
  - 1.41 "Series B Preferred Stock" means shares of the Company's Series B Preferred Stock, par value \$0.0001 per share.

2. Registration Rights. The Company covenants and agrees as follows:

### 2.1 Demand Registration.

(a) Form S-1 Demand. If at any time after the earlier of (i) one hundred eighty (180) days after the effective date of the registration statement for the IPO or (ii) five (5) years following the closing of the transactions contemplated in the Purchase Agreement, the Company receives a request from Holders of at least fifty percent (50%) of the Registrable Securities then outstanding that the Company file a Form S-1 registration statement with respect to Registrable Securities having an anticipated aggregate offering price, net of selling Expenses, of at least \$20 million, then the Company shall (x) within ten (10) days after the date such request is given, give notice thereof (the "Demand Notice") to all Holders other than the Initiating Holders; and (y) as soon as practicable, and in any event within ninety (90) days after the date such request is given by the Initiating Holders, file a Form S-1 registration statement under the Securities Act covering all Registrable Securities that the Initiating Holders requested to be registered and any additional Registrable Securities requested to be included in such registration by any other Holders, as specified by notice given by each such Holder to the Company within twenty (20) days of the date the Demand Notice is given, and in each case, subject to the limitations of Subsections 2.1(c) and 2.3. Holders shall be entitled to demand up to two (2) firmly underwritten registrations pursuant to this Subsection 2.1(a).

(b) Form S-3 Demand. If at any time when it is eligible to use a Form S-3 registration statement, the Company receives a request from Holders of at least fifty percent (50%) of the Registrable Securities then outstanding that the Company file a Form S-3 registration statement with respect to outstanding Registrable Securities of such Holders having an anticipated aggregate offering price, net of Selling Expenses, of at least \$1 million, then the Company shall (i) within ten (10) days after the date such request is given, give a Demand Notice to all Holders other than the Initiating Holders; and (ii) as soon as practicable, and in any event within forty-five (45) days after the date such request is given by the Initiating Holders, file a Form S-3 registration statement under the Securities Act covering all Registrable Securities requested to be included in such registration by any other Holders, as specified by notice given by each such Holder to the Company within twenty (20) days of the date the Demand Notice is given, and in each case, subject to the limitations of Subsections 2.1(c) and 2.3.

(c) Notwithstanding the foregoing obligations, if the Company furnishes to Holders requesting a registration pursuant to this <u>Subsection 2.1</u> a certificate signed by the Company's chief executive officer stating that in the good faith judgment of the Board it would be materially detrimental to the Company and its stockholders for such registration statement to either become effective or remain effective for as long as such registration statement otherwise would be required to remain effective, because such action would (i) materially interfere with a significant acquisition, corporate reorganization, or other similar transaction involving the Company; (ii) require premature disclosure of material information that the Company has a bona fide business purpose for preserving as confidential; or (iii) render the Company unable to comply with requirements under the Securities Act or Exchange Act, then the Company shall have the right to defer taking action with respect to such filing, and any time periods with respect to filing or effectiveness thereof shall be tolled correspondingly, for a period of not more than ninety (90) days after the request of the Initiating Holders is given; provided, however, that the Company may not invoke this right more than twice in any twelve (12) month period.

(d) The Company shall not be obligated to effect, or to take any action to effect, any registration pursuant to <u>Subsection 2.1(a)</u>: (i) during the period that is sixty (60) days before the Company's good faith estimate of the date of filing of, and ending on a date that is one hundred eighty (180) days after the effective date of, a Company-initiated registration, provided that the Company is actively employing in good faith commercially reasonable efforts to cause such registration statement to become effective; (ii) after the Company has effected two (2) registrations pursuant to <u>Subsection 2.1(a)</u>; or (iii) if the Initiating Holders propose to dispose of shares of Registrable Securities that may be immediately registered on Form S-3 pursuant to a request made pursuant to <u>Subsection 2.1(b)</u>. The Company shall not be obligated to effect, or to take any action to effect, any registration pursuant to <u>Subsection 2.1(b)</u>: (i) during the period that is thirty (30) days before the Company's good faith estimate of the date of filing of, and ending on a date that is ninety (90) days after the effective date of, a Company-initiated registration, <u>provided</u> that the Company is actively employing in good faith commercially reasonable efforts to cause such registration statement to become effective; or (ii) if the Company has effected two (2) registrations pursuant to <u>Subsection 2.1(b)</u> within the twelve (12) month period immediately preceding the date of such request. A registration shall not be counted as "effected" for purposes of this <u>Subsection 2.1(d)</u> until such time as the applicable registration statement has been declared effective by the SEC, unless the Initiating Holders withdraw their request for such registration, elect not to pay the registration statement shall be counted as "effected" for purposes of this <u>Subsection 2.1(d)</u>.

2.2 <u>Company Registration</u>. If the Company proposes to register (including, for this purpose, a registration effected by the Company for stockholders other than the Holders) any of its securities under the Securities Act in connection with the public offering of such securities solely for cash (other than in an Excluded Registration), the Company shall, at such time, promptly give each Holder notice of such registration. Upon the request of each Holder given within twenty (20) days after such notice is given by the Company, the Company shall, subject to the provisions of <u>Subsection 2.3</u>, cause to be registered all of the Registrable Securities that each such Holder has requested to be included in such registration. The Company shall have the right to terminate or withdraw any registration initiated by it under this <u>Subsection 2.2</u> before the effective date of such registration, whether or not any Holder has elected to include Registrable Securities in such registration. The expenses (other than Selling Expenses) of such withdrawn registration shall be borne by the Company in accordance with <u>Subsection 2.6</u>.

# 2.3 Underwriting Requirements.

(a) If, pursuant to Subsection 2.1, the Initiating Holders intend to distribute the Registrable Securities covered by their request by means of an underwriting, they shall so advise the Company as a part of their request made pursuant to Subsection 2.1, and the Company shall include such information in the Demand Notice. The underwriter(s) will be selected by the Company and shall be reasonably acceptable to a majority in interest of the Initiating Holders. In such event, the right of any Holder to include such Holder's Registrable Securities in such registration shall be conditioned upon such Holder's participation in such underwriting and the inclusion of such Holder's Registrable Securities in the underwriting to the extent provided herein. All Holders proposing to distribute their securities through such underwriting shall (together with the Company as provided in Subsection 2.4(e)) enter into an underwriting agreement in customary form with the underwriter(s) selected for such underwriting. Notwithstanding any other provision of this Subsection 2.3, if the underwriter(s) advise(s) the Initiating Holders in writing that marketing factors require a limitation on the number of shares to be underwritten, then the Initiating Holders shall so advise all Holders of Registrable Securities that otherwise would be underwritten pursuant hereto, and the number of Registrable Securities that may be included in the underwriting shall be allocated among such Holders of Registrable Securities, including the Initiating Holders, in proportion (as nearly as practicable) to the number of Registrable Securities held by the Holders to be included in such underwriting shall not be reduced unless all other securities are first entirely excluded from the underwriting. To facilitate the allocation of shares in accordance with the above provisions, the Company or the underwriters may round the number of shares allocated to any Holder to the nearest one hundred (100) shares.

(b) In connection with any offering involving an underwriting of shares of the Company's capital stock pursuant to Subsection 2.2, the Company shall not be required to include any of the Holders' Registrable Securities in such underwriting unless the Holders accept the terms of the underwriting as agreed upon between the Company and its underwriters, and then only in such quantity as the underwriters in their sole discretion determine will not jeopardize the success of the offering by the Company. If the total number of securities, including Registrable Securities, requested by stockholders to be included in such offering exceeds the number of securities to be sold (other than by the Company) that the underwriters in their reasonable discretion determine is compatible with the success of the offering, then the Company shall be required to include in the offering only that number of such securities, including Registrable Securities, which the underwriters and the Company in their sole discretion determine will not jeopardize the success of the offering. If the underwriters determine that less than all of the Registrable Securities requested to be registered can be included in such offering, then the Registrable Securities that are included in such offering shall be allocated among the selling Holders in proportion (as nearly as practicable to) the number of Registrable Securities owned by each selling Holder or in such other proportions as shall mutually be agreed to by all such selling Holders. To facilitate the allocation of shares in accordance with the above provisions, the Company or the underwriters may round the number of shares allocated to any Holder to the nearest one hundred (100) shares. Notwithstanding the foregoing, in no event shall (i) the number of Registrable Securities included in the offering be reduced unless all other securities (other than securities to be sold by the Company) are first entirely excluded from the offering or (ii) the number of Registrable Securities included in the offering be reduced below twenty-five percent (25%) of the total number of securities included in such offering, unless such offering is the IPO, in which case the selling Holders may be excluded further if the underwriters make the determination described above and no other stockholder's securities are included in such offering. For purposes of the provision in this Subsection 2.3(b) concerning apportionment, for any selling Holder that is a partnership, limited liability company, or corporation, the partners, members, retired partners, retired members, stockholders, and Affiliates of such Holder, or the estates and Immediate Family Members of any such partners, retired partners, members, and retired members and any trusts for the benefit of any of the foregoing Persons, shall be deemed to be a single "selling Holder," and any pro rata reduction with respect to such "selling Holder" shall be based upon the aggregate number of Registrable Securities owned by all Persons included in such "selling Holder," as defined in this sentence.

- 2.4 <u>Obligations of the Company</u>. Whenever required under this <u>Section 2</u> to effect the registration of any Registrable Securities, the Company shall, as expeditiously as reasonably possible:
- (a) prepare and file with the SEC a registration statement with respect to such Registrable Securities and use its commercially reasonable efforts to cause such registration statement to become effective and, upon the request of the Holders of a majority of the Registrable Securities registered thereunder, keep such registration statement effective for a period of up to one hundred twenty (120) days or, if earlier, until the distribution contemplated in the registration statement has been completed; <u>provided</u>, <u>however</u>, that (i) such one hundred twenty (120) day period shall be extended for a period of time equal to the period the Holder refrains, at the request of an underwriter of Common Stock (or other securities) of the Company, from selling any securities included in such registration, and (ii) in the case of any registration of Registrable Securities on Form S-3 that are intended to be offered on a continuous or delayed basis, subject to compliance with applicable SEC rules, such one hundred twenty (120) day period shall be extended for up to ninety (90) days, if necessary, to keep the registration statement effective until all such Registrable Securities are sold;
- (b) prepare and file with the SEC such amendments and supplements to such registration statement, and the prospectus used in connection with such registration statement, as may be necessary to comply with the Securities Act in order to enable the disposition of all securities covered by such registration statement;
- (c) furnish to the selling Holders such numbers of copies of a prospectus, including a preliminary prospectus, as required by the Securities Act, and such other documents as the Holders may reasonably request in order to facilitate their disposition of their Registrable Securities;
- (d) use its commercially reasonable efforts to register and qualify the securities covered by such registration statement under such other securities or blue-sky laws of such jurisdictions as shall be reasonably requested by the selling Holders; <u>provided</u> that the Company shall not be required to qualify to do business or to file a general consent to service of process in any such states or jurisdictions, unless the Company is already subject to service in such jurisdiction and except as may be required by the Securities Act;
- (e) in the event of any underwritten public offering, enter into and perform its obligations under an underwriting agreement, in usual and customary form, with the underwriter(s) of such offering;
- (f) use its commercially reasonable efforts to cause all such Registrable Securities covered by such registration statement to be listed on a national securities exchange or trading system and each securities exchange and trading system (if any) on which similar securities issued by the Company are then listed;
- (g) provide a transfer agent and registrar for all Registrable Securities registered pursuant to this Agreement and provide a CUSIP number for all such Registrable Securities, in each case not later than the effective date of such registration;

(h) promptly make available for inspection by the selling Holders, any underwriter(s) participating in any disposition pursuant to such registration statement, and any attorney or accountant or other agent retained by any such underwriter or selected by the selling Holders, all financial and other records, pertinent corporate documents, and properties of the Company, and cause the Company's officers, directors, employees, and independent accountants to supply all information reasonably requested by any such seller, underwriter, attorney, accountant, or agent, in each case, as necessary or advisable to verify the accuracy of the information in such registration statement and to conduct appropriate due diligence in connection therewith;

- (i) notify each selling Holder, promptly after the Company receives notice thereof, of the time when such registration statement has been declared effective or a supplement to any prospectus forming a part of such registration statement has been filed; and
- (j) after such registration statement becomes effective, notify each selling Holder of any request by the SEC that the Company amend or supplement such registration statement or prospectus.

In addition, the Company shall ensure that, at all times after any registration statement covering a public offering of securities of the Company under the Securities Act shall have become effective, its insider trading policy shall provide that the Company's directors may implement a trading program under Rule 10b5-1 of the Exchange Act.

- 2.5 <u>Furnish Information</u>. It shall be a condition precedent to the obligations of the Company to take any action pursuant to this <u>Section 2</u> with respect to the Registrable Securities of any selling Holder that such Holder shall furnish to the Company such information regarding itself, the Registrable Securities held by it, and the intended method of disposition of such securities as is reasonably required to effect the registration of such Holder's Registrable Securities.
- 2.6 Expenses of Registration(a). All expenses (other than Selling Expenses) incurred in connection with registrations, filings, or qualifications pursuant to Section 2, including all registration, filing, and qualification fees; printers' and accounting fees; fees and disbursements of counsel for the Company; and the reasonable fees and disbursements, not to exceed \$50,000, of one (1) counsel for the selling Holders ("Selling Holder Counsel"), shall be borne and paid by the Company; provided, however, that the Company shall not be required to pay for any expenses of any registration proceeding begun pursuant to Subsection 2.1 if the registration request is subsequently withdrawn at the request of the Holders of a majority of the Registrable Securities to be registered (in which case all selling Holders shall bear such expenses pro rata based upon the number of Registrable Securities that were to be included in the withdrawn registration), unless the Holders of a majority of the Registrable Securities agree to forfeit their right to one (1) registration pursuant to Subsections 2.1(a) or 2.1(b), as the case may be; provided further that if, at the time of such withdrawal, the Holders shall have learned of a material adverse change in the condition, business, or prospects of the Company from that known to the Holders at the time of their request and have withdrawn the request with reasonable promptness after learning of such information then the Holders shall not be required to pay any of such expenses and shall not forfeit their right to one (1) registration pursuant to Subsections 2.1(a) or 2.1(b). All Selling Expenses relating to Registrable Securities registered pursuant to this Section 2 shall be borne and paid by the Holders pro rata on the basis of the number of Registrable Securities registered on their behalf.

2.7 <u>Delay of Registration</u>. No Holder shall have any right to obtain or seek an injunction restraining or otherwise delaying any registration pursuant to this Agreement as the result of any controversy that might arise with respect to the interpretation or implementation of this <u>Section 2</u>.

2.8 <u>Indemnification</u>. If any Registrable Securities are included in a registration statement under this <u>Section 2</u>:

(a) To the extent permitted by law, the Company will indemnify and hold harmless each selling Holder, and the partners, members, officers, directors, and stockholders of each such Holder; legal counsel and accountants for each such Holder; any underwriter (as defined in the Securities Act) for each such Holder; and each Person, if any, who controls such Holder or underwriter within the meaning of the Securities Act or the Exchange Act, against any Damages, and the Company will pay to each such Holder, underwriter, controlling Person, or other aforementioned Person any legal or other expenses reasonably incurred thereby in connection with investigating or defending any claim or proceeding from which Damages may result, as such expenses are incurred; provided, however, that the indemnity agreement contained in this Subsection 2.8(a) shall not apply to amounts paid in settlement of any such claim or proceeding if such settlement is effected without the consent of the Company, which consent shall not be unreasonably withheld, nor shall the Company be liable for any Damages to the extent that they arise out of or are based upon actions or omissions made in reliance upon and in conformity with written information furnished by or on behalf of any such Holder, underwriter, controlling Person, or other aforementioned Person expressly for use in connection with such registration.

(b) To the extent permitted by law, each selling Holder, severally and not jointly, will indemnify and hold harmless the Company, and each of its directors, each of its officers who has signed the registration statement, each Person (if any), who controls the Company within the meaning of the Securities Act, legal counsel and accountants for the Company, any underwriter (as defined in the Securities Act), any other Holder selling securities in such registration statement, and any controlling Person of any such underwriter or other Holder, against any Damages, in each case only to the extent that such Damages arise out of or are based upon actions or omissions made in reliance upon and in conformity with written information furnished by or on behalf of such selling Holder expressly for use in connection with such registration; and each such selling Holder will pay to the Company and each other aforementioned Person any legal or other expenses reasonably incurred thereby in connection with investigating or defending any claim or proceeding from which Damages may result, as such expenses are incurred; provided, however, that the indemnity agreement contained in this Subsection 2.8(b) shall not apply to amounts paid in settlement of any such claim or proceeding if such settlement is effected without the consent of the Holder, which consent shall not be unreasonably withheld; and provided further that in no event shall the aggregate amounts payable by any Holder by way of indemnity or contribution under Subsections 2.8(b) and 2.8(d) exceed the proceeds from the offering received by such Holder (net of any Selling Expenses paid by such Holder), except in the case of fraud or willful misconduct by such Holder.

(c) Promptly after receipt by an indemnified party under this Subsection 2.8 of notice of the commencement of any action (including any governmental action) for which a party may be entitled to indemnification hereunder, such indemnified party will, if a claim in respect thereof is to be made against any indemnifying party under this Subsection 2.8, give the indemnifying party notice of the commencement thereof. The indemnifying party shall have the right to participate in such action and, to the extent the indemnifying party so desires, participate jointly with any other indemnifying party to which notice has been given, and to assume the defense thereof with counsel mutually satisfactory to the parties; provided, however, that an indemnified party (together with all other indemnified parties that may be represented without conflict by one (1) counsel) shall have the right to retain one (1) separate counsel, with the fees and expenses to be paid by the indemnifying party, if representation of such indemnified party by the counsel retained by the indemnifying party would be inappropriate due to actual or potential differing interests between such indemnified party and any other party represented by such counsel in such action and provided, further, that prior to assuming control of such defense, the indemnifying party must (i) acknowledge that, if the facts as alleged by the claimant in such claim are true, it would have an indemnity obligation for the expenses, losses, claims, damages and liabilities resulting from such claim as provided hereunder and (ii) must furnish the indemnified party with reasonable evidence that the indemnifying party has adequate resources to defend such claim and fulfill its indemnity obligations hereunder. The indemnifying party shall not be entitled to assume or maintain control of the defense of any claim and shall pay the fees and expenses of one (1) counsel retained by the indemnified party if (A) the indemnifying party does not deliver the acknowledgment referred to in clause (i) above within thirty (30) days of receipt of notice of the claim, (B) the claim relates to or arises in connection with any criminal proceeding, action, indictment or allegation, (C) the claim seeks an injunction or equitable relief against the indemnified party or any of its affiliates or (D) the indemnifying party has failed or is failing to prosecute or defend vigorously the claim. No indemnifying party in the defense of any such action shall, except with the consent of each indemnified party, consent to entry of any judgment or enter into any settlement that does not include as an unconditional term thereof the giving by the claimant or plaintiff to such indemnified party of a release from all liability in respect of such action. The failure to give notice to the indemnifying party within a reasonable time of the commencement of any such action shall relieve such indemnifying party of any liability to the indemnified party under this Subsection 2.8, to the extent that such failure materially prejudices the indemnifying party's ability to defend such action. The failure to give notice to the indemnifying party will not relieve it of any liability that it may have to any indemnified party otherwise than under this Subsection 2.8.

(d) To provide for just and equitable contribution to joint liability under the Securities Act in any case in which either: (i) any party otherwise entitled to indemnification hereunder makes a claim for indemnification pursuant to this Subsection 2.8 but it is judicially determined (by the entry of a final judgment or decree by a court of competent jurisdiction and the expiration of time to appeal or the denial of the last right of appeal) that such indemnification may not be enforced in such case, notwithstanding the fact that this Subsection 2.8 provides for indemnification in such case, or (ii) contribution under the Securities Act may be required on the part of any party hereto for which indemnification is provided under this Subsection 2.8, then, and in each such case, such parties will contribute to the aggregate losses, claims, damages, liabilities, or expenses to which they may be subject (after contribution from others) in such proportion as is appropriate to reflect the relative fault of each of the indemnifying party and the indemnified party in connection with the statements, omissions, or other actions that resulted in such loss, claim, damage, liability, or expense, as well as to reflect any other relevant equitable considerations. The relative fault of the indemnifying party and of the indemnified party shall be determined by reference to, among other things, whether the untrue or allegedly untrue statement of a material fact, or the omission or alleged omission of a material fact, relates to information supplied by the indemnifying party or by the indemnified party and the parties' relative intent, knowledge, access to information, and opportunity to correct or prevent such statement or omission; provided, however, that, in any such case (x) no Holder will be required to contribute any amount in excess of the public offering price of all such Registrable Securities offered and sold by such Holder pursuant to such registration statement, and (y) no Person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) will be entitled to contribution from any Person who was not guilty of such fraudulent misrepresentation; and provided further that in no event shall a Holder's liability pursuant to this Subsection 2.8(d), when combined with the amounts paid or payable by such Holder pursuant to Subsection 2.8(b), exceed the proceeds from the offering received by such Holder (net of any Selling Expenses paid by such Holder), except in the case of willful misconduct or fraud by such Holder.

- (e) Unless otherwise superseded by an underwriting agreement entered into in connection with the underwritten public offering, the obligations of the Company and Holders under this <u>Subsection 2.8</u> shall survive the completion of any offering of Registrable Securities in a registration under this <u>Section 2</u>, and otherwise shall survive the termination of this Agreement.
- (f) Notwithstanding the foregoing, to the extent that the provisions on indemnification and contribution contained in the underwriting agreement entered into in connection with the underwritten public offering are in conflict with the foregoing provisions, the provisions in the underwriting agreement shall control.
- 2.9 <u>Reports Under Exchange Act</u>. With a view to making available to the Holders the benefits of SEC Rule 144 and any other rule or regulation of the SEC that may at any time permit a Holder to sell securities of the Company to the public without registration or pursuant to a registration on Form S-3, the Company shall:
- (a) make and keep available adequate current public information, as those terms are understood and defined in SEC Rule 144, at all times after the effective date of the registration statement filed by the Company for the IPO;
- (b) use commercially reasonable efforts to file with the SEC in a timely manner all reports and other documents required of the Company under the Securities Act and the Exchange Act (at any time after the Company has become subject to such reporting requirements); and
- (c) furnish to any Holder, so long as the Holder owns any Registrable Securities, forthwith upon request (i) to the extent accurate, a written statement by the Company that it has complied with the reporting requirements of SEC Rule 144 (at any time after ninety (90) days after the effective date of the registration statement filed by the Company for the IPO), the Securities Act, and the Exchange Act (at any time after the Company has become subject to such reporting requirements), or that it qualifies as a registrant whose securities may be resold pursuant to Form S-3 (at any time after the Company so qualifies); and (ii) such other information as may be reasonably requested in availing any Holder of any rule or regulation of the SEC that permits the selling of any such securities without registration (at any time after the Company has become subject to the reporting requirements under the Exchange Act) or pursuant to Form S-3 (at any time after the Company so qualifies to use such form).

2.10 <u>Limitations on Subsequent Registration Rights(a)</u>. From and after the date of this Agreement, the Company shall not, without the prior written consent of the Holders of a majority of the Registrable Securities then outstanding, enter into any agreement with any holder or prospective holder of any securities of the Company that would allow such holder or prospective holder (i) to include such securities in any registration unless, under the terms of such agreement, such holder or prospective holder may include such securities in any such registration only to the extent that the inclusion of such securities will not reduce the number of the Registrable Securities of the Holders that are included; or (ii) to initiate a demand for registration of any securities held by such holder or prospective holder; <u>provided</u> that this limitation shall not apply to any additional Investor who becomes a party to this Agreement in accordance with <u>Subsection 6.9</u>.

2.11 "Market Stand-off" Agreement(a). Each Holder hereby agrees that it will not, without the prior written consent of the managing underwriter, during the period commencing on the date of the final prospectus relating to the registration by the Company of shares of its Common Stock or any other equity securities under the Securities Act on a registration statement on Form S-1 or Form S-3, and ending on the date specified by the Company and the managing underwriter (such period not to exceed one hundred eighty (180) days in the case of the IPO, or such other period as may be requested by the Company or an underwriter to accommodate regulatory restrictions on (1) the publication or other distribution of research reports and (2) analyst recommendations and opinions, including, but not limited to, the restrictions contained in FINRA Rule 2711(f)(4) or NYSE Rule 472(f)(4), or any successor provisions or amendments thereto), (i) lend; offer; pledge; sell; contract to sell; sell any option or contract to purchase; purchase any option or contract to sell; grant any option, right, or warrant to purchase; or otherwise transfer or dispose of, directly or indirectly, any shares of Common Stock or any securities convertible into or exercisable or exchangeable (directly or indirectly) for Common Stock (whether such shares or any such securities are then owned by the Holder or are thereafter acquired) or (ii) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of such securities, whether any such transaction described in clause (i) or (ii) above is to be settled by delivery of Common Stock or other securities, in cash, or otherwise. The foregoing provisions of this Subsection 2.11 shall apply only to the IPO, shall not apply to the sale of any shares to an underwriter pursuant to an underwriting agreement, or the transfer of any shares to any trust for the direct or indirect benefit of the Holder or the immediate family of the Holder, provided that the trustee of the trust agrees to be bound in writing by the restrictions set forth herein, and provided further that any such transfer shall not involve a disposition for value, and shall be applicable to the Holders only if all officers and directors are subject to the same restrictions and the Company uses commercially reasonable efforts to obtain a similar agreement from all stockholders individually owning more than one percent (1%) of the Company's outstanding Common Stock (after giving effect to conversion into Common Stock of all outstanding Preferred Stock). The underwriters in connection with such registration are intended third-party beneficiaries of this Subsection 2.11 and shall have the right, power and authority to enforce the provisions hereof as though they were a party hereto. Each Holder further agrees to execute such agreements as may be reasonably requested by the underwriters in connection with such registration that are consistent with this <u>Subsection 2.11</u> or that are necessary to give further effect thereto. Any discretionary waiver or termination of the restrictions of any or all of such agreements by the Company or the underwriters shall apply pro rata to all Holders subject to such agreements, based on the number of shares subject to such agreements.

### 2.12 Restrictions on Transfer.

(a) The Preferred Stock and the Registrable Securities shall not be sold, pledged, or otherwise transferred, and the Company shall not recognize and shall issue stop-transfer instructions to its transfer agent with respect to any such sale, pledge, or transfer, except upon the conditions specified in this Agreement, which conditions are intended to ensure compliance with the provisions of the Securities Act. A transferring Holder will cause any proposed purchaser, pledgee, or transferee of the Preferred Stock and the Registrable Securities held by such Holder to agree to take and hold such securities subject to the provisions and upon the conditions specified in this Agreement.

(b) Each certificate, instrument, or book entry representing (i) the Preferred Stock, (ii) the Registrable Securities, and (iii) any other securities issued in respect of the securities referenced in clauses (i) and (ii), upon any stock split, stock dividend, recapitalization, merger, consolidation, or similar event, shall (unless otherwise permitted by the provisions of <u>Subsection 2.12(c))</u> be notated with a legend substantially in the following form:

THE SECURITIES REPRESENTED HEREBY HAVE BEEN ACQUIRED FOR INVESTMENT AND HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933. SUCH SHARES MAY NOT BE SOLD, PLEDGED, OR TRANSFERRED IN THE ABSENCE OF SUCH REGISTRATION OR A VALID EXEMPTION FROM THE REGISTRATION AND PROSPECTUS DELIVERY REQUIREMENTS OF SAID ACT.

THE SECURITIES REPRESENTED HEREBY MAY BE TRANSFERRED ONLY IN ACCORDANCE WITH THE TERMS OF AN AGREEMENT BETWEEN THE COMPANY AND THE STOCKHOLDER, A COPY OF WHICH IS ON FILE WITH THE SECRETARY OF THE COMPANY.

The Holders consent to the Company making a notation in its records and giving instructions to any transfer agent of the Restricted Securities in order to implement the restrictions on transfer set forth in this <u>Subsection 2.12</u>.

- (c) The holder of such Restricted Securities, by acceptance of ownership thereof, agrees to comply in all respects with the provisions of this Section 2. Before any proposed sale, pledge, or transfer of any Restricted Securities, unless there is in effect a registration statement under the Securities Act covering the proposed transaction, the Holder thereof shall give notice to the Company of such Holder's intention to effect such sale, pledge, or transfer. Each such notice shall describe the manner and circumstances of the proposed sale, pledge, or transfer in sufficient detail and, if reasonably requested by the Company, shall be accompanied at such Holder's expense by either (i) a written opinion of legal counsel who shall, and whose legal opinion shall, be reasonably satisfactory to the Company, addressed to the Company, to the effect that the proposed transaction may be effected without registration under the Securities Act; (ii) a "no action" letter from the SEC to the effect that the proposed sale, pledge, or transfer of such Restricted Securities without registration will not result in a recommendation by the staff of the SEC that action be taken with respect thereto; or (iii) any other evidence reasonably satisfactory to counsel to the Company to the effect that the proposed sale, pledge, or transfer of the Restricted Securities may be effected without registration under the Securities Act, whereupon the Holder of such Restricted Securities shall be entitled to sell, pledge, or transfer such Restricted Securities in accordance with the terms of the notice given by the Holder to the Company. The Company will not require such a legal opinion or "no action" letter (x) in any transaction in compliance with SEC Rule 144; or (y) in any transaction in which such Holder distributes Restricted Securities to an Affiliate of such Holder for no consideration; provided that each transferee agrees in writing to be subject to the terms of this Subsection 2.12. Each certificate, instrument, or book entry representing the Restricted Securities transferred as above provided shall be notated with, except if such transfer is made pursuant to SEC Rule 144, the appropriate restrictive legend set forth in Subsection 2.12(b), except that such certificate instrument, or book entry shall not be notated with such restrictive legend if, in the opinion of counsel for such Holder and the Company, such legend is not required in order to establish compliance with any provisions of the Securities Act.
- (d) The registration rights described herein may be transferred by a Holder to current and former partners and members, and Affiliates of such Holder and to other Persons acquiring at least 21,000 shares of the Company's outstanding capital stock of any class or series (as adjusted for any stock split, stock dividend, combination, or other recapitalization or reclassification effected after the date hereof), <u>provided</u> that before any proposed transfer, the Holder thereof shall give notice, in writing, to the Company of such Holder's intention to effect such transfer.
- 2.13 <u>Termination of Registration Rights</u>. The right of any Holder to request registration or inclusion of Registrable Securities in any registration pursuant to Subsections 2.1 or 2.2 shall terminate upon the earliest to occur of:
  - (a) the closing of a Deemed Liquidation Event, as such term is defined in the Certificate of Incorporation;
- (b) such time as Rule 144 or another similar exemption under the Securities Act is available for the sale of all of such Holder's shares without limitation during a three (3)-month period without registration; and
  - (c) the third anniversary of the IPO.
  - 3. Information and Observer Rights.
- 3.1 <u>Delivery of Financial Statements</u>. The Company shall deliver to each Investor, and only to Major Investors in the case of <u>Subsection</u> <u>3.1(c)</u> below, in each case that the Board has reasonably determined not to be a Competitor:
- (a) as soon as practicable, but in any event within one hundred twenty (120) days after the end of each fiscal year of the Company (i) a balance sheet as of the end of such year, (ii) statements of income and of cash flows for such year, and (iii) a statement of stockholders' equity as of the end of such year, all such financial statements reviewed by independent public accountants of regionally recognized standing selected by the Company;

(b) as soon as practicable, but in any event within forty-five (45) days after the end of each quarter of each fiscal year of the Company, unaudited statements of income and cash flows for such fiscal quarter, and an unaudited balance sheet and a statement of stockholders' equity as of the end of such fiscal quarter, all prepared in accordance with GAAP (except that such financial statements may (i) be subject to normal year-end audit adjustments; and (ii) not contain all notes thereto that may be required in accordance with GAAP);

(c) as soon as practicable, but in any event within two (2) weeks following the approval of the Board, including the vote of at least a majority of the Preferred Directors then seated, a budget and business plan for the next fiscal year, including balance sheets, income statements, and statements of cash flow and, promptly after prepared, any other budgets or revised budgets prepared by the Company (such budget and business plan is collectively referred to herein as the "Budget"); provided, however, that the Budget may be amended at any time with the approval of the Board, including the vote of at least a majority of the Preferred Directors then seated; and

(d) such other information relating to the financial condition, business, prospects, or corporate affairs of the Company as any Investor may from time to time reasonably request; provided, however, that the Company shall not be obligated under this Subsection 3.1(d) to provide information (i) that the Company reasonably determines in good faith to be a trade secret or confidential information (unless covered by an enforceable confidentiality agreement, in a form acceptable to the Company); or (ii) the disclosure of which would adversely affect the attorney-client privilege between the Company and its counsel. If, for any period, the Company has any subsidiary whose accounts are consolidated with those of the Company, then in respect of such period the financial statements delivered pursuant to the foregoing sections shall be the consolidated and consolidating financial statements of the Company and all such consolidated subsidiaries.

(e) Notwithstanding anything else in this <u>Subsection 3.1</u> to the contrary, the Company may cease providing the information set forth in this <u>Subsection 3.1</u> during the period starting with the date sixty (60) days before the Company's good-faith estimate of the date of filing of a registration statement if it reasonably concludes it must do so to comply with the SEC rules applicable to such registration statement and related offering; <u>provided</u> that the Company's covenants under this <u>Subsection 3.1</u> shall be reinstated at such time as the Company is no longer actively employing its commercially reasonable efforts to cause such registration statement to become effective.

3.2 <u>Inspection(a)</u>. The Company shall permit each Investor (<u>provided</u> that the Board has not reasonably determined that such Investor is a Competitor), at such Investor's expense, to visit and inspect the Company's properties; examine its books of account and records; and discuss the Company's affairs, finances, and accounts with its officers, during normal business hours of the Company as may be reasonably requested by the Investor; <u>provided</u>, <u>however</u>, that the Company shall not be obligated pursuant to this <u>Subsection 3.2</u> to provide access to any information that it reasonably and in good faith considers to be a trade secret or confidential information (unless covered by an enforceable confidentiality agreement, in form acceptable to the Company) or the disclosure of which would adversely affect the attorney-client privilege between the Company and its counsel.

- 3.3 Observer Rights(a). As long as Bayer owns not less than fifteen percent (15%) of the shares of Series B Preferred Stock it is purchasing under the Purchase Agreement (or an equivalent amount of Common Stock issued upon conversion thereof), the Company shall invite a representative of Bayer to attend all meetings of the Board in a nonvoting observer capacity and, in this respect, shall give such representative copies of all notices, minutes, consents, and other materials that it provides to its directors; provided, however, that such representative shall agree to hold in confidence all information so provided; and provided further, that the Company reserves the right to withhold any information and to exclude such representative from any meeting or portion thereof if access to such information or attendance at such meeting could adversely affect the attorney-client privilege between the Company and its counsel or result in disclosure of trade secrets or a conflict of interest, or as otherwise determined by the Board.
- 3.4 <u>Termination of Information and Observer Rights</u>. The covenants set forth in <u>Subsection 3.1</u>, <u>Subsection 3.2</u> and <u>Subsection 3.3</u> shall terminate and be of no further force or effect (i) immediately before the consummation of the IPO or (ii) upon a Deemed Liquidation Event, as such term is defined in the Certificate of Incorporation, whichever event occurs first.
- 3.5 <u>Confidentiality(a)</u>. Each Investor agrees that such Investor will keep confidential and will not disclose, divulge, or use for any purpose (other than to monitor its investment in the Company) any confidential information obtained from the Company pursuant to the terms of this Agreement (including notice of the Company's intention to file a registration statement), unless such confidential information (a) is known or becomes known to the public in general (other than as a result of a breach of this <u>Subsection 3.5</u> by such Investor), (b) is or has been independently developed or conceived by such Investor without use of the Company's confidential information, or (c) is or has been made known or disclosed to such Investor by a third party without a breach of any obligation of confidentiality such third party may have to the Company; <u>provided</u>, <u>however</u>, that an Investor may disclose confidential information (i) to its attorneys, accountants, consultants, and other professionals to the extent necessary to obtain their services in connection with monitoring its investment in the Company; (ii) to any prospective purchaser of any Registrable Securities from such Investor, if such prospective purchaser agrees to be bound by the provisions of this <u>Subsection 3.5</u>; (iii) to any Affiliate, partner, member, stockholder, or wholly owned subsidiary of such Investor in the ordinary course of business, <u>provided</u> that such Investor informs such Person that such information is confidential and directs such Person to maintain the confidentiality of such information; or (iv) as may otherwise be required by law, <u>provided</u> that, to the extent permitted by applicable law, the Investor promptly notifies the Company of such disclosure and takes reasonable steps to minimize the extent of any such required disclosure. Notwithstanding the foregoing, Bayer (i) acknowledges that certain of its Affiliates may be Competitors and (ii) agrees that it shall not disclose any of the Company's confidential information to any of Bayer's

3.6 <u>Thiel Observer</u>. The Company shall permit a representative of The Thiel Foundation to attend each meeting of the Board in accordance with, and subject to, the provisions and limitations contained in the Research Grant and License Agreement, dated as of September 23, 2016, by between The Thiel Foundation and the Company.

## 4. Rights to Future Stock Issuances.

4.1 Right of First Offer(a). Subject to the terms and conditions of this Subsection 4.1 and applicable securities laws, if the Company proposes to offer or sell any New Securities, the Company shall first offer such New Securities to each Major Investor as long as such Major Investor is an "accredited investor" (as such term is defined under the Securities Act). A Major Investor shall be entitled to apportion the right of first offer hereby granted to it in such proportions as it deems appropriate, among (i) itself, (ii) its Affiliates, and (iii) its beneficial interest holders, such as limited partners, members or any other Person having "beneficial ownership," as such term is defined in Rule 13d-3 promulgated under the Exchange Act, of such Major Investor ("Investor Beneficial Owners"); provided that each such Affiliate or Investor Beneficial Owner (x) is not a Competitor or FOIA Party, unless such party's purchase of New Securities is otherwise expressly consented to by the Board, (y) agrees to enter into this Agreement and each of the Third Amended and Restated Voting Agreement (the "Voting Agreement") and Second Amended and Restated Right of First Refusal and Co-Sale Agreement (the "ROFR Agreement") of even date herewith among the Company, the Investors and the other parties named therein, as an "Investor" under each such agreement (provided that any Competitor or FOIA Party shall not be entitled to any rights as a Major Investor under Subsections 3.1, 3.2 and 4.1 hereof), and (z) agrees to purchase at least such number of New Securities as are allocable hereunder to the Major Investor holding the fewest number of Preferred Stock and any other Derivative Securities then held by such Major Investor.

(b) The Company shall give notice (the "Offer Notice") to each Major Investor, stating (i) its bona fide intention to offer such New Securities, (ii) the number of such New Securities to be offered, and (iii) the price and terms, if any, upon which it proposes to offer such New Securities. If the consideration to be paid for the New Securities is not cash, the fair market value of the consideration shall be determined in good faith by the Board and a reasonably detailed explanation of the Board's determination of such value shall be included in the Offer Notice. All Major Investors electing to participate in the offering of such New Securities shall pay the cash equivalent thereof as so determined.

(c) By notification to the Company within twenty (20) days after the Offer Notice is given, each Major Investor may elect to purchase or otherwise acquire, at the price and on the terms specified in the Offer Notice, up to that portion of such New Securities which equals the proportion that the Common Stock then held by such Major Investor (including all shares of Common Stock then issuable (directly or indirectly) upon conversion and/or exercise, as applicable, of the Preferred Stock and any other Derivative Securities then held by such Major Investor) bears to the total Common Stock of the Company then outstanding (assuming full conversion and/or exercise, as applicable, of all Preferred Stock and any other Derivative Securities then outstanding). At the expiration of such twenty (20) day period, the Company shall promptly notify each Major Investor that elects to purchase or acquire all the shares available to it (each, a "Fully Exercising Investor") of any other Major Investor's failure to do likewise. During the ten (10) day period commencing after the Company has given such notice, each Fully Exercising Investor may, by giving notice to the Company, elect to purchase or acquire, in addition to the number of shares specified above, up to that portion of the New Securities for which Major Investors were entitled to subscribe but that were not subscribed for by the Major Investors which is equal to the proportion that the Common Stock issued and held, or issuable (directly or indirectly) upon conversion and/or exercise, as applicable, of Preferred Stock and any other Derivative Securities then held by such Fully Exercising Investor bears to the Common Stock issued and held, or issuable (directly or indirectly) upon conversion and/or exercise, as applicable, of the Preferred Stock and any other Derivative Securities then held, by all Fully Exercising Investors who wish to purchase such unsubscribed shares. The closing of any sale pursuant to this <u>Subsection 4.1(b)</u> shall occur within the later of 90 days of

(d) If all New Securities referred to in the Offer Notice are not elected to be purchased or acquired as provided in <u>Subsection 4.1(b)</u>, the Company may, during the 90 day period following the expiration of the periods provided in <u>Subsection 4.1(b)</u>, offer and sell the remaining unsubscribed portion of such New Securities to any Person or Persons at a price not less than, and upon terms no more favorable to the offeree than, those specified in the Offer Notice. If the Company does not enter into an agreement for the sale of the New Securities within such period, or if such agreement is not consummated within thirty (30) days of the execution thereof, the right provided hereunder shall be deemed to be revived and such New Securities shall not be offered unless first reoffered to the Major Investors in accordance with this <u>Subsection 4.1</u>.

(e) The right of first offer in this <u>Subsection 4.1</u> shall not be applicable to (i) Exempted Securities (as defined in the Certificate of Incorporation); (ii) shares of Preferred Stock issued pursuant to the Purchase Agreement; or (iii) shares of Common Stock issued in the IPO.

4.2 <u>Termination</u>. The covenants set forth in <u>Subsection 4.1</u> shall terminate and be of no further force or effect (i) immediately before the consummation of the IPO or (ii) upon a Deemed Liquidation Event, as such term is defined in the Certificate of Incorporation, whichever event occurs first.

### 5. Additional Covenants.

5.1 <u>Insurance</u>. The Company shall use commercially reasonable efforts to maintain, until the Board (including the approval of at least three (3) Preferred Directors) determines otherwise, (a) a Directors and Officers liability insurance policy in an amount satisfactory to the Board and (b) insurance policies in such amounts and covering such risks as the Board reasonably believes to be adequate for the conduct of the Company's business (subject to reasonable deductibles) to allow it to replace any of its properties that might be damaged or destroyed and in all other respects customary for similarly situated companies. Additionally, the Company shall use commercially reasonable efforts to obtain, within ninety (90) days following the Closing (as defined in the Purchase Agreement), and thereafter shall use commercially reasonable efforts to maintain, until the Board determines otherwise, term "key-person" insurance on Richard Andrews in the amount of \$3,000,000 (or such lesser amount as is approved by the Board); provided that the Company shall only be obligated to obtain such policy if the Board (including the approval of at least three (3) Preferred Directors) determines that the cost, coverage and other terms and conditions of such policy are commercially reasonable and economically justifiable for the Company.

5.2 Employee Stock. Unless otherwise approved by the Board (including the approval of at least three (3) Preferred Directors), all future employees and consultants of the Company who purchase, receive options to purchase, or receive awards of shares of the Company's capital stock after the date hereof shall be required to execute restricted stock or option agreements, as applicable, providing for (i) vesting of shares over a four (4) year period, with the first twenty-five percent (25%) of such shares vesting following twelve (12) months of continued employment or service, and the remaining shares vesting in equal monthly installments over the following thirty-six (36) months and (ii) a market stand-off provision substantially similar to that in Subsection 2.11. In addition, unless otherwise approved by the Board (including the approval of at least three (3) Preferred Directors), the Company shall retain a "right of first refusal" on employee transfers until the Company's IPO and shall have the right to repurchase unvested shares at cost upon termination of employment of a holder of restricted stock.

5.3 <u>Termination of Covenants</u>. The covenants set forth in this <u>Section 5</u> shall terminate and be of no further force or effect (i) immediately before the consummation of the IPO or (ii) upon a Deemed Liquidation Event, as such term is defined in the Certificate of Incorporation, whichever event occurs first.

5.4 <u>Successor Indemnification</u>. If the Company or any of its successors or assignees consolidates with or merges into any other Person and is not the continuing or surviving corporation or entity of such consolidation or merger, then to the extent necessary, proper provision shall be made so that the successors and assignees of the Company assume the obligations of the Company with respect to indemnification of members of the Board as in effect immediately before such transaction, whether such obligations are contained in the Company's Bylaws, its Certificate of Incorporation, or elsewhere, as the case may be.

5.5 Indemnification Matters. The Company hereby acknowledges that one (1) or more of the directors nominated to serve on the Board by the Investors (each a "Fund Director" and collectively, the "Fund Directors") may have certain rights to indemnification, advancement of expenses and/or insurance provided by one (1) or more of the Investors and certain of their affiliates (collectively, the "Fund Indemnitors"). The Company hereby agrees for matters falling within the scope of such Fund Director's directorship of the Company (a) that it is the indemnitor of first resort (i.e., its obligations to any such Fund Director are primary and any obligation of the Fund Indemnitors to advance expenses or to provide indemnification for the same expenses or liabilities incurred by such Fund Director are secondary), (b) that it shall be required to advance the full amount of expenses incurred by such Fund Director and shall be liable for the full amount of all expenses, judgments, penalties, fines and amounts paid in settlement by or on behalf of any such Fund Director to the extent legally permitted and as required by the Company's Certificate of Incorporation or Bylaws of the Company (or any agreement between the Company and such Fund Director), without regard to any rights such Fund Director may have against the Fund Indemnitors, and, (c) that it irrevocably waives, relinquishes and releases the Fund Indemnitors from any and all claims against the Fund Indemnitors for contribution, subrogation or any other recovery of any kind in respect thereof. The Company further agrees that no advancement or payment by the Fund Indemnitors on behalf of any such Fund Director with respect to any claim for which such Fund Director has sought indemnification from the Company shall affect the foregoing and the Fund Indemnitors shall have a right of contribution and/or be subrogated to the extent of such advancement or payment to all of the rights of recovery of such Fund Director against the Company. Notwithstanding the foregoing, if it is found that any Fund Director committed gross negligence or willful misconduct, or breached his or her fiduciary duties, any amounts advanced in respect of such matter shall be reimbursed to the Company.

5.6 Right to Conduct Activities. The Company hereby agrees and acknowledges that each of Bayer HealthCare LLC, Bios Partners, Connecticut Innovations, Incorporated and KdT Venture Fund I LP (together with their respective Affiliates, collectively, the "Investment Funds") is a professional investment fund, and The Thiel Foundation is a private foundation, and as such each of them invests in numerous portfolio companies and research projects, some of which may be deemed competitive with the Company's business (as currently conducted or as currently proposed to be conducted). The Company hereby agrees that, to the extent permitted under applicable law, neither any Investment Fund nor The Thiel Foundation shall be liable to the Company for any claim arising out of, or based upon, (i) the investment by such Investment Fund or The Thiel Foundation in any entity competitive with the Company, or (ii) actions taken by any partner, officer or other representative of an Investment Fund or The Thiel Foundation to assist any such competitive company, whether or not such action was taken as a member of the board of directors of such competitive company or otherwise, and whether or not such action has a detrimental effect on the Company; provided, however, that the foregoing shall not relieve (x) any of the Investors from liability associated with the unauthorized disclosure of the Company's confidential information obtained pursuant to this Agreement, or (y) any director or officer of the Company from any liability associated with his or her fiduciary duties to the Company.

5.7 Qualified Small Business Stock. The Company shall use commercially reasonable efforts to cause the shares of Preferred Stock, as well as any shares into which such shares are converted, within the meaning of Section 1202(f) of the Internal Revenue Code (the "Code"), to constitute "qualified small business stock" as defined in Section 1202(c) of the Code; <u>provided, however</u>, that such requirement shall not be applicable if the Board, including at least three (3) Preferred Directors, determines, in its good-faith business judgment, that such qualification is inconsistent with the best interests of the Company. The Company shall submit to its stockholders (including the Investors) and to the Internal Revenue Service any reports that may be required under Section 1202(d)(1)(C) of the Code and the regulations promulgated thereunder. In addition, within twenty (20) business days after any Investor's written request therefor, the Company shall, at its option, either (i) deliver to such Investor a written statement indicating whether (and what portion of) such Investor's interest in the Company constitutes "qualified small business stock" as defined in Section 1202(c) of the Code or (ii) deliver to such Investor's interest in the Company constitutes "qualified small business stock" as defined in Section 1202(c) of the Code.

- 5.8 <u>Matters Requiring Investor Director Approval</u>. So long as the holders of Series B Preferred Stock are entitled to elect one or more Series B Directors, the Company hereby covenants and agrees with each of the Investors that it shall not, and shall not cause or permit any subsidiary of the Company, as applicable, to, without approval of the Board, which approval must include the affirmative vote of each Series B Director:
- (a) make, or permit any subsidiary to make, any loan or advance to, or own any stock or other securities of, any subsidiary or other corporation, partnership, or other entity unless it is wholly owned by the Company;
- (b) make, or permit any subsidiary to make, any loan or advance to any Person, including, without limitation, any employee or director of the Company or any subsidiary, except advances and similar expenditures in the ordinary course of business of the Company or such subsidiary, as applicable, or under the terms of an employee stock or option plan approved by the Board;
- (c) guarantee, directly or indirectly, or permit any subsidiary to guarantee, directly or indirectly, any indebtedness except for trade accounts of the Company or any subsidiary arising in the ordinary course of business of the Company or such subsidiary, as applicable,;
  - (d) make any investment inconsistent with any investment policy approved by the Board;
- (e) enter into or be a party to any transaction with any director, officer or employee of the Company or any "associate" (as defined in Rule 12b-2 promulgated under the Exchange Act) of any such Person, other than employee compensation arrangements entered into in the ordinary course of business of the Company or such subsidiary, as applicable, consistent with past practices;
- (f) approve, amend or abandon the annual operating budget or business plan of the Company or make any expenditure that is not contemplated by any then-applicable operating budget of the Company or any subsidiary, as applicable; or
- (g) Adopt any accounting rules, practices and policies other than as required by GAAP or maintain or prepare books, records or financial statements in any manner materially inconsistent therewith.
- 5.9 <u>Board Matters</u>. Unless otherwise determined by the vote of a majority of the directors then in office, the Board shall meet at least quarterly in accordance with an agreed-upon schedule. The Company shall reimburse the nonemployee directors for all reasonable out-of-pocket travel expenses incurred (consistent with the Company's travel policy) in connection with attending meetings of the Board. Each committee of the Board shall include the Series B Directors and one (1) of the other Preferred Directors.
- 5.10 Expenses of Counsel. In the event of a transaction which is a Sale of the Company (as defined in the Voting Agreement), the reasonable fees and disbursements (not to exceed \$50,000) of one (1) counsel for the Major Investors ("Investor Counsel"), in their capacities as stockholders, shall be borne and paid by the Company. Promptly after receiving Board approval for a transaction which, if consummated would constitute a Sale of the Company, the Company shall use commercially reasonable efforts to obtain the ability to share with the Investor Counsel (and such counsel's clients) and to share, subject to all applicable confidentiality requirement and agreements, the confidential information (including, without limitation, letters of intent, term sheets and transaction documents) memorializing any of the transactions which, individually or when aggregated with others would constitute the Sale of the Company. In the event that Investor Counsel deems it appropriate, in its reasonable discretion, to enter into a joint defense agreement or other arrangement to enhance the ability of the parties to protect their communications and other reviewed materials under the attorney client privilege, the Company shall, and shall direct its counsel to, execute and deliver to Investor Counsel and its clients such an agreement in form and substance reasonably acceptable to the Company and to Investor Counsel.

### 6. Miscellaneous.

6.1 Successors and Assigns. The rights under this Agreement may be assigned (but only with all related obligations) by a Holder to a transferee of Registrable Securities that (i) is an Affiliate of a Holder; (ii) is a Holder's Immediate Family Member or trust for the benefit of an individual Holder or one (1) or more of such Holder's Immediate Family Members; or (iii) after such transfer, holds at least 50,000 shares of Registrable Securities (subject to appropriate adjustment for stock splits, stock dividends, combinations, and other recapitalizations); provided, however, that (x) the Company is, within a reasonable time after such transfer, furnished with written notice of the name and address of such transferee and the Registrable Securities with respect to which such rights are being transferred; and (y) such transferee agrees in a written instrument delivered to the Company to be bound by and subject to the terms and conditions of this Agreement, including the provisions of Subsection 2.11. For the purposes of determining the number of shares of Registrable Securities held by a transferee, the holdings of a transferee (1) that is an Affiliate or stockholder of a Holder; (2) who is a Holder's Immediate Family Member; or (3) that is a trust for the benefit of an individual Holder or such Holder's Immediate Family Member shall be aggregated together and with those of the transferring Holder; provided further that all transferees who would not qualify individually for assignment of rights shall, as a condition to the applicable transfer, establish a single attorney-in-fact for the purpose of exercising any rights, receiving notices, or taking any action under this Agreement. The terms and conditions of this Agreement inure to the benefit of and are binding upon the respective successors and permitted assignees of the parties. Nothing in this Agreement, express or implied, is intended to confer upon any party other than the parties hereto or their respective successors and permitted assignees any rights, remedi

6.2 <u>Governing Law</u>. This Agreement shall be governed by the internal law of the State of Delaware, without giving effect to principles of conflicts of law.

6.3 <u>Counterparts</u>. This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Counterparts may be delivered via facsimile, email (including pdf or any electronic signature complying with the U.S. federal ESIGN Act of 2000, e.g., www.docusign.com) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes.

6.4 <u>Titles and Subtitles</u>. The titles and subtitles used in this Agreement are for convenience only and are not to be considered in construing or interpreting this Agreement.

### 6.5 Notices.

(a) All notices and other communications given or made pursuant to this Agreement shall be in writing and shall be deemed effectively given upon the earlier of actual receipt or (a) personal delivery to the party to be notified, (b) when sent, if sent by email or facsimile during normal business hours of the recipient, and if not sent during normal business hours, then on the recipient's next business day, (c) five (5) days after having been sent by registered or certified mail, return receipt requested, postage prepaid, or (d) one (1) business day after the business day of deposit with a nationally recognized overnight courier, freight prepaid, specifying next-business day delivery, with written verification of receipt. All communications shall be sent to the respective parties at their addresses as set forth on Schedule A hereto, or to such email address, facsimile number, or address as subsequently modified by written notice given in accordance with this Subsection 6.5. If notice is given to the Company, it shall be sent to 21 Business Park Drive, Suite 6, Branford, CT 06405, Attention: Chief Executive officer, and a copy (which shall not constitute notice) shall also be sent to Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C., One Financial Center, Boston, MA 02111, Attention: William C. Hicks. If notice is given to the Bayer, it shall be sent to, Attention:, and a copy (which shall not constitute notice) shall also be sent to (i) Bayer U.S. LLC, Attention: and (ii) Orrick Herrington & Sutcliffe LLP, 1000 Marsh Road, Menlo Park, CA 94025, Attention: Matthew Gemello, Ramy Shweiky, Email: mgemello@orrick.com, rshweiky@orrick.com; and if notice is given to the Investors, it shall be sent to the addresses as set forth on Schedule A hereto, or to such email address, facsimile number, or address as subsequently modified by written notice given in accordance with this Subsection 6.5.

(b) <u>Consent to Electronic Notice</u>. Each Investor consents to the delivery of any stockholder notice pursuant to the Delaware General Corporation Law (the "**DGCL**"), as amended or superseded from time to time, by electronic transmission pursuant to Section 232 of the DGCL (or any successor thereto) at the email address or the facsimile number as on the books of the Company. Each Investor agrees to promptly notify the Company of any change in such stockholder's email address, and that failure to do so shall not affect the foregoing.

6.6 Amendments and Waivers. Any term of this Agreement may be amended, modified or terminated and the observance of any term of this Agreement may be waived (either generally or in a particular instance, and either retroactively or prospectively) only with the written consent of the Company and the holders of at least 66.67% of the Registrable Securities then outstanding; provided that the Company may in its sole discretion waive compliance with Subsection 2.12(c); and provided further that any provision hereof may be waived by any waiving party on such party's own behalf, without the consent of any other party. Notwithstanding the foregoing, (a) this Agreement may not be amended, modified or terminated and the observance of any term hereof may not be waived with respect to any Investor without the written consent of such Investor, unless such amendment, modification, termination, or waiver applies to all Investors in the same fashion (it being agreed that a waiver of the provisions of Section 4 with respect to a particular transaction shall be deemed to apply to all Investors in the same fashion if such waiver does so by its terms, notwithstanding the fact that certain Investors may nonetheless, by agreement with the Company, purchase securities in such transaction) and (b) Subsections 3.1 and 3.2, Section 4 and any other section of this Agreement applicable to the Major Investors (including this clause (b) of this Subsection 6.6) may not be amended, modified, terminated or waived without the written consent of the holders of at least a majority of the Registrable Securities then outstanding and held by the Major Investors. Notwithstanding the foregoing, Schedule A hereto may be amended by the Company from time to time to add transferees of any Registrable Securities in compliance with the terms of this Agreement without the consent of the other parties; and Schedule A hereto may also be amended by the Company after the date of this Agreement without the consent of the other parties to add information regarding any additional Investor who becomes a party to this Agreement in accordance with Subsection 6.9. The Company shall give prompt notice of any amendment, modification or termination hereof or waiver hereunder to any party hereto that did not consent in writing to such amendment, modification, termination, or waiver. Any amendment, modification, termination, or waiver effected in accordance with this Subsection 6.6 shall be binding on all parties hereto, regardless of whether any such party has consented thereto. No waivers of or exceptions to any term, condition, or provision of this Agreement, in any one (1) or more instances, shall be deemed to be or construed as a further or continuing waiver of any such term, condition, or provision.

- 6.7 <u>Severability</u>. In case any one (1) or more of the provisions contained in this Agreement is for any reason held to be invalid, illegal or unenforceable in any respect, such invalidity, illegality, or unenforceability shall not affect any other provision of this Agreement, and such invalid, illegal, or unenforceable provision shall be reformed and construed so that it will be valid, legal, and enforceable to the maximum extent permitted by law.
- 6.8 <u>Aggregation of Stock</u>. All shares of Registrable Securities held or acquired by Affiliates shall be aggregated together for the purpose of determining the availability of any rights under this Agreement and such Affiliated persons may apportion such rights as among themselves in any manner they deem appropriate.
- 6.9 <u>Additional Investors</u>. Notwithstanding anything to the contrary contained herein, if the Company issues additional shares of Preferred Stock after the date hereof, any purchaser of such shares of Preferred Stock may become a party to this Agreement by executing and delivering an additional counterpart signature page to this Agreement, and thereafter shall be deemed an "Investor" for all purposes hereunder. No action or consent by the Investors shall be required for such joinder to this Agreement by such additional Investor, so long as such additional Investor has agreed in writing to be bound by all of the obligations as an "Investor" hereunder.
- 6.10 Entire Agreement. This Agreement (including any Schedules and Exhibits hereto) constitutes the full and entire understanding and agreement among the parties with respect to the subject matter hereof and supersedes all prior communications, representations, understandings and agreements of the parties with respect to the subject matter hereof including, without limitation, the Prior Agreement. The Prior Agreement is hereby amended in its entirety and restated herein. All provisions of, rights granted under and covenants made in the Prior Agreement are hereby waived, released and superseded in their entirety and shall have no further force or effect.

6.11 <u>Dispute Resolution</u>. The parties (a) hereby irrevocably and unconditionally submit to the jurisdiction of the state courts of Connecticut and to the jurisdiction of the United States District Court for the District of Connecticut, in each case, located in New Haven County, Connecticut, for the purpose of any suit, action or other proceeding arising out of or based upon this Agreement, (b) agree not to commence any suit, action or other proceeding arising out of or based upon this Agreement except in the state courts of Connecticut or the United States District Court for the District of Connecticut, in each case, located in New Haven County, Connecticut and (c) hereby waive, and agree not to assert, by way of motion, as a defense, or otherwise, in any such suit, action or proceeding, any claim that it is not subject personally to the jurisdiction of the above-named courts, that its property is exempt or immune from attachment or execution, that the suit, action or proceeding is brought in an inconvenient forum, that the venue of the suit, action or proceeding is improper or that this Agreement or the subject matter hereof may not be enforced in or by such court.

WAIVER OF JURY TRIAL: EACH PARTY HEREBY WAIVES ITS RIGHTS TO A JURY TRIAL OF ANY CLAIM OR CAUSE OF ACTION BASED UPON OR ARISING OUT OF THIS AGREEMENT, THE OTHER TRANSACTION DOCUMENTS (AS DEFINED IN THE PURCHASE AGREEMENT), THE SECURITIES (AS DEFINED IN THE PURCHASE AGREEMENT) OR THE SUBJECT MATTER HEREOF OR THEREOF. THE SCOPE OF THIS WAIVER IS INTENDED TO BE ALL-ENCOMPASSING OF ANY AND ALL DISPUTES THAT MAY BE FILED IN ANY COURT AND THAT RELATE TO THE SUBJECT MATTER OF THIS TRANSACTION, INCLUDING, WITHOUT LIMITATION, CONTRACT CLAIMS, TORT CLAIMS (INCLUDING NEGLIGENCE), BREACH OF DUTY CLAIMS, AND ALL OTHER COMMON LAW AND STATUTORY CLAIMS. THIS SECTION HAS BEEN FULLY DISCUSSED BY EACH OF THE PARTIES HERETO AND THESE PROVISIONS WILL NOT BE SUBJECT TO ANY EXCEPTIONS. EACH PARTY HERETO HEREBY FURTHER WARRANTS AND REPRESENTS THAT SUCH PARTY HAS REVIEWED THIS WAIVER WITH ITS LEGAL COUNSEL, AND THAT SUCH PARTY KNOWINGLY AND VOLUNTARILY WAIVES ITS JURY TRIAL RIGHTS FOLLOWING CONSULTATION WITH LEGAL COUNSEL

Each of the parties to this Agreement consents to personal jurisdiction for any equitable action sought in the U.S. District Court for the District of Connecticut or any court of the State of Connecticut having subject matter jurisdiction and located in New Haven County, Connecticut.

6.12 <u>Delays or Omissions</u>. No delay or omission to exercise any right, power, or remedy accruing to any party under this Agreement, upon any breach or default of any other party under this Agreement, shall impair any such right, power, or remedy of such nonbreaching or nondefaulting party, nor shall it be construed to be a waiver of or acquiescence to any such breach or default, or to any similar breach or default thereafter occurring, nor shall any waiver of any single breach or default be deemed a waiver of any other breach or default theretofore or thereafter occurring. All remedies, whether under this Agreement or by law or otherwise afforded to any party, shall be cumulative and not alternative.

[Signature Pages Follow]

IN WITNESS WHEREOF, the parties have executed this Second Amended and Restated Investors' Rights Agreement as of the date first written above.

# **COMPANY:**

Azitra Inc

By: /s/ Richard Andrews

Name: Richard Andrews
Title: Chief Executive Officer

	INVESTORS:	
If an Entity:	If an Individual:	
PRINT NAME OF ENTITY ABOVE		
By: Name: Title:	Print Name:	

#### EXECUTIVE EMPLOYMENT AGREEMENT

This Executive Employment Agreement (the "Agreement"), is made and entered into this 22nd day of April, 2021 (the "Effective Date"), and is by and between Azitra Inc. ("Company"), and Francisco Salva ("Executive").

WHEREAS, Company wishes to employ Executive to serve as its President and Chief Executive Officer;

WHEREAS, Executive represents that Executive possesses the necessary skills to perform the duties of this position and that Executive has no obligation to any other person or entity which would prevent, limit or interfere with Executive's ability to do so; and

WHEREAS, Executive and Company desire to enter into a formal Executive Employment Agreement to assure the harmonious performance of the affairs of Company.

NOW, THEREFORE, in consideration of the mutual promises, terms, provisions, and conditions contained herein, the parties agree as follows:

1. Title and Duties. Subject to the terms and conditions of this Agreement, Executive's position with Company shall be President and Chief Executive Officer reporting to Company's Board of Directors (the "Board"). Executive will be elected a director of the Company promptly after the Commencement Date and shall remain a director for the duration of the Term. Executive accepts such employment upon the terms and conditions set forth herein, and agrees to perform to the best of Executive's ability the duties normally associated with such position and as reasonably determined by the Board in its sole discretion. While serving hereunder, Executive shall devote substantially all of Executive's business time and energies to the business and affairs of Company, provided that, so long as such activities do not materially interfere with Executive's performance of Executive's duties hereunder, nothing contained in Agreement shall prevent or limit: (a) Executive's right to manage Executive's personal investments or personal financial or legal matters including, without limitation, the right to make passive investments in the securities of (i) any entity which Executive does not control, directly or indirectly, and which does not compete with Company, or (ii) any publicly held entity, so long as Executive's aggregate direct and indirect interest does not exceed two percent (2%) of the issued and outstanding securities of any class of securities of such publicly held entity; (b) Executive's right to engage in the business and professional activities set forth on Exhibit A hereto; (c) subject to prior approval of the Board, Executive's right to serve as a member of the board of directors of any entity that does not compete with the Company; or (d) Executive's participation in civic, political and charitable activities, including, subject to prior approval of the Board, as a member of a board of a civic, political or charitable organization.

# 2. Term; Termination.

- (a) <u>Term</u>. Subject to the terms hereof, Executive's employment hereunder shall commence on April 30, 2021 (the "Commencement Date") and shall continue until terminated hereunder by either party (such term of employment shall be referred to herein as the "Term").
- (b) <u>Termination</u>. Notwithstanding anything else contained in this Agreement, Executive's employment hereunder shall terminate upon the earliest to occur of the following:
  - (i) Death. Immediately upon Executive's death;
  - (ii) Termination by the Company.
  - (A) <u>Termination Due to Disability</u>. Notwithstanding anything else contained in this Agreement, Company may terminate Executive's employment due to Executive's Disability by written notice to Executive that Executive's employment is being terminated as a result of Executive's Disability, which termination shall be effective on the date of such notice or such later date as specified in writing by Company. For the purposes of this Agreement, "Disability" shall mean Executive's incapacity or inability to perform Executive's duties and responsibilities as contemplated herein for one hundred twenty (120) days or more within any one (1) year period (cumulative or consecutive), because Executive's physical or mental health has become so impaired as to make it impossible or impractical for Executive to perform the duties and responsibilities contemplated hereunder with or without accommodation. Executive's physical or mental health shall be determined by a medical expert appointed by mutual agreement between Company and Executive following such expert's examination of Executive. Executive hereby consents to such examination and consultation regarding Executive's health and ability to perform as aforesaid.
  - (B) For Cause. Company may terminate Executive's employment for Cause by written notice by Company to Executive that Executive's employment is being terminated for Cause, which termination shall be effective pursuant to the process set forth below; provided that if Executive has cured the circumstances giving rise to Cause (as such cure right may be applicable pursuant to the terms and conditions set forth below) then such termination shall not be effective. For the purposes of this Agreement, "Cause" shall mean: (1) fraud, embezzlement, or illegal misconduct in connection with Executive's duties under this Agreement; (2) conviction of a felony involving fraud, dishonesty or breach of trust; (3) willful misconduct or gross negligence in the performance of the duties delegated to Executive; (4) material breach of this Agreement; or (5) material breach of any non-competition, non-solicitation, non-disclosure, and intellectual property assignment agreement between Executive and Company; provided that "Cause" shall not be deemed to have occurred pursuant to this subsection (B) unless: (x) the Company notifies Executive in writing of the first occurrence of the Cause condition specifying in reasonable detail the particulars of such ground and that Company intends to terminate Executive's employment hereunder for such ground, and if such ground is curable, Executive has failed to cure such ground within a period of thirty (30) days from the date of such written notice (the "Cause Cure Period"); and (y) the Company terminates Executive's employment within sixty (60) days following conclusion of the Cause Cure Period. For purposes of clarification, the above-listed conditions shall apply separately to each occurrence of Cause and failure to adhere to such conditions in the event of Cause shall not disqualify the Company from asserting Cause for any subsequent occurrence of Cause.

- (C) <u>Without Cause</u>. Company may terminate Executive's employment without Cause, by written notice by Company to Executive that Executive's employment is being terminated without Cause, which termination shall be effective thirty (30) days after the date of such notice.
- (iii) <u>Termination by Executive</u>. Notwithstanding anything else contained in this Agreement, Executive may terminate Executive's employment hereunder as follows:
  - (A) For Good Reason. Executive may terminate Executive's employment for Good Reason by written notice by Executive to Company that Executive is terminating Executive's employment for Good Reason, which termination shall be effective pursuant to the process set forth below; provided that if Company has cured the circumstances giving rise to Good Reason then such termination shall not be effective. For purposes of this Agreement, "Good Reason" shall mean: (A) a material reduction in Executive's then-current Base Salary (except for an across the board salary reduction based on the Company's financial performance similarly affecting all or substantially all senior management employees of the Company); (B) a material diminution in Executive's authority, duties or responsibilities; (C) a material change in the geographic location at which the Executive provides services to the Company outside of Pennsylvania, Connecticut or a fifty (50) mile radius from the then-current location; or (D) any action or inaction by Company that constitutes a material breach of this Agreement; provided that "Good Reason" shall not be deemed to have occurred unless: (1) Executive notifies the Company in writing of the first occurrence of the Good Reason condition within thirty (30) days of such ground first occurring; (2) Executive cooperates in good faith with the Company's efforts to cure such ground for a period of thirty (30) days from the date of such written notice (the "Good Reason Cure Period"); and (3) notwithstanding such efforts, if the Good Reason condition exists, Executive terminates Executive's employment within sixty (60) days following conclusion of the Good Reason Cure Period. For purposes of clarification, the above-listed conditions shall apply separately to each occurrence of Good Reason and failure to adhere to such conditions in the event of Good Reason shall not disqualify Executive from asserting Good Reason for any subsequent occurrence of Good Reason.
  - (B) <u>Without Good Reason</u>. Executive may terminate Executive's employment without Good Reason by written notice by Executive to Company that Executive is terminating Executive's employment, which termination shall be effective sixty (60) days after the date of such notice.

# 3. Compensation.

- (a) <u>Base Salary</u>. While Executive is employed hereunder, Executive shall earn a base salary at the annual rate of four hundred twenty thousand dollars (\$420,000.00) (the "Base Salary"). The Base Salary will be subject to periodic review and increase at the Board's discretion. The Base Salary shall be payable in substantially equal periodic installments, at least on a monthly basis, in accordance with Company's payroll practices as in effect from time to time. Company shall deduct from each such installment all amounts required to be deducted or withheld under applicable law or under any employee benefit plan in which Executive participates.
- (b) Annual Bonus. Executive shall be eligible to receive an annual performance bonus (the "Annual Bonus") for all years in which Executive is employed by Company hereunder. The Annual Bonus potential shall be in an amount up to thirty-five percent (35%) of Executive's Base Salary. The amount of the Annual Bonus shall be based on factors such as Executive's work performance, Company's financial performance, Company's business forecasts, Company's determination of Executive's achievement of milestones for the applicable year, and economic conditions generally. The actual amount of the Annual Bonus shall be determined by the Board in its sole discretion. The Annual Bonus shall be paid to Executive in no event later than March 15th of the calendar year immediately following the calendar year to which it pertains. Subject to Section 4(b) hereof, Executive must be employed by Company on December 31st of the calendar year to which the Annual Bonus relates in order to be eligible for, and to be deemed as having earned, such Annual Bonus. Company shall deduct from the Annual Bonus all amounts required to be deducted or withheld under applicable law or under any employee benefit plan in which Executive participates. Any bonus for the fiscal year in which Executive's employment begins will be prorated, based on the number of days Executive is employed by the Company during that fiscal year.
- (c) Equity. Pursuant to the terms of Company's Stock Incentive Plan (the "Plan"), and subject to the approval of the Board promptly following the Commencement Date, Executive shall receive an option to purchase up to the equivalent of a maximum of 5% of Company common stock on a fullydiluted basis (the "Stock Option"), at a per share exercise price equal to the Fair Market Value (as defined in the Plan) of Company common stock on the date of grant, subject to the eligibility and vesting requirements of the Plan. 80% of the shares subject to the Stock Option shall be subject to standard timebased vesting (the "Time-Based Shares"). The remaining 20% of the shares subject to the Stock Option shall vest at the completion of the following clinical milestone: the first patient first dosed (FPFD) in the first-in-human clinical trial with ATR-12 (i.e., LEKTI-expressing S. epidermidis) or a substitute Live Biotherapeutic Product (LBP) if ATR-12 is not progressed. The determination of completion of the milestone shall be made in the reasonable judgment of the Board. The Stock Option shall be, to the maximum extent permissible, treated as an "incentive stock option" within the meaning of Section 422 of the Internal Revenue Code and the rules and regulations thereunder (collectively, the "Code"). The Stock Option shall be evidenced in writing by, and subject to the terms and conditions of the Plan and Company's standard form of stock option agreement, which agreement shall expire ten (10) years from the date of grant (except as otherwise provided in such agreement or the Plan). As more fully explained in the Plan and/or such stock agreement: (i) any unvested option shares shall be subject to forfeiture in the event of Executive's termination for any reason, other than as provided in Section 4(b) hereof; and (ii) twenty five percent (25%) of the Time-Based Shares shall vest on the first (1st) anniversary of the Commencement Date, the remaining seventy five percent (75%) of the Time-Based Shares shall vest in substantially equal monthly installments over the thirty-six (36) months following such first anniversary; provided that Executive remains employed by Company on the vesting date (except as otherwise provided in such agreement or the Plan, and subject to Section 4(b) hereof).

- (d) <u>Vacation and Fringe Benefits</u>. Executive will be entitled to four (4) weeks' vacation each calendar year, accruing in accordance with the vacation policies established by the Company from time to time. Executive shall be entitled to participate in all other fringe benefits provided to employees at the same level as Executive. Executive understands that, except when prohibited by applicable law, Company's benefit plans and fringe benefits, if any, may be amended by Company from time to time in its sole discretion.
- (e) Reimbursement of Expenses. Company shall reimburse Executive for all ordinary and reasonable out-of-pocket business expenses incurred by Executive in furtherance of Company's business in accordance with Company's policies with respect thereto as in effect from time to time. Executive must submit any request for reimbursement no later than ninety (90) days following the date that such business expense is incurred. All reimbursements provided under this Agreement shall be made or provided in accordance with the requirements of Section 409A ("Section 409A") of the Code and the rules and regulations thereunder, including, where applicable, the requirement that (i) any reimbursement is for expenses incurred during Executive's lifetime (or during a shorter period of time specified in this Agreement); (ii) the amount of expenses eligible for reimbursement during a calendar year may not affect the expenses eligible for reimbursement in any other calendar year; (iii) the reimbursement of an eligible expense shall be made no later than the last day of the calendar year following the year in which the expense is incurred; and (iv) the right to reimbursement or in kind benefits is not subject to liquidation or exchange for another benefit.
- (f) <u>Indemnification</u>. Executive shall be eligible for coverage under any applicable as may be available Company Directors' and Officers' ("D&O") insurance policies to the same extent and in the same manner to which Company's similarly situated executives are entitled to coverage under Company D&O insurance policies, subject to the terms and conditions of any such Company D&O insurance policies.

#### 4. Termination Payments; Severance Benefit.

(a) <u>Payment of Accrued Obligations</u>. Regardless of the reason for any employment termination hereunder, Company shall pay to Executive: (i) the portion of Executive's Base Salary that has accrued prior to any termination of Executive's employment and has not yet been paid; (ii) any unpaid Annual Bonus relating to the calendar year prior to the year in which Executive's employment terminates; (iii) the portion of Executive's vacation days, if any, that have accrued prior to any termination of Executive's employment and has not yet been used; and (iv) the amount of any expenses properly incurred by Executive on behalf of Company prior to any such termination and has not yet been reimbursed (together, the "Accrued Obligations") promptly following the effective date of termination, and otherwise within any timeframe required by law. Executive's entitlement to other compensation or benefits under any Company plan or policy shall be governed by and determined in accordance with the terms of such plan or policy, except as otherwise specified in this Agreement. In the event of Company's termination of Executive's employment for Cause or Executive's termination of Executive's employment without Good Reason, Executive shall be eligible for the Accrued Obligations and shall not be eligible for any severance or severance-type payments, other than as expressly set forth herein.

- (b) <u>Severance in the Event of Termination Without Cause or Resignation for Good Reason</u>. Subject to Section 4(c), in the event that Executive's employment hereunder is terminated by Company without Cause or terminated by Executive for Good Reason, then, in addition to the Accrued Obligations:
  - (i) If Executive's employment is terminated pursuant to Section 4(b) on or before the first anniversary of the Commencement Date, the Company shall pay Executive an amount equal to continuation of Executive's monthly Base Salary (but not taking into account any reduction giving rise to a basis for termination for Good Reason) for a six (6) month period, with such payments to be made in accordance with Company's normal payroll practices and schedules, less all customary and required taxes and employment-related deductions. If Executive's employment is terminated pursuant to Section 4(b) following the first anniversary of the Commencement Date, the Company shall pay Executive an amount equal to continuation of Executive's monthly Base Salary (but not taking into account any reduction giving rise to a basis for termination for Good Reason) for a twelve (12) month period, with such payments to be made in accordance with Company's normal payroll practices and schedules, less all customary and required taxes and employment-related deductions.
  - (ii) In the event that Executive is eligible for coverage under a Company health insurance plan, if any, and Executive has elected to have coverage thereunder and was covered thereunder prior to termination, and in the event that Executive chooses to exercise Executive's right under the Consolidated Omnibus Budget Reconciliation Act of 1985 ("COBRA") to continue Executive's participation in such plan, Company shall pay its normal share of the costs for such coverage for a period of up to twelve (12) months from termination, to the same extent that such insurance is provided to persons then currently employed by Company. Company shall deduct from each of the installments due under Section 4(b)(i) the portion of the monthly premium due from Executive in accordance with the terms of such coverage. Notwithstanding any other provision of this Agreement, this obligation shall cease on the date Executive becomes eligible to receive health insurance benefits through any other employer, and Executive agrees to provide Company with written notice immediately upon becoming eligible for such benefits. Executive's acceptance of any payment on Executive's behalf or coverage provided hereunder shall be an express representation to Company that Executive has no such eligibility.
  - (iii) The Company shall pay Executive a prorated amount of any Annual Bonus relating to the fiscal year in which Executive's employment is terminated, based on the number of days Executive was employed during such fiscal year divided by three hundred sixty-five (365), subject to achievement of the performance targets established for the applicable fiscal year and paid at such time as bonuses for the applicable fiscal year are paid to other senior executives of the Company.
  - (iv) Executive shall become vested in the additional number of outstanding Time-Based Shares granted to Executive by Company that would have otherwise vested had Executive remained in employment for an additional three (3) months after the termination date.

The payments and benefits described in subsections (i) through (iv) collectively are referred to as the Severance Benefit. The Severance Benefit is expressly subject to the conditions described above and in Section 4(c) below. Any payment or benefit made as part of such Severance Benefit shall be paid less all required taxes and employment-related deductions.

- (c) <u>Conditions</u>. Company shall not be obligated to provide Executive any payment, benefit and/or vesting described in Section 4(b) unless and until Executive has returned Company property and executed without revocation a separation agreement substantially in the form attached hereto as Exhibit B, with such changes that are reasonably recommended by the Company's legal counsel to comply with applicable law, which must be signed by Executive, returned to Company and be enforceable and irrevocable no later than fifty-two (52) days following Executive's separation from service (the "Review Period"), and which shall include, at a minimum, the provision of the Severance Benefit due from Company to Executive as applicable, a complete general release of claims against Company and its affiliated entities and each of their officers, directors and employees, and terms relating to mutual non-disparagement, non-competition, confidentiality and cooperation similar in scope, duration and substance to those terms set forth in Company's Non-Competition, Non-Solicitation, Non-Disclosure, and Intellectual Property Agreement described in Section 5 below. If Executive executes and does not revoke such agreement within the Review Period, then provision of payments, benefits and/or vesting shall commence on the first (1st) day following the Review Period, provided that if the last day of the Review Period occurs in the calendar year following the year of termination, then the payment shall not commence until January 2 of such subsequent calendar year, and further provided that, as applied to Section 4(b)(i) and (ii) as applicable, the first payments/benefits shall include in a lump sum all amounts that were otherwise payable to Executive from the date of Executive's separation from service occurred through such first payment.
- (d) No Other Payments or Benefits Owing. The payments and benefits set forth in this Section 4 shall be the sole amounts owing to Executive upon termination of Executive's employment for the reasons set forth above and Executive shall not be eligible for any other payments or other forms of compensation or benefits.
- 5. <u>Non-Competition, Non-Solicitation, Non-Disclosure Agreement</u>. In light of the competitive and proprietary aspects of the business of Company, and as a condition of Executive's employment hereunder, Executive agrees to sign and abide by Company's Non-Competition, Non-Solicitation, Non-Disclosure, and Inventions Assignment Agreement.

### 6. Code Sections 409A and 280G.

- (a) In the event that the payments or benefits set forth in Section 4 constitute "non-qualified deferred compensation" subject to Section 409A, then the following conditions apply to such payments or benefits:
  - (i) Any termination of Executive's employment triggering payment of benefits under Section 4 must constitute a "separation from service" under Section 409A(a)(2)(A)(i) of the Code and Treas. Reg. §1.409A-1(h) before distribution of such benefits can commence. To the extent that the termination of Executive's employment does not constitute a separation of service under Section 409A(a)(2)(A)(i) of the Code and Treas. Reg. §1.409A-1(h) (as the result of further services that are reasonably anticipated to be provided by Executive to Company at the time Executive's employment terminates), any such payments under Section 4 that constitute deferred compensation under Section 409A shall be delayed until after the date of a subsequent event constituting a separation of service under Section 409A(a)(2)(A)(i) of the Code and Treas. Reg. §1.409A-1(h). For purposes of clarification, this Section 6(a) shall not cause any forfeiture of benefits on Executive's part, but shall only act as a delay until such time as a "separation from service" occurs.
  - (ii) Notwithstanding any other provision with respect to the timing of payments under Section 4 if, at the time of Executive's termination, Executive is deemed to be a "specified employee" of Company (within the meaning of Section 409A(a)(2)(B)(i) of the Code), then limited only to the extent necessary to comply with the requirements of Section 409A, any payments to which Executive may become entitled under Section 4 which are subject to Section 409A (and not otherwise exempt from its application) shall be withheld until the first (1st) business day of the seventh (7th) month following the termination of Executive's employment, at which time Executive shall be paid an aggregate amount equal to the accumulated, but unpaid, payments otherwise due to Executive under the terms of Section 4.
- (b) It is intended that each installment of the payments and benefits provided under Section 4 shall be treated as a separate "payment" for purposes of Section 409A. Neither Company nor Executive shall have the right to accelerate or defer the delivery of any such payments or benefits except to the extent specifically permitted or required by Section 409A.
- (c) Notwithstanding any other provision of this Agreement to the contrary, this Agreement shall be interpreted and at all times administered in a manner that avoids the inclusion of compensation in income under Section 409A, or the payment of increased taxes, excise taxes or other penalties under Section 409A. The parties intend this Agreement to be in compliance with Section 409A. Executive acknowledges and agrees that Company does not guarantee the tax treatment or tax consequences associated with any payment or benefit arising under this Agreement, including but not limited to consequences related to Section 409A.
- (d) If any payment or benefit Executive would receive under this Agreement, when combined with any other payment or benefit Executive receives pursuant to a Change of Control (for purposes of this section, a "Payment") would: (i) constitute a "parachute payment" within the meaning of Section 280G the Code; and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the "Excise Tax"), then such Payment shall be either: (A) the full amount of such Payment; or (B) such lesser amount (with cash payments being reduced before stock option compensation) as would result in no portion of the Payment being subject to the Excise Tax, whichever of the foregoing amounts, taking into account the applicable federal, state and local employments taxes, income taxes, and the Excise Tax, results in Executive's receipt, on an after-tax basis, of the greater amount of the Payment notwithstanding that all or some portion of the Payment may be subject to the Excise Tax.

### 7. General.

(a) <u>Notices</u>. Except as otherwise specifically provided herein, any notice required or permitted by this Agreement shall be in writing and shall be delivered as follows with notice deemed given as indicated: (i) by personal delivery when delivered personally; (ii) by overnight courier upon written verification of receipt; (iii) by facsimile transmission upon acknowledgment of receipt of electronic transmission; or (iv) by certified or registered mail, return receipt requested, upon verification of receipt.

Notices to Executive shall be sent to the last known address in Company's records or such other address as Executive may specify in writing.

Notices to Company shall be sent to:

Azitra Inc. 21 Business Park Drive Branford, CT 06405 Attention: Chair, Board of Directors

with a copy to:

Mintz, Levin, Cohn, Ferris, Glovsky & Popeo, P.C. One Financial Center Boston, MA 02111 Attn: William Hicks, Esq.

- (b) <u>Modifications and Amendments</u>. The terms and provisions of this Agreement may be modified or amended only by written agreement executed by the parties hereto.
- (c) <u>Waivers and Consents</u>. The terms and provisions of this Agreement may be waived, or consent for the departure therefrom granted, only by written document executed by the party entitled to the benefits of such terms or provisions. No such waiver or consent shall be deemed to be or shall constitute a waiver or consent with respect to any other terms or provisions of this Agreement, whether or not similar. Each such waiver or consent shall be effective only in the specific instance and for the purpose for which it was given, and shall not constitute a continuing waiver or consent.
- (d) <u>Assignment</u>. Company may assign its rights and obligations hereunder to any person or entity that succeeds to all or substantially all of Company's business or that aspect of Company's business in which Executive is principally involved. Executive may not assign Executive's rights and obligations under this Agreement without the prior written consent of Company.
- (e) <u>Governing Law; Jury Waiver</u>. This Agreement and the rights and obligations of the parties hereunder shall be construed in accordance with and governed by the law of Massachusetts without giving effect to the conflict of law principles thereof. Any legal action or proceeding with respect to this Agreement shall be brought in the courts of the Commonwealth of Pennsylvania or the United States of America for the Eastern District of Pennsylvania. By execution and delivery of this Agreement, each of the parties hereto accepts for itself and in respect of its property, generally and unconditionally, the exclusive jurisdiction of the aforesaid courts. ANY ACTION, DEMAND, CLAIM OR COUNTERCLAIM ARISING UNDER OR RELATING TO THIS AGREEMENT SHALL BE RESOLVED BY A JUDGE ALONE AND EACH OF COMPANY AND EXECUTIVE WAIVES ANY RIGHT TO A JURY TRIAL THEREOF.

- (f) <u>Headings and Captions</u>. The headings and captions of the various subdivisions of this Agreement are for convenience of reference only and shall in no way modify or affect the meaning or construction of any of the terms or provisions hereof.
- (g) <u>Entire Agreement</u>. This Agreement, together with the other agreements specifically referenced herein, embodies the entire agreement and understanding between the parties hereto with respect to the subject matter hereof and supersedes all prior oral or written agreements and understandings relating to the subject matter hereof. No statement, representation, warranty, covenant or agreement of any kind not expressly set forth in this Agreement shall affect, or be used to interpret, change or restrict, the express terms and provisions of this Agreement.
- (h) <u>Counterparts</u>. This Agreement may be executed in two or more counterparts, and by different parties hereto on separate counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. For all purposes a signature by fax or .pdf shall be treated as an original.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the date first written above.

FRANCISCO SALVA	AZITRA INC.	
Francisco Salva	/s/ Travis Whitfill	
Printed name	By:	
/s/ Francisco Salva	Name: Travis Whitfill	
Signature	Title:	
Address:		
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### **EXHIBIT A**

### **Business and Professional Activities**

- 1. Accelerator Life Science Partners ("Accelerator") Accelerator is a seed stage venture capital firm. The Company understands that Executive has an honorary "Operating Partner" title from Accelerator. Executive is not an employee, his relationship does not have any formal time commitments and he is not being compensated. Executive has advised the Company that the use of the term "Partner" in Executive's title itself does not imply or confer actual partnership status, interests or authority; Executive's role is to identify seed stage projects that Executive believes will be of interest to Accelerator. However, Executive has no obligation to do so. If Accelerator agrees to fund a project Executive introduces to it, Accelerator is willing to assign Executive shares in the company.
- 2. <u>Vincerx Pharma, Inc. ("Vincerx")</u> Vincerx is a publicly-traded, clinical-stage biopharmaceutical company focused on developing new therapies to address unmet medical needs for the treatment of cancer. Executive is a member of the board of directors of Vincerx.

## EXHIBIT B

# **Form of Separation Agreement**

[to be provided by Company]

### Via Hand Delivery and FedEx

[INSERT DATE]

Re: Separation Agreement

The purpose of this letter agreement (the "Agreement") is to confirm the terms of your separation of employment from Azitra Inc. ("Company"). As more fully set forth below, the Company desires to provide you with separation pay and benefits in exchange for certain agreements by you. You may take up to twenty one (21) days from the date of this letter set forth above to review and execute this Agreement, and this Agreement shall become effective on the eighth (8<sup>th</sup>) day following the date that you sign it (the "Effective Date").

- 1. <u>Payment as of Separation Date</u>. As of the Separation Date, the Company will provide you with your final paycheck, which will include all salary and/or wages owed to you for work performed through the Separation Date, accrued but unused vacation through the Separation Date if any, unpaid Annual Bonus relating to the prior year if any, and unreimbursed business expenses incurred through the Separation Date in accordance with Company policy. Other than as provided herein, any entitlement you may have under a Company-provided benefit plan or program shall terminate as of the Separation Date, except as required by law and/or in accordance with plan or program terms. As of the Separation Date, your employment with the Company shall conclude, and you no longer shall be entitled to payment of base salary, bonus or other form of compensation by virtue of your employment, except as set forth in this Agreement
- 2. <u>Separation Benefit</u>. In exchange for the mutual promises set forth in this Agreement including, without limitation execution and non-revocation of the release set forth below, the Company agrees to provide you with the following payments and benefits (together, the "Separation Benefit"):
- (a) Payment of an amount equal to [six (6) or twelve (12) months] of your current Base Salary (i.e., not including bonuses or other forms of compensation). Payment will be made in equal installments over a period of [six (6) or twelve (12) months] pursuant to the Company's standard payroll practices beginning on the Company's first regularly-scheduled payroll date following the execution and non-revocation of this Agreement, and subject to applicable withholdings and deductions.
- (b) [f applicable] Payment of the Company's share of normal costs for Executive's coverage under the Consolidated Omnibus Budget Reconciliation Act of 1985 ("COBRA") for a period of up to twelve (12) months from termination, to the same extent that such insurance is provided to persons then currently employed by Company. Executive's portion of monthly premium costs shall be deducted by the Company from the payments set forth above in Section 2(a). Notwithstanding any other provision of this Agreement, this obligation shall cease on the date Executive becomes eligible to receive health insurance benefits through any other employer, and Executive agrees to provide Company with written notice immediately upon becoming eligible for such benefits. Executive's acceptance of any payment on Executive's behalf or coverage provided hereunder shall be an express representation to Company that Executive has no such eligibility.

- (c) Payment of a prorated Annual Bonus attributable to the fiscal year in which Executive's employment is terminated, and subject to applicable withholdings and deductions, based on the number of days Executive was employed during such fiscal year divided by three hundred sixty-five (365), subject to achievement of the performance targets established for the applicable fiscal year and paid at such time as bonuses for the applicable fiscal year are paid to other senior executives of the Company.
- (d) Vesting in the additional number of outstanding Time-Based Shares, as defined in Section 3(c) of Executive's Employment Agreement, granted to Executive by Company that would have otherwise vested had Executive remained in employment for an additional three (3) months after the Separation Date.
- (e) The Separation Benefit shall not constitute a severance plan and shall confer no benefit on anyone other than the parties hereto. You acknowledge and agree that, except for the specific financial consideration set forth herein, you are not entitled to any other compensation from Company, including, without limitation, wages, bonuses, vacation pay, holiday pay, or any other form of compensation or benefit.
- (f) As of and following the Separation Date, you shall not have any right to participate in or acquire any stock options or other equity incentives under any Company equity plan or program. Except for as provided in Section 2(d) above, and in your Employment Agreement, and the Equity Agreement, you represent and agree that (i) you do not own any other common stock, stock options, or other equity interest in the Company, (ii) you have no right to acquire any further stock options, common stock, equity or other interest in the Company and you will not in the future have any right to acquire any further equity or other interest in the Company, and (iii) you shall not have any right to vest in any additional stock or stock options under any Company equity, stock and/or stock option plan or program (of whatever name or kind) that you may have participated in or were eligible to participate in during your employment with the Company.
- 3. <u>Full Payment</u>. You and the Company acknowledge and agree that the Separation Benefits in Section 1 and 2 above are expressly conditioned upon your execution of this Agreement and that, except for the Separation Benefits, any accrued but unused leave payments to which you may be entitled under applicable law and unreimbursed authorized business expenses, the payment and arrangements herein shall constitute full and complete satisfaction of any and all amounts properly due and owing to you as a result of your employment with the Company and the termination thereof, including, but not limited to, salary, wages, bonuses, accrued vacation/paid time off, notice periods, premiums, leaves, housing allowances, relocation costs, interest, severance, outplacement costs, fees, reimbursable expenses, commissions, stock, stock options, vesting, and any and all other benefits and compensation due to you.
- 4. <u>Cooperation</u>. For a period of twelve (12) months following the Separation Date, you shall cooperate fully with Company (upon reasonable advance notice and at times that do not materially interfere with your professional activities) in connection with any matter relating to your employment, including but not limited to: (a) assisting Company with the transition of your duties and responsibilities to Company personnel; (b) meeting with Company personnel regarding matters in which you have been involved as an employee, including any contract matters or audits; (c) assisting in the defense or prosecution of claims now in existence or which may be brought or threatened in the future against or on behalf of Company, including claims or actions by or against its officers, directors or employees; (d) preparing for, attending and participating in any legal proceeding, including affidavits, depositions, consultation, discovery or trial; and (e) assisting Company with internal and external audits, inspections, proceedings or other inquiries. Should you be contacted by any person or entity adverse to Company (for example, by any party representing an individual or entity), you shall promptly notify [INSERT]. You shall be reimbursed for any reasonable costs and expenses approved in advance by Company and incurred in connection with providing such cooperation under this section.

### 5. Continuing Covenants; Return of Property.

- (a) You expressly acknowledge and agree that you shall abide by the Confidentiality, Non-Competition, Non-Solicitation, Non-Disclosure, and Inventions Assignment Agreement dated [INSERT] with Company (the "Covenants Agreements"), which are expressly incorporated herein by reference, and which shall survive and remain in full force and effect following the Separation Date. By signing this Agreement and accepting the payments, benefits and consideration described herein, you reaffirm your obligations under the Covenants Agreement.
- (b) You acknowledge and agree that, other than as permitted herein, you have returned to Company and have not retained any Company files, documents or property or any copies thereof, in any form or media, including any cell phone, computer, keys and key cards. You agree that you shall not disclose any Company trade secrets or confidential and proprietary information, and shall abide by all common law and statutory obligations relating to protection and non-disclosure of Company's trade secrets and confidential and proprietary information.
- 6. <u>Confidentiality</u>. This Agreement shall be held confidential by you and shall not be publicized or disclosed to any third party, *provided* that: (a) disclosure may be made to an immediate family member, legal counsel or financial advisor who agrees to be bound by these confidentiality obligations; and (b) nothing herein shall restrict you from making any disclosures mandated by state or federal law, or participating in an investigation with a state or federal agency, or providing documents or information to a state or federal agency, if requested by the agency to do so.
- 7. Non-Disparagement. You shall not make negative public comments or otherwise disparage the Company and its subsidiaries and affiliates or any of its or their respective officers, directors, employees, shareholders, agents or products other than in the good faith performance of your duties to the Company, conferring in confidence with your legal representatives or in truthful testimony given in response to a lawful subpoena or similar court or governmental order. Members of the Company's Board of Directors shall not make negative public comments or otherwise disparage you other than in the good faith internal evaluation of your performance with the Company, conferring in confidence with the Company's legal representatives or in truthful testimony given in response to a lawful subpoena or similar court or governmental order

### 8. Release of Claims.

(a) Release. You agree and acknowledge that by signing this Agreement, and for other good and valuable consideration provided for in this Agreement, you are waiving and releasing your right to assert any form of legal claim against the Company whatsoever for any alleged action. inaction or circumstance existing or arising from the beginning of time through the Effective Date. Your waiver and release herein is intended to bar any form of legal claim, charge, complaint or any other form of action (jointly referred to as "Claims") against the Company seeking any form of relief, including equitable relief, recovery of damages, or recovery of any other form of monetary recovery (including back pay, front pay, compensatory damages, emotional distress damages, punitive damages, attorney's fees and any other costs) for any alleged action, inaction or circumstance existing through the Effective Date. Without limiting the foregoing, you waive and release the Company from any waivable claim arising from or related to your employment relationship with the Company up through the Effective Date, including: (i) Claims under any Connecticut, Florida or any other state or federal statute, regulation or executive order (as amended) related to fair employment practices, discrimination, harassment, leaves of absence, wages, hours, compensation, equity, or any other terms and conditions of employment, including the Age Discrimination in Employment Act, the Older Workers Benefit Protection Act, the Civil Rights Act of 1866 and 1871, Title VII of the Civil Rights Act of 1964, the Civil Rights Act of 1991, the Equal Pay Act, the Americans With Disabilities Act, the Genetic Information Non-Discrimination Act, the Lilly Ledbetter Fair Pay Act, the National Labor Relations Act, the Family and Medical Leave Act, the Employee Retirement Income Security Act of 1974, COBRA, the Worker Adjustment and Retraining Notification Act, the Uniformed Services Employment and Reemployment Rights Act, the Florida Civil Rights Act (Fla. Stat. §§ 760.01-760.11), Lilly Ledbetter Fair Pay Act, the Connecticut Human Rights and Opportunities Law, the Connecticut Fair Employment Practices Act, the Connecticut Whistleblower Law, the Connecticut Free Speech Law, the anti-retaliation provision of the Connecticut Workers' Compensation Act, the Connecticut and Pennsylvania minimum wage and wage payment laws, the Pennsylvania Human Relations Act (43 Pa. Cons. Stat. § 951 et seq.), and any similar Pennsylvania statute, the Pennsylvania Equal Pay Law (43 Pa. Cons. Stat. § 336.1 et seq.), the Pennsylvania Whistleblower Law (43 Pa. Cons. Stat. § 1421 et seq.), the Pennsylvania Worker and Community Right to Know Act (35 Pa. Cons. Stat. Ann. § 7313), and any similar Connecticut, Pennsylvania or other state or federal statute. Please note that this Section specifically includes a waiver and release of Claims for payments or amounts covered by Pennsylvania or Connecticut wage payment statutes and overtime wage statutes (including, for instance, hourly wages, salary, overtime, minimum wages, commissions, vacation pay, holiday pay, sick leave pay, dismissal pay, bonus pay or severance pay); (ii) Claims under any Connecticut, Pennsylvania or any other state or federal common law theory, including wrongful discharge, retaliation, breach of express or implied contract, promissory estoppel, unjust enrichment, breach of a covenant of good faith and fair dealing, violation of public policy, defamation, interference with contractual or business relations, intentional or negligent infliction of emotional distress, invasion of privacy, misrepresentation, deceit, fraud or negligence or any claim to attorneys' fees under any applicable statute or common law theory of recovery; and (iii) any other Claim arising under other Connecticut, Pennsylvania or other state or federal statute or common law.

<sup>&</sup>lt;sup>1</sup> For the purposes of this section, the parties agree that the term "Company" shall include Azitra Inc. and its divisions, affiliates, parents and subsidiaries, and its and their respective officers, directors, shareholders, owners, employees, attorneys, agents and assigns.

- (b) Release Limitation. Notwithstanding the foregoing, this Section 8 does not: (i) release the Company from any obligation expressly set forth in this Agreement; (ii) waive or release any legal claims which you may not waive or release by law, including under workers' compensation laws; (iii) waive any rights you may have to indemnification and/or legal defense from the Company pursuant to applicable law, insurance policies maintained by the Company, or the Company's charter, bylaws, or other governing documents and agreements; or (iv) prohibit you from challenging the validity of this release under federal law, from filing a charge or complaint of employment related discrimination with the Equal Employment Opportunity Commission ("EEOC") or similar state agency, from participating in any investigation or proceeding conducted by the EEOC or similar state agency, or from providing documents or information to the EEOC or similar state agency. Your waiver and release, however, are intended to be a complete bar to any recovery or personal benefit by or to you with respect to any claim (except those which cannot be released under law), including those raised through a charge with the EEOC. Accordingly, nothing in this Section 8 shall be deemed to limit the Company's right to seek immediate dismissal of such charge or complaint on the basis that your signing of this Agreement constitutes a full release of any individual rights under the federal discrimination laws, or to seek restitution to the extent permitted by law of the economic benefits provided to you under this Agreement in the event you successfully challenge the validity of this release and prevail in any claim under the federal discrimination laws.
- 9. <u>ADEA/OWBPA Review and Revocation Period</u>. You and the Company acknowledge that you are over the age of 40 and that you, therefore, have specific rights under the Age Discrimination in Employment Act ("ADEA") and the Older Workers Benefit Protection Act (the "OWBPA"), which prohibit discrimination on the basis of age. It is the Company's desire and intent to make certain that you fully understand the provisions and effects of this Agreement, which includes a release of claims under the ADEA and OWBPA. To that end, you have been encouraged and given the opportunity to consult with legal counsel for the purpose of reviewing the terms of this Agreement. Consistent with the provisions of the ADEA and OWBPA, the Company is providing you with <u>twenty one (21) days</u> following your Separation Date in which to consider and accept the terms of this Agreement by signing below and returning it to [INSERT]. You may rescind your assent to this Agreement if, within <u>seven (7) days</u> after you sign this Agreement, you deliver by hand, electronic mail or certified mail (certified, return receipt and postmarked within such 7-day period) a notice of rescission to [INSERT] at the above-referenced address.
- 10. <u>Material Breach</u>. A breach of any of Sections 4, 5, 6, 7, 8, and 9 of this Agreement shall constitute a material breach of this Agreement and, in addition to any other legal or equitable remedy available to Company, shall entitle Company to recover the value of any Separation Benefit paid to you hereunder.

11. <u>Taxes</u>. The Separation Benefit shall be reduced by all applicable federal, state, local and other deductions, taxes, and withholdings. Company does not guarantee the tax treatment or consequences associated with any payment or benefit under this Agreement, including under Section 409A of the Internal Revenue Code of 1986 ("Code Section 409A"). For purposes of this Agreement, a termination of employment will be determined consistent with the rules relating to a "separation from service" as defined in Section 409A. To the extent that any provision of this Agreement is ambiguous as to its compliance with Section 409A, the provision will be read in such a manner so that all payments hereunder comply with Section 409A. To the extent any payment under this Agreement may be classified as a "short-term deferral" within the meaning of Section 409A, such payment shall be deemed a short-term deferral, even if it may also qualify for an exemption from Section 409A under another provision of Section 409A. Consistent with Section 4(g) of the Employment Agreement, payments pursuant to this section are intended to constitute separate payments for purposes of Section 1.409A-2(b)(2) of the Treasury Regulations.

12. General. This Agreement, along with any agreement or agreement provisions expressly incorporated by reference herein (including your Employment Agreement, Equity Agreement, and Covenants Agreement), which are incorporated herein and shall survive pursuant to their specific terms and conditions) supersedes any and all prior or contemporaneous agreements between you and Company, and sets forth the entire agreement between you and Company. No modifications shall be deemed valid unless reduced to writing and signed by the parties hereto. The failure of Company to seek enforcement of any provision of this Agreement shall not be construed as a waiver of such provision or Company's right to seek enforcement of such provision in the future. The provisions of this Agreement are severable, and if for any reason any part hereof shall be found to be unenforceable, the remaining provisions shall be enforced in full. This Agreement shall be deemed to have been made in Connecticut, shall take effect as an instrument under seal within Connecticut, and shall be governed by and construed in accordance with the laws of Connecticut, without giving effect to conflict of law principles. The parties agree that any action, claim or counterclaim relating to the terms of this Agreement shall be commenced in Connecticut in a state or federal court of competent jurisdiction, and that venue for such actions shall lie exclusively in Connecticut. Both parties hereby waive and renounce in advance any right to a trial by jury in connection with such legal action.

You acknowledge that, before entering into this Agreement: (i) you have been afforded sufficient time to understand the terms of this Agreement; (ii) you have had the opportunity to consult with an attorney or advisor of your choosing, and have been advised to do so; (iii) the agreements and obligations hereunder are made voluntarily, knowingly and without duress, and that no promises or representations have been made to you by any person to induce you to enter into this Agreement other than the express terms herein and (iv) you have read this Agreement and understand all of its terms. This Agreement may be signed on one or more copies, each of which when signed shall be deemed to be an original, and all of which together shall constitute one and the same Agreement.

If the foregoing correctly sets forth our understanding, please sign, date and return the enclosed copy of this Agreement to [INSERT] within twenty one (21) days following your receipt of this Agreement.

	Azitra Inc.
	By:
	Dated:
Confirmed and Agreed:	
Dated:	
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