Dear Fellow Shareholders,

Thank you for the opportunity to share Armata's progress since our last Annual Shareholder Meeting, nine months ago. The team has been laser focused on the critical development of our two clinical phage cocktails. Our first multi-phage cocktail is developed for inhaled application for the treatment of chronic pulmonary *Pseudomonas aeruginosa* infection in people with cystic fibrosis and non-cystic fibrosis bronchiectasis. The second phage cocktail is being developed to treat *Staphylococcus aureus* bacteremia, an acute clinical indication for which antibiotic-resistance continues to be a growing problem. We believe this dual approach of treating both chronic and acute infections provides the pathway to start definitive pivotal trials in 2025, the critical next step for Armata in advancing the clinical development of these novel pathogen-specific therapeutics towards registration and commercialization.

To achieve these goals, the Company has ensured progress in three crucial areas:

1. Completion of construction of Armata's new state-of-the-art R&D and advanced biologics manufacturing facility consisting of:

    - ~7,000 sq. ft. of R&D laboratory space operational in September 2023;
    - Administrative and office space operational in September 2023, sized to accommodate future growth;
    - ~10,000 sq. ft. of cGMP clean rooms including a state-of-the-art fill and finish suite expected to be completed in June 2024;
    - ~3,000 sq. ft. of quality control laboratories expected to be completed in June 2024.

    We believe this will allow Armata to remain on its aggressive process development and manufacturing timelines to meet regulatory end of Phase 2 meetings for pivotal trial design and to support subsequent production of clinical trial material for definitive late-stage studies. This facility represents a significant step towards firmly establishing Armata's position as a leader in the development of phage-based therapeutics.

2. Armata's research and development team has completed the engineering of both the *Pseudomonas* and *Staphylococcus* production hosts enabling higher titers and greater purity to support execution of pivotal trials. Armata's advanced process development capabilities ensure that we are a leader in the field in phage purity, allowing us to dose escalate in both inhaled and intravenous routes of administration.

3. Our clinical operations team continues to accelerate the enrollment of our two parallel Phase 2 trials. Our NCFB *Pseudomonas* trial ("Tail*wind*") is 75% enrolled and we expect to complete enrollment in June or July 2024. Our *Staphylococcus* bacteremia trial

("diSArm") is over 50% enrolled and continues to dose escalate and be well-tolerated due to the phage purity; we expect enrollment of this trial to be completed by the end of 2024.

In parallel, our management team is focused on containing costs and ensuring that resources are efficiently focused on clinical trial execution backed by rigorous core science.

I am personally proud to be part of the committed team at Armata. Our continued strong progress is a result of the passion and dedication of each employee to achieve Armata's mission of meeting the global challenge of antibiotic resistance by developing high-impact, best-in-class phage therapeutics for all patients in need.

The Armata team has great optimism for our future. I would like to thank our shareholders for supporting our efforts and sharing in our lofty goals.

Sincerely,

Deborah Birx
Chief Executive Officer

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

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2023
or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from to

Commission File Number 001-37544

ARMATA PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Washington	**91-1549568**
(State or other jurisdiction of incorporation and organization)	(I.R.S. Employer Identification No.)
5005 McConnell Avenue **Los Angeles, CA 90066** (Address of principal executive offices, including zip code)	**(310) 665-2928** (Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.01 per share	ARMP	NYSE American

Securities registered pursuant to Section 12(g) of the Act: None.

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes ☐ No ☒

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of June 30, 2023, the aggregate market value of voting stock held by non-affiliates of the Registrant, based on the closing price of the Common Stock on June 30, 2023 (the last business day of the Registrant's most recently completed second quarter) as quoted on the NYSE American, was approximately $12.5 million.

As of March 15, 2024, 36,148,539 shares of the Registrant's Common Stock were outstanding.

Document Incorporated by Reference

Portions of the registrant's Definitive Proxy Statement relating to the 2024 Annual Meeting of Stockholders, which will be filed with the Securities and Exchange Commission within 120 days after the end of the registrant's fiscal year ended December 31, 2023, are incorporated by reference into Part III of this Annual Report on Form 10-K.

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ARMATA PHARMACEUTICALS, INC.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (this "Annual Report") and certain information incorporated herein by reference contain forward-looking statements, which are provided under the "safe harbor" protection of the Private Securities Litigation Reform Act of 1995. These statements relate to future events, results or to our future financial performance and involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or events to be materially different from any future results, performance or events expressed or implied by the forward-looking statements. Forward-looking statements in this Annual Report include, but are not limited to, statements regarding:

- our estimates regarding anticipated operating losses, capital requirements and needs for additional funds;
- our ability to raise additional capital when needed and to continue as a going concern;
- our ability to manufacture, or otherwise secure the manufacture of, sufficient amounts of our product candidates for our preclinical studies and clinical trials;
- our clinical development plans, including planned clinical trials;
- our research and development plans, including our clinical development plans;
- our ability to select combinations of phages to formulate our product candidates;
- our development of bacteriophage-based therapies;
- the potential use of bacteriophages to treat bacterial infections;
- the potential future of antibiotic resistance;
- our ability for bacteriophage therapies to disrupt and destroy biofilms and restore sensitivity to antibiotics;
- our planned development strategy, presenting data to regulatory agencies and defining planned clinical studies;
- the expected timing of additional clinical trials, including Phase 1b/Phase 2 or registrational clinical trials;
- our ability to manufacture and secure sufficient quantities of our product candidates for clinical trials;
- the drug product candidates to be supplied by us for clinical trials;
- the potential for bacteriophage technology being uniquely positioned to address the global threat of antibiotic resistance;
- the safety and efficacy of our product candidates;
- our anticipated regulatory pathways for our product candidates;
- the activities to be performed by specific parties in connection with clinical trials;
- our ability to successfully complete preclinical and clinical development of, and obtain regulatory approval of our product candidates and commercialize any approved products on our expected timeframes or at all;
- our pursuit of additional indications;

- the content and timing of submissions to and decisions made by the U.S. Food and Drug Administration (the "FDA") and other regulatory agencies;
- our ability to leverage the experience of our management team and to attract and retain management and other key personnel;
- the capacities and performance of our suppliers, manufacturers, contract research organizations ("CROs") and other third parties over whom we have limited control;
- our ability to staff and maintain our Marina del Rey production facility under fully compliant current Good Manufacturing Practices ("cGMP");
- the actions of our competitors and success of competing drugs or other therapies that are or may become available;
- our expectations with respect to future growth and investments in our infrastructure, and our ability to effectively manage any such growth;
- the size and potential growth of the markets for any of our product candidates, and our ability to capture share in or impact the size of those markets;
- the benefits of our product candidates;
- potential market growth and market and industry trends;
- maintaining collaborations with third parties including our partnerships with the Cystic Fibrosis Foundation ("CFF"), and the U.S. Department of Defense (the "DoD");
- potential future collaborations with third parties and the potential markets and market opportunities for product candidates;
- our ability to achieve our vision, including improvements through engineering and success of clinical trials;
- our ability to meet anticipated milestones in the development and testing of the relevant product;
- our ability to be a leader in the development of phage-based therapeutics;
- the expected use of proceeds from the $16.3 million DoD grant;
- the effects of government regulation and regulatory developments, and our ability and the ability of the third parties with whom we engage to comply with applicable regulatory requirements;
- the accuracy of our estimates regarding future expenses, revenues, capital requirements and need for additional financing;
- our expectations regarding future planned expenditures;
- our ability to achieve and maintain effective internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act;
- our ability to obtain, maintain and successfully enforce adequate patent and other intellectual property protection of any of our products and product candidates;

- our ability to protect our intellectual property, including pending and issued patents;
- our ability to operate our business without infringing the intellectual property rights of others;
- our ability to advance our clinical development programs;
- the effects of the ongoing conflict between the Ukraine and Russia and the recent and potential future bank failures or other geopolitical events; and
- statements of belief and any statement of assumptions underlying any of the foregoing.

In some cases, you can identify these statements by terms such as "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "will," "would" or the negative of those terms, and similar expressions. These forward-looking statements reflect our management's beliefs and views with respect to future events and are based on estimates and assumptions as of the date of this Annual Report and are subject to risks and uncertainties. We discuss many of these risks in greater detail in the section entitled "Risk Factors." Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management 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 addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Annual Report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain. Given these uncertainties, you should not place undue reliance on any of the forward-looking statements included in this Annual Report. In addition, this Annual Report also contains estimates, projections and other information concerning our industry, our business, and the markets for our product candidates, as well as data regarding market research, estimates and forecasts prepared by our management. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. These statements are based upon information available to us as of the date of this Annual Report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information.

Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in any forward-looking statements, whether as a result of new information, future events, or otherwise.

This Annual Report includes trademarks and registered trademarks of Armata Pharmaceuticals, Inc. Products or service names of other companies mentioned in this Annual Report may be trademarks or registered trademarks of their respective owners.

As used in this Annual Report, unless the context requires otherwise, the "Company," "we," "us" and "our" refer to Armata Pharmaceuticals, Inc. and its wholly owned subsidiaries.

PART I

Item 1. BUSINESS

Overview

We are a clinical-stage biotechnology company focused on the development of pathogen-specific bacteriophage therapeutics for the treatment of antibiotic-resistant and difficult-to-treat bacterial infections using our proprietary bacteriophage-based technology. We see bacteriophages as an alternative to antibiotics and an essential response to growing bacterial resistance to current classes of antibiotics. Bacteriophages or "phages" have a powerful and highly differentiated mechanism of action that enables binding to and killing of targeted bacteria while preserving the human microbiome. This is in direct contrast to traditional broad-spectrum antibiotics which can alter the human microbiome increasing susceptibility to opportunistic pathogens, such as *C. difficile*. We believe that phages represent a promising means to effectively treat bacterial infections as an alternative to broad-spectrum antibiotics, especially for patients with bacterial infections resistant to current standard of care therapies, including the multidrug-resistant or "superbug" strains of bacteria. We are a leading developer of phage therapeutics and are uniquely positioned to address the growing worldwide threat of antibiotic-resistant bacterial infections. We are completing two critical Phase 2 trials to ensure a pathway towards pivotal Phase 3 trials.

We are combining our proprietary approach and expertise in identifying, characterizing and developing both naturally-occurring and engineered (synthetic) bacteriophages with our proprietary phage-specific host-engineered current good manufacturing practice ("cGMP") manufacturing capabilities to advance a target pipeline of high-quality bacteriophage product candidates for advanced development. We are advancing two lead candidates to address both chronic and acute bacterial infections.

Our first lead candidate focused primarily on chronic bacterial infections is the clinical phage candidate for *Pseudomonas aeruginosa* (*"P. aeruginosa"*). On October 14, 2020, we received the approval to proceed from the U.S. Food and Drug Administration (the "FDA") for our Investigational New Drug ("IND") application for AP-PA02. In the first quarter of 2023, Armata announced positive topline results from the completed "SWARM-*P.a.*" study – a Phase 1b/2a, multicenter, double-blind, randomized, placebo-controlled, single ascending dose ("SAD") and multiple ascending dose ("MAD") clinical trial to evaluate the safety and tolerability of inhaled AP-PA02 in subjects with cystic fibrosis ("CF") and chronic pulmonary *P. aeruginosa* infection. Data indicated that AP-PA02 was well-tolerated with a treatment emergent adverse event profile similar to placebo. Pharmacokinetcs (PK) findings confirm AP-PA02 can be effectively delivered to the lungs through nebulization with minimal systemic exposure, with single ascending doses and multiple ascending doses resulting in a proportional increase in exposure as measured in induced sputum and exposure achievement relatively consistent across patient subjects. Additionally, bacterial levels of *P. aeruginosa* in the sputum measured at several timepoints suggest improvement in bacterial load reduction for subjects treated with AP-PA02 at the end of treatment as compared to placebo after ten days of dosing. In addition, a correlation was seen between increasing phage dose and reduction in the bacterial load supporting the biologic plausibility of a bacterial specific mechanism of action and creating the opportunity for phage as a therapeutic alternative to inhaled antibiotics. This study was supported by the Cystic Fibrosis Foundation ("CFF"), which granted Armata a Therapeutics Development Award of $5.0 million. Following these promising Phase 1b/2a results of favorable safety and tolerability profile and plausible mechanism of action, an additional confirmatory Phase 2 trial was initiated in patients with similar chronic pulmonary infections due to *Pseudomonas aeruginosa*.

On February 22, 2022, Armata announced that it had received from the FDA the approval to proceed for our IND application for AP-PA02, in a second indication, non-cystic fibrosis bronchiectasis ("NCFB"). We initiated a Phase 2 trial ("Tailwind") in NCFB in 2022 and reported first patient dosing in the first quarter of 2023. The "Tailwind" study is a Phase 2, multicenter, double-blind, randomized, placebo-controlled study to evaluate the safety, phage kinetics, and efficacy of inhaled AP-PA02 phage therapeutic in subjects with NCFB and chronic pulmonary *Pseudomonas aeruginosa* infection. We are actively accelerating enrollment and increasing phage dosing with the goal of defining a safe and promising biologic correlation for a Phase 3 definitive trial in 2025 which will evaluate phage as an alternative to antibiotics in chronic pulmonary infections.

In parallel, we have an acute bacterial infection clinical development plan focused on *Staphylococcus aureus* bacteremia, a difficult-to-treat and often life-threatening infection that can result in high morbidity and mortality and for which bacterial resistance to antibiotics is growing.

We are advancing a phage product candidate for *Staphylococcus aureus* (*"S. aureus"*) for the treatment of complicated *S. aureus* bacteremia, AP-SA02. On June 15, 2020, we entered into an agreement (the "MTEC Agreement") with the Medical Technology Enterprise Consortium ("MTEC"), pursuant to which we expect to receive a $15.0 million grant and entered into a three-year program administered by the U.S Department of Defense (the "DoD") through MTEC with funding from the Defense Health Agency and Joint Warfighter Medical Research Program. On September 29, 2022, the MTEC Agreement was modified to increase the total award by $1.3 million to $16.3 million and extend the term into the second half of 2024. The grant is being used to partially fund a Phase 1/2, multi-center, randomized, double-blind, placebo-controlled dose escalation study that will assess the safety, tolerability, and efficacy of our phage-based candidate, AP-SA02, for the treatment of adults with *S. aureus* bacteremia. On November 17, 2021, Armata announced that it had received from the FDA the approval to proceed for our IND application for AP-SA02. We are focused on accelerating enrollment of the Phase 2a segment of the "diSArm" study, evaluating safety with higher intravenous doses, which is possible due to the high purity of Armata's phage product candidates. We are committed to developing a definitive efficacy trial in 2025 focused on phage as an alternative to broad-spectrum antibiotics and/or antibiotic sparing to decrease the utilize of broad-spectrum antibiotics and their detrimental impact on the normal human microbiome.

On August 1, 2022, Armata announced that it had received from the FDA the approval to proceed for our IND application for AP-SA02, in a second indication, prosthetic joint infections ("PJI"). We had planned to initiate a Phase 1b/2a trial in 2023, however in light of the growing concerns of both PJI and wound infections, we are revising the protocol to include both indications. Driven by data from the bacteremia study, and with sufficient funding, we may in the future initiate a Phase 1b/2a trial to assess the safety and tolerability of intravenous and intra-articular AP-SA02 as an adjunct to standard of care antibiotics in adults undergoing treatment of periprosthetic joint infections and/or wound infections caused by *S. aureus*.

We remain committed to conducting randomized controlled clinical trials required for FDA approval in order to move toward the commercialization of its phage products as alternatives to traditional antibiotics, providing a potential method of treating patients suffering from drug-resistant and difficult-to-treat bacterial infections.

Recent Financing

2024 Credit Agreement

On March 4, 2024, we entered into a credit and security agreement (the "2024 Credit Agreement") for a loan in an aggregate amount of $35.0 million with Innoviva Strategic Opportunities LLC ("Innoviva SO"), a wholly owned subsidiary of Innoviva, Inc. (NASDAQ: INVA) (collectively, "Innoviva"), our principal stockholder and a related party. The 2024 loan bears interest at an annual rate of 14% and matures on June 4, 2025. Principal and accrued interest are payable at maturity. Repayment of the Loan is guaranteed by our domestic subsidiaries, and the loan is secured by substantially all of our assets. Concurrently with the execution of the 2024 loan, we amended certain provisions of the Convertible Loan and Credit Agreement to, among other things, conform certain terms relating to permitted indebtedness and permitted liens.

2023 Credit Agreement

On July 10, 2023, we entered into a credit and security agreement (the "2023 Credit Agreement") for a loan in an aggregate amount of $25.0 million with Innoviva. This loan bears interest at an annual rate of 14% and matures on January 10, 2025. Principal and accrued interest are payable at maturity. Repayment of the loan is guaranteed by our domestic subsidiaries, and the loan is secured by substantially all of our assets.

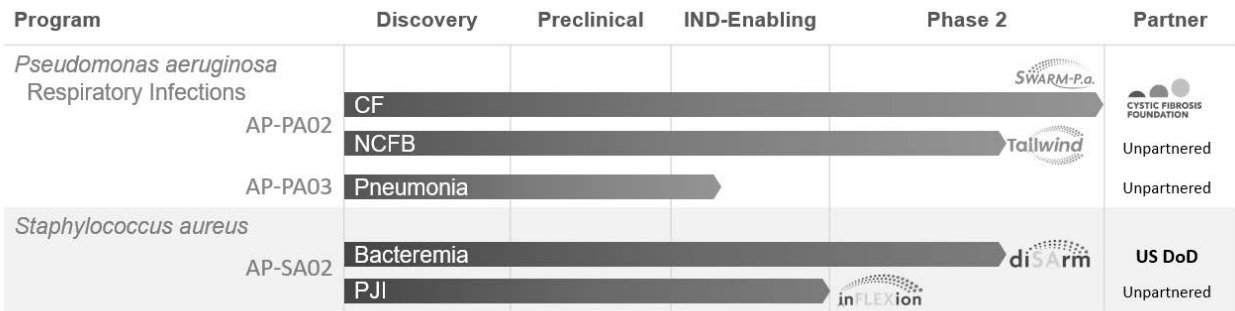
2023 Convertible Credit Agreement

On January 10, 2023, we entered into a secured convertible credit and security agreement (the "Convertible Credit Agreement") with Innoviva, which was amended in July 2023. The Convertible Credit Agreement provides for a secured term loan facility in an aggregate amount of $30.0 million, which bears interest at a rate of 8.0% per annum, and matures on January 10, 2025. Repayment of this loan is guaranteed by our domestic subsidiaries and foreign material subsidiaries, and the convertible loan is secured by substantially all of our assets and the subsidiary guarantors. The Convertible Credit Agreement provides for various conversion and repayment options, including the conversion of principal and accrued interest into the shares of common stock upon a Qualified Financing (as defined below) and we have an option to repay the loan prior to maturity.

The Convertible Credit Agreement provides that if there is a financing from new investors of at least $30.0 million (a "Qualified Financing"), the outstanding principal amount of and all accrued and unpaid interest on the Convertible Loan shall be converted into shares of common stock, at a price per share equal to a 15.0% discount to the lowest price per share for common stock paid by investors in such Qualified Financing. The Convertible Credit Agreement also required us to file a registration statement for the resale of all securities issued to the lender in connection with any conversion under the Convertible Credit Agreement, which we originally filed on February 13, 2023 and which was declared effective by the Securities and Exchange Commission (the "SEC") on April 6, 2023. The Convertible Credit Agreement also confers upon the lender the option to convert any outstanding Convertible Loan amount, including all accrued and unpaid interest thereon, at the lender's option, into shares of common stock at a price per share equal to the greater of book value or market value per share of common stock on the date immediately preceding the effective date of the Convertible Credit Agreement, which was $1.52 (as may be appropriately adjusted for any stock split, combination or similar act).

Pipeline

The following chart summarizes the status of our phage product candidate development programs and partners.



US Department of Defense (Naval Medical Research Command, US Army Medical Research Acquisition Activity, Defense Health Agency)
CF: cystic fibrosis; NCFB: non-CF bronchiectasis; PJI: prosthetic joint infection

Strategy

Our strategy is to demonstrate the safety, tolerability and definitive efficacy of multiple phage products in randomized controlled clinical trials required for FDA approval and to support commercialization in both acute and chronic indications of high unmet medical need, including bacterial infections caused by multidrug-resistant and difficult-to-treat pathogens. Our fully integrated product development capabilities from bench to clinic enable the discovery of optimal phage product candidates, and include the effective adaptation of phages to uniquely engineered host cells, essential for efficient process development and resulting in improved purity, stability, and manufacturability, to power rigorous clinical trials. Our microbiological surveillance and synthetic biology capabilities drive long-term product life cycle management. We intend to:

- Advance clinical trials of AP-PA02 in patients with CF and NCFB, both chronic pulmonary *P. aeruginosa* infections, as an alternative to inhaled antibiotics.

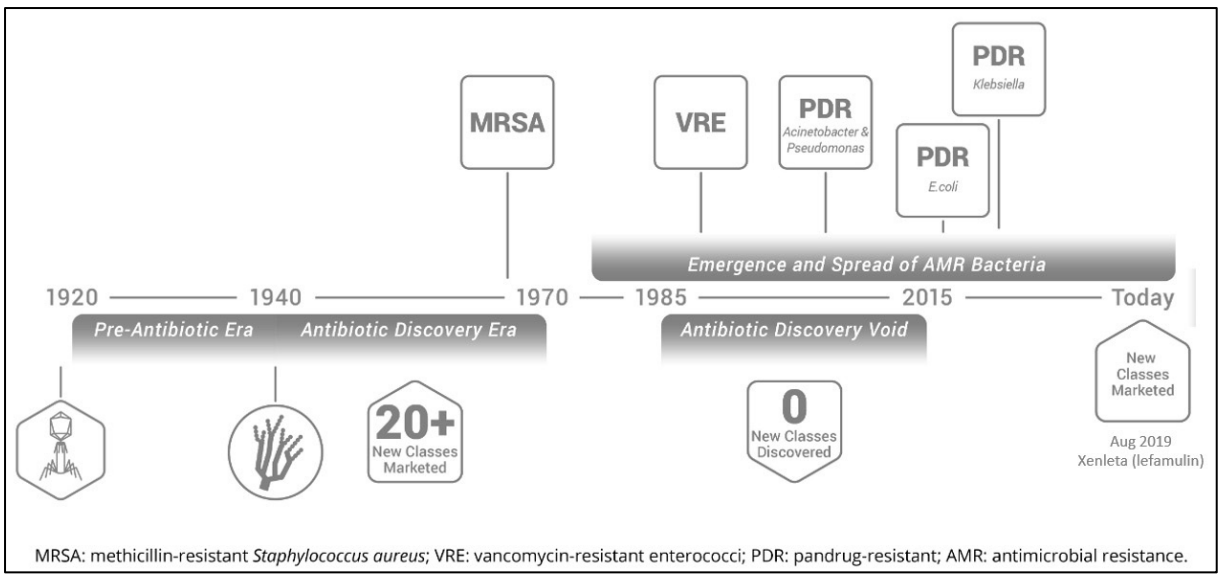
- Develop bacteriophage therapeutics, including AP-PA03, for the treatment of other antibiotic-resistant and difficult-to-treat *P. aeruginosa* infections such as acute bacterial pneumonia.

- Advance clinical trials of AP-SA02 in patients with bacteremia due to acute infection with *S. aureus*, including MRSA, as an alternative to antibiotics or to significantly limit duration of antibiotic use.

- Develop AP-SA02 for the treatment of other antibiotic-resistant and difficult-to-treat *S. aureus* infections such as PJI and wound infections.

The Need for New Anti-Infective Therapies

The introduction of penicillin in the early 1940s marked the start of the antibiotic discovery era, during which more than 20 new classes of antibiotic were marketed over a period of three decades. The first case of the "superbug", Methicillin-resistant *S. aureus* ("MRSA"), in the United States occurred in 1968. A void in the discovery of new classes of antibiotics lasting approximately 30 years drove the emergence and spread of antibiotic-resistant bacteria, including vancomycin-resistant *enterococci* ("VRE"), and pandrug-resistant strains of *Acinetobacter baumannii*, *P. aeruginosa*, *Escherichia coli* and *Klebsiella pneumoniae*.



The dramatic and continuous emergence of antibiotic-resistant bacteria, and the lack of novel next generation antibiotics in the pipeline, has prompted calls to action from many of the world's major health bodies such as the U.S. Centers for Disease Control and Prevention (the "CDC"), and the World Health Organization (the "WHO"), who warn of an "antibiotic cliff" and a "post-antibiotic era." A growing list of infections – such as pneumonia, tuberculosis, bacteremia/septicemia, gonorrhea, and foodborne diseases – are becoming harder, and sometimes impossible, to treat as antibiotics become less effective. In 2009, the European Antimicrobial Resistance Surveillance System concluded that "the loss of effective antimicrobial therapy increasingly threatens the delivery of crucial health services in hospitals and in the community." This conclusion was reinforced by The Antimicrobial Availability Task Force of the Infectious Diseases Society of America (the "IDSA"), and the European Centre for Disease Prevention and Control in conjunction with the European Medicines Agency (the "EMA").

The IDSA and the WHO regard antimicrobial resistance as one of the greatest threats to human health worldwide. The Review on Antimicrobial Resistance, a global project commissioned by the British government and the Wellcome Trust, reports that at least 700,000 people die each year of drug resistance in illnesses that include bacterial infections. The report predicts that, by 2050, 10 million lives a year worldwide (more people than currently die from cancer) and a cumulative $100 trillion of economic output are at risk due to the rise of drug-resistant infections. The CDC estimates

that at least 2 million people in the United States develop infections due to resistant bacteria resulting in more than 23,000 deaths each year. A 2018 study from the Washington University School of Medicine indicated that the number of deaths would be between 153,113 and 162,044, which suggests that the CDC estimates may be dramatic underestimations. It is estimated that 50% of hospital-acquired infections are resistant to first-line anti-infective therapies. The cumulative annual healthcare costs for treating drug-resistant bacterial infections in the United States alone is calculated at $21 billion to $34 billion, with over 8 million additional hospital days. It is for these reasons that we believe there is a critical and pressing need to develop new and novel antibacterial therapies to combat the rise in antibiotic-resistance bacteria.

Increased public funding as well as foundation funding will be essential to bring new approaches forward through full cycle development. Definitive clinical trials to test promising novel therapeutics as alternatives to classic antibiotics must be funded in order to combat the growing issue of drug-resistant bacterial infections across the globe.

Anti-Infective Therapeutics Market

The market opportunity for antibiotics is large, with the market estimated to exceed $58 billion in annual sales globally by 2027. Almost one in every five deaths worldwide occurs as a result of infection and, according to the WHO, many bacterial infections will become difficult or impossible to cure as the efficacy of current standard-of-care antibiotics wanes. Despite the advances in antimicrobial and vaccine development, infectious diseases still remain the third-leading cause of death in the United States and the second-leading cause of death worldwide.

The number of new antibiotics approved by the FDA and other global regulatory authorities has declined consistently over the last two decades. A recent review from WHO on the number of new antibiotics currently in the pipeline shows that just 12 new antibiotics have entered the market in the five years from 2017-21, and there are fewer than 30 under development in clinical trials against pathogens considered critical by WHO such as Pseudomonas aeruginosa This is compared with more than 2,000 new product candidates in the drug pipeline for cancer. Historically, the success rate from Phase 1 to marketing approval is only one in five for infectious disease products. We, therefore, believe there is a need for new approaches to treat serious and life-threatening bacterial infections.

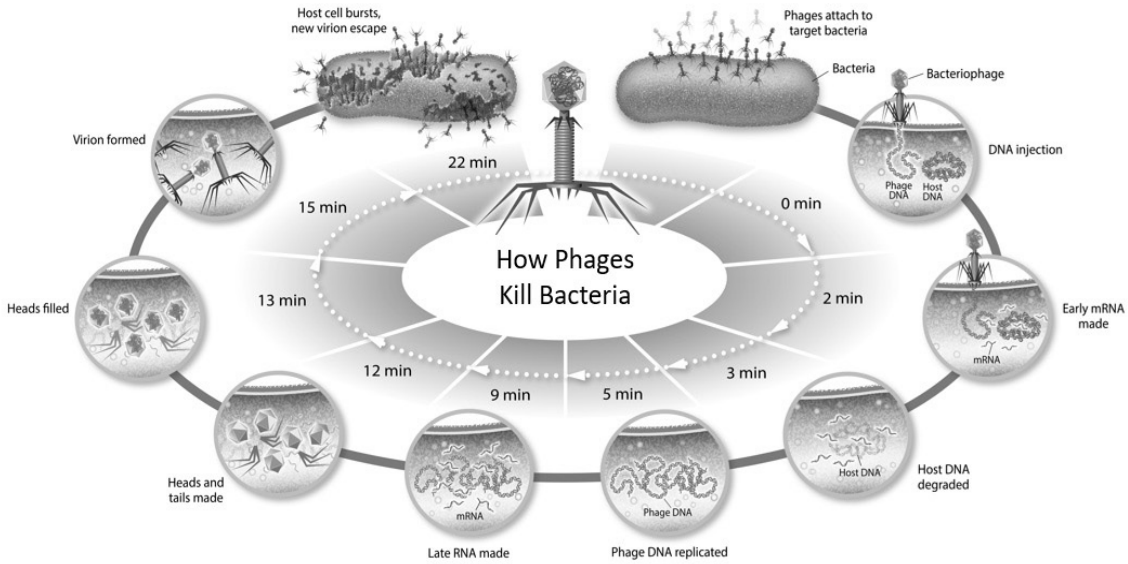
Hospital-acquired (nosocomial) infections are a major healthcare problem throughout the world, affecting developed countries as well as resource-poor countries. The WHO reports that hospital-acquired infections are among the major causes of death and increased morbidity among hospitalized patients. In the US alone, the CDC estimates that hospital-acquired infections account for ~1.7 million infections and 99,000 associated deaths each year.

Compounding the above situations is the alarming and continuing rise in the prevalence of multidrug-resistant bacterial infections. This, coupled with the lack of new antibiotics in current discovery and development pipelines, has generated a significant clinical management problem worldwide, leading to increases in morbidity and mortality due to these antibiotic-resistant bacteria as well as increases in healthcare costs.

Bacteriophage therapy has the potential to be an alternative to antibiotics in treating bacterial infections.

Bacteriophage Therapy

Bacteriophages, also known as phages, are ubiquitous viruses, found wherever bacteria exist. It is estimated there are more bacteriophages than every other organism on Earth combined. Phages are natural predators of bacteria, and the name “bacteriophage” translates as “eaters of bacteria”. Phages infect and rapidly kill the bacterial host by multiplying inside and then bursting through the cell membrane in order to release the next generation of phages into the surrounding environment, ready to infect and kill additional nearby target bacterial cells until the bacteria have been eliminated. When there are no target bacteria left for the phages to infect, the phages are removed through the body’s natural clearance processes. In contrast to broad-spectrum antibiotics, phages are highly targeted to specific bacteria, and do not attack the normal human microbiome on the skin, the gut or other areas critical to maintaining our defenses against more opportunistic infections like *C. difficile*.



Phages have the potential to provide both an alternative to, and/or a synergistic approach with, antibiotic therapy. Phages offer several differentiating attributes compared to classic antibiotics:

- Highly specific/selective bactericidal agents, sparing the microbiome. Since each strain of phage specifically binds and kills only a particular bacterial host, phages may be a precision tool to reduce or eliminate specific strains of harmful bacteria without exposing patients to risks of eliminating the beneficial bacteria of our microbiomes through the use of current standard of care antibiotics. Such risks could include serious opportunistic infections such as *Clostridium difficile* infection and VRE infection.

- No known toxicities associated with chemical structures. Antibiotic use is often associated with toxicities (e.g. kidneys, bone marrow, hearing). Phages are highly unlikely to carry structural features or be metabolized by the body to produce structural elements that confer chemical toxicities associated with small molecules.

- Distinct mechanism of bactericidal action. Since phages use different mechanisms of action, their activity is independent of antibiotic resistance and as such could provide much needed therapy for multi-drug resistant infections.

- Replication competent. It is possible that phage replication at the site of infection facilitates effective dosing.

- High potential for added functionality through genetic engineering. Phage genomes can be modified to confer benefits that address limitations, if any, that are observed during clinical development. Traits such as host range, burst size and biofilm disruption can be improved. These potential improvements help to assure phage therapeutics efficacy in difficult settings and over time as new isolates emerge.

Phages were discovered in 1915 at the Pasteur Institute and were shown to kill bacteria taken from patients suffering from dysentery. Furthermore, it was noted that phage numbers rose as patients recovered from infection, suggesting a direct association. Throughout the pre-antibiotic era, phages were widely used as an effective therapeutic agent to combat a variety of bacterial infections. However, phage use was displaced by the common use of broad-spectrum antibiotics in the early 1940s, with antibiotics being seen for many years as the superior treatment to combat bacterial disease, particularly in Western medicine. This attitude persisted until the development of the wide-ranging, and in some cases total, resistance to antibiotics seen within the last 10 years. We believe that the continuing emergence of antibiotic-resistant bacteria provides the opportunity to revitalize phage use.

There are hundreds of cases published in the scientific and medical literature describing the use of phage therapy in human medicine over more than 90 years, mostly in the former Soviet Union and Eastern Europe. Phage therapy is still commonly used today in Russia, Poland and Georgia, with numerous reports of success in treating serious infectious diseases caused by many pathogenic bacterial species. However, the safety and effectiveness of these therapies have not been conclusively established due to the lack of randomized controlled clinical studies.

Recently, Western medicine has seen a rise in the clinical evaluation of phages. In the United Kingdom, two early-stage clinical trials of *P. aeruginosa* phage cocktails showed no adverse effects in patients. One study (Phase 1/2a) demonstrated efficacy in a small trial of 12 patients with chronic multidrug-resistant *P. aeruginosa* otitis treated with a cocktail of six natural phages. Since 2016, there have been a number of "compassionate use" cases in which patients suffering from various serious or life-threatening infections have been treated with phage therapy under physician-sponsored Emergency Investigational New Drug Applications with high rates of success and no adverse effects attributable to the therapy. Most notable was the well-documented case in 2016 of Tom Patterson, whose disseminated multidrug-resistant *Acinetobacter baumannii* infection was successfully treated with phage-based therapeutic cocktails administered intravenously and intraperitoneally. An 82-year-old male with an aortic graft (heart implant) infected with pandrug-resistant *P. aeruginosa* was successfully treated with a single application of phage, marking Yale University's first case using phage therapy under Emergency IND. By early 2019, Yale University had treated more than half-a-dozen compassionate use cases, the majority individuals with CF with antibiotic-resistant lung infection. In 2018, a 15-year-old CF patient with a disseminated *Mycobacterium abscessus* lung infection was treated intravenously with a three-phage cocktail following lung transplantation. That patient's case represents another milestone for phage therapy – the first person to be treated with genetically modified phages.

A consistent takeaway from these early phage therapy uses, and from the more recent clinical trials and compassionate use cases, is that phage therapy is generally well tolerated, with generally no reports of serious adverse events when administered by inhalation. Intravenous use of phage has been more limited due to bacterial cell wall and other contaminants in the final phage product. Phages have previously received approvals for use in cleaning food facilities and as a food additive for human consumption by the FDA and the EMA, and as agricultural bacterial pest treatments by the United States Department of Agriculture. Phages have met the criteria to be considered as "generally recognized as safe", or "GRAS", in the food and food contact surface categories.

With the growing problem of antimicrobial resistance, we believe it is essential that phage safety and efficacy be demonstrated by conducting rigorous well-powered clinical trials required for FDA approval, in order to move toward commercialization of phage therapy as an alternative to traditional antibiotics and to bring a potential solution to all patients suffering from drug-resistant bacterial infections. Armata has been focused on enhancing the overall quality of its manufactured phages through engineering and adaptation to maximize production titers while ensuring high level of purity.

Target Markets and Medical Need

Pulmonary Bacterial Infections

P. aeruginosa is consistently recognized by the CDC, and other public health agencies, as among the most dangerous and difficult-to-treat pathogens associated with significant impacts on health, quality of life, and economic burden. Regular standard-of-care antibiotics treatments often fail to completely eradicate the pathogen, and the problem is further complicated by rising rates of antibiotic resistance due to a growing number of multidrug-resistant isolates emerging, particularly with long term use. *P. aeruginosa* is particularly problematic for CF patients given that their already compromised immune system leads to chronic infections. In addition to CF lung infections, *P. aeruginosa* is responsible for other respiratory infections with high unmet medical need, including NCFB and hospitalized pneumonia.

P. aeruginosa Infection is a Major Cause of Morbidity and Mortality in Cystic Fibrosis

CF is a genetic disease caused by mutations in the CF transmembrane conductance regulator ("CFTR") gene. CF affects over 40,000 people in the United States (105,000 people worldwide) with approximately 1,000 new diagnoses per year. Dysfunction of the CFTR gene leads to dysfunction in multiple organs, but particularly the lungs, where a

failure of hydration of airway secretions results in thick mucus, chronic inflammation, airway remodeling, and recurrent infections. Lung function continues to decline over time, punctuated by pulmonary exacerbations with increased cough, shortness of breath, and infections that result in rapid declines in lung function. For these reasons, CF remains the most common fatal hereditary lung disease.

Outcomes for people with CF have improved significantly in recent years through early screening, the development and use of CFTR modulators, and other therapies. However, people with CF still suffer significant morbidity and mortality due to pulmonary infection with *P. aeruginosa*. Chronic *P. aeruginosa* infections occur in 45% of CF patients by age 40, and are strongly associated with worsening lung function, frequent pulmonary exacerbations, and increased mortality. In 2022, the median predicted survival age was 68 years. Although many patients with chronic *P. aeruginosa* benefit from routine suppressive inhaled antibiotic therapy, large numbers of CF patients still experience clinical deterioration despite these treatments, hence the need for more effective therapies, ideally with a different mechanism of action compared to traditional antibiotics, for the treatment of chronic *P. aeruginosa* infection. GlobalData projects that total antibiotic sales in the CF market will exceed $900 million in the United States in 2030.

Non-Cystic Fibrosis Bronchiectasis

NCFB is a chronic respiratory disease affecting more than 100,000 people in the United States and 200,000 people in Europe, characterized by recurrent respiratory infections that lead to a vicious cycle of impaired mucociliary clearance, chronic infection, bronchial inflammation, and progressive lung function loss. *P. aeruginosa* is the most prevalent pathogen responsible for these recurrent infections. It is found in approximately 30% of cases and is associated with enhanced disease progression, including poorer lung function and lower quality of life, more frequent exacerbations, 7-fold increase in hospitalizations, and 3-fold increase in death. NCFB patients frequently become chronically colonized with multidrug-resistant strains of *P. aeruginosa* because of the need for repeated courses of antibiotic treatment. There are currently no approved inhaled antibiotics for the treatment of NCFB patients with chronic *P. aeruginosa* respiratory infections.

Hospitalized Pneumonia

Hospital-acquired pneumonia and ventilated-associated pneumonia is one of the most common causes of death among all hospital-acquired infections, with approximately 300,000 hospitalizations each year in the United States due to *Pseudomonas*. Infection with *Pseudomonas* results in mortality rates ranging as high as 35-50%, drives considerable healthcare costs (in excess of $40,000 per patient), and accounts for around 50% of all intensive care unit antibiotics.

Staphylococcus aureus Infections

Bacteremia

Bacteremia is a bacterial infection of the bloodstream. A common diagnosis, the CDC estimates that up to 1.7 million people in the U.S. develop bacteremia each year. *S. aureus* is the most commonly identified pathogen in both hospital- and community-acquired bloodstream infections. Annually in the U.S. there are approximately 200,000 hospitalizations for *S. aureus* bacteremia (“SAB”). Despite conventional antibiotics, mortality in SAB results in the death of up to 40% of all cases and 57% of patients over the age of 85. Patients with comorbidities such as alcoholism, malignancy, diabetes, end-stage renal disease requiring hemodialysis, and immunosuppression are at even higher risk for death when SAB develops. Age-adjusted mortality assessments show that SAB mortality is higher than that of AIDS, tuberculosis, or viral hepatitis, and comparable to mortality rates for breast or prostate cancer. Outcomes are even poorer for SAB due to methicillin-resistant *S. aureus* (“MRSA”), classified as a serious threat to global health by the CDC and a high priority threat by the WHO, with higher rates of complications and increased mortality as compared to methicillin-susceptible *S. aureus* (“MSSA”). Average hospital costs to patients with nosocomial SAB ranges between $40,000 (MSSA) and $114,000 (MRSA). Treatment failures are common in SAB, with highest rates due to MRSA. These failures can be attributed in part to poor penetration of some tissues by antibiotics, slow onset of bactericidal effects, emerging resistance patterns, and biofilm formation. While biofilms can render traditional antibiotics ineffective, phages may have the ability to penetrate the biofilm allowing rapid and efficient infection of the host and amplification at the site of infection. Daptomycin (approved in 2005; based on clinical cure rates of less than 50%) and vancomycin are the

only two antibiotics with label indications in the U.S. for the treatment of SAB, and the emergence of drug-resistant *S. aureus* isolates, including to these two standard of care drugs, represents a major threat in terms of increasing morbidity, mortality and health care utilization.

Prosthetic Joint Infection and Wound Infection

The total number of prosthetic joint infection ("PJI")-related revision surgeries is expected to more than double from 70,000 in 2020 to 144,000 in 2040 in the United States and European Union Five (France, Germany, Italy, Spain, and the United Kingdom), at an annual growth rate of 5.6% due to a growing elderly population. The United States is the largest market for PJI, accounting for 61% of PJI-related revision surgery in 2020 (estimated to be 71% by 2040), each estimated to cost $150,000. *S. aureus* PJI infections are among the most commonly observed, accounting for up to 47% of all infections. PJI caused by biofilm-forming bacteria, such as *S. aureus*, is challenging to treat and requires both surgery and long-term antibiotic use. Lack of efficacy against biofilms is a common cause of re-infection or treatment failure in PJI. Moreover, growing antibiotic resistance complicates treatment strategies and antibiotic choice for the treatment of PJI. Phage therapy has been successful in patients who have failed conventional antibiotic treatment, including two 2020 case studies in which phages were administered by intravenous or intraarticular routes and shown to be generally well tolerated. Similarly, secondary and tertiary wound infections due to *S. aureus* are a growing issue worldwide.

Platform Technologies

Synthetic Phage Platform

Phages, natural predators of bacteria, have been in an uninterrupted battle for millions of years – evolving to kill or evade. These powerful natural well-adapted phages can be purposely engineered to be more efficient killers. The use of synthetic biology tools enables us to precisely engineer natural phages in ways that further improve their pharmacological properties and antimicrobial activity. Attributes of engineered phages can include expanded host range, improved potency which is a fundamental drug property that can translate into improved clinical efficacy, and importantly, biofilm disruption, which is a critical aspect of serious infections that needs to be addressed.

Phage Discovery and Phenotyping:
Development of synthetic phage products that target a specific pathogen begins with the isolation of powerful natural phages from environmental and clinical samples. Our large library of multidrug-resistant pathogens and microbiome targets aids in the identification of the optimal phage candidates for downstream engineering.

Bioinformatics Powers Engineering:
We employ next-generation sequencing, proprietary sequencing databases and software, bioinformatics, and comparative genomics, for the analyses of our phages.

Engineering Host and Phage to Confer Desirable Properties:
Depending on the target pathogen, identified natural phages are engineered to enable desirable phenotypes such as wide host range, payload expression, biofilm degradation, resistance prevention, and bioactive peptide display. Engineered phages are evaluated both in vitro and in vivo to determine pharmacological and toxicological parameters to confirm their potential in the clinic.

Formulation Development and Chemistry, Manufacturing, and Controls:
We have developed and acquired highly skilled process development and phage manufacturing expertise to manage our proprietary platforms with proven capabilities from the bench to clinic. Our research and development facilities are equipped with cGMP compliant manufacturing suites enabling the production,

purification, testing and release of reproducible batches of phage clinical trial material exhibiting high purity and high titer designed to be tolerated for both intravenous and inhaled administration.

Preclinical and Clinical Development Programs

Overview

We are committed to developing novel phage therapies, with drug development expertise and product development capabilities that span bench to clinic, including in-house phage-specific cGMP manufacturing. Our phage discovery platform in which we screen panels of clinically-relevant isolates against our extensive phage library utilizing proprietary methods that identify phage combinations with superior attributes, together with our phage-specific cGMP compliant manufacturing facilities, uniquely enables us to efficiently identify optimal product candidates. Our microbiological surveillance and synthetic biology capabilities drive long-term product life cycle management.

Our therapeutic phage candidates aim to address areas of significant unmet medical need, by targeting key drug-resistant bacteria, including those on the WHO's global priority pathogens list, and the priority pathogens list issued by the CDC. The long-term potential for phage therapy is broad reaching, including potential use as front-line therapy. However, first indications will be as adjunct therapy in indications with high unmet need, which demands careful patient population selection to assure that a treatment effect with the phage cocktail can be observed over and above the efficacy of standard-of-care antibiotics.

We are developing and advancing a broad pipeline of natural and synthetic phage candidates, including clinical candidates for *P. aeruginosa* and *S. aureus*, two bacterial pathogens known to have significant morbidity and mortality despite standard-of-care antibiotic usage. *P. aeruginosa* and *S. aureus* are causative agents for difficult-to-treat infections: *P. aeruginosa*, with its mucoid and multidrug-resistant strains, is a dominant culprit in chronic respiratory infections in CF and NCFB patients as well as acute pneumonia in hospitalized patients; *S. aureus*, with its heteroresistant and MRSA strains, has been implicated in systemic (e.g., bacteremia) as well as prosthetic-related and wound infections. By advancing randomized controlled clinical trials using *P. aeruginosa* and *S. aureus* natural phage cocktails, Armata will gain experience treating site-specific as well as systemic infections.

***Pseudomonas aeruginosa* Phage Product Candidate, AP-PA02**

Historical Background

AP-PA02 was developed as a next-generation replacement for AP-PA01 (previously known as AB-PA01). A total of 10 patients with serious or life-threatening *P. aeruginosa* infections not responding to antibiotic therapy were treated with AP-PA01, along with antibiotics, under single-patient expanded access programs in the United States (authorized under Emergency INDs by the FDA) and in Australia (authorized under the Special Access Scheme by the Australian Therapeutic Goods Administration). The treated patients' infections included bacteremia, native and prosthetic valve endocarditis, recurrent pneumonia (CF, post-transplant), ventilated-associated pneumonia, prosthetic joint infection, ventricular assist device infection, and septicemia due to burns. Investigators concluded that intravenous and nebulized administration of AP-PA01 was well-tolerated with no treatment-related serious adverse events. One of these cases was published in August 2019, in the peer-reviewed journal Infection, after AP-PA01 was used to successfully treat a CF patient who had developed a multidrug-resistant *P. aeruginosa* infection. Another success with AP-PA01, used to treat a 77-year-old with ventilated-associated pneumonia and empyema, was published in November 2019, in the American Journal of Respiratory and Critical Care Medicine. We no longer offer AP-PA01 through any expanded access program.

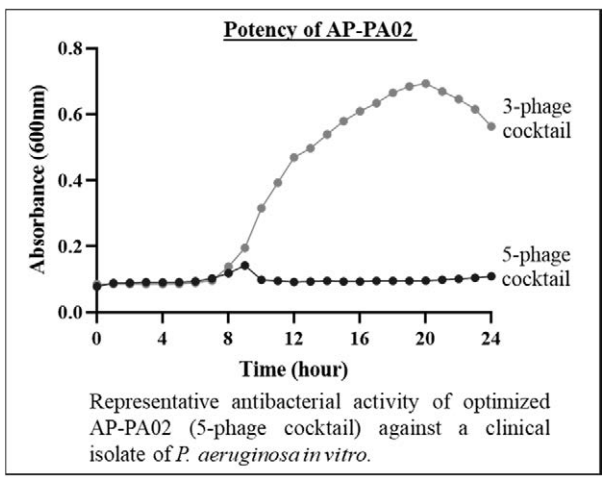
In August 2018, we held a Type B pre-IND meeting with the U.S. FDA regarding a proposed Phase 1/2 clinical study of AP-PA01 for the treatment of *P. aeruginosa* respiratory infections (ventilated-associated pneumonia). Feedback from the FDA in September 2018 included: agreement on product specifications, manufacturing and analytical plan, and a stability program. Furthermore, the FDA noted that preclinical toxicology studies are not required for AP-PA01 to enter clinical development.

Human exposure through treatment of single patients with AP-PA01 under the expanded access program has been helpful in demonstrating the promise and safety of phage therapy. Feedback from the pre-IND meeting has been insightful for the regulatory path required for phage therapeutics in general, and specifically for a phage product candidate intended for respiratory infection. We, therefore, have leveraged our experiences with AP-PA01 to derive a development plan for the next-generation product candidate, AP-PA02.

Preclinical Development of AP-PA02

AP-PA02 is one example of the novel candidates to emerge from our robust research and development capabilities, and significantly improves upon our original *P. aeruginosa* phage product candidate, AP-PA01. The phages that comprise AP-PA02 were selected with desired attributes for a product candidate targeting *P. aeruginosa* lung infections. Different methods were deployed, including microbiological, bioinformatics and comparative genomics, in order to identify optimal attributes for the product candidate. Susceptibility, killing kinetics, and biofilm eradication, was assessed using *P. aeruginosa* isolates from CF patients to determine antimicrobial activity and potency of AP-PA02. Viability in relevant biological fluids, and compatibility with current standard of care therapies for CF patients, was verified to confirm suitability of AP-PA02 for clinical use in this patient population. Immune stimulation was assessed to assure the lack of inflammatory impact by AP-PA02. Animal studies were conducted to provide insight into safe and efficacious dose levels that would support the expectation of pharmacological activity (i.e., antimicrobial potential of phage) in the lung compartment following an inhaled route of administration. In parallel, we initiated manufacturing feasibility and process optimization efforts with the goal of achieving high-quality phage product free of endotoxin and host cell proteins whilst maintaining adequate phage titers.

AP-PA02 is comprised of a cocktail of adapted natural *P. aeruginosa* phages originating from distinct families and subfamilies, targeting multiple receptor classes, functioning with compatibility (i.e., the phages don't interfere with one another) and cooperativity (i.e., the phages work together for a better outcome), and further characterized by being highly potent and having a broad host range and overlap. Prior to initiating the SWARM-*P.a.* trial (described below), our clinical isolate screening and phage collections yielded a three-phage AP-PA02 cocktail with compelling host-range coverage. We subsequently modified AP-PA02 to include additional phage genera that increase potency and broaden coverage of strains of *P. aeruginosa* found in CF patients. The optimized five-phage AP-PA02 cocktail provided coverage against at least 90% of tested CF clinical isolates and has shown superior *in vitro* potency as well as improved efficacy in an animal model of infection. The improvements in AP-PA02 reflect our core strategy of utilizing clinical isolate surveillance data to drive enhancement of product composition.



Representative antibacterial activity of optimized AP-PA02 (5-phage cocktail) against a clinical isolate of *P. aeruginosa in vitro.*

Preclinical highlights of AP-PA02 include:

- Significantly reduced *P. aeruginosa* biofilm mass *in vitro*;

- Persistence of active phage particles in the lung;
- Limited systemic and off-target organ distribution;
- Significantly decreased mortality in a murine model of acute *P. aeruginosa* lung infection;
- Components are stable in blood and sputum;
- Not antagonistic with tobramycin nor aztreonam; and
- Components maintain activity in the presence of other CF therapies.

We developed AP-PA02 as a sterile liquid formulation, suitable for delivery by inhalation. Clinical trial material of AP-PA02 is currently manufactured under cGMP at our production facility in Marina del Rey, California.

Clinical Development of AP-PA02 in Cystic Fibrosis: *Completed Phase 1b/2a Study*

On October 14, 2020, Armata received approval for the study to proceed from the FDA for its IND to initiate the "SWARM-*P.a.*" study – a Phase 1b/2a, multicenter, double-blind, randomized, placebo-controlled, single ascending dose ("SAD") and multiple ascending dose ("MAD") clinical trial to evaluate the safety, tolerability and phage recovery profile of AP-PA02 administered by inhalation in subjects with cystic fibrosis and chronic pulmonary *Pseudomonas aeruginosa* infection. Primary Endpoints (SAD and MAD) included incidence and severity of treatment-emergent, adverse events. Secondary Endpoints (MAD) included changes in *P. aeruginosa* colony-forming units. We looked at clinical parameters as a part of exploratory endpoints for the SAD and MAD cohorts. The SWARM-*P.a.* study was supported by a $5 million Therapeutics Development Award from the CFF.

In the first quarter of 2023, Armata announced positive topline results from the completed "SWARM-*P.a.*" study. Data indicate that AP-PA02 was well-tolerated with a treatment emergent adverse event profile similar to placebo. Pharmacokinetcs (PK) findings confirm that AP-PA02 can be effectively delivered to the lungs through nebulization with minimal systemic exposure, with single ascending doses and multiple ascending doses resulting in a proportional increase in exposure as measured in induced sputum and exposure achievement relatively consistent across patient subjects. Additionally, bacterial levels of *P. aeruginosa* in the sputum measured at several timepoints suggest improvement in bacterial load reduction for subjects treated with AP-PA02 at the end of treatment as compared to placebo after ten days of dosing.

Additive Clinical Indication for Our AP-PA02 P. aeruginosa Phage Product Candidate: Ensuring Patient Population for Definitive Phase 3 Trial

With positive outcomes from the first clinical study, SWARM-*P.a.*, we initiated a follow-on Phase 2 study investigating the efficacy of AP-PA02 in NCFB patients chronically infected with *P. aeruginosa.* Screening *P. aeruginosa* isolates from people diagnosed with NCFB revealed that the five-phage AP-PA02 cocktail offers broad coverage and robust potency in this indication as well. On February 22, 2022, Armata announced that it had received from the FDA the approval to proceed for our IND application for AP-PA02, in a second indication, NCFB. The Company initiated a Phase 2 trial ("Tailwind") in NCFB in late 2022 and reported first patient dosing in the first quarter of 2023. The "Tailwind" study is a Phase 2, multicenter, double-blind, randomized, placebo-controlled study to evaluate the safety, phage kinetics, and efficacy of inhaled AP-PA02 phage therapeutic in subjects with NCFB and chronic pulmonary *Pseudomonas aeruginosa* infection. Throughout 2023, the Company worked closely with clinical sites to rapidly expand enrollment to position the Phase 2 trial for completion in 2024 and have data available to support a pivotal trial in 2025. Enrollment of the Phase 2 trial is ongoing, with AP-PA02 continuing to demonstrate a favorable safety and tolerability profile, and insights from blinded data of the relationship between phage dose and microbiological impact on *P. aeruginosa* confirms the findings in the cystic fibrosis SWARM-*P.a.* Phase 2a trial. We are carefully evaluating the impact of AP-PA02 on *P. aeruginosa* in patients not taking antibiotics in order to confirm the independent impact of phage treatment.

AP-PA03 for Antibiotic-Resistant and Difficult-to-Treat Acute Bacterial Pneumonia

Conversely and representing the different physiology of acute pneumonia lung infections as compared to chronic CF and NCFB respiratory infections, a novel cocktail is in development for the clinical indication of acute hospitalized pneumonia. We have deployed our extensive *P. aeruginosa* clinical isolate collection and phage library to identify a candidate phage cocktail, AP-PA03.

Staphylococcus aureus Phage Product Candidate, AP-SA02

Historical Background

AP-SA02 was developed as a more advanced version of AP-SA01 (previously known as AB-SA01).

The therapeutic potential of AP-SA01 has been demonstrated through:

- Efficacy in murine methicillin-resistant and methicillin-susceptible *S. aureus* pneumonia models, and sheep sinus biofilm model.

- Demonstration of safety and tolerability in two completed investigator-initiated Phase 1 studies (topical administration: intact skin of healthy adults; intrasinal administration: patients suffering from *S. aureus*-derived chronic rhinosinusitis).

- AP-SA01 was provided for use under single-patient expanded access programs in the United States (Emergency INDs, per the Food and Drug Administration) or Australia (Special Access Scheme, per the Australian Therapeutic Goods Administration). A total of 18 patients with serious or life-threatening *S. aureus* infections (including bacteremia, endocarditis, ventricular-assist device infection, prosthetic joint infection) not responding to standard-of-care antibiotic therapy were treated with AP-SA01. AP-SA01 was administered intravenously, with most patients treated for 14 days, every 12 hours as an adjunct to antibiotic therapy. Investigators concluded that intravenous administration of AP-SA01 was well-tolerated with no treatment-related serious adverse events. We no longer offer AP-SA01 through any expanded access program.

Human exposure through treatment of single patients with AP-SA01 under the expanded access program has been helpful in demonstrating the promise of phage therapy and warrants further study to support safety and efficacy through randomized controlled trials required to support registration. Feedback from a Type B pre-IND meeting with the FDA in August 2018 has been insightful for the regulatory path required for phage therapeutics in general, and specifically for a phage product candidate intended for systemic delivery. We therefore have leveraged our experiences with AP-SA01 to derive a development plan for AP-SA02.

Product Optimization: Development of AP-SA02

AP-SA02 is a novel biologic product candidate comprised of a cocktail of adapted natural lytic phages that target the problematic pathogen, *S. aureus*.

Preclinical highlights of AP-SA02 include:

- Potent antimicrobial activity against approximately 95% of *S. aureus* clinical isolates tested, including drug-resistant isolates (MRSA: methicillin-resistant *S. aureus* and VRSA: vancomycin-resistant *S. aureus*);

- Unique mechanism of action offers independent or synergistic benefit with standard of care antibiotics;

- Component phages are stable and retain infectivity after exposure to relevant biological fluids; and

- Penetrates pre-existing *S. aureus* biofilms.

We have developed AP-SA02 as a sterile solution, suitable for delivery by intravenous administration. Clinical trial material of AP-SA02 is currently manufactured under cGMP at our production facility in Marina del Rey, California to support the required regulatory filing(s) for clinical entry in the United States and ex-U.S.

Clinical Development of AP-SA02 in Bacteremia

On November 17, 2021, Armata received approval for the study to proceed from the FDA for its IND to initiate the "diSArm" study – a Phase 1b/2a, randomized, double-blind, placebo-controlled, multiple ascending dose escalation study of the safety, tolerability, and efficacy of intravenous AP-SA02 as an adjunct to best available antibiotic therapy compared to best available antibiotic therapy alone for the treatment of adults with bacteremia due to *Staphylococcus aureus*. The objectives of this study are to: (i) demonstrate safety and tolerability of multiple different dose levels of AP-SA02; (ii) evaluate optimal dosing through safety, pharmacokinetics and microbial efficacy; and (iii) explore efficacy through evaluation of key meaningful endpoints. The study is being conducted at sites in the United States and also at sites abroad in Australia.

The Phase 1b/2a study is partially funded by a $15.0 million award from the DoD through MTEC with funding from the Defense Health Agency and Joint Warfighter Medical Research Program. On September 29, 2022, the MTEC Agreement was modified to increase the total award by $1.3 million to $16.3 million and extend the term into the second half of 2024.

Data from this Phase 1b/2a study will be invaluable for a follow-on trial that is being designed to demonstrate efficacy of AP-SA02 in treating *S. aureus* bacteremia. We anticipate findings from the Phase 1b/2a study will provide the basis for constructing a robust trial strategy for registration which can be the basis for an End-of-Phase-2 meeting with the FDA that enables us to obtain agreement on a path to approval in late 2024, early 2025.

Additional Clinical Indications for AP-SA02

Improved patient outcomes are needed for other *Staphylococcal* infections, in settings such as PJI and wound infections, for which antimicrobial resistance is a growing concern. We believe AP-SA02 could also have a meaningful impact in these indications, particularly infections caused by methicillin-resistant *S. aureus* ("MRSA"). On August 1, 2022, we announced that we had received from the FDA the approval to proceed for our IND application for AP-SA02, in a second indication, PJI. We had planned to initiate a Phase 1b/2a trial in 2023; however, in light of the growing concerns of both PJI and wound infection, we are revising the protocol to include both indications, which will assess the safety and tolerability of intravenous and intra-articular AP-SA02 as an adjunct to standard of care antibiotics in adults undergoing debridement, antibiotics, and implant retention for the treatment of periprosthetic joint infections and/or wound infections caused by *S. aureus*.

Discovery Research

In addition to developing our more advanced pipeline programs described above, we continue phage discovery efforts by screening other interesting bacterial targets against our phage library in order to further expand our pipeline. *Klebsiella pneumoniae* phage, for example, is a potentially important addition to treatment options for serious lung infections.

Furthermore, our team of microbiologists and synthetic biologists hunt for natural phages and evaluate the suitability of these natural phages for engineering and adaptation using our synthetic phage platform. These powerful natural well-adapted phages can be purposely engineered to be more efficient killers. The use of synthetic biology tools enables us to precisely engineer natural phages in ways that further improve their pharmacological properties and antimicrobial activity. Attributes of engineered phages can include expanded host range, improved potency which is a

fundamental drug property that can translate into improved clinical efficacy, and importantly, biofilm disruption, which is a critical aspect of serious infections that needs to be addressed.

Manufacturing

We currently produce clinical quantities of each of our bacteriophage product candidates at our cGMP-compliant manufacturing facility in Marina del Rey, California. This facility has approximately 35,500 square feet of laboratory and office space, including 3,000 square feet of cGMP laboratory space, designed to produce clinical quantities of each of our product candidates and to perform in-house Quality Control ("QC") testing. We operate in-house process development activities through to the production, purification, formulation, and release of our therapeutic phage cocktails for use in human clinical trials. Our facility is licensed by the California Department of Public Health for drug manufacturing and is subject to periodic, unannounced inspections for compliance with cGMP and other state and federal laws and regulations. The facility is subject to periodic inspections by the City of Los Angeles and Los Angeles County for fire hazard and waste management and is in compliance with all applicable regulations. Our facility is staffed with an independent Quality Unit and Manufacturing and Facilities personnel trained under cGMPs.

Our current formulations for our *P. aeruginosa* and *S. aureus* phage product candidates are intended for inhaled and intravenous delivery, both requiring our drug products to be sterile. Our Marina del Rey facility is capable of manufacturing sterile drug products, utilizing ISO-certified cleanrooms and ISO 5-certified biological safety cabinets. The facility also houses an ISO 5-certified closed system isolator. We may further optimize future formulations of our product candidates which may or may not require assurance of sterility.

For our manufacturing facility we have been able to access and hire highly skilled process development and phage manufacturing expertise and believe that we have control of our proprietary platform from phage identification through final product fill and finish and release. Manufacturing campaigns are managed by a specialist team of our internal staff, which is designed to promote compliance with the technical aspects and regulatory requirements of the manufacturing process. We have developed a cGMP-compliant manufacturing process that utilizes both industry standard and proprietary methods for the manufacture of our product candidates. Our process is designed to be scalable to meet our clinical study needs, and to fulfill the requirements of regulators for human studies.

Although our facility is capable of manufacturing our phage product candidates, we rely on, and may continue to rely on, third-party contract manufacturers for the manufacture of certain raw materials, components, or packaging of the product candidates that may be developed for clinical testing, as well as for commercialization. We are constructing the new manufacturing facility in Los Angeles, California and plan to move manufacturing processes to this new facility in the second half of 2024.

Intellectual Property

General

Our goal is to protect the proprietary technology that we believe is important to our business, including to obtain, maintain and enforce patent protection for our product candidates, formulations, processes, methods and any other proprietary technologies, preserve our trade secrets and operate without infringing on the proprietary rights of other parties, both in the United States and in other countries. Our policy is to actively seek to obtain, where appropriate, the broadest intellectual property protection possible for our current product candidates and any future product candidates, proprietary information and proprietary technology through a combination of contractual arrangements and patents, both in the United States and abroad. However, patent protection may not afford us with complete protection against competitors who seek to circumvent our patents.

We also rely on trademarks, trade secrets, know-how, continuing technological innovation and in-licensing opportunities to develop and maintain our proprietary position. We also depend upon the skills, knowledge, experience and know-how of our management and research and development personnel, as well as that of our advisors, consultants and other contractors. To help protect our proprietary processes and know-how, which is not patentable, and for inventions for which patents may be difficult to enforce, we currently and will in the future rely on trade secret

protection and contractual obligations with third parties to protect our interests and to develop and maintain our competitive position. To this end, we require all of our employees, consultants, advisors and other contractors to enter into agreements with contractual obligations that prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business.

Our success in preserving market exclusivity for our product candidates relies on patent protection, including extensions to this where appropriate, and on data exclusivity relating to an approved biologic. This may be extended by orphan drug and/or pediatric use protection where appropriate. Once any regulatory period of data exclusivity expires, depending on the status of our patent coverage, we may not be able to prevent others from marketing and selling biosimilar versions of our product candidates. We are also dependent upon the diligence of our appointed agents in national jurisdictions, acting for and on our behalf, which manage the prosecution of pending domestic and foreign patent applications and maintain granted domestic and foreign patents.

Because patent applications in the United States and certain other jurisdictions are maintained in secrecy for 18 months or potentially even longer, and because publication of discoveries in the scientific or patent literature often lags behind actual discoveries and patent application filings, we cannot be certain of the priority of inventions covered by pending patent applications. Accordingly, we may not have been the first to invent the subject matter disclosed in some of our patent applications or the first to file patent applications covering such subject matter, and we may have to participate in interference proceedings or derivation proceedings declared by the United States Patent and Trademark Office (the "USPTO") to determine priority of invention.

Bacteriophage Patent Portfolio

As of December 31, 2023, we owned or had exclusive license rights to a total of 151 patents and applications: 13 U.S. patents, 10 U.S. patent applications, 73 foreign patents, and 55 foreign patent applications, with nominal expiration on various dates between 2024 and 2044. Patent term adjustments or patent term extensions could result in later expiration dates. We believe these patents and applications cover our lead phage therapeutic programs and use thereof, synthetic phage and methods of manufacture thereof, beneficial effects of bacteriophage treatment - including treatment and prevention of bacteria-associated cancers, bacteriophage combinations, the sequential use of bacteriophages in combination with conventional antibiotics, genetic sequence variations, methods to reduce antibiotic resistance, methods to treat bacterial biofilms, methods to design therapeutic combination panels of bacteriophage, disinfection methods using bacteriophages, and bacteriophage mutants having increased bacterial host spectra.

Competition

The development and commercialization of new drugs is highly competitive. We face competition from many different sources, including commercial pharmaceutical and biotechnology enterprises, academic institutions, government agencies and private and public research institutions all seeking to develop novel treatment modalities for bacterial infections. Many of our competitors have significantly greater financial, product development, manufacturing and marketing resources than us. Large pharmaceutical companies have extensive experience in clinical development and obtaining regulatory approval for drug products. In addition, many universities and private and public research institutes are active in antibacterial research, some in direct competition with us. We also may compete with these organizations to recruit scientists and clinical development personnel.

Our ability to compete successfully will depend largely on our ability to leverage our collective experience in drug discovery, development and commercialization to:

- discover and develop medicines that are differentiated from other products in the market;
- obtain patent and/or proprietary protection for our products and technologies;
- obtain required regulatory approvals;

- obtain a commercial partner;
- commercialize our drugs, if approved; and
- attract and retain high-quality research, development and commercial personnel.

Key factors affecting the success of any approved product include its efficacy, safety profile, drug interactions, method of administration, pricing, reimbursement and level of promotional activity relative to those of competing drugs.

The majority of phage companies are focused on aspects outside of human health such as agriculture, food, environmental, veterinary, biocontrol, manufacturing, and diagnostics. There are a handful of small biotechnology companies developing bacteriophage products to treat human diseases. To our knowledge, several biotechnology companies in the United States and Europe, including Adaptive Phage Therapeutics, BiomX Inc., Intralytix, Inc., Locus Biosciences, Inc., TechnoPhage, SA, Felix Biotechnology, as well as academic institutions, have discovery stage or clinical programs utilizing naturally occurring phages or synthetic biology approaches to genetically modify bacteriophages to remove or input genes to improve therapeutic properties such as increases to the bacterial host range to infect a larger number of bacterial strains and decrease the need for using multiple phages in a product.

Our bacteriophage programs may compete with or be synergistic with currently approved antibiotics, and experimental approaches such as novel antibiotics, antimicrobial peptides, antimicrobial vaccines, metals, antisense, monoclonal antibodies and possibly microbiome manipulation.

Sales and Marketing

We have full worldwide commercial rights to all of our phage-based product candidates to treat drug-resistant bacterial infections, including our product candidates: AP-PA02 and AP-PA03 for the treatment of *P. aeruginosa* infections, and AP-SA02 for the treatment of *S. aureus* infections. We believe we can maximize the value of our company by retaining substantial global commercialization rights to these product candidates and, where appropriate, entering into partnerships to develop and commercialize these product candidates.

We have not yet established a sales, marketing or product distribution infrastructure because our lead candidates are still in early clinical development. Subject to receiving marketing approvals or earlier, we intend to either partner the commercial rights to our products with existing companies that have the wherewithal and resources to commercialize building the necessary marketing and sales infrastructure to market and sell our current product candidates. We also intend to explore the use of a variety of distribution agreements and commercial partnerships in those territories where we do not establish a sales force for any of our product candidates that obtain marketing approval.

Material Agreements

Strategic Alliances and Research Agreements

MTEC Grant

On June 15, 2020, we entered into a Research Project Award agreement (the "MTEC Agreement") with the Medical Technology Enterprise Consortium ("MTEC"), pursuant to which we received a $15.0 million grant and entered into a three-year program administered by the U.S. Department of Defense through MTEC managed by the Naval Medical Research Command with funding from the Defense Health Agency and Joint Warfighter Medical Research Program. On September 29, 2022, the MTEC Agreement was modified to increase the total award by $1.3 million to $16.3 million and extend the term into the second half of 2024. The MTEC funds are used to partially fund a Phase 1b/2a, randomized, double-blind, placebo-controlled, dose escalation clinical study of the Company's therapeutic phage-based candidate, AP-SA02, for the treatment of complicated *Staphylococcus aureus* bacteremia infections. The MTEC Agreement specifies that the grant is paid to the Company over the term of the award through a cost reimbursable model, based on agreed-upon cost share percentages, and the grant money received is not refundable to MTEC.

Upon license or commercialization of intellectual property developed with the funding from the MTEC Agreement, additional fees will be due to MTEC. The Company will elect whether to (a) pay a fixed royalty amount, which is subject to a cap based upon total funding received, or (b) pay an additional assessment fee, which would also be subject to a cap based upon a percentage of total funding received.

The MTEC Agreement is effective through October 30, 2024. The MTEC Agreement may be terminated in whole or in part, 30 calendar days following written notice from the Company to MTEC. In addition, MTEC has the right to terminate the MTEC Agreement upon material breach by the Company.

CFF Therapeutics Development Award

On March 13, 2020, the Company entered into an award agreement (the "Award Agreement") with CFF, pursuant to which the Company received a Therapeutics Development Award of $5.0 million (the "CFF Award"). The CFF Award has funded a portion of the Company's Phase 1b/2a clinical trial of the *Pseudomonas aeruginosa* ("*P. aeruginosa*") phage candidate, AP-PA02, as a treatment for airway infections in people with cystic fibrosis ("CF").

The first payment under the Award Agreement, in the amount of $1.0 million, became due upon signing the Award Agreement and was received in April 2020. The remainder of the Award was paid to the Company incrementally in installments upon the achievement of certain milestones related to the development program and progress of the Phase 1b/2a clinical trial of AP-PA02, as set forth in the Award Agreement. The final milestone was achieved in the fourth quarter of 2023 and the milestone payment was received in the first quarter of 2024.

If the Company ceases to use commercially reasonable efforts directed to the development of AP-PA02, or any other product (as defined in the Award Agreement), for a period of 360 days (an "Interruption") and fails to resume the development of the product after receiving from CFF notice of an Interruption, then the Company must either repay the amount of the CFF Award actually received by the Company, plus interest, or grant to CFF (1) an exclusive (even as to the Company), worldwide, perpetual, sublicensable license under technology developed under the Award Agreement that covers the product for use in treating infections in CF patients (the "CF Field"), and (2) a non-exclusive, worldwide, perpetual, sublicensable license under certain background intellectual property covering the product, to the extent necessary to commercialize the Product in the CF Field.

Upon commercialization by the Company of any product, the Company will owe a fixed royalty amount to CFF, which is to be paid in installments determined, in part, based on commercial sales volumes of the product. The Company will be obligated to make an additional fixed royalty payment upon achieving specified sales milestones. The Company may also be obligated to make a payment to CFF if the Company transfers, sells or licenses the product in the CF Field, or if the Company enters into a change of control transaction.

The term of the Award Agreement commenced on March 10, 2020 and expires on the earlier of the date on which the Company has paid CFF all of the fixed royalty payments set forth therein, the effective date of any license granted to CFF following an Interruption, or upon earlier termination of the Award Agreement. Either CFF or the Company may terminate the Award Agreement for cause, which includes the Company's material failure to achieve certain development milestones. The Company's payment obligations survive the termination of the Award Agreement.

License Agreements

Amended and Restated Research Collaboration and Option to License Agreement with Merck

Pursuant to the terms of the Amended and Restated Research and Option to License Agreement (the "Research and Option Agreement"), entered into by and between us and Merck Sharp & Dohme Corp. ("Merck"), we were engaged in generating broad host range synthetic bacteriophage candidate(s) targeting an undisclosed infectious disease agent(s), pursuant to the criteria set forth in the research plan.

We granted to Merck an exclusive, worldwide license in our patent rights, and our interest in any joint patent rights, with the right to grant and authorize sublicenses, for any and all uses of any product candidates, or products, developed through the research plans set forth in the Research and Option Agreement in a specific field of use. Further, in exchange for milestone payments associated with product development and regulatory achievements and royalty payments based on net sales of products developed, we granted to Merck an exclusive, worldwide license, with the right to grant and authorize sublicenses, in our background intellectual property and know-how, solely to make, have made, use, import, offer to sell and sell (but not genetically modify) the product candidates, or products, developed through the research plans set forth in the Research and Option Agreement in the specific field of use.

On December 14, 2022, Armata received a notice of termination, which became effective on March 14, 2023, in accordance with Section 8.2.1 of the Research and Option Agreement.

License Agreement with United Kingdom Secretary of State for the Department of Health

In January 2011, upon completion of our acquisition of Biocontrol Ltd., we assumed a license agreement entered into in March 2007 between Biocontrol Ltd. and the Health Protection Agency, Centre for Emergency Preparedness and Response, to use certain intellectual property rights to develop treatments for bacterial biofilm infections. The agreement was subsequently assigned to the United Kingdom Secretary of State for the Department of Health ("DoH").

Under the license agreement, we have obtained exclusive rights to a patent portfolio related to the use of bacteriophages combined with biofilm-disrupting agents in treating biofilm infections. In consideration for the exclusive license, we may be required to pay to the DoH certain milestone payments in the aggregate of up to £10,000 per product, as well as single digit percentage royalty on net sales of products incorporating licensed intellectual property.

The license agreement will remain in effect until the expiration of the last patent exclusively licensed under the license agreement. If we default on any milestone or royalty payments, or upon breach by us of certain other terms of the license agreement, the DoH may either terminate the license agreement immediately upon written notice or modify the license to be non-exclusive upon 30 days' written notice.

Facilities

Our corporate headquarters are located in Los Angeles, California, with an address of 5005 McConnell Avenue, Los Angeles, CA 90066. On October 28, 2021, we entered into a lease for 56,300 square feet of office, research and development and manufacturing space under a non-cancellable lease (the "2021 Lease"). The 2021 Lease payment start date was May 1, 2022, and the total lease term is for 16 years and runs through 2038. Office space and research laboratories have been fully occupied since the third quarter of 2023, with cGMP manufacturing space (~10,000 sq. ft.) expected to be fully constructed in the second half of 2024.

We have a facility located in Marina del Rey, California, with an address of 4503 Glencoe Avenue, Marina del Rey, CA 90292, where we currently lease 35,500 square feet of office, research and development and manufacturing space. The lease expires on December 31, 2031. The facility includes approximately 3,000 square feet of cGMP laboratory space, which currently serves to produce clinical quantities of our phage product candidates for ongoing human trials and to perform in-house QC testing. As we move our manufacturing into the McConnell facility by mid-2024, we are actively seeking a sub-tenant at the Glencoe location to take over the remaining term of the 4503 Glencoe Avenue lease.

In addition, we lease a 5,000 square foot facility located in Sydney, Australia, which includes 4,000 square feet of laboratory space providing capabilities to support phage product development and manufacturing process development.

We believe that our facilities are adequate for our current and long-term needs. Additionally, we believe the newly constructed McConnell facility, offering expanded manufacturing capacity, will allow us to pursue contract manufacturing opportunities for phage and other advanced biologics.

Legal Proceedings

From time to time, we are a party to certain litigation that is either judged to be not material or that arises in the ordinary course of business. We intend to vigorously defend our interests in these matters. We expect that the resolution of these matters will not have a material adverse effect on our business, financial condition or results of operations. However, due to the uncertainties inherent in litigation, no assurance can be given as to the outcome of these proceedings.

As of the date of this Annual Report, we are not subject to any material legal proceedings.

Government Regulation

Government authorities in the United States, at the federal, state and local level, and other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of drug and biological products such as those we are developing. Generally, before a new drug or biologic can be marketed, considerable data demonstrating its quality, safety, efficacy, purity, and/or potency must be obtained, organized into a format specific for each regulatory authority, submitted for review and approved by the regulatory authority where the product is intended to be marketed.

United States Product Development Process

The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable FDA requirements at any time during the product development process or approval process, or after approval, may subject an applicant to administrative or judicial sanctions. FDA sanctions could include refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us. The process required by the FDA before a biological product may be marketed in the United States generally involves the following:

- Completion of preclinical laboratory tests, animal studies and formulation studies according to good laboratory practice requirements ("GLP") or other applicable regulations;

- Submission to the FDA of an IND application, which must be granted before human clinical trials may begin in the United States or internationally if submitting results to the FDA;

- Performance of adequate and controlled human clinical trials according to the FDA's regulations commonly referred to as good clinical practices ("GCPs") and any additional requirements for the protection of human research subjects and their health information, to establish the safety and efficacy of the proposed biological product for its intended use or uses;

- Submission to the FDA of a Biologics License Application ("BLA") for a new biological product;

- Satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities where the biological product is produced to assess compliance with the FDA's cGMP regulations, to assure that the facilities, methods and controls are adequate to preserve the biological product's identity, strength, quality and purity;

- Potential FDA inspection of the nonclinical study sites and clinical trial sites that generated the data in support of the BLA; and

- FDA's approval of the BLA, which must occur before a biological product can be marketed or sold in the United States.

The lengthy process of seeking required approvals and the continuing need for compliance with applicable statutes and regulations require the expenditure of substantial resources even when approvals are inherently uncertain.

The strategies, nature, and technologies of bacteriophage products are different from those of conventional antibiotic therapy products. From the regulatory requirements established to ensure the safety, efficacy and quality of bacteriophage preparations, there are several major points to consider during the development, manufacturing, characterization, preclinical study and clinical trial of bacteriophage products. The major issues include:

- Phage preparation design (single agent versus phage mixes and wild-type phage versus genetically engineered phage);

- Proof of concept in development of phage products;

- Selectivity of bacteriophage replication and targeting to specific species of bacteria;

- Relevant animal models in preclinical studies; and

- Clinical safety and efficacy.

Preclinical Studies and IND

Before testing any compounds with potential therapeutic value in humans, the biological product candidate enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product biology, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the biological product candidate. The conduct of the preclinical tests must comply with federal regulations and requirements, including good laboratory practices described in 21 CFR Part 58 (GLP). The sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND application. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA places the IND on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a product candidate at any time before or during clinical trials due to safety concerns or non-compliance. Accordingly, we cannot be certain that submission of an IND application will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate such clinical trial.

Clinical Trials

Clinical trials involve the administration of the product candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by the sponsor. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject inclusion and exclusion criteria and the parameters to be used to monitor subject safety. Each protocol must be submitted to the FDA. Clinical trials must be conducted in accordance with GCP requirements. Further, each clinical trial must be

reviewed and approved by an independent institutional review board ("IRB") or ethics committee if conducted outside of the United States, at or servicing each institution at which the clinical trial will be conducted. An IRB or ethics committee is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB or ethics committee also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. We intend to use third-party CROs to administer and conduct our planned clinical trials and will rely upon such CROs, as well as medical institutions, clinical investigators and consultants, to conduct our trials in accordance with our clinical protocols. The failure by any of such third parties to meet expected timelines, adhere to our protocols or meet regulatory standards could adversely impact the subject product development program and we remain legally responsible for compliance with applicable laws and regulations governing the conduct of these clinical trials.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1: The product candidate is initially introduced into healthy human subjects and tested primarily for safety and dosage tolerance. Absorption, metabolism, distribution and excretion may also be tested.

- Phase 2: The product candidate is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product candidate for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule.

- Phase 3: Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for product labeling. Generally, two adequate and well-controlled Phase 3 clinical trials are required by the FDA and other regulatory authorities for approval of a marketing application.

Post-approval studies, or Phase 4 clinical trials, may be requested by the FDA as a condition of approval and are conducted after initial marketing approval. These studies are used to gain additional experience from the treatment of patients in the intended therapeutic indication.

Progress reports detailing the results of the clinical trials must be submitted annually to the FDA and written safety reports must be submitted to the FDA and the investigators for serious and unexpected adverse events or any finding from tests in laboratory animals that suggest that there may be a significant risk for human subjects. The FDA or the sponsor or, if used, the sponsor's data safety monitoring board may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB or ethics committee can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's or ethics committee's requirements or if the pharmaceutical product has been associated with unexpected serious harm to patients. Suspension of a clinical trial due to safety risks attributed to the investigational product will result in termination of the trial and possibly others that are underway.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the physical characteristics of the product candidate as well as finalize a process for manufacturing the product candidate in commercial quantities in accordance with cGMP requirements. To help reduce the risk of the introduction of adventitious agents or other impurities with the use of biological products, the Public Health Service Act emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the sponsor must develop methods for testing the identity, strength, quality, potency, and purity of the final biological product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the biological product candidate does not undergo unacceptable deterioration over its shelf life.

FDA Review and Approval Processes

In order to obtain approval to market a biological product in the United States, a BLA that provides data establishing to the FDA's satisfaction the safety and effectiveness of the investigational product candidate for the proposed indication must be submitted to the FDA. The application includes all data available from nonclinical studies and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's manufacture and composition, and proposed labeling, among other things. The testing and approval processes require substantial time and effort and there can be no assurance that the FDA will accept the BLA for filing and, even if filed, that any approval will be granted on a timely basis, if at all.

Under the Prescription Drug User Fee Act, as amended ("PDUFA"), each BLA must be accompanied by a significant user fee. The FDA adjusts the PDUFA user fees on an annual basis. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA has 60 days from its receipt of a BLA to determine whether the application will be accepted for filing based on the agency's threshold determination that the application is sufficiently complete to permit substantive review. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. After the BLA is accepted for filing, the FDA reviews it to determine, among other things, whether the proposed product is safe and effective for its intended use, has an acceptable purity profile, and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, safety, strength, quality, potency, and purity. Under the goals and policies agreed to by the FDA under PDUFA, the FDA has 10 months from the filing date in which to complete its initial review of an original BLA and respond to the applicant, and six months from the filing date of an original BLA designated for priority review. The FDA does not always meet its PDUFA goal dates for standard and priority BLAs, and the review process is often extended by FDA requests for additional information or clarification.

Before approving a BLA, the FDA will conduct a preapproval inspection of the manufacturing facilities for the new product to determine whether they comply with cGMP requirements. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. The FDA also may audit data from clinical trials to ensure compliance with GCP requirements. Additionally, the FDA may refer applications for novel product candidates or those that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and, if so, under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. The FDA may ultimately decide that the BLA does not satisfy the criteria for approval. If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product 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, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making the product available in the United States for this type of disease or condition will be recovered from sales of the product. Orphan drug designation for a biologic must be requested before submitting a 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 drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan designation subsequently receives the first FDA approval for the rare disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication for seven years from the date of such approval. Additionally, the sponsor can benefit from certain financial incentives, including opportunities for grant funding towards clinical trial costs, research and development tax credits, and user fee waivers. If the same drug has already been approved, the proposed drug needs to demonstrate clinical superiority to obtain orphan exclusivity for the same indication, such as by means of greater effectiveness, greater safety or providing a major contribution to patient care, or in instances of drug supply issues.

Competitors, however, may receive approval of either a different product for the same indication or the same product for a different indication but that could be used off-label in the orphan indication. Orphan drug exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval before we do for the same product, as defined by the FDA, for the same indication we are seeking approval, or if our product is determined to be contained within the scope of the competitor's product for the same indication or disease. If one of our products designated as an orphan drug receives marketing approval for an indication broader than that which is designated, it may not be entitled to orphan drug exclusivity. Orphan drug status in the European Union has similar, but not identical, requirements and benefits.

Pediatric Information

Under the Pediatric Research Equity Act, a BLA or supplement to a BLA must contain data to assess the safety and efficacy of the biologic for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of pediatric data or full or partial waivers. A sponsor who is planning to submit a marketing application for a drug that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration must submit an initial Pediatric Study Plan ("PSP") within 60 days of an end-of-Phase 2 meeting or, if there is no such meeting, as early as practicable before the initiation of the Phase 3 or Phase 2/3 study. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach an agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from preclinical studies, early phase clinical trials and/or other clinical development programs.

Special FDA Expedited Review and Approval Programs

The FDA has various programs, including Fast Track designation, Limited Population, accelerated approval and priority review, that are intended to expedite the process for the development and FDA review of drugs that are intended for the treatment of serious or life-threatening diseases or conditions and demonstrate the potential to address unmet medical needs. The purpose of these programs is to provide important new drugs and biological products to patients earlier than under standard FDA review procedures.

To be eligible for a Fast Track designation, the FDA must determine, based on the request of a sponsor, that a product is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address an unmet medical need, or if the drug or biological product qualifies as a qualified infectious disease product under the Generating Antibiotic Incentives Now Act. The FDA will determine that a product will fill an unmet medical need if it will provide a therapy where none exists or provide a therapy that may be potentially superior to existing therapies based on efficacy or safety factors. We intend to request Fast Track designation for our product candidates if applicable.

Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a new drug or biological may request the FDA to designate the drug or biologic as a Fast Track product at any time during the clinical development of the product. Unique to a Fast Track product, the FDA may consider for review sections of the marketing application on a rolling basis before the complete application is submitted,

if the sponsor provides a schedule for the submission of the sections of the application, the FDA agrees to accept sections of the application and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application.

Any product submitted to the FDA for marketing, including under a Fast Track program, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review, accelerated approval, and, as of 2018, for antibacterial and antifungal therapies, approval under the Limited Population Pathway. Any product is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or if there is a significant improvement in the treatment, diagnosis or prevention of a disease compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug or biological product designated for priority review in an effort to facilitate the review. Additionally, a product may be eligible for accelerated approval. Drug or biological products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval, which means that they may be approved on the basis of adequate and well-controlled clinical trials establishing that the product has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity or mortality or other clinical benefits, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. The limited population pathway for antibacterial and antifungal drugs or biologics ("LPAD") may enable the streamlined development of safe and effective medicines that overcome the unmet needs of a limited population of patients with serious bacterial infections.

As a condition of approval, the FDA may require a sponsor of a drug or biological product receiving accelerated approval to perform post-marketing studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical endpoint, and the drug or biological product may be subject to accelerated withdrawal procedures. In addition, the FDA currently requires as a condition for accelerated approval and approval under LPAD pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. Fast Track designation, priority review and accelerated approval do not change the standards for approval but may expedite the development or approval process. Approval under LPAD is for a limited population of patients; labeling statements for the limited use of the product are removed when supplemental data substantiates expansion of the patient population.

Eligibility for a drug or biologic product to be licensed under LPAD includes treatment of a serious or life-threatening infection in a limited population of patients with unmet medical need. FDA also considers the severity, rarity or prevalence of the infection and the lack of alternative treatment in the limited population the therapeutic is intended for. It is possible for qualifying therapies to complete a streamlined clinical program to demonstrate substantial evidence of effectiveness and safety in the limited population. Drugs or biological products approved under LPAD can also receive fast track and breakthrough designations as well as accelerated and priority review of the marketing application. LPAD-required limitations of labeling are removed when supplemental data demonstrating a favorable benefit-risk profile in a broader population corroborates label expansion. We intend to request approval under LPAD in the BLA for our product candidates if applicable.

A sponsor can also request designation of a product candidate as a "breakthrough therapy." A breakthrough therapy is defined as a drug or biological product that is intended, alone or in combination with one or more other drugs or biological products, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the biological product or drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Drugs or biological products designated as breakthrough therapies are also eligible for accelerated approval. The FDA must take certain actions, such as holding timely meetings and providing advice, intended to expedite the development and review of an application for approval of a breakthrough therapy. We intend to request "breakthrough therapy" designation for our product candidates if applicable.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

FDA Post-Approval Requirements

Maintaining substantial compliance with applicable federal, state, local, and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Rigorous and extensive FDA regulation of new products continues after approval, particularly with respect to cGMP. We may rely on third parties for the production of commercial quantities of any products that we may commercialize. We and third-party manufacturers of our products are required to comply with applicable requirements in the cGMPs, including quality control and quality assurance and maintenance of records and documentation. We cannot be certain that we or our present or future suppliers will be able to comply with the cGMP and other FDA requirements. Other post-approval requirements applicable to biological products include reporting of cGMP deviations that may affect the identity, potency, purity and overall safety of a distributed product, record-keeping requirements, reporting of adverse effects, reporting updated safety and efficacy information, and complying with electronic record and signature requirements. After a BLA is approved, the product also may be subject to official lot release. As part of the manufacturing process, 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 by the FDA, the manufacturer submits samples of each lot of product to the FDA 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. The FDA also may perform certain confirmatory tests on lots of some products, such as viral vaccines, before releasing the lots for distribution by the manufacturer. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, potency, and effectiveness of biological products.

Discovery of previously unknown problems or the failure to comply with the applicable regulatory requirements, by us or our suppliers, may result in restrictions on the marketing of a product or withdrawal of the product from the market as well as possible civil or criminal sanctions and adverse publicity. FDA sanctions could include refusal to approve pending applications, withdrawal of an approval, clinical hold, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, mandated corrective advertising or communications with doctors, debarment, restitution, disgorgement of profits, or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

Biological product manufacturers and other entities involved in the manufacture and distribution of approved products are required to register their facilities with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMPs and other laws. In addition, changes to the manufacturing process or facility generally require prior FDA approval before being implemented and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

Labeling, Marketing and Promotion

The FDA closely regulates the labeling, marketing and promotion of drugs and biological products, including direct-to-consumer advertising, promotional activities involving the internet, and industry-sponsored scientific and educational activities. While doctors are free to prescribe any product approved by the FDA for any use, a company can only make claims relating to safety and efficacy of a product that are consistent with FDA approval, and the company is allowed to actively market a product only for the particular use and treatment approved by the FDA. In addition, any claims we make for our products in advertising or promotion must be appropriately balanced with important safety information and otherwise be adequately substantiated. Failure to comply with these requirements can result in adverse publicity, warning letters, corrective advertising, injunctions and potential civil and criminal penalties.

Patent Term Restoration and Extension

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, including the United States ("U.S."), the base term is 20 years from the filing date of the earliest-filed non-provisional patent application from which the patent claims priority. The term of a U.S. patent can be lengthened by patent term adjustment, which compensates the owner of the patent for administrative delays at the USPTO. Depending upon the timing, duration and specifics of FDA approval of our drugs, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term

Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one half the time between the effective date of an IND, and the submission date of an NDA or BLA, plus the time between the submission date of an NDA or BLA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension, and the extension must be applied for prior to expiration of the patent. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration.

Some foreign jurisdictions, including Europe and Japan, have analogous patent term extension provisions, which allow for extension of the term of a patent that covers a drug approved by the applicable foreign regulatory agency.

Biologics Price Competition and Innovation Act of 2009: Biosimilars and Interchangeable Biologic Products

The Biologics Price Competition and Innovation Act of 2009 amended the Public Health Service Act to create an abbreviated approval pathway for two types of "generic" biologics — biosimilars and interchangeable biologic products, and provides for a twelve-year data exclusivity period for the first approved biological product, or reference product, against which a biosimilar or interchangeable application is evaluated; however, if pediatric clinical trials are performed and accepted by the FDA, the twelve-year data exclusivity period will be extended for an additional six months. A biosimilar product is defined as one that is highly similar to a reference product notwithstanding minor differences in clinically inactive components and for which there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity and potency of the product. An interchangeable product is a biosimilar product that may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.

The biosimilar applicant must demonstrate that the product is biosimilar based on data from (1) analytical studies showing that the biosimilar product is highly similar to the reference product; (2) animal studies (including toxicity); and (3) one or more clinical trials to demonstrate safety, purity and potency in one or more appropriate conditions of use for which the reference product is approved. In addition, the applicant must show that the biosimilar and reference products have the same mechanism of action for the conditions of use on the label, route of administration, dosage and strength, and the production facility must meet standards designed to assure product safety, purity and potency.

An application for a biosimilar product may not be submitted until four years after the date on which the reference product was first approved. The first approved interchangeable biologic product will be granted an exclusivity period of up to one year after it is first commercially marketed, but the exclusivity period may be shortened under certain circumstances.

Pediatric Exclusivity

Pediatric exclusivity is a type of marketing exclusivity available in the United States under the Best Pharmaceuticals for Children Act, which provides for an additional six months of marketing exclusivity and may be available if a sponsor conducts clinical trials in children in response to a written request from the FDA (the "Written Request"). If the Written Request does not include clinical trials in neonates, the FDA is required to include its rationale for not requesting those clinical trials. The FDA may request studies on approved or unapproved indications in separate Written Requests. The issuance of a Written Request does not require the sponsor to undertake the described clinical trials.

Diagnostics

We may employ companion diagnostics to help us to more accurately identify patients within a particular bacterial strain, both during our clinical trials and in connection with the commercialization of our product candidates that we are developing or may in the future develop. Companion diagnostics can identify patients who are most likely to benefit from a particular therapeutic product; identify patients likely to be at increased risk for serious side effects as a result of treatment with a particular therapeutic product; or monitor response to treatment with a particular therapeutic product for the purpose of adjusting treatment to achieve improved safety or effectiveness. Companion diagnostics are regulated as

medical devices by the FDA and, as such, require either clearance or approval prior to commercialization. The level of risk combined with available controls to mitigate risk determines whether a companion diagnostic device requires Premarket Approval Application approval or is cleared through the 510(k) premarket notification process. For a novel therapeutic product for which a companion diagnostic device is essential for the safe and effective use of the product, the companion diagnostic device should be developed and approved or 510(k)-cleared contemporaneously with the therapeutic. The use of the companion diagnostic device will be stipulated in the labeling of the therapeutic product.

Other U.S. Healthcare Laws and Compliance Requirements

In addition to FDA restrictions on the marketing of pharmaceutical products, we may be subject to various federal and state laws targeting fraud and abuse in the healthcare industry. These laws may impact, among other things, our business or financial arrangements and relationships through which we market, sell and distribute the products, if any, for which we obtain approval. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid 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, 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 federal False Claims Act or federal civil money penalties statute;

- federal civil and criminal false claims laws and civil monetary penalties laws, such as the federal False Claims Act, which impose criminal and civil penalties and authorize civil whistleblower or qui tam actions, against individuals or entities for, among other things: knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent; making, using or causing to be made or used, a false statement or record material to a false or fraudulent claim or obligation to pay or transmit money or property to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the federal government;

- the anti-inducement law, which prohibits, among other things, the offering or giving of remuneration, which includes, without limitation, any transfer of items or services for free or for less than fair market value (with limited exceptions), to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular supplier of items or services reimbursable by a federal or state governmental program;

- The Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH"), which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare 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;

- HIPAA, as amended by HITECH, and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective

business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information;

- the federal transparency requirements under the Affordable Care Act (the "ACA"), including the provision commonly referred to as the Physician Payments Sunshine Act, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually to the U.S. Department of Health and Human Services information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members;

- federal government price reporting laws, which require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs; and

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

Additionally, we are subject to state and foreign equivalents of each of the healthcare laws described above, among others, some of which may be broader in scope and may apply regardless of the payor. Many U.S. states have adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare services reimbursed by any source, not just governmental payors, including private insurers. In addition, some states have passed laws that require pharmaceutical companies to comply with the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and/or the Pharmaceutical Research and Manufacturers of America's Code on Interactions with Healthcare Professionals. Several states also impose other marketing restrictions or require pharmaceutical companies to make marketing or price disclosures to the state. There are ambiguities as to what is required to comply with these state requirements, and if we fail to comply with an applicable state law requirement, we could be subject to penalties. Finally, there are state and foreign laws governing the privacy and security of health information, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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 business activities could be subject to challenge under one or more of such laws.

Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including penalties, fines, imprisonment and/or exclusion or suspension from federal and state healthcare programs such as Medicare and Medicaid and debarment from contracting with the U.S. government. In addition, private individuals have the ability to bring actions on behalf of the U.S. government under the federal False Claims Act as well as under the false claims laws of several states.

Law enforcement authorities are increasingly focused on enforcing fraud and abuse laws, and it is possible that some of our practices may be challenged under these laws. Efforts to ensure that our current and future business arrangements with third parties, and our business generally, will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices, including our arrangements with physicians and other healthcare providers, some of whom receive stock options as compensation for services provided, may not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In

addition, the approval and commercialization of any of our product candidates outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

If any of the physicians or other healthcare 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 healthcare programs, which may also adversely affect our business.

Additional Regulation

In addition to the foregoing, state and federal laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservancy and Recovery Act and the Toxic Substances Control Act, affect our business. These and other laws govern our use, handling and disposal of various biological, chemical and radioactive substances used in, and wastes generated by, our operations. If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines. We believe that we are in material compliance with applicable environmental laws and that continued compliance therewith will not have a material adverse effect on our business. We cannot predict, however, how changes in these laws may affect our future operations.

U.S. Foreign Corrupt Practices Act

The U.S. Foreign Corrupt Practices Act, to which we are subject, prohibits corporations and individuals from engaging in certain activities to obtain or retain business or to influence a person working in an official capacity. It is illegal to pay, offer to pay or authorize the payment of anything of value to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity.

U.S. Healthcare Reform

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medical products. For example, in March 2010, the ACA was enacted, which, among other things, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; introduced a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; extended the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care plans; imposed mandatory discounts for certain Medicare Part D beneficiaries as a condition for manufacturers' outpatient drugs coverage under Medicare Part D; subjected drug manufacturers to new annual fees based on pharmaceutical companies' share of sales to federal healthcare programs; imposed a new federal excise tax on the sale of certain medical devices; created a new Patient Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research; and established the Center for Medicare Innovation at the Centers for Medicare and Medicaid to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

Since its enactment, there have been a number of significant changes to the ACA. On October 13, 2017, President Trump signed an Executive Order terminating the cost-sharing subsidies that reimburse insurers under the Affordable Care Act. Several state Attorneys General filed suit to stop the administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017. In addition, CMS has recently proposed regulations that would give states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. In January 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the Affordable Care Act to waive, defer, grant exemptions from, or delay the implementation of any provision of the Affordable Care Act that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices.

The Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer sponsored insurance plan, the annual fee imposed on certain health insurance providers based on market share, and the medical device exercise tax on non-exempt medical devices. Further, the Bipartisan Budget Act of 2018, among other things, amends the ACA, effective January 1, 2019, to reduce the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." Congress will likely consider other legislation to replace or modify elements of the Affordable Care Act. We continue to evaluate the effect that the Affordable Care Act and its possible repeal, replacement or further modification could have on our business. It is uncertain the extent to which any such changes may impact our business or financial condition.

In addition, the Budget Control Act of 2011 and the Bipartisan Budget Act of 2015 led to aggregate reductions of Medicare payments to providers of up to 2% per fiscal year that will remain in effect through 2027 unless additional Congressional action is taken. Further, on January 2, 2013, the American Taxpayer Relief Act was signed into law, which, among other things, reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. More recently, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which have resulted in several recent Congressional inquiries and proposed bills designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for pharmaceutical products. 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.

We expect that additional foreign, federal and state healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in limited coverage and reimbursement and reduced demand for our products, once approved, or additional pricing pressures.

Government Regulation Outside of the United States

In addition to regulations in the United States, we will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials of drug products as well as the approval, manufacture and distribution of our product candidates. Because biologically sourced raw materials are subject to unique contamination risks, their use may be restricted in some countries. Whether or not we obtain FDA approval for a product candidate, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Clinical Trials

Certain countries outside of the United States have a regulatory process similar to the U.S. process that requires the submission of a clinical trial application ("CTA") much like the IND prior to the commencement of human clinical trials. In the European Union, for example, CTA must be submitted for each clinical trial to the national health authority and an independent ethics committee in each country in which the trial is to be conducted, much like the FDA and an IRB, respectively. Clinical trial application must be accompanied by an investigational medicinal product dossier with supporting information prescribed by the Clinical Trials Directive (and corresponding national laws of the member states) and further detailed in applicable guidance documents. Once the CTA is approved in accordance with a country's requirements, the clinical trial may proceed. A similar process to the one described for the European Union is required in

Israel for initiation of clinical trials. The requirements and process governing the conduct of clinical trials vary from country to country. In all cases, the clinical trials must be conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

Approval Process

In order to market our products, we must obtain a marketing approval for each product and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing in comparison to the testing carried out for the U.S. approval. The time required to obtain approval in foreign countries may differ substantially from that required to obtain FDA approval. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries. The regulatory approval process outside the United States generally is subject to all of the same risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country.

To obtain marketing approval of a medicinal product under the European Union regulatory system, an applicant must submit a marketing authorization application ("MAA"), under either a centralized or a decentralized procedure. The decentralized procedure is based on a collaboration among the member states selected by the applicant. In essence, the applicant chooses a 'lead' member state that will carry out the scientific assessment of the MAA and review the product information. The other member states must recognize the outcome of such assessment and review except in case of a "serious potential risk to public health." The decentralized procedure results in the grant of a national marketing authorization in each selected country. That procedure is available for all medicinal products unless they fall into the mandatory scope of the centralized procedure. In practice, it is used for over-the-counter, not highly innovative products, generic products and, increasingly, for biosimilars.

The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid for all European Union member states. The centralized procedure is compulsory for certain medicinal products, including for medicinal products produced by certain biotechnological processes, products designated as orphan medicinal products, advanced therapy medicinal products ("ATMPs") and products with a new active substance and indicated for the treatment of certain diseases. For products with a new active substance and indicated for the treatment of other diseases, products that are highly innovative or for which a centralized process is in the interest of patients, the centralized procedure is optional.

Under the centralized procedure, the Committee for Medicinal Products for Human Use ("CHMP"), the main scientific committee established at the EMA, is responsible for conducting the scientific assessment of the future medicinal product. The CHMP is also responsible for several post-authorization and maintenance activities, such as the assessment of modifications or extensions to an existing marketing authorization. The maximum timeframe for the evaluation of an MAA is 210 days, excluding clock stops. The European Commission grants or refuses the marketing authorization, following a procedure that involves representatives of the member states. The European Commission's decision is in accordance with the CHMP scientific assessment except in very rare cases.

Pursuant to Regulation (EC) 1394/2007, specific rules apply to ATMPs, a category that is comprised of gene therapy medical products, somatic cell therapy medicinal products, and tissue-engineered medicinal products. Those rules have triggered the adoption of guidelines on manufacturing, clinical trials and pharmacovigilance that adapt the general regulatory requirements to the specific characteristics of ATMPs. Regulation (EC) 1394/2007 introduced a "hospital exemption." which authorizes hospitals to develop ATMP for their internal use without having obtained a marketing authorization and to complying with European Union pharmaceutical law. The hospital exemption, which is in essence a compounded ATMP, has been transposed in all Member States, sometimes in such a way that the ATMPs under the hospital exemption are competitive alternatives to ATMPs with marketing authorization. The broad use of the hospital exemption by national hospitals led the European Commission to discuss with the Member States a more reasonable application of the hospital exemption that would not undermine the common legal regime for ATMP.

Marketing authorization is 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 the competent authority of the

authorizing member state. 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 six months before the marketing authorization ceases to be valid. Once renewed, the marketing authorization is valid for an unlimited period, unless the European Commission or the national competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional renewal. Any authorization which is not followed by the actual placing of the medicinal product on the European Union market (in case of centralized procedure) or on the market of the authorizing member state within three years after authorization ceases to be valid (the so-called sunset clause).

Orphan Designation

Countries other than the United States have adopted a specific legal regime to support the development and marketing of drugs and biologics for rare diseases.

For example, in the European Union, Regulation 141/2000 organizes the grant of orphan drug designations to promote the development of products that are intended for the diagnosis, prevention or treatment of life threatening or chronically debilitating conditions affecting not more than five in 10,000 persons in the European Economic Area (the European Union, plus Iceland, Liechtenstein and Norway) (or where it is unlikely that the development of the medicine would generate sufficient return to justify the investment) and for which no satisfactory method of diagnosis, prevention or treatment has been authorized or, if a method exists, the product would be of significant benefit to those affected. The EMA's Committee for Orphan Medicinal Products ("COMP") examines if the orphan criteria are met and gives opinions thereon, and the orphan status is granted by the European Commission. The meeting of the criteria for orphan designation is examined again by the COMP at the time of approval of the medicinal product, which typically occurs several years after the grant of the orphan designation. If the criteria for orphan designation are no longer met at that time, the European Commission withdraws the orphan status.

In the European Union, orphan drug designation entitles the sponsor to financial incentives such as reduction of fees or fee waivers and to ten years of market exclusivity granted following medicinal product approval. Market exclusivity precludes the EMA or a national regulatory authority from validating another MAA, and the European Commission or a national regulatory authority from granting another marketing authorization, for the same or similar medicinal product and the same therapeutic indication, for that time period. This 10-year period may be reduced to six years if 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. The orphan exclusivity may be lost vis-à-vis another medicinal product in cases the manufacturer is unable to assure sufficient quantity of the medicinal product to meet patient needs or if that other product is proved to be clinically superior to the approved orphan product. A drug is clinically superior if it is safer, more effective or makes a major contribution to patient care. Orphan drug designation must be requested before submitting a MAA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process, and it does not afford any regulatory exclusivity until a marketing authorization is granted.

Expedited Development and Approval

Mechanisms are in place in many jurisdictions that allow an earlier approval of the drug so that it reaches patients with unmet medical needs earlier. The European Union, for example, has instituted several expedited approval mechanisms including two mechanisms that are specific to the centralized procedure:

- the accelerated approval: the EMA may reduce the maximum timeframe for the evaluation of an MAA from 210 days to 150 days when the future medicinal product is of major interest from the point of view of public health, in particular from the viewpoint of therapeutic innovation; and

- the conditional marketing authorization: as part of its marketing authorization process, the European Commission may grant marketing authorizations on the basis of less complete data than is normally required.

A conditional marketing authorization may be granted when the CHMP finds that, although comprehensive clinical data referring to the safety and efficacy of the medicinal product have not been supplied, all the following requirements are met:

- the risk/benefit balance of the medicinal product is positive;
- it is likely that the applicant will be in a position to provide the comprehensive clinical data;
- unmet medical needs will be addressed; and
- 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 is still required.

The granting of a conditional marketing authorization is typically restricted to situations in which only the clinical part of the application is not yet fully complete. Incomplete preclinical or quality data may however be accepted if duly justified and only in the case of a product intended to be used in emergency situations in response to public health threats.

Conditional marketing authorizations are valid for one year, on a renewable basis. The conditions to which approval is subject will typically require the holder to complete ongoing trials or to conduct new trials with a view to confirming that the risk/benefit balance is positive and to collect pharmacovigilance data. Once the conditions to which the marketing authorization is subject are fulfilled, the conditional marketing authorization is transformed into a regular marketing authorization. If, however, the conditions are not fulfilled within the timeframe set by the EMA, the conditional marketing authorization ceases to be renewed.

The EMA has also implemented the so-called "PRIME" (PRIority MEdicines) status in order support the development and accelerate the approval of complex innovative medicinal products addressing an unmet medical need. PRIME status enables early dialogue with the relevant EMA scientific committees and, possibly, some payors and thus reinforces the EMA's scientific and regulatory support. It also opens accelerated assessment of the MAA as PRIME status, is normally reserved for medicinal products that may benefit from accelerated assessment, i.e., medicines of major interest from a public health perspective, in particular from a therapeutic innovation perspective.

Finally, all medicinal products (i.e., decentralized and centralized procedures) may benefit from an MAA "under exceptional circumstances." This marketing authorization is close to the conditional marketing authorization as it is reserved to medicinal products to be approved for severe diseases or unmet medical needs and the applicant does not hold the complete data set legally required for the grant of a marketing authorization. However, unlike the conditional marketing authorization, the applicant does not have to provide the missing data and will never have to. The risk/benefit of the medicinal product is reviewed annually. As a result, although the MAA "under exceptional circumstances" is granted definitively, the risk/benefit balance of the medicinal product is reviewed annually and the marketing authorization is withdrawn in case the risk/benefit ratio is no longer favorable.

Pediatrics

Mandatory testing in the pediatric population is required in more and more jurisdictions. The European Union has enacted a complex and very stringent system that has inspired other jurisdictions, including the United States and Switzerland. Any application for approval of (i) a medicinal product containing a new active substance or (ii) a new therapeutic indication, pharmaceutical form or route of administration of an already authorized medicinal product that contains an active substance still protected by a supplementary protection certificate ("SPC") or a patent that qualifies for an SPC, must include pediatric data. Otherwise, the application is not validated by the competent regulatory authority. The submission of pediatric data is mandatory in those cases, even if the application concerns adult use. Submission of pediatric data is not required or fully required if the EMA granted, respectively, a full or partial waiver to pediatric development. Moreover, that submission can be postponed if the EMA grants a deferral in order not to delay the submission of the MAA for the adult population.

The pediatric data are generated through the implementation of a pediatric investigation plan ("PIP") that is proposed by the company after completion of the PK studies in adults and agreed upon by the EMA, typically after some modifications. The PIP lists all the studies to conduct and measures to take in order to prove the safety and efficacy of the future medicinal product when used in children. The EMA may agree to modify the PIP at the company's request. The scope of the PIP is the adult therapeutic indication or the condition of which the adult application is part or even the mechanism of action of the active substance, at the EMA's quasi-discretion. This very broad discretion enables the EMA to require companies to develop children indications that are different from the adult indications.

Completion of a PIP renders the company eligible for a pediatric reward, which can be six-month extension of the term of the SPC or, in the cases of orphan medicinal products, two additional years of market exclusivity. The reward is subject, among other conditions, to the PIP being fully completed, to the pediatric medicinal product being approved in all the member states, and to the results of the pediatric studies being mentioned, in one way or another (for example, the approval of a pediatric indication), in the summary of product characteristics of the product.

Post-Marketing Requirements

Many countries impose post-marketing requirements similar to those imposed in the United States, in particular safety monitoring or pharmacovigilance. In the European Union, pharmacovigilance data are the basis for the competent regulatory authorities imposing the conduct of post-approval safety or efficacy study, including on off-label use. Non-compliance with those requirements can result in significant financial penalties as well as the suspension or withdrawal of the marketing authorization.

Supplementary Protection Certificate and Regulatory Exclusivities

In some countries other than the United States, some of our patents may be eligible for limited patent term extension, depending upon the timing, duration and specifics of the regulatory approval of our product candidates and any future product candidates. Furthermore, authorized drugs and biologics may benefit from regulatory exclusivities (in additional to patent protection resulting from patents).

In the European Union, Regulation (EC) 469/2009 institutes a SPC. An SPC is an extension of the term of a patent that compensates for the patent protection lost because of the legal requirements to conduct safety and efficacy tests and to obtain a marketing authorization before placing a medicinal product on the market. An SPC may be applied for any active substance that is protected by a "basic patent" (a patent chosen by the patent holder, which can be a product, process or application patent) and has not been placed on the market as a medicinal product before having obtained a marketing authorization in accordance with European Union pharmaceutical law. The term of the SPC is maximum five years, and the combined patent and SPC protection may not exceed fifteen years from the date of the first marketing authorization in the European Economic Area ("EEA"). SPC rights are restricted by both the basic patent and the marketing authorization, i.e., the SPC grants the same rights as those conferred by the basic patent but limited to the active substance covered by the marketing authorization (and any use as medicinal product approved afterwards).

While SPC are regulated at the European level, they are granted by the national patent offices. The grant of an SPC requires a basic patent granted by the national patent office and a marketing authorization, which is the first marketing authorization for the active substance as a medicinal product in the country. Furthermore, no SPC must have already been granted to the active substance, and the application for the SPC must be filed with the national patent office within six months of the first marketing authorization in the EEA or the grant of the basic patent, whichever is the latest.

In the future, we may apply for an SPC for one or more of our currently owned or licensed European patents to add patent life beyond their current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant MAA.

Furthermore, in the European Union, medicinal products may benefit from the following regulatory exclusivities: data exclusivity, market protection, market exclusivity, and pediatric reward.

A medicinal product that contains a new active substance (reference medicinal product) is granted eight years of data exclusivity followed by two years of market protection. Data exclusivity prevents other companies from referring to the non-clinical and clinical data in marketing authorization dossier of the reference medicinal product for submission of generic MAA purposes, and market protection prevents other companies from placing generics on the market. Pursuant to the concept of global marketing authorization, any further development of that medicinal product (e.g., new indication, new form, change to the active substance) by the marketing authorization holder does not trigger any new or additional protection. The authorization of any new development is considered as "falling" into the initial marketing authorization with regard to regulatory protection; hence, the new development only benefits from the regulatory protection that remains when it is authorized. The only exception is a new therapeutic indication that is considered as bringing a significant clinical benefit in comparison to the existing therapies. Such new indication will add one-year of market protection to the global marketing authorization, provided that it is authorized within the first eight years of authorization (i.e., during the data exclusivity period). Moreover, a new therapeutic indication of a "well-established substance" benefits from one-year data exclusivity but limited to the non-clinical and clinical data supporting the new indication. Any active substance approved for at least ten years in the EEA qualifies as well-established substance.

Biosimilars may be approved through an abbreviated approval pathway after the expiration of the eight-year data exclusivity period and may be marketed after the 10- or 11-year market protection period. The approval of biosimilars requires the applicant to demonstrate similarity between the biosimilar and the biological medicinal product and to submit the non-clinical and clinical data defined by the EMA. The biosimilar legal regime has been mainly developed through EMA's scientific guidelines applicable to categories of biological active substances. Unlike in the United States, interchangeability is regulated by each member state.

Market exclusivity is a regulatory protection exclusively afforded to medicinal products with an orphan status. Market exclusivity precludes the EMA or a national regulatory authority from validating another MAA, and the European Commission or a national regulatory authority from granting another marketing authorization, for a same or similar medicinal product and a same therapeutic indication, for a period of ten years from approval (see above).

Pediatric reward is another regulatory exclusivity. Completion of a PIP renders the company eligible for a pediatric reward, which can be six-month extension of the term of the SPC or, in the cases of orphan medicinal products, two additional years of market exclusivity (see above). In case a PIP is completed on a voluntary basis, i.e., for an approved medicinal product that is not or no longer protected by an SPC or a basic patent, the pediatric reward takes the form of a "pediatric use marketing authorization". That special authorization does not fall into the global marketing authorization and thus benefits from eight years of data exclusivity followed by two or three years of market protection.

Other Healthcare Laws and Compliance Requirements Outside of the United States

Much like the Anti-Kickback Statute prohibition in the United States, the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the European Union. The provision of benefits or advantages to physicians is mainly governed by the national anti-bribery laws of the member states, such as the UK Bribery Act 2010, or national anti-kickback provisions (France, Belgium, etc.). Infringement of these laws could result in substantial fines and imprisonment. In certain member states, payments made to physicians must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual member states. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the member states. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

Much like the U.S. Foreign Corrupt Practices Act, to which we are subject, that prohibits corporations and individuals from engaging in certain activities to obtain or retain business or to influence a person working in an official capacity, similar rules apply to many other countries worldwide such as France (Loi Sapin) or the United Kingdom (UK Bribery Act). It is illegal to pay, offer to pay or authorize the payment of anything of value to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity.

Pricing and Reimbursement

Although none of our product candidates has been commercialized for any indication, if they are approved for marketing, commercial success of our product candidates will depend, in part, upon the availability of third-party reimbursement from payors at the federal, state and private levels. Third-party payors include government healthcare programs, such as Medicare and Medicaid, private health insurers and managed-care plans. We anticipate third-party payors will provide reimbursement for our products. However, these third-party payors are increasingly challenging the price and examining the cost effectiveness of medical products and services. In addition, significant uncertainty exists as to the reimbursement status of newly approved healthcare products. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost effectiveness of our products. Our product candidates may not be considered cost effective. It is time consuming and expensive for us to seek reimbursement from third-party payors. Reimbursement may not be available or sufficient to allow us to sell our products on a competitive and profitable basis.

We expect that there will continue to be a number of federal and state proposals to implement governmental pricing controls and limit the growth of healthcare costs, including the cost of prescription drugs.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product, or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products.

Historically, products launched in the European Union do not follow price structures of the United States and generally tend to be significantly lower.

Employees and Human Capital

As of March 1, 2024, we had 66 full-time employees. Of the 66 full-time employees, 54 were engaged in research and development activities and 12 employees were engaged in finance, legal, human resources, facilities and general management. We have no collective bargaining agreements with our employees, we have not experienced any work stoppages and we believe our relations with our employees are good.

Our human resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing, and integrating our existing and prospective employees. The principal purposes of our incentive plans are to attract, retain and motivate selected employees, consultants, advisors and directors through the granting of stock-based compensation awards and cash-based performance awards, as applicable. We provide a comprehensive benefits package to help employees manage their health, well-being, finances, and life outside of work, including health insurance, dental and vision insurance, life insurance, accidental death and dismemberment issuance, short-term and long-term disability insurance, paid sick leave, a defined contribution plan, an employee stock purchase plan, a flexible spending account program, and paid vacation time. We value the health, safety, and wellbeing of our employees and their families.

Diversity and Inclusion

We are committed to our continued efforts to increase diversity and foster an inclusive work environment. We recruit the best qualified employees regardless of gender, ethnicity, or other protected traits and it is our policy to fully comply with all laws (domestic and foreign) applicable to discrimination in the workplace. Our diversity, equity and inclusion principles are also reflected in our employee training and policies. We continue to enhance our diversity, equity and inclusion policies that are guided by our executive leadership team.

Health, Safety and Well-Being

Protecting the health, safety and well-being of colleagues and, all of whom are essential to delivering our business objectives, is an integral part of how we operate. In response to the COVID-19 pandemic in 2020, we instituted a remote work protocol to help ensure the safety of our employees, our community, and to adhere to federal, state, and local requirements and the CDC recommendations of social distancing and limited public exposure in connection with the COVID-19 pandemic. We did not implement any furlough, layoff, or salary reductions during this time. These precautions have been instrumental in protecting our workforce and helping ensure continued development of our pipeline. We continue to evaluate our pandemic preparedness and response procedures and the advisability of continuing operations based on federal, state and local guidance, evolving data concerning the pandemic and the best interests of our employees, third parties with whom we collaborate, and our stockholders.

Compensation and Benefits

Our commitment to pay equity for all colleagues is rooted in our core values and our intention is to continue to build a diverse and inclusive workforce. We are committed to equitable pay practices for employees based on role, education, experience, performance, and location and Armata conducts pay equity reviews on an annual basis. We believe that we must offer and maintain market competitive compensation and benefit programs for our employees in order to attract and retain qualified personnel. In addition to cash compensation, we provide equity compensation, healthcare and insurance benefits, health savings and flexible spending accounts, paid time off, family leave, and employee assistance programs. We also have a defined contribution plan in the United States, enabling eligible employees to contribute a portion of their salaries and bonuses to the plans, and we match, in cash, a portion of the employee contributions.

Corporate History and Reorganization

Our company was created as a result of a business combination of Armata (formerly known as AmpliPhi) with C3J that became effective on May 9, 2019. Immediately prior to the closing of the Merger, AmpliPhi changed its name to Armata Pharmaceuticals, Inc.

C3J's predecessor, C3 Jian, Inc., was incorporated under the laws of the State of California on November 4, 2005. On February 26, 2016, as part of a reorganization transaction, C3 Jian, Inc. merged with a wholly-owned subsidiary of C3J, and as part of this process, C3 Jian, Inc. was converted to a limited liability company organized under the laws of the State of California named C3 Jian, LLC. Prior to the Merger, C3J was privately held and was financed principally through a series of equity financings.

AmpliPhi was incorporated under the laws of the State of Washington in March 1989 as a wholly-owned subsidiary of Immunex Corporation and began operations as an independent company in 1992 as Targeted Genetics Corporation. In January 2011, AmpliPhi completed the acquisition of Biocontrol Ltd, an antimicrobial biotechnology company based in the United Kingdom, with the goal of developing their phage therapy programs using funding from the sale of our legacy gene therapy assets. In November 2012, AmpliPhi completed the acquisition of Special Phage Holdings Pty Ltd, a company based in Australia, with the goal of continuing research addressing the rapidly escalating problem of antibiotic resistance through the development of a series of bacteriophage-based treatments.

Available Information

All periodic and current reports and other filings that we are required to file with the Securities and Exchange Commission ("SEC"), including our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant Section 15(d) of the Securities Exchange Act of 1934, as amended, are available free of charge from the SEC's website (www.sec.gov) or through our Investor Relations website at https://investor.armatapharma.com. Our corporate headquarters are located in Los Angeles, California, with an address of 5005 McConnell Avenue, Los Angeles, CA 90066, and our telephone number is +1 (310) 665-2928. We maintain a website at https://www.armatapharma.com, to which we regularly post copies of our press releases as well as additional information about us. The information on our website is not incorporated by reference into this Annual Report

on Form 10-K or in any other report or document we submit to the SEC, and any references to our website are intended to be inactive textual references only.

Item 1A. Risk Factors

You should consider carefully the following information about the risks described below, together with the other information contained in this Annual Report and in our other public filings in evaluating our business. Investors should be aware that it is not possible to predict or identify all such factors and that the following is not meant to be a complete discussion of all potential risks or uncertainties. Additionally, our business is subject to general risks applicable to any company, such as economic conditions, geopolitical events, climate change, extreme weather and natural disasters. If known or unknown risks or uncertainties materialize, our business, financial condition, results of operations, cash flows, access to liquidity and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock would likely decline. The following discussion of risk factors contains forward-looking statements, as discussed in the Special Note Regarding Forward-Looking Statements *section in this Annual Report on Form 10-K.*

Summary of Risk Factors

Below is a summary of the principal factors that make an investment in our common Stock speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below and should be carefully considered, together with other information in this Annual Report on Form 10-K and our other filings with the SEC before making an investment decision regarding our common stock.

- There is substantial doubt about our ability to continue as a going concern, which may affect our ability to obtain future financing and may require us to curtail our operations. We will need substantial additional financing to develop our product candidates and implement our operating plans, including to support one or more pivotal trials in 2025 and beyond. If we fail to obtain additional financing, we may be delayed or unable to complete the development and commercialization of our product candidates;
- We have incurred losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future, and our future profitability is uncertain;
- If we fail to develop and maintain proper and effective processes and operating procedures as a non-traditional government contractor, our ability to adhere to the Department of Defense and related entity standards could impact our ongoing and future development financing awards from the U.S. government;
- We are seeking to develop antibacterial agents using bacteriophage and synthetic phage technology, a novel approach, which makes it difficult to predict the time and cost of development. No bacteriophage products have been approved in the United States or elsewhere.
- Results from preclinical studies and Phase 1 or 2 clinical trials of our product candidates or from single-patient expanded access treatments may not be predictive of the results of later stage clinical trials;
- We must continue to develop manufacturing processes for our product candidates and any delay in or our inability to do so would result in delays in our clinical trials;
- We rely on third parties to conduct our clinical trials, and their failure to perform their obligations in a timely or competent manner may delay development and commercialization of our product candidates;
- Our business operations and current and future relationships with clinical site investigators, healthcare professionals, consultants, third-party payors, patient organizations, and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties.
- Innoviva, our principal stockholder, beneficially owns greater than 50% of our outstanding shares of common stock, which causes us to be deemed a “controlled company” under the rules of the New York Stock Exchange (the “NYSE”). In addition, Innoviva’s interests in our business may be different than our other stockholders.

Risks Related to Our Financial Condition and Need for Additional Capital

There is substantial doubt about our ability to continue as a going concern, which may affect our ability to obtain future financing and may require us to curtail our operations. We will need substantial additional financing to develop our product candidates and implement our operating plans. If we fail to obtain additional financing, we may be delayed or unable to complete the development and commercialization of our product candidates.

The audited consolidated financial statements and accompanying notes thereto included disclosures that our recurring losses and negative cash flows from operations raise substantial doubt about our ability to continue as a going concern. Our financial statements as of December 31, 2023 and December 31, 2022 were prepared under the assumption that we will continue as a going concern and do not include any adjustments that might result from the outcome of this uncertainty. As of December 31, 2023, we had unrestricted cash and cash equivalents of $13.5 million, and we have had recurring losses from operations and negative operating cash flows since inception. In March 2024, we received an additional loan from Innoviva of $35.0 million. Our outstanding loans mature in January 2025 and in June 2025.

We will need to raise additional capital to support our operations and product development activities. Our ability to raise additional capital via equity or debt financing may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, financial markets in the United States and worldwide. We may also seek funds through arrangements with collaborators, grant agencies or others that may require us to relinquish rights to the product candidates that we might otherwise seek to develop or commercialize independently. If we are unable to secure additional funds when needed or on acceptable terms, we may be required to defer, reduce or eliminate significant planned expenditures, restructure, curtail or eliminate some or all of our development programs or other operations, dispose of technology or assets, pursue an acquisition of our company by a third party at a price that may result in a loss on investment for our stockholders, enter into arrangements that may require us to relinquish rights to certain of our product candidates, technologies or potential markets, file for bankruptcy or cease operations altogether. Any of these events could have a material adverse effect on our business, financial condition and results of operations.

While we believe that our existing resources will be sufficient to fund our planned operations into fiscal year 2024, we cannot provide assurances that our estimates will be accurate, that our plans will not change or that changed circumstances will not result in the depletion of our capital resources more rapidly than we currently anticipate. Our future funding requirements will depend on many factors, including:

- the costs and timing of our research and development activities;
- the progress and cost of our clinical trials and other research and development activities;
- manufacturing costs associated with our targeted phage therapies strategy and other research and development activities;
- the terms and timing of any collaborative, licensing, acquisition or other arrangements that we may establish;
- whether and when we receive future Australian tax rebates, if any;
- the costs and timing of seeking regulatory approvals;
- the costs of filing, prosecuting, defending and enforcing any patent applications, claims, patents and other intellectual property rights; and
- the costs of lawsuits involving us or our product candidates.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. Our ability to raise additional funds will depend, in part, on the success of our product development activities, including our targeted phage therapies strategy and any clinical trials we initiate, regulatory events, our ability to identify and enter into in-licensing or other strategic arrangements, and other events or conditions that may affect our value or prospects, as well as factors related to financial, economic and market conditions, many of which are beyond our control. There can be no assurances that sufficient funds will be available to us when required or on acceptable terms, if at all.

We have incurred losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future, and our future profitability is uncertain.

Clinical trials and activities associated with discovery research are costly. We do not expect to generate any revenue from the commercial sales of our product candidates in the near term, and we expect to continue to have significant losses for the foreseeable future.

Our ability to generate meaningful revenue and achieve profitability depends on successfully completing the development of, and obtaining the regulatory approvals necessary to, commercialize our product candidates. If any of our product candidates fail in clinical trials or if any of our product candidates do not gain regulatory approval, or if any of our product candidates, if approved, fail to achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our ability to generate future revenues from product sales depends heavily on our success in:

- completing research and preclinical and clinical development of our product candidates;
- seeking and obtaining regulatory and marketing approvals for product candidates for which we complete clinical trials;
- developing a sustainable, scalable, reproducible, and transferable manufacturing process for our product candidates;
- launching and commercializing product candidates for which we obtain regulatory and marketing approval, either by establishing a sales force, marketing and distribution infrastructure, or by collaborating with a partner;
- obtaining market acceptance of any approved products;
- addressing any competing technological and market developments;
- implementing additional internal systems and infrastructure, as needed;
- identifying and validating new product candidates;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter;
- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how; and
- attracting, hiring and retaining qualified personnel.

Even if one or more of the product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product. Our expenses could increase beyond expectations if we are required by the FDA, the European Medicines Agency ("EMA"), or other foreign regulatory authorities to perform clinical trials and other studies in addition to those that we currently anticipate. Even if we are able

to generate revenues from the sale of any approved products, we may not become profitable and may need to obtain additional funding to continue operations.

As of December 31, 2023, our accumulated deficit was $308.8 million and we expect to incur losses for the foreseeable future. We have devoted, and will continue to devote for the foreseeable future, substantially all of our resources to research and development of our product candidates. Additional information regarding our results of operations may be found in our consolidated financial statements included in Item 8 in the Annual Report and in "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in Item 7 in this Annual Report.

If we fail to develop and maintain proper and effective processes and operating procedures as a non-traditional government contractor, our ability to adhere to the Department of Defense and related entity standards could impact our ongoing and future development financing awards from the U.S. government.

On June 15, 2020, we entered into an agreement with the Medical Technology Enterprise Consortium ("MTEC Agreement"), pursuant to which we received a $15.0 million grant and have entered into a three-year program administered by the DoD through MTEC with funding from the Defense Health Agency and Joint Warfighter Medical Research Program. On September 29, 2022, the MTEC Agreement was modified to increase the total grant by $1.3 million to $16.3 million and extend the term into the third quarter of 2024. We plan to use the grant to partially fund a Phase 1b/2a, randomized, double-blind, placebo-controlled, dose-escalation clinical study of Armata's therapeutic phage-based candidate, AP-SA02, for the treatment of *S. aureus* bacteremia. As an organization, we are relatively new to government contracting and new to the regulatory compliance obligations that such contracting entails. If we fail to maintain compliance with those obligations, we may be subject to potential liability and may result in the termination of our government contracts, including the MTEC Agreement.

Government contracts and grants normally contain additional requirements that may increase our costs of doing business and expose us to liability for failure to comply with these terms and conditions. These requirements include, for example:

- tracking of contract costs and maintenance of effective controls over tracking of such costs;
- completion and submission of periodic reporting packages;
- mandatory financial audits and potential liability for failing such audits; and
- mandatory socioeconomic compliance requirements, including labor standards, non-discrimination, and affirmative action programs, and environmental compliance requirements.

While we believe we are in compliance with all requirements under the MTEC Agreement, potential failure to maintain such compliance could result in reduction of the grant or termination of the contract, which could in turn negatively impact our business.

Risks Related to Our Business

We are seeking to develop antibacterial agents using bacteriophage and synthetic phage technology, a novel approach, which makes it difficult to predict the time and cost of development. No bacteriophage products have been approved in the United States or elsewhere.

We are developing our product candidates with bacteriophage and synthetic phage technology. We have not, nor to our knowledge has any other company, received regulatory approval from the FDA or equivalent foreign agencies for a pharmaceutical drug based on this approach. While *in vitro* studies have characterized the behavior of bacteriophages in cell cultures and there exists a body of literature regarding the use of phage therapy in humans, the safety and efficacy of phage therapy in humans has not been extensively studied in well-controlled modern clinical trials. Most of the prior research on phage-based therapy was conducted in the former Soviet Union prior to and immediately after World War II

and lacked appropriate control group design or lacked control groups at all. Furthermore, the standard of care has changed substantially during the ensuing decades since those studies were performed, diminishing the relevance of prior claims of improved cure rates. We cannot be certain that our approach will lead to the development of approvable or marketable drugs.

Developing phage-based therapies on a commercial scale will also require developing new manufacturing processes and techniques. We and our third-party collaborators may experience delays in developing manufacturing capabilities for our product candidates and may not be able to do so at the scale required to efficiently conduct the clinical trials required to obtain regulatory approval of our product candidates, or to manufacture commercial quantities of our products, if approved.

In addition, the FDA or other regulatory agencies may lack experience in evaluating the safety and efficacy of drugs based on these approaches, which could lengthen the regulatory review process, increase our development costs and delay or prevent commercialization of our product candidates.

Results from preclinical studies and Phase 1 or 2 clinical trials of our product candidates or from single-patient expanded access treatments may not be predictive of the results of later stage clinical trials.

Preclinical studies, including studies of our product candidates in animal disease models, may not accurately predict the result of human clinical trials of those product candidates. In particular, promising animal studies suggesting the efficacy of prototype phage products in the treatment of bacterial infections, such as *P. aeruginosa* and *S. aureus,* may not predict the ability of these products to treat similar infections in humans. Despite promising data in our completed Phase 1 clinical trials, our phage technology may be found not to be safe or efficacious in treating bacterial infections alone or in combination with other agents, when studied in later-stage clinical trials.

In addition, we have used our bacteriophage technology in the area of targeted medicine under single-patient expanded access guidelines, which permit the use of phage therapy outside of clinical trials, in the United States and Australia. Despite prior single-patient expanded access successes, no assurance can be given that we will have similar single-patient expanded access treatment successes in the future. Single-patient expanded access is a term that is used to refer to the use of an investigational drug or therapy outside of a clinical trial to treat a patient with a serious or immediately life-threatening disease or condition who has no comparable or satisfactory alternative treatment options. Regulators often allow single-patient expanded access on a case-by-case basis for an individual patient or for defined groups of patients with similar treatment needs. In some countries, such as Australia, the treating physician can administer treatment under single-patient expanded access guidelines without pre-approval from the applicable regulatory authority.

To satisfy FDA or foreign regulatory approval standards for the commercial sale of our product candidates, we must demonstrate in adequate and controlled clinical trials that our product candidates are safe and effective. Success in early clinical trials, including Phase 1 and Phase 2 trials, or in our single-patient expanded access program does not ensure that later clinical trials will be successful. Our initial results from early stage clinical trials or our single-patient expanded access program also may not be confirmed by later analysis or subsequent larger clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in earlier clinical trials and most product candidates that commence clinical trials are never approved for commercial sale.

Delays in our clinical trials could result in us not achieving anticipated developmental milestones when expected, increased costs and delay our ability to obtain regulatory approval for and commercialize our product candidates.

Delays in our ability to commence or enroll patients for our clinical trials could result in us not meeting anticipated clinical milestones and could materially impact our product development costs and delay regulatory approval of our

product candidates. Planned clinical trials may not be commenced or completed on schedule, or at all. Clinical trials can be delayed for a variety of reasons, including:

- delays in the development of manufacturing capabilities for our product candidates to enable their consistent production at clinical trial scale;
- failures in our internal manufacturing operations that result in our inability to consistently and timely produce bacteriophages in sufficient quantities to support our clinical trials;
- the availability of financial resources to commence and complete our planned clinical trials;
- delays in reaching a consensus with clinical investigators on study design;
- delays in reaching a consensus with regulatory agencies on trial design or in obtaining regulatory approval to commence a trial;
- delays in obtaining clinical materials;
- slower than expected patient recruitment for participation in clinical trials;
- failure by clinical trial sites, other third parties, or us to adhere to clinical trial agreements;
- delays in reaching agreement on acceptable clinical trial agreement terms with prospective sites or obtaining institutional review board approval; and
- adverse safety events experienced during our clinical trials.

Completion of clinical trials depends, among other things, on our ability to enroll a sufficient number of patients, which is a function of many factors, including:

- the therapeutic endpoints chosen for evaluation;
- the eligibility criteria defined in the protocol;
- the perceived benefit of the product candidate under study;
- the size of the patient population required for analysis of the clinical trial's therapeutic endpoints;
- our ability to recruit clinical trial investigators and sites with the appropriate competencies and experience;
- our ability to obtain and maintain patient consents; and
- competition for patients from clinical trials for other treatments.

Difficulties in enrolling patients in our clinical trials, could increase the costs or affect the timing or outcome of these clinical trials. This is particularly true with respect to diseases with relatively small patient populations. If we do not successfully commence or complete our clinical trials on schedule, the price of our common stock may decline.

We must continue to develop manufacturing processes for our product candidates and any delay in or our inability to do so would result in delays in our clinical trials.

We are developing novel manufacturing processes for our product candidates at our current facility in Marina Del Rey, California. We are constructing the new manufacturing facility in Los Angeles, California and plan to move manufacturing processes to this new facility in the second half of 2024. The manufacturing processes for our product candidates, and the scale-up of such processes for clinical trials, are novel, and there can be no assurance that we will be able to complete this work in a timely manner, if at all. The manufacture of our product candidates requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers often encounter difficulties in production, particularly in scaling up for commercial production. These problems include difficulties with production costs and yields, quality control, including stability of the equipment and product candidates and quality assurance testing, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. If we were to encounter any of these difficulties, our ability to provide our products to patients in our clinical trials or to commercially launch a product would be jeopardized. Any delay or interruption could postpone the completion of our clinical trials, increase the costs associated with maintaining our clinical trial program, and, depending upon the period of delay, require us to commence new trials at significant additional expense or terminate the trials completely.

Any delay in the development or scale up of these manufacturing processes could delay the start of clinical trials and harm our business. In the event our facility in Los Angeles, California, does not receive a satisfactory cGMP inspection for the manufacture of our product candidates, we may need to fund additional modifications to our manufacturing process, conduct additional validation studies, or find alternative manufacturing facilities, any of which would result in significant cost to us as well as a delay of up to several years in obtaining approval for such product candidate.

Our manufacturing facility will be subject to ongoing periodic inspection by the FDA for compliance with cGMP regulations. Compliance with these regulations and standards is complex and costly, and there can be no assurance that we will be able to comply. Any failure to comply with applicable regulations could result in sanctions being imposed (including fines, injunctions and civil penalties), failure of regulatory authorities to grant marketing approval of our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecution.

Any of these factors could cause a delay of clinical trials, regulatory submissions, approvals or commercialization of our products, entail higher costs or result in our being unable to effectively commercialize our products. Furthermore, if we fail to deliver the required commercial quantities on a timely basis, pursuant to provided specifications and at commercially reasonable prices, we may be unable to meet demand for our products and would lose potential revenues.

If we are unable to obtain FDA approval of our products, we will not be able to commercialize our products in the United States.

We need FDA approval prior to marketing our product candidates in the United States. If we fail to obtain FDA approval to market our product candidates, we will be unable to sell our products in the United States, which will significantly impair our ability to generate any revenues.

This regulatory review and approval process, which includes evaluation of pre-clinical studies and clinical trials of our product candidates as well as the evaluation of our manufacturing processes, is lengthy, expensive and uncertain. To receive approval, we must, among other things, demonstrate with substantial evidence from well-controlled clinical trials that our product candidates are both safe and effective for each indication for which approval is sought. Satisfaction of the approval requirements typically takes several years and the time needed to satisfy them may vary substantially, based on the type, complexity and novelty of the product. We do not know if or when we might receive regulatory approvals, including approval for an Investigational New Drug application ("IND application"), for any of our product candidates currently under development, other than for our product candidates AP-PA02 and AP-SA02, for which we received FDA clearance of our respective IND applications. Moreover, approvals that we obtain may not cover all of the clinical

indications for which we are seeking approval, or could contain significant limitations in the form of narrow indications, warnings, precautions or contra-indications with respect to conditions of use. In such event, our ability to generate revenues from such products would be greatly reduced and our business would be harmed.

The FDA has substantial discretion in the approval process and may either refuse to consider any of our applications for substantive review or may form the opinion after review of our data that one or more of our applications are insufficient to approve our product candidates. If the FDA does not consider or approve any of our applications, it may require that we conduct additional clinical, pre-clinical or manufacturing validation studies and submit that data before it will reconsider our application. Depending on the extent of these or any other studies, approval of any applications that we submit may be delayed by several years, or may require us to expend more resources than we have available. It is also possible that additional studies, if performed and completed, may not be successful or considered sufficient by the FDA for approval or even to make our applications approvable. If any of these outcomes occur, we may be forced to abandon one or more of our applications for approval, which might significantly harm our business and prospects.

It is possible that none of our products or any product we may seek to develop in the future will ever obtain the appropriate regulatory approvals necessary for us to commence product sales. Any delay in obtaining, or an inability to obtain, applicable regulatory approvals would prevent us from commercializing our products, generating revenues and achieving and sustaining profitability.

We may conduct clinical trials for our products or product candidates outside the United States and the FDA may not accept data from such trials.

We completed an investigator-sponsored clinical trial of AP-SA01 at the University of Adelaide in Australia for CRS in December 2016. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of such study data by the FDA is subject to certain conditions. For example, the study must be well designed and conducted and performed by qualified investigators in accordance with ethical principles. The study population must also adequately represent the U.S. population, and the data must be applicable to the United States population and U.S. medical practice in ways that the FDA deems clinically meaningful. Generally, the patient population for any clinical studies conducted outside of the United States must be representative of the population for whom we intend to label the product in the United States. In addition, such studies would be subject to the applicable local laws and FDA acceptance of the data would be dependent upon its determination that the studies also complied with all applicable U.S. laws and regulations. There can be no assurance the FDA will accept data from trials conducted outside of the United States. Further, with respect to AP-SA01, we have changed the product formulation to AP-SA02 and any work related to AP-SA01 may not be relevant to the FDA or other international regulatory authorities.

We are subject to significant regulatory approval requirements, which could delay, prevent or limit our ability to market our product candidates.

Our research and development activities, preclinical studies, clinical trials and the anticipated manufacturing and marketing of our product candidates are subject to extensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in Europe and elsewhere. There can be no assurance that our manufacturing facilities will satisfy the requirements of the FDA or comparable foreign authorities. We require the approval of the relevant regulatory authorities before we may commence commercial sales of our product candidates in a given market. The regulatory approval process is expensive and time-consuming, and the timing of receipt of regulatory approval is difficult to predict. Our product candidates could require a significantly longer time to gain regulatory approval than expected, or may never gain approval. We cannot be certain that, even after expending substantial time and financial resources, we will obtain regulatory approval for any of our product candidates. A delay or denial of regulatory approval could delay or prevent our ability to generate product revenues and to achieve profitability.

Changes in regulatory approval policies during the development period of any of our product candidates, changes in, or the enactment of, additional regulations or statutes, or changes in regulatory review practices for a submitted product application may cause a delay in obtaining approval or result in the rejection of an application for regulatory approval.

Regulatory approval, if obtained, may be made subject to limitations on the indicated uses for which we may market a product. These limitations could adversely affect our potential product revenues. Regulatory approval may also require costly post-marketing follow-up studies. In addition, the labeling, packaging, adverse event reporting, storage, advertising, promotion and record-keeping related to the product will be subject to extensive ongoing regulatory requirements. Furthermore, for any marketed product, its manufacturer and its manufacturing facilities will be subject to continual review and periodic inspections by the FDA or other regulatory authorities. Failure to comply with applicable regulatory requirements may, among other things, result in fines, suspensions of regulatory approvals, product recalls, product seizures, operating restrictions and criminal prosecution.

We rely on third parties to conduct our clinical trials and to obtain materials or supplies necessary to conduct trials or to manufacture our product candidates, and their failure to perform their obligations in a timely or competent manner may delay development and commercialization of our product candidates.

We use third parties, such as clinical research organizations, to assist in conducting our clinical trials and for many aspects of our manufacturing process development of our product candidates. However, we may face delays outside of our control if these parties do not perform their obligations in a timely or competent fashion or if we are forced to change service providers. This risk is heightened for clinical trials conducted outside of the United States, where it may be more difficult to ensure that clinical trials are conducted in compliance with FDA requirements. Any third party that we hire to conduct clinical trials may also provide services to our competitors, which could compromise the performance of their obligations to us. If we experience significant delays in the progress of our clinical trials and in our plans to submit Biologics License Applications, the commercial prospects for product candidates could be harmed and our ability to generate product revenue would be delayed or prevented.

Our business operations and current and future relationships with clinical site investigators, healthcare professionals, consultants, third-party payors, patient organizations, and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties.

Our business operations and current and future arrangements with clinical site investigators, healthcare professionals, consultants, third-party payors, patient organizations, and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we market, sell, and distribute our product candidates, if approved. Such laws include, but are not limited to, the U.S. Anti-Kickback Statute, U.S. civil and criminal false claims laws, the U.S. federal Beneficiary Inducement Statute, HIPAA, and state and local laws and regulations. Some of these laws may apply differently to, and may have different requirements for, and effects on, our business, rendering compliance complex and possibly burdensome. We cannot predict how future changes to these laws may impact our business.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices, including our relationships with physicians and other healthcare providers, may not comply with current or future statutes, regulations, agency guidance, 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 the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal, and administrative penalties; damages; fines; exclusion from government-funded healthcare programs, such as Medicare and Medicaid or similar programs in other jurisdictions; integrity oversight and reporting obligations to resolve allegations of non-compliance; disgorgement; individual imprisonment; contractual damages; reputational harm; diminished profits; 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 not be in compliance with applicable laws, they may be subject to criminal, civil, or administrative sanctions, including exclusions from government-funded healthcare programs and imprisonment, which could affect our ability to operate our business. Furthermore, defending against any of these actions can be costly, time-consuming, and may require significant personnel resources. Therefore, even if we are successful in defending against any actions that may be brought against us, our business may be impaired.

We face potential liability related to the privacy of health information we may obtain from the patients in our clinical trials if we fail to comply with privacy laws.

Most healthcare providers are subject to privacy and security regulations promulgated under HIPAA, as amended by HITECH. We are not currently classified as a covered entity or business associate under HIPAA and thus are not subject to its requirements or penalties. However, any person may be prosecuted under HIPAA's criminal provisions either directly or under aiding-and-abetting or conspiracy principles. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a HIPAA-covered healthcare provider or research institution that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information. In addition, if we receive sensitive personally identifiable information, including health information, we may be subject to state laws requiring notification of affected individuals and state regulators if a breach of personal information occurs, which is a broader class of information than the health information protected by HIPAA.

We cannot assure you that we, our CROs, our clinical trial sites, and our clinical trial principal investigators with access to personally identifiable and other sensitive or confidential information relating to the patients in our clinical trials will not breach contractual obligations, or that we or they will not experience data security breaches or attempts thereof. This could have a corresponding effect on our business, including putting us in breach of our obligations under privacy laws and regulations as discussed above, which could in turn adversely affect our business, financial condition, results of operations, and prospects. We cannot assure you that our contractual measures and our own privacy and security-related safeguards will protect us from the risks associated with the third-party processing, storage, and transmission of such information.

Compliance with global privacy and data security requirements could result in additional costs and liabilities to us or inhibit our ability to collect and process data globally, and the failure to comply with such requirements could subject us to significant fines and penalties, which could have a material adverse effect on our business, financial condition, results of operations, or prospects.

The regulatory framework for the collection, use, safeguarding, sharing, transfer, and other processing of information worldwide is rapidly evolving and is likely to remain uncertain for the foreseeable future. Globally, many jurisdictions have established their own data security and privacy frameworks. In the United States, there are a broad variety of data protection laws that are either currently in place or under way and a wide range of enforcement agencies at both the state and federal levels have the authority to review companies for privacy and data security concerns based on general consumer protection laws. The Federal Trade Commission ("FTC"), and state Attorneys General have been aggressive in reviewing privacy and data security protections for consumers. New laws also are being considered at both the state and federal levels. For example, the California Consumer Privacy Act (the "CCPA"), which went into effect on January 1, 2020, provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. Many other states are considering similar legislation. A broad range of legislative measures also have been introduced at the federal level. There also is the threat of consumer class actions related to these laws and the overall protection of personal data.

Additionally, the CCPA was amended by the California Privacy Rights Act, which significantly amends the CCPA and imposes additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It will also create a new California data protection agency authorized to issue substantive regulations, which could result in increased privacy and information security enforcement. The majority of the provisions went into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required. Similar laws have passed in, or are being considered by, other states. The enactment of such laws in other states could result in potentially conflicting requirements, which would make compliance challenging and costly.

The FTC and many state attorneys general continue to enforce federal and state consumer protection laws against companies for online collection, use, dissemination and security practices that appear to be unfair or deceptive. For example, according to the FTC, failing to take appropriate steps to keep consumers' personal information secure can constitute unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission

Act. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. We may also be subject to new state laws governing the privacy of consumer health data, including information concerning individual health conditions and treatment.

The data privacy laws in the European Union (the "EU") have also been significantly reformed. The collection, use, disclosure, transfer, or other processing of personal data regarding individuals in the EU, including personal health data, is subject to the General Data Protection Regulation, (EU) 2016/679 (the "GDPR"). The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. The GDPR has expanded the definition of personal data to include coded data and requiring changes to informed consent practices and more detailed notices for clinical trial patients and investigators. In addition, the GDPR also imposes strict rules on the transfer of personal data to countries outside the EU, including the United States and, as a result, increases the scrutiny that clinical trial sites located in the European Economic Area should apply to transfers of personal data from such sites to countries that are considered to lack an adequate level of data protection, such as the United States. The GDPR also permits data protection authorities to require destruction of improperly gathered or used personal information or impose substantial fines for violations of the GDPR, which can be up to 4% of global revenues or €20 million, whichever is greater, and it also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. In addition, the GDPR provides that EU member states may make their own additional laws and regulations limiting the processing of personal data, including genetic, biometric, or health data.

Furthermore, since the United Kingdom is no longer part of the EU, its data protection regulatory regime will be independent of the EU. From January 1, 2021, companies have had to comply with the GDPR and also the United Kingdom GDPR, which, together with the amended United Kingdom Data Protection Act 2018, retains the GDPR in UK national law. The relationship between the United Kingdom and the EU in relation to certain aspects of data protection law remains unclear. In addition, the longer term economic, legal, political, regulatory, and social framework to be put in place between the United Kingdom and the EU has had, and may continue to have, a material and adverse effect on global economic conditions and the stability of global financial markets and may significantly reduce global market liquidity and restrict the ability of key market participants to operate in certain financial markets. Any of these factors could depress economic activity and restrict our access to capital, which could materially and adversely affect our business, financial condition, and results of operations.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent protection for our technology and product candidates, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and drugs similar or identical to ours, and our ability to successfully commercialize our technology and product candidates may be adversely affected.

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our product candidates. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our technology and product candidates. If we do not adequately protect our intellectual property, competitors may be able to use our technologies and erode or negate any competitive advantage that we may have, which could harm our business and ability to achieve profitability. To protect our proprietary positions, we file patent applications in the United States and abroad related to our novel technologies and product candidates that are important to our business.

The patent application and prosecution process is expensive and time-consuming. We, our current licensees, or any future licensors and licensees may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. We or our current licensees, or any future licensors or licensees may also fail to identify patentable aspects of our research and development before it is too late to obtain patent protection.

Therefore, these and any of our patents and applications may not be prosecuted and enforced in a manner consistent with our best interests. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, such as with respect to proper priority claims, inventorship, claim scope or patent term adjustments. If our current licensees, or any future licensors or licensees, are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised, and we might not be able to prevent third parties from making, using and selling competing products. If there are material defects in the form or preparation of our patents or patent applications, such patents or applications may be invalid and/or unenforceable. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how. Any of these outcomes could impair our ability to prevent competition from third parties.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. No consistent policy regarding the breadth of claims allowed in biotechnology and pharmaceutical patents has emerged to date in the United States or in many foreign jurisdictions. For example, European patent law currently restricts the patentability of methods of treatment of the human body more than United States law does. In addition, the determination of patent rights with respect to pharmaceutical compounds and technologies commonly involves complex legal and factual questions, which has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Furthermore, recent changes in patent laws in the United States, including the America Invents Act of 2011, may affect the scope, strength and enforceability of our patent rights or the nature of proceedings that may be brought by us related to our patent rights.

We may not be aware of all third-party intellectual property rights potentially relating to our current and future product candidates. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. Similarly, should we own any patents or patent applications in the future, we may not be certain that we were the first to file for patent protection for the inventions claimed in such patents or patent applications. As a result, the issuance, scope, validity and commercial value of our patent rights cannot be predicted with any certainty. Moreover, we may be subject to a third-party pre-issuance submission of prior art to the U.S. Patent and Trademark Office, or USPTO, or become involved in derivation, ex-parte reexamination, or inter partes review proceedings in the USPTO or similar proceedings elsewhere, challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. If the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Our pending and future patent applications may not result in patents being issued that protect our technology or product candidates, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection against competing products or processes sufficient to achieve our business objectives, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner. Our competitors may seek to market generic versions of any approved products by submitting abbreviated new drug applications to the FDA in which they claim that patents owned or licensed by us are invalid, unenforceable and/or not infringed. Alternatively, our competitors may seek approval to market their own products similar to or otherwise competitive with our products. In these circumstances, we may need to defend and/or assert our patents, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find our patents invalid and/or unenforceable.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may

result in loss of exclusivity or freedom to operate, a patent being held unenforceable, and/or in one or more patent claims being narrowed or invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could significantly harm our business.

There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our technology or product candidates, including interference proceedings before the USPTO. Intellectual property disputes arise in several areas including with respect to patents, use of other proprietary rights and the contractual terms of license arrangements. Third parties may assert claims against us based on existing or future intellectual property rights. The outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance.

If we are found to infringe a third-party's intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing product candidate or product. Alternatively, we may be required to obtain a license from such third party to use the infringing technology and continue developing, manufacturing or marketing the infringing product candidate. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative effect on our business.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States could be less extensive than those in the United States. In some cases, we may not be able to obtain patent protection for certain licensed technology outside the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States, even in jurisdictions where we do pursue patent protection. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, even in jurisdictions where we do pursue patent protection or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions.

Competitors may use our technologies in jurisdictions where we have not pursued and obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product candidates and preclinical programs and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents, if pursued and obtained, or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful.

Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patent and trademark protection for our product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect our trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties prior to beginning research or disclosing proprietary information. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets. Despite these efforts and the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information due to our reliance on third parties, increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements.

Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. In addition, we may not be able to obtain adequate remedies for any such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets.

Moreover, our competitors may independently develop knowledge, methods and know-how equivalent to our trade secrets. Competitors could purchase our products and replicate some or all the competitive advantages we derive from our development efforts for technologies on which we do not have patent protection. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

Risks Related to Our Industry

We face substantial competition, which may result in others discovering, developing, or commercializing products before or more successfully than we do.

The development and commercialization of new drug products is highly competitive. We face competition from major multi-national pharmaceutical companies, biotechnology companies, specialty pharmaceutical companies and generic drug companies with respect to our current and future product candidates. There are several large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of product candidates for the treatment of drug-resistant infections. Potential competitors also include academic institutions, government agencies and other public and private research organizations. Our competitors may succeed in developing, acquiring or licensing technologies and drug products that are more effective, more effectively marketed and sold or less costly than our product candidates, which could render our product candidates non-competitive and obsolete.

If our competitors obtain marketing approval from the FDA, the EMA or other comparable regulatory authorities for their product candidates more rapidly than we do, it could result in our competitors establishing a strong market position before we are able to enter the market.

Regulation of generic and biosimilar products varies around the world and such regulation is complex and subject to ongoing interpretation and implementation by regulatory agencies and courts. Particularly for biosimilars, health authority guidelines and legislative actions could make it less burdensome for competitor products to enter the market and further incentivize uptake of biosimilars. In the United States, the FDA has issued several “interchangeability” designations for biosimilar products, and is expected to continue doing so in the future. These designations could – subject to state law requirements – enable pharmacies to substitute biosimilars for innovator biological products. Given

the importance of biologic products to our clinical-stage pipeline, such regulation could have a material adverse effect on our business.

Many of our competitors have greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do as an organization. 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 and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any product candidates that we may develop. Our competitors also may obtain approval from the FDA, the EMA or other comparable regulatory agencies for their product candidates more rapidly than we may obtain approval for ours, which could result in product approval delays if a competitor obtains market exclusivity from the FDA or the EMA, or our competitors establish a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic drugs. Additional drugs may become available on a generic basis over the coming years. If our product candidates achieve marketing approval, we expect that they will be priced at a significant premium over competitive generic drugs.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercially sell any drugs that we may develop. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- reduced resources of our management to pursue our business strategy;
- decreased demand for any product candidates or products that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- significant costs to defend the resulting litigation;
- substantial monetary awards paid to clinical trial participants or patients;
- loss of revenue; and
- the inability to commercialize any drugs that we may develop.

We currently hold product liability insurance coverage in an amount that may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of our product candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Even if we receive regulatory approval to market our product candidates, the market may not be receptive to our product candidates upon their commercial introduction, which would negatively affect our ability to achieve profitability.

Our product candidates may not gain market acceptance among physicians, patients, healthcare payors and the medical community. The degree of market acceptance of any approved products will depend on a number of factors, including:

- the effectiveness of the product;
- the prevalence and severity of any side effects;
- potential advantages or disadvantages over alternative treatments;
- relative convenience and ease of administration;
- the strength of marketing and distribution support;
- the price of the product, both in absolute terms and relative to alternative treatments; and
- sufficient third-party coverage or reimbursement.

If our product candidates receive regulatory approval but do not achieve an adequate level of acceptance by physicians, healthcare payors and patients, we may not generate product revenues sufficient to attain profitability.

Reduced prices and reimbursement rates due to the actions of governments, payors, or competition or other healthcare cost containment initiatives such as restrictions on use, may negatively impact profits.

The continuing efforts of governments, pharmaceutical benefit management organizations, insurance companies, managed care organizations and other payors of health care costs to contain or reduce costs of health care may adversely affect the price, market access, and total revenues of our products. These organizations, together with governments, have increasingly imposed utilization management tools favoring the use of generic products. As these practices expand, we may face difficulty in obtaining or maintaining timely or adequate pricing or formulary placement of our products. In addition, we have experienced and expect to continue to experience increased competitive activity, which has resulted in lower overall prices for our products.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (together, "PPACA") and other legislative or regulatory requirements or potential legislative or regulatory actions regarding healthcare and insurance matters, along with the trend toward managed healthcare in the U.S., could adversely influence the purchase of healthcare products and reduce demand and prices for our products. In addition, in certain foreign markets, the pricing of prescription drugs is subject to government control and reimbursement may in some cases be unavailable. We believe that pricing pressures will continue and may increase.

More recently, presidential administrations and the U.S. Congress have taken actions in an effort to modify or replace PPACA and to implement or pass other reforms to the healthcare system, including proposed legislation related to the pricing of pharmaceuticals. There is uncertainty with respect to any potential changes that may be proposed and what the impact, if any, will be on our business, including the impact on coverage and reimbursement for healthcare items and services covered by plans that were authorized by PPACA. However, we cannot predict the ultimate content, timing or effect of any healthcare reform legislation or the impact of potential legislation on us.

We expect that additional state and federal healthcare reform measures will be considered and potentially adopted, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products once approved or additional pricing pressures and may adversely affect our operating results.

Our product candidates may be subject to government price controls that may affect our revenue.

There has been heightened governmental scrutiny in the United States and abroad of pharmaceutical pricing practices considering the rising cost of prescription drugs and biologics. In the United States, such scrutiny has resulted in several recent Congressional inquiries and proposed and enacted federal legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, the former Trump Administration's budget proposal for fiscal year 2020 contained further drug price control measures that could be enacted during the 2020 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. The former Trump Administration also released a "Blueprint", or plan, to lower drug prices and reduce out-of-pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out-of-pocket costs of drug products paid by consumers.

HHS has solicited feedback on some of these measures and has implemented others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage plans the option to use step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. On November 20, 2020, CMS issued an interim final rule through the CMS Innovation Center whereby Medicare Part B reimbursement for "certain high-cost prescriptions drugs" would be no more than most-favored-nation price (i.e., the lowest price) after adjustments, for a pharmaceutical product that the drug manufacturer sells in a member country of the Organization for Economic Cooperation and Development that has a comparable per-capita gross domestic product. On December 28, 2020, the United States District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. While some of these and other measures may require additional authorization to become effective, members of Congress and the Biden Administration have indicated that they will continue to seek new legislative and/or administrative measures to control drug costs. For example, the recently enacted Inflation Reduction Act contains provisions designed to limit the prices paid by Medicare for various prescription drugs. At the state level, legislatures have become increasingly aggressive in passing legislation and implementing 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.

Outside of the United States, particularly in the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain coverage and reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed.

Risks Related to Our Common Stock

Innoviva, our principal stockholder, beneficially owns greater than 50% of our outstanding shares of common stock, which causes us to be deemed a "controlled company" under the rules of NYSE. In addition, Innoviva's interests in our business may be different than our other stockholders.

As of December 31, 2023, Innoviva owns 69.5% of our outstanding shares and 19,364,647 warrants to purchase shares of our common stock. If Innoviva were to exercise the warrants held by them, they would hold approximately 80.1% of our issued and outstanding shares of common stock. As a result, Innoviva owns more than 50% of our outstanding shares, and as such, we are a "controlled company" under the rules of the NYSE. Under these rules, a company of which more than 50% of the voting power is held by an individual, a group or another company is a "controlled company" and, as such, may elect to be exempt from certain corporate governance requirements, including requirements that:

- a majority of the board of directors consist of independent directors;

- the board of directors maintain a nominating and corporate governance comprised solely of independent directors and with a written charter addressing the committee's purpose and responsibilities; and

- the board of directors maintain a compensation committee comprised solely of independent directors and with a written charter addressing the committee's purpose and responsibilities.

As a "controlled company," we may elect to rely on some or all of these exemptions, however, we do not intend to take advantage of any of these exemptions. Despite the fact we do not intend to take advantage of these exemptions, our status as a controlled company could make our common stock less attractive to some investors or otherwise harm our stock price.

Innoviva's large ownership stake may allow it to exert a substantial influence on actions requiring a stockholder vote, potentially in a manner that you do not support, including amendments to our articles of incorporation, adoption of measures that could delay or prevent a change in control or impede a merger, takeover, or other business combination involving us, and approval of other major corporate transactions. In addition, Innoviva's stock ownership may discourage a potential acquirer from making a tender offer or otherwise attempting to obtain control of us, which in turn could reduce our stock price or prevent our stockholders from realizing a premium over our stock price. Accordingly, our stockholders other than Innoviva may be unable to influence management and exercise control over our business.

The price of our securities has been volatile and may continue to be so, and purchasers of our securities could incur substantial losses.

The price of our securities has been volatile and may continue to be so. Between January 1, 2023 and December 31, 2023, the high and low sales prices of our common stock as reported on The New York Stock Exchange American varied between $1.10 and $4.35 per share. The stock market in general and the market for biotechnology and biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the companies' operating performance, in particular during the last several years.

As of December 31, 2023, we had outstanding common warrants to purchase an aggregate of 19,365,847 shares of our common stock at a weighted-average exercise price of $3.59 per share. We also have outstanding options to exercise 3,165,216 shares of our common stock at a weighted-average exercise price of $5.04 per share. To the extent any of our outstanding warrants or options are exercised, additional shares of our common stock will be issued which will result in dilution to our security holders and could also have an adverse effect on the market price of our common stock.

Raising additional capital may cause dilution to our stockholders, restrict our operations, and/or require us to relinquish rights to our technologies or product candidates.

Until such time, if ever, that we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, and strategic collaboration and licensing arrangements. The terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our common stock to decline. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, licensing or assigning our intellectual property rights, declaring dividends, and possibly other restrictions.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders' interests will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our Common Stockholders.

Attempting to secure additional financing may also divert our management from our day-to-day activities, which could impair or delay our ability to develop our product candidates. Furthermore, if, in the future, one or more banks or financial institutions enter receivership or become insolvent in response to financial conditions affecting the banking

system or financial markets, our ability to access our existing cash, cash equivalents, and marketable securities may be threatened and could have a material impact on our business and financial condition.

If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce, or terminate our product development or future commercialization efforts. Alternatively, we could be required to seek collaborators for our product candidates at an earlier stage than would otherwise be desirable or on terms that are less favorable than might otherwise be available. We might need to relinquish or license on unfavorable terms our rights to our product candidates in markets where we otherwise would seek to pursue development and commercialization ourselves, or to license our intellectual property to others who could develop products that will compete with our products. Any of these actions could have a material adverse effect on our business, financial condition, results of operations, and prospects.

General Risk Factors

Unfavorable global economic conditions, whether brought about by material global crises, health epidemics, military conflicts or war, geopolitical and trade disputes or other factors, may adversely affect our business and financial results.

Our business is sensitive to global economic conditions, which can be adversely affected by epidemics and other public health crises, political and military conflict, trade and other international disputes, significant natural disasters (including as a result of climate change) or other events that disrupt macroeconomic conditions. Adverse macroeconomic conditions, including inflation, slower growth or recession, new or increased tariffs and other barriers to trade, changes to fiscal and monetary policy or government budget dynamics (particularly in the pharmaceutical and biotech areas), tighter credit, higher interest rates, volatility in financial markets, high unemployment, labor availability constraints, currency fluctuations and other challenges in the global economy have in the past adversely affected, and may in the future adversely affect, us and our business partners and suppliers.

Further, military conflicts or wars (such as the ongoing conflicts between Russia and Ukraine and Israel and Palestine) can cause exacerbated volatility and disruptions to various aspects of the global economy. The uncertain nature, magnitude, and duration of hostilities stemming from such conflicts, including the potential effects of sanctions and counter-sanctions, or retaliatory cyber-attacks on the world economy and markets, have contributed to increased market volatility and uncertainty, which could have an adverse impact on macroeconomic factors that affect our business and operations, such as worldwide supply chain issues. It is not possible to predict the short- and long-term implications of military conflicts or wars or geopolitical tensions which could include further sanctions, uncertainty about economic and political stability, increases in inflation rate and energy prices, cyber-attacks, supply chain challenges and adverse effects on currency exchange rates and financial markets.

Additionally, the operations of our suppliers and manufacturers may be located in areas that are prone to earthquakes, wildfires and other natural disasters. Such operations and facilities are also subject to the risk of interruption by drought, power shortages, nuclear power plant accidents and other industrial accidents, terrorist attacks and other hostile acts, ransomware and other cybersecurity attacks, labor disputes, public health crises, and other events beyond the Company's control. Global climate change is resulting in certain types of natural disasters occurring more frequently or with more intense effects. Such events can create delays or interruptions to the Company's development efforts and inefficiencies in the Company's supply and manufacturing chain. Significant delays in our development efforts could materially impact our ability to obtain regulatory approval and to commercialize our products.

Any public health crises may affect our operations and those of third parties on which we rely, including our business partners and suppliers. The COVID-19 pandemic has had an adverse impact on the global economy, including as a result of impacts associated with protective health measures that we, other businesses and governments are taking or might have to take again in the future to manage the pandemic.

Without limiting the foregoing, we have experienced and/or may in the future experience:

- delays in receiving authorization from regulatory authorities to initiate any planned clinical trials, inspections, reviews and approvals of products;

- delays or difficulties enrolling patients in our clinical trials;
- delays in or disruptions to the conduct of preclinical programs and clinical trials;
- constraints on the movement of products and supplies through the supply chain, which can disrupt our ability to conduct clinical trials and develop our products;
- price increases in raw materials and capital equipment, as well as increasing price competition in our markets;
- adverse impacts on our workforce and/or key employees; and
- increased risk that counterparties to our contractual arrangements will become insolvent or otherwise unable to fulfill their contractual obligations.

Our operations could be disrupted by failure of our information systems or cyber-attacks.

Our operations could be disrupted if our information systems fail, if we are unsuccessful in implementing necessary upgrades or if we are subject to cyber-attacks. Our business depends on the efficient and uninterrupted operation of our computer and communications systems and networks, hardware and software systems and our other information technology. We collect and maintain information, which includes confidential and proprietary information as well as personal information regarding our employees, in digital form. Data maintained in digital form is subject to risk of cyber-attacks, which are increasing in frequency and sophistication. Cyber-attacks could include the deployment of harmful malware, viruses, worms, and other means to affect service reliability and threaten data confidentiality, integrity and availability. Despite our efforts to monitor and safeguard our systems to prevent data compromise, the possibility of a future data compromise cannot be eliminated entirely, and risks associated with intrusion, tampering, and theft remain. A failure of our systems, or an inability to successfully expand the capacity of these systems, or an inability to successfully integrate new technologies into our existing systems could have a material adverse effect on our business, results of operations, financial condition, and cash flows.

The Company's and its vendors' sophisticated information technology operations are spread across multiple, sometimes inconsistent, platforms, which pose difficulties in maintaining data integrity across systems. The ever-increasing use and evolution of technology, including cloud-based computing, creates opportunities for the unintentional or improper dissemination or destruction of confidential information stored in the Company's systems.

Any breach of our security measures or the accidental loss, inadvertent disclosure, unapproved dissemination, misappropriation or misuse of trade secrets, proprietary information or other confidential information, whether as a result of theft, hacking, fraud, trickery or other forms of deception, or for any other cause, could adversely affect our business position. Further, any such interruption, security breach, loss or disclosure of confidential information could result in financial, legal, business and reputational harm to the Company and could have a material adverse effect on our business, financial condition, results of operations, cash flows and stock price.

Item 1B. UNRESOLVED STAFF COMMENTS

None.

Item 1C. Cybersecurity

Cybersecurity Risk Management and Strategy

We recognize the importance of assessing, identifying, and managing material risks associated with cybersecurity threats, as such term is defined in Item 106(a) of Regulation S-K. These risks include operational risks, intellectual property or trade secret theft, improper disclosure of confidential information, fraud, extortion, harm to employees or customers, and violation of data privacy or security laws.

Cybersecurity risks related to our business, technical operations, privacy, and compliance issues are identified and addressed through a multi-faceted approach including third-party assessments, internal information technology ("IT")

audits, and IT security reviews. To defend, detect, and respond to cybersecurity incidents, we perform cybersecurity reviews of systems and applications; audits of applicable data policies; vulnerability assessments and penetration testing using external third-party tools to test security control; security incident and event management; continuous monitoring, and threat intelligence gathering; conduct employee training; and implement appropriate changes.

We leverage third-party expertise to audit and test our cybersecurity program and perform employee awareness training. These include periodic reviews of cybersecurity threats and related controls, including review of periodic penetration testing conducted by independent third parties.

We maintain a cyber liability insurance plan underwritten by multiple insurance companies, which provides protection against certain potential losses arising from cybersecurity incidents.

Security events and data incidents are evaluated, ranked by severity, and prioritized for response and remediation. Incidents are evaluated to determine materiality as well as operational and business impact, and reviewed for privacy impact.

Our business strategy, results of operations and financial condition have not been materially affected by risks from cybersecurity threats, including as a result of previously identified cybersecurity incidents, but we cannot provide assurance that they will not be materially affected in the future by such risks or any future material incidents. For more information on our cybersecurity related risks, see Item 1A Risk Factors of this Annual Report on Form 10-K.

Cybersecurity Governance

Cybersecurity is an important part of our risk management processes and an area of focus for our Board of Directors and management. Our Board of Directors delegated oversight of Cybersecurity to the Audit Committee. Our board members receive reports and presentations on data privacy and security, which address relevant cybersecurity issues, and which can span a wide range of topics, including but not limited to, recent developments, evolving standards, vulnerability assessments, review of risks from third parties such as service providers and suppliers, and the current threat environment. These updates are presented by IT third-party experts, finance, and legal departments. Our board members also engage in ad hoc conversations with management on cybersecurity-related news events and updates to our cybersecurity risk management and strategy programs.

The Audit Committee’s cybersecurity-related oversight includes the following:

- Receiving notice of, and providing guidance with respect to, material cybersecurity incidents;
- Reviewing our risks and cybersecurity programs and policies;
- Overseeing our management and mitigation of cybersecurity risks and potential breach incidents;
- Reviewing reports and key metrics on the Company’s cybersecurity and related risk management programs;
- Reviewing the progress of major technology-related proposals, plans, projects and architecture decisions to ensure that these projects and decisions support our overall business strategy.

Our management engages with third-party experts who have significant IT expertise and broad cybersecurity experience, including in cybersecurity threat management, cybersecurity training and education, incident response, cyber forensics, insider threats, business continuity and disaster recovery, and regulatory compliance. Such individuals have significant prior work experience in various roles involving IT security, auditing, compliance, systems, and programming. These individuals are informed about and monitor the prevention, mitigation, detection, and remediation of cybersecurity incidents and design.

Item 2. PROPERTIES

Our corporate headquarters are located in Los Angeles, California, with an address of 5005 McConnell Avenue, Los Angeles, CA 90066. On October 28, 2021, we entered into a lease for approximately 56,300 sq. ft. of office, research and development and manufacturing space under a non-cancellable lease (the "2021 Lease"). The 2021 Lease payment start date was May 1, 2022, and the total lease term is for 16 years and runs through 2038. Office space and research laboratories have been fully occupied since the third quarter of 2023, with cGMP manufacturing space (~10,000 sq. ft.) expected to be fully constructed and occupied in the second half of 2024.

We have a property located in Marina del Rey, California, with an address of 4503 Glencoe Avenue, Marina del Rey, CA 90292, where we currently lease 35,500 square feet of laboratory and office space. The lease expires on December 31, 2031. The facility includes 19,500 square feet of BSL2 laboratory space dedicated to phage product development. The facility includes approximately 3,000 square feet of cGMP laboratory space, designed to produce clinical quantities of our phage product candidates for human trials and to perform in-house QC testing. We are actively seeking a sub-tenant to take over the remaining term of the lease from mid-2024.

In addition, we lease a 5,000 square foot facility located in Sydney, Australia, which includes 4,000 square feet of laboratory space providing capabilities to support phage product development and manufacturing process development.

We believe that our existing office and laboratory space is sufficient to meet our needs for the foreseeable future.

Item 3. LEGAL PROCEEDINGS

From time to time, we may be involved in disputes, including litigation, relating to claims arising out of operations in the normal course of business. Any of these claims could subject us to costly legal expenses and, while management generally believes that there is adequate insurance to cover many different types of liabilities, our insurance carriers may deny coverage or policy limits may be inadequate to fully satisfy any damage awards or settlements. If this were to happen, the payment of any such awards could have a material adverse effect on the consolidated results of operations and financial position. Additionally, any such claims, whether or not successful, could damage our reputation and business. We are currently not a party to any legal proceedings, the adverse outcome of which, in management's opinion, individually or in the aggregate, would have a material adverse effect on our consolidated results of operations or financial position.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Our common stock is traded on the NYSE American under the symbol "ARMP."

Holders of Common Stock

As of March 15, 2024, there were 73 holders of record of our common stock. As of such date, there were 36,148,539 shares of our common stock outstanding.

Dividends

We have never declared or paid any cash dividends on our common stock. We currently intend to retain all available funds and any future earnings to support our operations and finance the growth and development of our business. Any future determination related to our dividend policy will be made at the discretion of our board of directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements, contractual restrictions, business prospects and other factors our board of directors may deem relevant.

Securities Authorized for Issuance Under Equity Compensation Plans

Securities Authorized for Issuance Under Equity Compensation Plans: See Part III, Item 12 of this Form 10-K for additional information required.

Recent Sales of Unregistered Securities

None.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Item 6. [Reserved]

None.

Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with the consolidated financial statements and the related notes contained elsewhere in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis are set forth elsewhere in this Annual Report on Form 10-K, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. See "Special Note Regarding Forward-Looking Statements." Our actual results may differ substantially from those referred to herein due to a number of factors, including but not limited to risks described in the section entitled "Risk Factors" and elsewhere in this Annual Report on Form 10-K.

Overview

We are a clinical-stage biotechnology company focused on the development of pathogen-specific bacteriophage therapeutics for the treatment of antibiotic-resistant and difficult-to-treat bacterial infections using our proprietary bacteriophage-based technology. We see bacteriophages as an alternative to antibiotics and an essential response to growing bacterial resistance to current classes of antibiotics. Bacteriophages or "phages" have a powerful and highly differentiated mechanism of action that enables binding to and killing of targeted bacteria while uniquely preserving the human microbiome. This is in direct contrast to traditional broad-spectrum antibiotics which can alter the human microbiome increasing susceptibility to opportunistic pathogens, such as *C. difficile*. We believe that phages represent a promising means to effectively treat bacterial infections as an alternative to broad- spectrum antibiotics, especially for patients with bacterial infections resistant to current standard of care therapies, including the multidrug-resistant or "superbug" strains of bacteria. We are a leading developer of phage therapeutics and are uniquely positioned to address the growing worldwide threat of antibiotic-resistant bacterial infections. We are completing two critical Phase 2 trials to ensure a pathway towards pivotal Phase 3 trials.

We are combining our proprietary approach and expertise in identifying, characterizing and developing both naturally occurring and engineered (synthetic) bacteriophages with our proprietary phage-specific host-engineered

current good manufacturing practice ("cGMP") manufacturing capabilities to advance a target pipeline of high-quality bacteriophage product candidates for advanced development. We are uniquely advancing two lead candidates to address both chronic and acute bacterial infections.

Our first lead candidate focused primarily on chronic bacterial infections is the clinical phage candidate for Pseudomonas aeruginosa ("P. aeruginosa"). On October 14, 2020, we received the approval to proceed from the U.S. Food and Drug Administration (the "FDA") for our Investigational New Drug ("IND") application for AP-PA02. In the first quarter of 2023, we announced positive topline results from the completed "SWARM-*P.a.*" study – a Phase 1b/2a, multicenter, double-blind, randomized, placebo-controlled, single ascending dose ("SAD") and multiple ascending dose ("MAD") clinical trial to evaluate the safety and tolerability of inhaled AP-PA02 in subjects with cystic fibrosis ("CF") and chronic pulmonary *P. aeruginosa* infection. Data indicate that AP-PA02 was well-tolerated with a treatment emergent adverse event profile similar to placebo. Pharmacokinetics (PK) findings confirm AP-PA02 can be effectively delivered to the lungs through nebulization with minimal systemic exposure, with single ascending doses and multiple ascending doses resulting in a proportional increase in exposure as measured in induced sputum and exposure achievement relatively consistent across patient subjects. Additionally, bacterial levels of *P. aeruginosa* in the sputum measured at several timepoints suggest improvement in bacterial load reduction for subjects treated with AP-PA02 at the end of treatment as compared to placebo after ten days of dosing. In addition, a correlation was seen between increasing phage dose and reduction in the bacterial load supporting the biologic plausibility of a bacterial specific mechanism of action and creating the opportunity for phage as a therapeutic alternative to inhaled antibiotics. This study is supported by the Cystic Fibrosis Foundation ("CFF"), which granted us a Therapeutics Development Award of $5.0 million. Following the promising Phase 1b/2a results of favorable safety and tolerability profile and plausible mechanism of action, an additional confirmatory Phase 2 trial was initiated in NCFB patients with similar chronic pulmonary infections due to *Pseudomonas aeruginosa*.

On February 22, 2022, we announced that we had received from the FDA the approval to proceed for our IND application for AP-PA02, in a second indication, non-cystic fibrosis bronchiectasis ("NCFB"). We initiated a Phase 2 trial ("Tailwind") in NCFB in 2022 and reported first patient dosing in the first quarter of 2023. The "Tailwind" study is a Phase 2, multicenter, double-blind, randomized, placebo-controlled study to evaluate the safety, phage kinetics, and efficacy of inhaled AP-PA02 phage therapeutic in subjects with NCFB and chronic pulmonary *Pseudomonas aeruginosa* infection. We are actively accelerating enrollment and increasing phage dosing with the goal of defining a safe and promising biologic correlation for a Phase 3 definitive trial in 2025 which will evaluate phage as an alternative to antibiotics in chronic pulmonary infections.

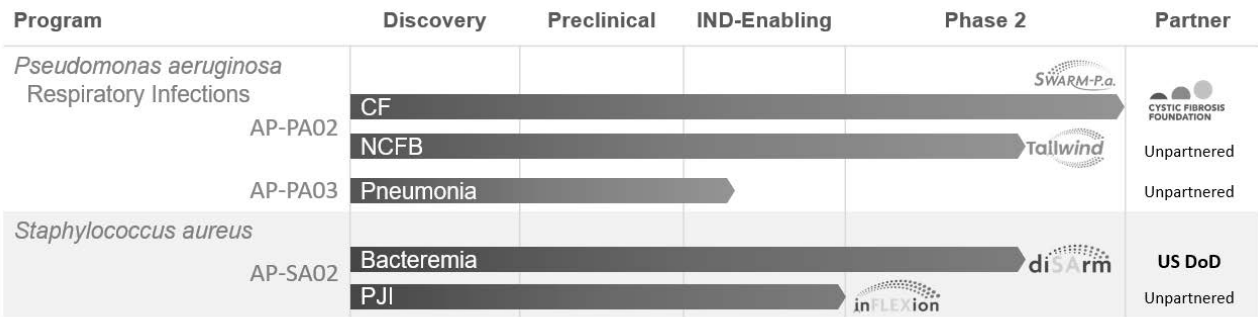
In parallel, we have an acute bacterial infection clinical development plan focused on *Staphylococcus aureus* bacteremia, a difficult-to-treat and often life-threatening human infections that can result in high morbidity and mortality and for which bacterial resistance to antibiotics is growing.

A key advantage of our phage manufacturing expertise is the purity profiles of our phage products, including AP-SA02, our phage product candidate for *Staphylococcus aureus* ("*S. aureus*"); this has enabled us to pursue treatment of complicated *S. aureus* bacteremia, where repetitive intravenous dosing is required. On June 15, 2020, we entered into an agreement (the "MTEC Agreement") with the Medical Technology Enterprise Consortium ("MTEC"), pursuant to which we expect to receive a $15.0 million grant and entered into a three-year program administered by the U.S Department of Defense (the "DoD") through MTEC with funding from the Defense Health Agency and Joint Warfighter Medical Research Program. On September 29, 2022, the MTEC Agreement was modified to increase the total award by $1.3 million to $16.3 million and extend the term into the second half of 2024. The grant is being used to partially fund a Phase 1/2, multi-center, randomized, double-blind, placebo- controlled dose escalation study that will assess the safety, tolerability, and efficacy of our phage-based candidate, AP-SA02, for the treatment of adults with *S. aureus* bacteremia. On November 17, 2021, we announced that we had received from the FDA the approval to proceed for our IND application for AP-SA02. We are focused on accelerating enrollment of the Phase 2a segment of the "diSArm" study, evaluating safety with higher intravenous doses, which is possible due to the high purity of our phage product candidates. We are committed to developing a definitive efficacy trial in 2025 focused on phage as an alternative to broad-spectrum antibiotics and/or antibiotic sparing to decrease the utilize of broad-spectrum antibiotics and their detrimental impact of the normal human microbiome.

On August 1, 2022, we announced that we had received from the FDA the approval to proceed for our IND application for AP-SA02, in a second indication, prosthetic joint infections ("PJI"). We had planned to initiate a Phase 1b/2a trial in 2023, however in light of the growing concerns of both PJI and wound infection, we are revising the protocol to include both indications. Driven by data from the bacteremia study, and with sufficient funding, we may in the future initiate a Phase 1b/2a trial to assess the safety and tolerability of intravenous and intra-articular AP-SA02 as an adjunct to standard of care antibiotics in adults undergoing treatment of periprosthetic joint infections and/or wound infections caused by *S. aureus*.

We remain committed to conducting randomized controlled clinical trials required for FDA approval in order to move toward the commercialization of its phage products as alternatives to traditional antibiotics, providing a potential method of treating patients suffering from drug-resistant and difficult-to-treat bacterial infections.

The following chart summarizes the status of our phage product candidate development programs and partners.



US Department of Defense (Naval Medical Research Command, US Army Medical Research Acquisition Activity, Defense Health Agency)
CF: cystic fibrosis; NCFB: non-CF bronchiectasis; PJI: prosthetic joint infection

We have incurred net losses since our inception and our operations to date have been primarily limited to research and development and raising capital. As of December 31, 2023, we had an accumulated deficit of $308.8 million. We currently expect to use our existing cash and cash equivalents for the focused research and development of our current product candidates and for working capital and other general corporate purposes. We anticipate that a substantial portion of our capital resources and efforts in the foreseeable future will be focused on completing the development and seeking to obtain regulatory approval of our product candidates. We do not expect to generate product revenue unless and until we successfully complete development and obtain marketing approval for at least one of our product candidates. We may also use a portion of our existing cash and cash equivalents for the potential acquisition of, or investment in, product candidates, technologies, formulations or companies that complement our business, although we have no current understandings, commitments or agreements to do so.

Our existing cash and cash equivalents together with the $35.0 million loan proceeds received in March 2024 will not be sufficient to enable us to complete all necessary development of any potential product candidates. Accordingly, we will be required to obtain further funding through one or more other public or private equity offerings, debt financings, collaboration, strategic financing, grants or government contract awards, licensing arrangements or other sources. Our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and potential disruptions to, and volatility in, financial markets in the United States and worldwide. Adequate additional funding may not be available to us on acceptable terms, or at all. If we are unable to raise capital when needed or on acceptable terms, we may be required to defer, reduce or eliminate significant planned expenditures, restructure, curtail or eliminate some or all of our development programs or other operations, dispose of assets, enter into arrangements that may require us to relinquish rights to certain of our product candidates, technologies or potential markets, file for bankruptcy or cease operations altogether. Any of these events could have a material adverse effect on our business, financial condition and results of operations and result in a loss of investment by our stockholders.

Recent Events

2024 Credit Agreement

On March 4, 2024, we entered into a credit and security agreement (the "2024 Credit Agreement") for a loan in an aggregate amount of $35.0 million with Innoviva Strategic Opportunities LLC ("Innoviva SO"), a wholly owned subsidiary of Innoviva, Inc. (NASDAQ: INVA) (collectively, "Innoviva"), our principal stockholder and a related party. The 2024 loan bears interest at an annual rate of 14% and matures on June 4, 2025. Principal and accrued interest are payable at maturity. Repayment of the Loan is guaranteed by our domestic subsidiaries, and the loan is secured by substantially all of our assets and our subsidiary guarantors. Concurrently with the execution of the 2024 loan, we amended certain provisions of the Convertible Loan and Credit Agreement to, among other things, conform certain terms relating to permitted indebtedness and permitted liens.

2023 Credit Agreement

On July 10, 2023, we entered into the Credit Agreement with Innoviva,. The Credit Agreement provides for a secured term loan facility in an aggregate amount of $25.0 million (the "Loan") at an interest rate of 14.0% per annum and has a maturity date of January 10, 2025. Principal and accrued interest are payable at maturity. Repayment of the Loan is guaranteed by our domestic subsidiaries, and the Loan is secured by substantially all of our assets and our subsidiary guarantors.

The Credit Agreement contains customary affirmative and negative covenants and representations and warranties, including financial reporting obligations and certain limitations on indebtedness, liens, investments, distributions (including dividends), collateral, investments, mergers or acquisitions and fundamental corporate changes. The Credit Agreement also includes customary events of default, including payment defaults, breaches of provisions under the loan documents, certain losses or impairment of collateral and related security interests, the occurrence of certain events that could reasonably be expected to have a "material adverse effect" as set forth in the Credit Agreement, certain bankruptcy or insolvency events, and a material deviation from our operating budget.

The Loan was initially recognized at fair value of $21.2 million and subsequently accounted for at the amortized cost net of debt issuance costs and debt discount. We amortized $0.9 million of debt issuance costs and debt discount during the year ended December 31, 2023 using the effective interest method. The Loan's annual effective interest rate was 27.3% as of December 31, 2023.

2023 Convertible Credit Agreement

On January 10, 2023, we entered into the Convertible Credit Agreement with Innoviva. The Convertible Credit Agreement provides for a secured term loan facility in an aggregate amount of $30.0 million (the "Convertible Loan") which bears interest at a rate of 8.0% per annum, and was scheduled to mature on January 10, 2024. Concurrently with the execution of the Credit Agreement, we amended certain provisions of the Convertible Credit Agreement, to, among other changes, extend the maturity of the Convertible Loan to January 10, 2025.

Repayment of the Convertible Loan is guaranteed by our domestic subsidiaries and foreign material subsidiaries, and the Convertible Loan is secured by substantially all of our assets and the subsidiary guarantors.

The Convertible Credit Agreement provides that if there is a financing from new investors of at least $30.0 million (a "Qualified Financing"), the outstanding principal amount of, and all accrued and unpaid interest on, the Convertible Loan shall be converted into shares of our common stock at a price per share equal to a 15.0% discount to the lowest price per share for common stock paid by investors in a Qualified Financing (which price paid by investors in a Qualified Financing may not be less than a 15.0% discount to the closing price of common stock immediately prior to the consummation of a Qualified Financing event). The Convertible Credit Agreement also required us to file a registration statement (the "Registration Statement") for the resale of all securities issued to the lender in connection with any conversion under the Convertible Credit Agreement, which we originally filed on February 13, 2023 and which was declared effective by the SEC on April 6, 2023. The Convertible Credit Agreement also confers upon the lender the option to convert any outstanding Convertible Loan amount, including all accrued and unpaid interest thereon, at the lender's option, into shares of common stock at a price per share equal to the greater of book value or market value per share of common stock on the date immediately preceding the effective date of the Convertible Credit Agreement, which was $1.52 (as may be appropriately adjusted for any stock split, combination or similar act).

On July 10, 2023, in connection with the Credit Agreement with Innoviva, we amended the terms of the Convertible Loan, to, among other changes, extend the maturity of the Convertible Loan to January 10, 2025. We concluded that the amendment is an extinguishment for accounting purposes. We recognized a $1.8 million gain as the change in fair value of the convertible debt before the extinguishment date, July 10, 2023. We estimated fair value of the combined Loan and the Convertible Loan before and after modification and recognized an extinguishment loss of $3.9 million in the consolidated statements of operations for the year ended December 31, 2023. We recognized a $23.6 million loss as the change in fair value of the Convertible Loan from July 10, 2023 to December 31, 2023.

Results of Operations

Comparison of years ended December 31, 2023 and 2022

The following table summarizes our results of operations for the years ended December 31, 2023 and 2022 (dollars in thousands):

	Year Ended December 31,		Change	
	2023	2022	Amount	%
Grant revenue	$ 4,529	$ 5,508	$ (979)	(17.8%)
Operating expenses				
Research and development	33,770	35,017	(1,247)	(3.6%)
General and administrative	11,649	7,437	4,212	56.6%
Total operating expenses	45,419	42,454	2,965	7.0%
Loss from operations	(40,890)	(36,946)	(3,944)	10.7%
Other income (expense)				
Interest income	179	29	150	*
Interest expense	(2,626)	—	(2,626)	*
Change in fair value of convertible debt	(21,845)	—	(21,845)	*
Loss on convertible debt extinguishment	(3,863)	—	(3,863)	*
Total other (expense) income, net	(28,155)	29	(28,184)	*
Net loss	$ (69,045)	$ (36,917)	$ (32,128)	87.0%

* Not meaningful

Grant Revenue

We recognized $4.5 million and $5.5 million of grant revenue for the years ended December 31, 2023 and 2022, respectively, which represents MTEC's share of the clinical development costs incurred for our AP-SA02 program for the treatment of *Staphylococcus aureus* bacteremia.

Research and Development

The following table summarizes our research and development expenses for the years ended December 31, 2023 and 2022 (dollars in thousands):

	Year Ended December 31,		Change	
	2023	2022	Amount	%
External costs:				
Clinical trial expenses	$ 9,982	$ 10,795	$ (813)	(7.5%)
Other research and development costs, including consulting, laboratory supplies and other	4,665	3,963	702	17.7%
Total external costs	14,647	14,758	(111)	(0.8%)
Internal costs:				
Personnel-related costs	9,665	11,638	(1,973)	(17.0%)
Facilities and overhead costs	9,458	8,621	837	9.7%
Total research and development expense:	$ 33,770	$ 35,017	$ (1,247)	(3.6%)

Research and development expenses decreased by $1.2 million, from $35.0 million for the year ended December 31, 2022 to $33.8 million for the year ended December 31, 2023.

Clinical trial costs decreased by $0.8 million, from $10.8 million for the year ended December 31, 2022, to $9.9 million for the year ended December 31, 2023. The decrease is primarily due to a decrease in clinical trial expenses for AP-PA02 Cystic Fibrosis study and AP-SA02 Prosthetic Joint Infection study, offset by an increase in clinical trial expenses for AP-PA02 Non-Cystic Fibrosis Bronchiectasis study and AP-SA02 Bacteremia study, based on the progress of our clinical trials.

Other external research and development costs increased by $0.7 million from $4.0 million for the year ended December 31, 2022 to $4.7 million for the year ended December 31, 2023. We recognized $0.3 million and $1.0 million credits to research and development expenses related to the CFF grant for the years ended December 31, 2023 and 2022, respectively. Our spending on laboratory supplies decreased by $1.4 million, which was partially offset by a $1.2 million increase in consulting expenses.

Our external research and development expenses by project for the years ended December 31, 2023 and 2022 were as follows (in thousands):

		Year Ended December 31,	
		2023	2022
Product	**Project name**		
AP-PA02	Non-Cystic Fibrosis Bronchiectasis	$ 4,922	$ 2,709
AP-PA02	Cystic Fibrosis	1,692	3,483
AP-SA02	Bacteremia	4,789	4,254
AP-SA02	Prosthetic Joint Infection	202	560
	Expenses not allocated by projects*	3,042	3,752
	Total external costs	$ 14,647	$ 14,758

- Expenses not allocated by projects include consultants, lab supplies and outsource service expenses

Personnel-related costs, including employee payroll and related expenses, decreased by $2.0 million, from $11.6 million for the year ended December 31, 2022 to $9.7 million for the year ended December 31, 2023, largely due to a decrease in payroll and related taxes of $0.9 million and recruiting expenses of $0.3 million, as well as employee stock-based compensation expenses decrease of $0.8 million, which was primarily due to the full vesting of awards issued in prior periods.

Facilities and overheads increased by $0.8 million from $8.6 million for the year ended December 31, 2022 to $9.4 million for the year ended December 31, 2023, largely as a result of an increase in lease expense of $1.0 million, an increase of $0.2 million related to laboratory equipment maintenance costs, partially offset by a decrease of $0.4 million in expensed noncapitalizable lab equipment.

General and Administrative

General and administrative expenses were $11.6 million and $7.4 million for the years ended December 31, 2023 and 2022, respectively. The increase of $4.2 million is primarily related to an increase of $3.7 million in legal, accounting and other consulting expenses, a one-time expense of $0.5 million related to the prepaid financing costs, an increase of $0.3 million in other facilities and overhead expenses, an increase of $0.2 million in leases and recruiting expenses, and a net decrease in personnel-related costs of $0.6 million, including a stock-based compensation expense decrease of $1.3 million, related to the full vesting of awards issued in prior periods and a reversal of expense related to certain equity awards modifications, offset by a $0.7 million increase in severance costs payable to two former employees.

Interest Income

Interest income for the years ended December 31, 2023 and 2022 was $0.2 million and less than $0.1 million, respectively, which was related to interest income earned on our cash, cash equivalents and restricted cash balances.

Interest Expense

We recognized interest expense of $2.6 million for the year ended December 31, 2023, which relates to the interest and the amortization of debt discount and issuance costs for the Loan received from Innoviva in July 2023. Interest expense is accrued at each period end and is payable at the Loan maturity in January 2025.

Change in Fair Value of Convertible Debt

We recognized a fair value of the convertible debt loss for the year ended December 31, 2023 of $21.9 million. The Convertible Loan received is accounted at fair value using a weighted probability of various settlement scenarios of the Convertible Loan during its term discounted to each reporting date. Conversion option scenarios are valued using an option pricing model with significant assumptions and estimates such as volatility, expected term and risk-free interest rates. Refer to Note 7, "*Convertible Debt*", in our consolidated financial statements included elsewhere in this Annual Report on Form 10-K for additional details.

Loss on Convertible Debt Extinguishment

We recognized a loss on convertible debt extinguishment for the year ended December 31, 2023 of $3.9 million which relates to the amendment to the Convertible Loan on July 10, 2023.The loss amount was estimated as a difference between the fair value of the Convertible Loan before and after modification. Refer to Note 7, "*Convertible Debt*", in our consolidated financial statements included elsewhere in this Annual Report on Form 10-K for additional details.

Liquidity, Capital Resources and Financial Condition

We have incurred net losses since our inception and have negative operating cash flows. Our cash and cash equivalents of $13.5 million as of December 31, 2023, together with the loan proceeds of $35.0 million received in March 2024, will not be sufficient to fund our operations for the next 12 months from the date of this Annual Report. We plan to control our expenses and to raise additional capital through a combination of public and private equity, debt financings, strategic alliances, and grant arrangements. These circumstances raise substantial doubt about our ability to continue as a going concern. While management believes this plan to raise additional funds will alleviate the conditions that raise substantial doubt, these plans are not entirely within its control and cannot be assessed as being probable of occurring. We may not be able to secure additional financing in a timely manner or on favorable terms, if at all**.**

In March 2024, we received a $35.0 million loan from Innoviva, which matures in June 2025 and bears interest at a rate of 14% per year. Principal and accrued interest are payable at maturity and may be prepaid at the Company's option.

During the year ended December 31, 2023, we received from Innoviva the Convertible Loan in the aggregate amount of $30.0 million and the Loan in the aggregate amount of $25.0 million from Innoviva. The Convertible Loan and the Loan mature in January 2025, and principal and accrued interest are payable at maturity. The Convertible Loan provides for various conversion and repayment options, including the conversion of principal and accrued interest into shares of our common stock upon a Qualified Financing and our option to repay the Convertible loan prior to maturity.

Future Capital Requirements

We will need to raise additional capital in the future to continue to fund our operations. Our future funding requirements will depend on many factors, including:

- the costs and timing of our research and development activities;
- the progress and cost of our clinical trials and other research and development activities;
- manufacturing costs associated with our targeted phage therapies strategy and other research and development activities;
- the costs of completing the construction and improvements of our leased premises to be used as our new headquarters. We expect to incur $5.4 million of additional expenses by mid-2024, which may increase or decrease as we complete the construction by mid 2024;
- the costs and timing of seeking regulatory approvals;
- the costs of filing, prosecuting and enforcing any patent applications, claims, patents and other intellectual property rights; and
- the costs of potential lawsuits involving us or our product candidates.

We may seek to raise capital through a variety of sources, including:

- the public equity market;
- private equity or debt financings;
- collaborative arrangements,
- government grants; or
- strategic financings.

Any additional fundraising efforts may divert our management team from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. Our ability to raise additional funds will depend, in part, on the success of our product development activities, including our targeted phage therapies strategy and any clinical trials we initiate, regulatory events, our ability to identify and enter into in-licensing or other strategic arrangements, and other events or conditions that may affect our value or prospects, as well as factors related to financial, economic and market conditions, many of which are beyond our control. We cannot be certain that sufficient funds will be available to us when required or on acceptable terms. If we are unable to secure additional funds on a timely basis or on acceptable terms, we may be required to defer, reduce or eliminate significant planned expenditures, restructure, curtail or eliminate some or all of our development programs or other operations, dispose of technology or assets, pursue an acquisition of our company by a third party at a price that may result in a loss on investment for our stockholders, enter into arrangements that may require us to relinquish rights to

certain of our product candidates, technologies or potential markets, file for bankruptcy or cease operations altogether. Any of these events could have a material adverse effect on our business, financial condition and results of operations, increase a risk of insolvency and loss of investment by our stockholders. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of such securities could result in dilution to our existing stockholders. Our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, financial markets in the United States and worldwide.

Cash Flows

The following table summarizes our sources and uses of cash for the periods presented (in thousands):

	Year Ended December 31,	
	2023	2022
Net cash used in operating activities	$ (47,423)	$ (32,481)
Net cash used in investing activities	(8,134)	(2,211)
Net cash provided by financing activities	53,988	44,016
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (1,569)	$ 9,324

Cash Flows Used in Operating Activities

Net cash used in operating activities was $47.4 million and $32.5 million for the years ended December 31, 2023 and 2022, respectively.

Cash used in operating activities in the year ended December 31, 2023 was primarily due to our net loss for the period of $69.0 million, adjusted by non-cash net expenses of $31.3 million and a net change of $9.7 million in our net operating assets and liabilities. The non-cash items consist of $21.8 million related to a loss from change in fair value of convertible debt, $3.9 million related to the Convertible Loan extinguishment loss, $2.6 million of non-cash interest expense on the Loan, $1.0 million related to depreciation and amortization expense, $1.0 million related to change in right-of-use asset, $0.9 million related to stock-based compensation expense. The changes in our net operating assets and liabilities were primarily due to a decrease of $13.5 million in operating lease liability, mainly related to payments for our new leased facility construction, which we expect to complete by mid-2024, and rent payments, a decrease of $1.1 million in accrued compensation, partially offset by a decrease of $4.8 million in prepaid expenses and other assets.

Cash used in operating activities in the year ended December 31, 2022 was primarily due to our net loss for the period of $36.9 million, adjusted by non-cash net expenses of $4.0 million and a net change of $0.4 million in our net operating assets and liabilities. The non-cash amounts consisted of $3.1 million related to stock-based compensation expense and $0.9 million related to depreciation and amortization expense. The changes in our net operating assets and liabilities were primarily due to an increase of $3.6 million in operating lease liability, an increase of $0.8 million in accrued compensation, an increase of $3.7 million in accounts payable and accrued liabilities, partially offset by an increase of $7.7 million in prepaid expenses and other current assets.

Cash Flows Used in Investing Activities

Net cash used in investing activities was $8.1 million and $2.2 million for the years ended December 31, 2023 and 2022, respectively, which is mostly attributable to purchases of laboratory and manufacturing equipment acquired for our new manufacturing facility. We expect our spending for property and equipment to decrease as our manufacturing facility will be ready by mid-2024.

Cash Flows from Financing Activities

Cash provided by financing activities for the year ended December 31, 2023 was $54.0 million, which consisted primarily of net proceeds from issuance of convertible debt of $29.1 million and net proceeds from issuance of long-term debt of $24.9 million.

Cash provided by financing activities for the year ended December 31, 2022 was $44.0 million, which consisted primarily of proceeds from the sale of common stock, net of offering costs of $44.4 million, proceeds from the exercise of stock options of $0.1 million, offset by payment of deferred offering costs of $0.5 million.

Off-Balance Sheet Arrangements

As of December 31, 2023, we did not have any off-balance sheet arrangements.

Critical Accounting Policies and Use of Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements as of December 31, 2023 and December 31, 2022, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, as well as the reported expenses incurred during the reporting periods. These estimates and assumptions are monitored and analyzed by us for changes in facts and circumstances, and material changes in these estimates and assumptions could occur in the future. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Changes in estimates are reflected in reported results for the period in which they become known. Actual results may differ from these estimates under different assumptions or conditions.

Although our significant accounting policies are described in more detail in Note 3, "*Significant Accounting Policies"*, to our consolidated financial statements included in this Annual Report on Form 10-K, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Accrued Research and Development

All research and development costs are expensed as incurred. Research and development costs consist primarily of salaries, employee benefits, costs associated with preclinical studies and clinical trials (including amounts paid to clinical research organizations and other professional services) and in process research and development expenses. Payments made prior to the receipt of goods or services to be used in research and development are capitalized until the goods or services are received.

We record accruals for estimated research and development costs, comprising payments for work performed by third-party contractors, laboratories, participating clinical trial sites, and others. Some of these contractors bill monthly based on actual services performed, while others bill periodically based upon achieving certain contractual milestones. For the latter, we accrue the expenses as goods or services are used or rendered. Clinical trial site costs related to patient enrollment are accrued as patients enter and progress through the trial. Judgments and estimates are made in determining the accrued balances at the end of the reporting period.

Fair Value Estimate of the Convertible Loan

In January 2023, we entered into the Convertible Credit Agreement with Innoviva, which was amended in July 2023. The Convertible Loan includes various conversion and repayment options, including the conversion of principal and accrued interest into shares of our common stock upon a Qualified Financing and our option to repay the Convertible Loan prior to maturity. Refer to Note 7, "*Convertible Debt*", in the consolidated financial statements included elsewhere in this Annual Report on Form 10-K for additional details.

We account for the Convertible Loan at fair value and changes in fair value are included in other income (expense) in the consolidated statements of operations in each reporting period. We estimate the fair value using a weighted probability of various settlement scenarios during the Convertible Loan term discounted to each reporting date. To estimate the fair value of the conversion option scenarios, we use an option pricing model with assumptions, such as volatility, expected term and risk-free interest rates. Changes in the fair value of our common stock and probabilities of scenarios significantly impact the fair value of the Convertible Loan. We expect to continue making these estimates until the Convertible Loan conversion or its maturity in January 2025.

As of December 31, 2023, we estimated the fair value of the Convertible Loan to be $58.6 million. For the year ended December 31, 2023, we recognized a change in fair value loss of $21.8 million in the consolidated statements of operations and comprehensive loss.

Recent Accounting Pronouncements

Refer to Note 3, "*Significant Accounting Policies*", of the notes to the consolidated financial statements contained elsewhere in this Annual Report on Form 10-K.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and are not required to provide the information required under this item.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

ARMATA PHARMACEUTICALS, INC.

INDEX TO AUDITED CONSOLIDATED FINANCIAL STATEMENTS

Armata Pharmaceuticals, Inc.

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of Armata Pharmaceuticals, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Armata Pharmaceuticals, Inc. (the Company) as of December 31, 2023 and 2022, and the related consolidated statements of operations, stockholders' (deficit) equity, and cash flows for the years then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2023 and 2022, and the results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

The Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has suffered recurring losses and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 2. The consolidated 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. 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.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Accrued clinical trial expenses and related research and development costs

Description of the Matter	During 2023, the Company incurred $33.8 million for research and development costs and as of December 31, 2023, the Company recorded $3.0 million for accrued clinical trial expenses. As described in Note 3 of the consolidated financial statements, the Company records accruals for estimated ongoing research and development costs, comprising payments for work performed by third party contractors, laboratories, participating clinical trial sites, and others. The Company accrues for the estimated ongoing clinical trial site costs based on patient enrollment and progress of the trial. Auditing management's accounting for accrued clinical trial expenses and related research and development costs is especially challenging as evaluating the progress or stage of completion of the activities under the Company's research and development agreements is dependent upon a high volume of data from third-party service providers and internal clinical personnel, which is tracked in spreadsheets and other end user computing programs.
How We Addressed the Matter in Our Audit	To test the completeness of the Company's accrued clinical trial expenses and related research and development costs, we obtained supporting evidence of the research and development activities performed for significant clinical trials. To assess the appropriate measurement of accrued clinical trial expenses and related research and development costs, our audit procedures included, among others, obtaining and inspecting significant agreements and agreement amendments, evaluating the Company's documentation of trial timelines and future projections of trial progress, confirming amounts incurred to-date with third-party service providers, and testing a sample of transactions and comparing the costs against related invoices and contracts. We also tested a sample of subsequent payments to evaluate the completeness of the accrued expenses and compared the results to the current year accrual.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2019.

San Diego, California

March 21, 2024

Armata Pharmaceuticals, Inc.
Consolidated Balance Sheets
(in thousands, except share and per share data)

	December 31, 2023	December 31, 2022
Assets		
Current assets		
Cash and cash equivalents	$ 13,523	$ 14,852
Prepaid expenses and other current assets	2,265	3,664
Other receivables	3,363	8,531
Total current assets	19,151	27,047
Restricted cash	5,720	5,960
Property and equipment, net	12,559	3,617
Operating lease right-of-use asset	44,717	43,035
In-process research and development	10,256	10,256
Goodwill	3,490	3,490
Other assets	2,470	2,429
Total assets	$ 98,363	$ 95,834
Liabilities and stockholders' (deficit) equity		
Current liabilities		
Accounts payable and accrued liabilities	$ 5,689	$ 6,034
Accrued compensation	768	1,828
Current portion of operating lease liabilities	9,481	17,011
Other current liabilities	523	—
Total current liabilities	16,461	24,873
Operating lease liabilities, net of current portion	28,583	31,804
Convertible debt	58,633	—
Long-term debt	23,674	—
Deferred tax liability	3,077	3,077
Total liabilities	130,428	59,754
Commitments and contingencies (Note 12)		
Stockholders' (deficit) equity		
Common stock, $0.01 par value; 217,000,000 shares authorized; 36,122,932 and 36,144,706 shares issued and outstanding at December 31, 2023 and 2022, respectively	361	361
Additional paid-in capital	276,393	275,493
Accumulated deficit	(308,819)	(239,774)
Total stockholders' (deficit) equity	(32,065)	36,080
Total liabilities and stockholders' (deficit) equity	$ 98,363	$ 95,834

The accompanying notes are an integral part of these consolidated financial statements.

Armata Pharmaceuticals, Inc.
Consolidated Statements of Operations
(in thousands, except share and per share data)

	Year Ended December 31,	
	2023	**2022**
Grant revenue	$ 4,529	$ 5,508
Operating expenses		
Research and development	33,770	35,017
General and administrative	11,649	7,437
Total operating expenses	45,419	42,454
Loss from operations	(40,890)	(36,946)
Other income (expense)		
Interest income	179	29
Interest expense	(2,626)	—
Change in fair value of convertible debt	(21,845)	—
Loss on convertible debt extinguishment	(3,863)	—
Total other (expense) income, net	(28,155)	29
Net loss	$ (69,045)	$ (36,917)
Per share information:		
Net loss per share, basic and diluted	$ (1.91)	$ (1.08)
Weighted average shares outstanding, basic and diluted	36,075,555	34,294,124

The accompanying notes are an integral part of these consolidated financial statements.

Armata Pharmaceuticals, Inc.
Consolidated Statements of Stockholders' (Deficit) Equity
(in thousands, except share data)

	Stockholders' (Deficit) Equity				
	Common Stock				
	Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' (Deficit) Equity
Balances, December 31, 2021	27,112,299	$ 271	$ 227,983	$ (202,857)	$ 25,397
Sale of common stock, net of issuance costs	9,000,000	90	44,301	—	44,391
Withholdings for taxes related to net share settlement of equity awards	(5,511)	—	(21)	—	(21)
Forfeiture of restricted stock awards	(369)	—	—	—	—
Exercise of stock options	38,287	—	125	—	125
Stock-based compensation	—	—	3,105	—	3,105
Net loss	—	—	—	(36,917)	(36,917)
Balances, December 31, 2022	36,144,706	361	275,493	(239,774)	36,080
Withholdings for taxes related to net share settlement of equity awards	(25,933)	—	(43)	—	(43)
Forfeiture of restricted stock awards	(27,341)	—	—	—	—
Exercise of stock options	1,500	—	5	—	5
Issuance of common stock upon vesting of restricted stock units	30,000	—	—	—	—
Stock-based compensation	—	—	938	—	938
Net loss	—	—	—	(69,045)	(69,045)
Balances, December 31, 2023	36,122,932	$ 361	$ 276,393	$ (308,819)	$ (32,065)

The accompanying notes are an integral part of these consolidated financial statements.

Armata Pharmaceuticals, Inc.
Consolidated Statements of Cash Flows
(in thousands)

	Year Ended December 31,	
	2023	2022
Operating activities:		
Net loss	$ (69,045)	$ (36,917)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	972	892
Stock-based compensation expense	938	3,105
Change in fair value of convertible debt	21,845	—
Non-cash interest expense	2,573	—
Non-cash interest income	(22)	—
Loss on convertible debt extinguishment	3,863	—
Change in right-of-use asset	1,018	—
Loss from disposal of property and equipment	81	—
Changes in operating assets and liabilities:	—	
Prepaid expenses and other assets	4,826	(7,662)
Accounts payable and accrued liabilities	39	3,665
Accrued compensation	(1,060)	793
Operating lease liability	(13,451)	3,643
Net cash used in operating activities	(47,423)	(32,481)
Investing activities:		
Purchases of property and equipment	(8,144)	(2,211)
Proceeds from sale of property and equipment	10	—
Net cash used in investing activities	(8,134)	(2,211)
Financing activities:		
Proceeds from issuance of convertible debt, net of issuance costs	29,101	—
Proceeds from issuance of long-term debt, net of issuance costs	24,925	—
Payment of deferred offering costs	—	(500)
Proceeds from sale of common stock, net of offering costs	—	44,391
Payments for taxes related to net share settlement of equity awards	(43)	—
Proceeds from exercise of stock options	5	125
Net cash provided by financing activities	53,988	44,016
Net (decrease) increase in cash, cash equivalents and restricted cash	(1,569)	9,324
Cash, cash equivalents and restricted cash, beginning of period	20,812	11,488
Cash, cash equivalents and restricted cash, end of period	$ 19,243	$ 20,812
Supplemental disclosure of cash flow information:		
Right-of-use asset obtained in exchange for operating lease liability	$ 2,700	$ 8,669
Property and equipment included in accounts payable	$ 217	$ 78

Reconciliation of cash, cash equivalents and restricted cash to the consolidated balance sheets:

	Year Ended December 31,	
	2023	2022
Cash and cash equivalents	$ 13,523	$ 14,852
Restricted cash	5,720	5,960
Cash, cash equivalents and restricted cash	$ 19,243	$ 20,812

The accompanying notes are an integral part of these consolidated financial statements.

Armata Pharmaceuticals, Inc.
Notes to Consolidated Financial Statements

1. Organization and Description of the Business

Armata Pharmaceuticals, Inc. ("Armata") together with its subsidiaries (the "Company"), is a clinical-stage biotechnology company focused on the development of pathogen-specific bacteriophage therapeutics for the treatment of antibiotic-resistant and difficult-to-treat bacterial infections using its proprietary bacteriophage-based technology.

Armata's common stock, par value $0.01 per share (the "Common Stock") is traded on the NYSE American exchange under the ticker symbol "ARMP".

The Company's principal stockholder, Innoviva Strategic Opportunities LLC ("Innoviva SO"), a wholly owned subsidiary of Innoviva Inc. ("Innoviva"), owns 69.4% of the Company's outstanding equity as of December 31, 2023. The Company also received $90.0 million in total debt financing from Innoviva SO during 2023 and in March 2024. Innoviva designees represent three out of eight Board of Directors seats during the year ended December 31, 2023, and cannot vote or take any action by written consent with respect to any shares of common stock held by Innoviva SO that represent, in the aggregate, more than 49.5% of the total number of shares of the Company's Common Stock for voting on the matters related to election or removal of the Company's board members or amending the bylaws of the Company to reduce the maximum number of directors or setting the number of directors who may serve on the board of the Company in accordance with the voting agreement. The voting agreement expires on the earlier of the fifth anniversary of the agreement's effective date, January 26, 2021, or the approval by the Food and Drug Administration (the "FDA") of any of the Company's product candidates for marketing and commercial distribution. Innoviva SO and Innoviva are related parties of the Company.

2. Liquidity and Going Concern

The Company has incurred significant operating losses since inception and has primarily relied on equity, debt and grant financing to fund its operations. As of December 31, 2023, the Company had an accumulated deficit of $308.8 million. The Company expects to continue to incur substantial losses, and its transition to profitability will depend on the successful development, approval and commercialization of product candidates and on the achievement of sufficient revenues to support its cost structure. The Company may never achieve profitability, and unless and until then, the Company will need to continue to raise additional capital. The existing cash and cash equivalents of $13.5 million as of December 31, 2023, together with a $35.0 million loan received from Innoviva in March 2024, will not be sufficient to fund its operations for the next 12 months from the date of these consolidated financial statements. These circumstances raise substantial doubt about the Company's ability to continue as a going concern.

The Company has prepared its consolidated financial statements on a going concern basis, which assumes that the Company will realize its assets and satisfy its liabilities in the normal course of business. The accompanying consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result from the outcome of the uncertainty concerning the Company's ability to continue as a going concern.

Recent Financing:

2024 Credit Agreement

On March 4, 2024, the Company entered into a credit and security agreement (the "2024 Credit Agreement") for a loan in an aggregate amount of $35.0 million with Innoviva SO. The 2024 loan bears interest at an annual rate of 14% and matures on June 4, 2025. Principal and accrued interest are payable at maturity. Repayment of the loan is guaranteed by the Company's domestic subsidiaries, and the loan is secured by substantially all of the assets of the Company and the subsidiary guarantors. Concurrently with the execution of the 2024 loan, we amended certain provisions of the Convertible Loan and Credit Agreement to, among other things, conform certain terms relating to permitted indebtedness and permitted liens.

2023 Credit Agreement

On July 10, 2023, the Company entered into a credit and security agreement (the "Credit Agreement") for a loan in an aggregate amount of $25.0 million (the "Loan") with Innoviva SO. The Loan bears interest at an annual rate of 14% and matures on January 10, 2025. Principal and accrued interest are payable at maturity. Repayment of the Loan is guaranteed by the Company's domestic subsidiaries, and the Loan is secured by substantially all of the assets of the Company and the subsidiary guarantors. See Note 8, *"Long Term debt"*, for additional details.

2023 Convertible Credit Agreement

On January 10, 2023, the Company entered into a secured convertible credit and security agreement (the "Convertible Credit Agreement") with Innoviva SO. The Convertible Credit Agreement provides for a secured term loan facility in an aggregate amount of $30.0 million (the "Convertible Loan"), which bears interest at a rate of 8.0% per annum and was scheduled to mature on January 10, 2024. Concurrently with the execution of the Credit Agreement, the Company amended certain provisions of the Convertible Credit Agreement to, among other changes, extend the term of the Convertible Loan to January 10, 2025. Repayment of the Convertible Loan is guaranteed by the Company's domestic subsidiaries and foreign material subsidiaries, and the Convertible Loan is secured by substantially all of the assets of the Company and the subsidiary guarantors.

The Convertible Credit Agreement provides for various conversion and repayment options, including the conversion of principal and accrued interest into the shares of the Company's Common Stock upon a Qualified Financing (as defined below) and the Company's option to repay the loan prior to maturity. See Note 7, *"Convertible debt"*, for additional details.

The Company plans to raise additional capital through equity offerings, debt financings, or other capital sources, including potential collaborations, licenses and other similar arrangements. While the Company believes this plan to raise additional funds will alleviate the conditions that raise substantial doubt about the Company's ability to continue as a going concern, these plans are not entirely within its control and cannot be assessed as being probable of occurring. The Company's ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, financial markets in the United States and worldwide. The Company may not be able to secure additional financing in a timely manner or on favorable terms, if at all. Furthermore, if the Company issues equity securities to raise additional funds, its existing stockholders may experience dilution, and the new equity securities may have rights, preferences and privileges senior to those of the Company's existing stockholders. If the Company raises additional funds through collaboration, licensing or other similar arrangements, it may be necessary to relinquish valuable rights to its potential products on terms that are not favorable to the Company. If the Company is unable to raise capital when needed or on attractive terms, it would be forced to delay, reduce or eliminate its research and development programs or other operations. If any of these events occur, the Company's ability to achieve the development and commercialization goals would be adversely affected.

3. Significant Accounting Policies

Basis of Presentation

The consolidated financial statements and accompanying notes have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") and applicable rules and regulations of the U.S. Securities and Exchange Commission for financial reporting.

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All intercompany accounts and transactions have been eliminated upon consolidation.

Any reference in the condensed consolidated financial statements to applicable guidance is meant to refer to authoritative U.S. GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB").

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of expenses during the reporting period. On an ongoing basis, the Company evaluates estimates and assumptions, including but not limited to those related to the fair value of the convertible debt, stock-based compensation expense, accruals for research and development costs, the valuation of deferred tax assets, impairment of goodwill and intangible assets and impairment of long-lived assets. Management bases its estimates on historical experience and on various other assumptions 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 materially from those estimates.

Segments

The Company operates and manages its business as one reportable operating segment, which is the business of developing a pathogen-specific bacteriophage therapeutics for the treatment of antibiotic-resistant and difficult-to-treat acute and chronic bacterial infections using its proprietary bacteriophage-based technology. The Company's chief executive officer, who is the chief operating decision maker, reviews financial information on an aggregate basis for allocating resources and evaluating financial performance. The long-lived assets of $12.4 million, which represents 98.8% of the Company's total long-lived assets, are maintained in the United States.

Concentration of Credit Risks and Certain Other Risks

Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash, cash equivalents, and marketable securities. As of December 31, 2023 and 2022, cash, cash equivalents and marketable securities were invested primarily in money market funds and U.S. treasury securities through highly rated financial institutions. Investments are restricted, in accordance with the Company's investment policy, to a concentration limit per issuer or sector.

Other receivables represents amounts due from Medical Technology Enterprise Consortium (Note 13) and reimbursement for tenant improvements (Note 12).

Cash and Cash Equivalents

Cash and cash equivalents consist primarily of deposits with commercial banks and financial institutions.

Restricted Cash

The Company defines restricted cash as cash and cash equivalents that cannot be withdrawn or used for general operating activities. The restricted cash consists of two irrevocable letters of credit with financial institutions related to the Company's operating leases (Note 12).

Fair Value of Financial Instruments

Financial instruments include cash equivalents, prepaid expenses and other receivables, restricted cash, accounts payable and accrued liabilities, accrued compensation and other current liabilities, convertible debt and long-term debt. The carrying amounts of the above assets and liabilities are generally considered to be representative of their respective fair values because of the short-term nature of those instruments. Convertible debt is accounted at fair value. Long-term debt was accounted at fair value at inception and its subsequent fair value is not significantly different from its amortized basis, as effective interest rate is considered at market.

Property and Equipment

Property and equipment are recorded at cost and depreciated over their estimated useful lives using the straight-line method. Maintenance and repairs that do not improve or extend the lives of the respective assets are expensed to operations as incurred. Upon disposal, retirement, or sale of an asset, the related cost and accumulated depreciation is removed from the accounts and any resulting gain or loss is included in the results of operations. Estimated useful lives for property and equipment are as follows:

	Estimated Useful Lives
Laboratory equipment	5 – 10 years
Office and computer equipment	3 – 5 years
Leasehold improvements	Shorter of lease term or useful life

Impairment of Long-Lived Assets

The Company reviews long-lived assets for impairment when events or changes in circumstances indicate the carrying value of the assets may not be recoverable. Recoverability is measured by comparison of the carrying values of the assets to future net undiscounted cash flows that the assets or the asset groups are expected to generate. An impairment loss is recognized when estimated future undiscounted cash flows expected to result from the use of the asset and its eventual disposition are less than the carrying amount of the asset. No impairment losses on long-lived assets have been recorded for the years ended December 31, 2023 or 2022.

In-Process Research and Development ("IPR&D")

IPR&D assets are intangible assets with indefinite lives and are not subject to amortization. The Company's IPR&D assets represent capitalized in-process bacteriophage development programs for *S. aureus* infections that the Company acquired through a business combination. Such assets are initially measured at their acquisition-date fair values and are subject to impairment testing at least annually until completion or abandonment of research and development efforts associated with the projects. Upon successful completion of each project, the Company makes a determination as to the then remaining useful life of the intangible asset and begins amortization.

The Company tests IPR&D assets for impairment as of December 31 of each year or more frequently if indicators of impairment are present. The authoritative accounting guidance provides an optional qualitative assessment for any indicators that indefinite-lived intangible assets are impaired. If it is determined that it is more likely than not that the indefinite-lived intangible assets, including IPR&D, are impaired, the fair value of the indefinite-lived intangible assets is compared with the carrying amount and impairment is recorded for any excess of the carrying amount over the fair value of the indefinite-lived intangible assets.

If and when a quantitative analysis of IPR&D assets is required based on the result of the optional qualitative assessment, the estimated fair value of IPR&D assets is calculated based on the income approach, which includes discounting expected future net cash flows associated with the assets to a net present value. The fair value measurements utilized to perform the impairment analysis are categorized within Level 3 of the fair value hierarchy. Management judgment is required in the forecast of future operating results that are used in the Company's impairment analysis. The estimates the Company uses are consistent with the plans and estimates that it uses to manage its business. Assumptions utilized in the Company's income approach model include the discount rate, timing of clinical studies and regulatory approvals, the probability of success of its research and development programs, timing of commercialization of these programs, forecasted sales, gross margin, selling, general and administrative expenses, capital expenditures, as well as anticipated growth rates.

As of December 31, 2023 and 2022, the Company performed the annual evaluation of its IPR&D assets for impairment. The Company used multi-period excess earnings method, a variation of the discounted cash flow approach. Management assumptions included expected revenue forecast, estimated expenses, rate of success, and a discount rate. The fair value of the bacteriophage development programs for *S. aureus* infections was greater than its carrying value as

a result of the quantitative analysis. Consequently, no impairment loss was recognized as of December 31, 2023 and 2022.

Goodwill

Goodwill, which has an indefinite useful life, represents the excess of purchase consideration over the fair value of net assets acquired in an acquisition. Goodwill is not subject to amortization and is required to be tested for impairment at least on an annual basis. The Company tests goodwill for impairment as of December 31 of each year. The Company determines whether goodwill may be impaired by comparing the carrying value of the single reporting unit, including goodwill, to the fair value of the reporting unit. If the fair value is less than the carrying amount, a more detailed analysis is performed to determine whether goodwill is impaired. The impairment loss, if any, is measured as the excess of the carrying value of the goodwill over the implied fair value of the goodwill and is recorded in the Company's consolidated statements of operations. The Company performed quantitative analysis of goodwill impairment and noted no impairment as of December 31, 2023 and 2022.

Research and Development

All research and development costs are expensed as incurred. Research and development costs consist primarily of salaries, employee benefits, costs associated with preclinical studies and clinical trials (including amounts paid to clinical research organizations and other professional services). Payments made prior to the receipt of goods or services to be used in research and development are capitalized until the goods or services are received.

The Company records accruals for estimated research and development costs, comprising payments for work performed by third-party contractors, laboratories, participating clinical trial sites, and others. Some of these contractors bill monthly based on actual services performed, while others bill periodically based upon achieving certain contractual milestones. For the latter, the Company accrues the expenses as goods or services are used or rendered. Clinical trial site costs related to patient enrollment are accrued as patients enter and progress through the trial. Judgments and estimates are made in determining the accrued balances at the end of the reporting period.

Stock-Based Compensation

Compensation expense related to stock options granted to employees and non-employees is measured at the grant date based on the estimated fair value of the award and is recognized on the accelerated attribution method over the requisite service period. To estimate the fair value of an award, the Company uses the Black-Scholes option pricing model. This model requires inputs such as expected term, expected volatility, expected dividend yield of stock and risk-free interest rate. Expected volatility is based on the historical volatility of the Company's own stock price as well as stock volatility of similar publicly traded peer companies. The expected term represents the period that the Company expects its stock options to be outstanding. The expected term assumption is estimated using the simplified method set forth in the U.S. Securities and Exchange Commission Staff Accounting Bulletin 110, which is the mid-point between the option vesting date and the expiration date. The risk-free rate is based on the U.S. Treasury yield curve in effect at the time of grant commensurate with the expected term assumption. The fair value of restricted stock units ("RSUs") and restricted stock awards ("RSAs") is determined based on the number of units granted and the closing price of the Company's Common Stock as of the grant date. The Company accounts for forfeitures in the period they occur. Stock-based compensation expense for an award with a performance condition is recognized when the achievement of such performance condition is determined to be probable. If the outcome of such performance condition is not determined to be probable or is not met, no compensation expense is recognized and any previously recognized compensation expense is reversed.

Foreign Currency Translations and Transactions

The functional currency of the Company and its wholly owned subsidiaries is the U.S. dollar. Assets and liabilities denominated in foreign currencies are translated to U.S. dollars using the exchange rates at the date of transaction or historical rates. Revenues and expenses from the Company's foreign subsidiaries are translated using the quarterly

average exchange rate in effect during the year. Foreign currency translation gains and losses are recorded as other income (expense) in the Company's consolidated statement of operations.

Transactions denominated in foreign currencies are initially measured in U.S. dollars using the exchange rate on the date of the transaction. Foreign currency denominated monetary assets and liabilities are subsequently re-measured at the end of each reporting period using the exchange rate at that date, with the corresponding foreign currency transaction gain or loss recorded in the consolidated statements of operations. Nonmonetary assets and liabilities are not subsequently re-measured.

Grants Revenue and Other Awards

The Company determines whether agreements are within the scope of Accounting Standard Codification ("ASC") Topic 606, *Revenue from contracts with customers* ("ASC 606") or other topics at the effective date of an agreement.

The Company also determines if grants and awards are in scope of ASC Topic 808, *Collaborative Arrangements* ("ASC 808"). To the extent the grant or award is within the scope of ASC 808, the Company recognizes the award upon achievement of certain milestones as credits to research and development expenses. For grant and awards outside the scope of ASC 808, the Company applies ASC 606 or International Accounting Standards No. 20, *Accounting for Government Grants and Disclosure of Government Assistance*, by analogy, and revenue is recognized when the Company incurs expenses related to the grant for the amount the Company is entitled to under the provisions of the agreement.

The Company also considers the guidance in ASC Topic 730, *Research and Development* ("ASC 730"), which requires an assessment, at the inception of the grant or award, of whether the agreement is a liability. If Armata is obligated to repay funds received regardless of the outcome of the related research and development activities, then the Company is required to estimate and recognize that liability. Alternatively, if the Company is not required to repay the funds, then payments received are recorded as revenue or contra-expense as the expenses are incurred.

As of December 31, 2023 and 2022, the Company recognized as other receivables in its consolidated balance sheets $1.5 million and $1.9 million, respectively, related to invoiced grant amounts that have not been received.

Leases

The Company determines if an arrangement contains a lease at inception. The Company currently has only operating leases. The Company recognizes a right-of-use operating lease asset and associated short- and long-term operating lease liability on its consolidated balance sheet for operating leases greater than one year. The right-of-use assets represent the Company's right to use an underlying asset for the lease term and the lease liabilities represent the Company's obligation to make lease payments arising from the lease arrangements. Right-of-use operating lease assets and lease liabilities are recognized based on the present value of the future minimum lease payments, including noncash lease payments, the Company will pay over the lease term. The Company determines the lease term at the inception of each lease, which includes renewal options only if the Company concludes that such options are reasonably certain to be exercised.

As the Company's leases do not provide an interest rate implicit in the lease, the Company uses its incremental borrowing rate, based on the information available as of the lease inception date or at the date of remeasurement in determining the present value of future payments. The Company recognizes rent expense for the minimum lease payments on a straight-line basis over the expected term of the leases. The Company recognizes period expenses, such as common area maintenance expenses, in the period such expenses are incurred.

Income Taxes

The Company utilizes the asset and liability method of accounting for income taxes. Deferred income taxes are recognized for the future tax consequences of temporary differences using enacted statutory tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. Temporary

differences include the differences between the financial statement carrying amounts and the tax basis of existing assets and liabilities and net operating loss and tax credit carryforwards. The effect on deferred taxes of a change in tax rates is recognized in income (expense) in the period that includes the enactment date. The Company evaluates the likelihood that deferred tax assets will be recovered from future taxable income. Valuation allowances are provided if, based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

The Company's income tax returns are based on calculations and assumptions that are subject to examination by the Internal Revenue Service and other tax authorities. In addition, the calculation of tax liabilities involves dealing with uncertainties in the application of complex tax regulations. The Company recognizes liabilities for uncertain tax positions based on a two-step process. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained on audit, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount that is more than 50% likely of being realized upon settlement.

Comprehensive Income (Loss)

Comprehensive income (loss) is composed of net loss and other comprehensive income (loss). The Company did not have other comprehensive income (loss) for the years ended December 31, 2023 and 2022, as such, the comprehensive income (loss) for these periods was equal to the net loss.

Basic and Diluted Net Loss per Share

Basic net loss per common share is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of Common Stock outstanding during the period, without consideration of potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of Common Stock and potentially dilutive securities outstanding for the period. For purposes of the diluted net loss per share calculation, the Common Stock warrants, Convertible Loan, unvested restricted stock awards and restricted stock units, and stock options are considered to be potentially dilutive securities. Basic and diluted net loss attributable to common stockholders per share is presented in conformity with the two-class method required for participating securities. Under the two-class method, warrants issued to Innoviva are assumed to participate in undistributed earnings on an as-exercised basis, in accordance with the warrant agreements. The Company's participating securities do not have a contractual obligation to share in the Company's losses. As such, the net loss was attributed entirely to common stockholders. Because the Company has reported a net loss for all periods presented, diluted net loss per common share is the same as basic net loss per common share for those periods.

Recently Adopted Accounting Pronouncements

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments - Credit Losses (Topic 326), Measurement of Credit Losses on Financial Instruments*. The standard amends the impairment model by requiring entities to use a forward-looking approach based on expected losses to estimate credit losses for most financial assets and certain other instruments that aren't measured at fair value through net income. For available-for-sale debt securities, entities will be required to recognize an allowance for credit losses rather than a reduction in carrying value of the asset. Entities will no longer be permitted to consider the length of time that fair value has been less than amortized cost when evaluating when credit losses should be recognized. This new guidance became effective for calendar-year smaller reporting public entities in the first quarter of 2023. The Company adopted this ASU as of January 1, 2023, which did not have an impact on its consolidated financial statements or related disclosures.

Recent Accounting Pronouncements Not Yet Adopted

In August 2020, the FASB issued ASU 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)* ("ASU 2020-06"). ASU 2020-06 eliminates the beneficial conversion and cash conversion accounting models for convertible instruments. It also amends the accounting for certain contracts in an entity's own equity that are currently accounted for as derivatives because of specific settlement provisions. In addition, ASU 2020-06 modifies how particular convertible instruments and certain

contracts that may be settled in cash or shares impact the diluted earnings per share computation. The amendments in ASU 2020-06 are effective for the Company as of January 1, 2024. Early adoption is permitted. The Company is currently evaluating the impact of ASU 2020-06 on its consolidated financial statements.

In October 2023, the FASB issued ASU 2023-06, *Disclosure Improvements: Codification Amendments in Response to the SEC's Disclosure Update and Simplification Initiative*. This ASU aligns the requirements in the ASC to the removal of certain disclosure requirements set out in Regulation S-X and Regulation S-K, announced by the SEC. The effective date for each amended topic in the ASC is either the date on which the SEC's removal of the related disclosure requirement from Regulation S-X or Regulation S-K becomes effective, or on June 30, 2027, if the SEC has not removed the requirements by that date. Early adoption is prohibited. The Company is currently evaluating the impact of adopting ASU 2023-06 on its consolidated financial statements.

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*. This ASU requires public entities to disclose information about their reportable segments' significant expenses and other segment items on an interim and annual basis. Public entities with a single reportable segment are required to apply the disclosure requirements in ASU 2023-07, as well as all existing segment disclosures and reconciliation requirements in ASC 280 on an interim and annual basis. ASU 2023-07 is effective for fiscal years beginning after December 15, 2023, and for interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. The Company is currently evaluating the impact of adopting ASU 2023-07 on its consolidated financial statements.

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures. This ASU requires public entities, on an annual basis, to provide disclosure of specific categories in the rate reconciliation, as well as disclosure of income taxes paid disaggregated by jurisdiction. ASU 2023-09 is effective for fiscal years beginning after December 15, 2024, with early adoption permitted. The Company is currently evaluating the impact of adopting ASU 2023-09 on its consolidated financial statements.

4. Fair Value Measurements

The Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible. The Company determines fair value based on assumptions that market participants would use in pricing an asset or liability in the principal or most advantageous market. When considering market participant assumptions in fair value measurements, the following fair value hierarchy distinguishes between observable and unobservable inputs, which are categorized in one of the following three levels:

- *Level 1:* Observable inputs such as unadjusted quoted prices in active markets for identical assets or liabilities at the measurement date.

- *Level 2:* Inputs (other than quoted prices included in Level 1) that are either directly or indirectly observable for the asset or liability. These include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active.

- *Level 3:* Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The Company's cash equivalents include investments in a money market fund of zero and $0.5 million as of December 31, 2023 and 2022, respectively, which are carried at fair value and represent Level 1 financial instruments under the fair value hierarchy.

The Company's Convertible Loan (Note 7) is measured at fair value and remeasured at each measurement period, with changes in fair value recorded as other income (expense) in the consolidated statement of operations. The Company estimates the fair value of its Convertible Loan using a weighted probability model of various debt settlement scenarios during its term discounted to the reporting date. Conversion option scenarios are valued using option pricing

models with assumptions and estimates such as volatility, expected term and risk-free interest rates. Level 3 fair value inputs include probability and timing of various settlement scenarios and selection of comparable companies.

The Company estimated fair value of its Convertible Loan using the following inputs.

	Year Ended December 31, 2023
Discount rate	21.01%-45.88%
Probabilities of settlement scenarios	0%-85%
Volatility	101.1%-123.6%
Expected term (in years)	0.2-1.5
Risk-free rate	4.62%-5.39%

The following table presents a summary of the changes in the fair value of the Company's Level 3 financial liabilities (in thousands):

	Convertible Loan Pre Modification	Convertible Loan Post Modification
Balance at December 31, 2022	$ —	$ —
Net proceeds from issuance of the Convertible Loan (1)	29,226	—
Initial recognition of modified Convertible Loan (1)	—	35,031
Change in fair value	(1,757)	23,602
Convertible Loan exchanged (2)	(31,332)	—
Loss on extinguishment	3,863	—
Balance at December 31, 2023	$ —	$ 58,633

(1) The Convertible Loan is carried at fair value in the consolidated balance sheets. As such, the principal and accrued interest are included in the determination of fair value.

(2) The Company concluded that the amendment to the Convertible Loan was an extinguishment for accounting purposes and the amount exchanged was the relative fair value allocated to the Convertible Loan at the extinguishment date (Note 7).

5. Net Loss per Share

The following outstanding securities at December 31, 2023 and 2022 have been excluded from the computation of diluted weighted average shares outstanding, as they would have been anti-dilutive:

	December 31, 2023	December 31, 2022
Outstanding stock options	3,165,216	3,352,803
Unvested restricted stock units	200,000	30,000
Restricted stock awards	—	99,666
Shares issuable upon the conversion of Convertible Loan	21,293,861	—
Outstanding warrants	19,365,847	20,549,338
Total	44,024,924	24,031,807

6. Balance Sheet Details

Property and Equipment, net

Property and equipment as of December 31, 2023 and 2022 consisted of the following (in thousands):

	December 31, 2023	December 31, 2022
Laboratory equipment	$ 19,678	$ 10,007
Furniture and fixtures	817	817
Office and computer equipment	438	449
Leasehold improvements	3,447	3,447
Total	24,380	14,720
Less: accumulated depreciation	(11,821)	(11,103)
Property and equipment, net	$ 12,559	$ 3,617

Depreciation and amortization expense totaled $1.0 million and $0.9 million for the years ended December 31, 2023 and 2022, respectively. Property and equipment not in use was $8.1 million and $1.0 million as of December 31, 2023 and 2022, respectively, and are included in the laboratory equipment in the table above. These assets are not depreciated until they are placed in service.

Other Receivables

Other receivables as of December 31, 2023 and 2022 consisted of the following (in thousands):

	December 31, 2023	December 31, 2022
Tenant improvement allowance receivable (Note 12)	$ 1,835	$ 6,595
Grant and award receivable	1,528	1,936
	$ 3,363	$ 8,531

Accounts Payable and Accrued Liabilities

Accounts payable and accrued liabilities as of December 31, 2023 and 2022 consisted of the following (in thousands):

	December 31, 2023	December 31, 2022
Accounts payable	$ 1,585	$ 1,678
Accrued clinical trial expenses	3,021	2,650
Other accrued expenses	1,083	1,706
	$ 5,689	$ 6,034

7. Convertible Debt

On January 10, 2023, the Company received the Convertible Loan in the aggregated amount of $30.0 million from Innoviva pursuant to the Convertible Credit Agreement. The Convertible Loan bears interest at a rate of 8.0% per annum and was scheduled to mature on January 10, 2024. The Convertible Credit Agreement was amended on July 10, 2023, in connection with the Credit Agreement with Innoviva to, among other changes, extend the maturity of the Convertible Loan to January 10, 2025. The Convertible Loan principal and accrued interest are payable at maturity. Repayment of the Convertible Loan is guaranteed by the Company's domestic subsidiaries and foreign material subsidiaries, and the Convertible Loan is secured by substantially all of the assets of the Company and the subsidiary guarantors.

The Convertible Credit Agreement provides that if there is a financing from new investors of at least $30.0 million (a "Qualified Financing"), the outstanding principal amount of and all accrued and unpaid interest on the Convertible

Loan shall be converted into shares of the Company's Common Stock, at a price per share equal to a 15.0% discount to the lowest price per share for Common Stock paid by investors in such Qualified Financing. The Convertible Credit Agreement also required the Company to file a registration statement for the resale of all securities issued to the lender in connection with any conversion under the Convertible Credit Agreement, which the Company originally filed on February 13, 2023 and which was declared effective by the SEC on April 6, 2023. The Convertible Credit Agreement also confers upon the lender the option to convert any outstanding Convertible Loan amount, including all accrued and unpaid interest thereon, at the lender's option, into shares of Common Stock at a price per share equal to the greater of book value or market value per share of Common Stock on the date immediately preceding the effective date of the Convertible Credit Agreement, which was market value of $1.52 (as may be appropriately adjusted for any stock split, combination or similar act).

The Company evaluated authoritative guidance for accounting for the Convertible Loan and concluded that the Convertible Loan should be accounted for at fair value under ASC 480, *Distinguish Liabilities from Equity*, due to the fact that the Convertible Loan will predominately be settled with the Company's Common Stock. Consequently, the Company recorded the Convertible Loan in its entirety at fair value on its consolidated balance sheet, with changes in fair value recorded as other income (expenses) in the consolidated statements of operations during each reporting period.

On July 10, 2023, in connection with the Credit Agreement with Innoviva, as discussed below, the Company amended the terms of the Convertible Credit Agreement, to, among other changes, extend the maturity of the Convertible Loan to January 10, 2025. The Company concluded that the amendment was an extinguishment for accounting purposes. The Company recognized a $1.8 million gain as the change in fair value of the Convertible Loan before the extinguishment date, July 10, 2023. The Company estimated fair value of the combined transaction, the Loan and the Convertible Loan, before and after modification and calculated an extinguishment loss of $3.9 million, which was recognized as other income (expense) in the consolidated statement of operations for the year ended December 31, 2023. The Company recognized a $23.6 million loss as the change in fair value of the Convertible Loan from July 10, 2023 to December 31, 2023.

8. Long-Term Debt

On July 10, 2023, the Company entered into the Credit Agreement with Innoviva. The Credit Agreement provides for a secured term loan facility in an aggregate amount of $25.0 million at an interest rate of 14.0% per annum and has a maturity date of January 10, 2025. Principal and accrued interest are payable at maturity. Repayment of the Loan is guaranteed by the Company's domestic subsidiaries, and the Loan is secured by substantially all of the assets of the Company and the subsidiary guarantors.

The Credit Agreement contains customary affirmative and negative covenants and representations and warranties, including financial reporting obligations and certain limitations on indebtedness, liens, investments, distributions (including dividends), collateral, investments, mergers or acquisitions and fundamental corporate changes. The Credit Agreement also includes customary events of default, including payment defaults, breaches of provisions under the loan documents, certain losses or impairment of collateral and related security interests, the occurrence of certain events that could reasonably be expected to have a "material adverse effect" as set forth in the Credit Agreement, certain bankruptcy or insolvency events, and a material deviation from the Company's operating budget.

The Loan was initially recognized at fair value of $21.2 million and subsequently recognized at the amortized cost net of debt issuance costs and debt discount of $3.8 million. Debt issuance costs and debt discount in the amount of $0.9 million were amortized to interest expense using the effective interest method during the year ended December 31, 2023 . The Loan's annual effective interest rate was 27.31% as of December 31, 2023. The Company recognized $2.6 million interest expense for the year ended December 31, 2023.

9. Stockholders' Equity (Deficit)

Private Investment

February 2022 Private Placement

On February 9, 2022, the Company entered into the February 2022 Securities Purchase Agreement to sell its Common Stock and warrants to Innoviva. Pursuant and subject to the terms and conditions of the February 2022 Securities Purchase Agreement and related agreements, Innoviva agreed to purchase 9,000,000 newly issued shares of the Company's Common Stock, at a price of $5.00 per share, and warrants to purchase up to 4,500,000 additional shares of Common Stock, with an exercise price of $5.00 per share. The stock purchases occurred in two tranches. On February 9, 2022, Innoviva purchased 3,614,792 shares of Common Stock and warrants to purchase 1,807,396 shares of Common Stock for an aggregate purchase price of approximately $18.1 million. On March 31, 2022, upon the Company's stockholders voting in favor of the transaction, Innoviva purchased 5,385,208 shares of Common Stock and warrants to purchase 2,692,604 shares of Common Stock for an aggregate purchase price of $26.9 million.

Warrants issued to Innoviva expire in five years from the respective issuance date. The Company reviewed the authoritative accounting guidance and determined that the warrants meet the criteria to be accounted for as permanent equity.

Warrants

On December 31, 2023 and 2022, outstanding Common Stock warrants to purchase shares of Common Stock, all classified as equity financial instruments, are as follows:

December 31, 2023	December 31, 2022		Exercise Price	Expiration Date
—	1,183,491	$	5.60	October 16, 2023
993,139	993,139	$	2.87	February 11, 2025
7,717,661	7,717,661	$	2.87	March 27, 2025
1,867,912	1,867,912	$	3.25	January 26, 2026
4,285,935	4,285,935	$	3.25	March 16, 2026
1,807,396	1,807,396	$	5.00	February 8, 2027
2,692,604	2,692,604	$	5.00	March 30, 2027
1,200	1,200	$	1,680.00	None
19,365,847	20,549,338			

Shares Reserved for Future Issuance

As of December 31, 2023 and 2022, the Company had reserved shares of its Common Stock for future issuance as follows:

	December 31, 2023	December 31, 2022
Stock options outstanding	3,165,216	3,352,803
Unvested restricted stock units	200,000	30,000
Employee stock purchase plan	9,748	9,748
Shares available for future grants under the 2016 Plan	2,368,160	570,570
Warrants outstanding	19,365,847	20,549,338
Shares issuable upon the conversion of Convertible Loan	21,293,861	—
Total shares reserved	46,402,832	24,512,459

10. Equity Incentive Plans

Stock Award Plans

The Company maintains a 2016 Equity Incentive Plan (the "2016 Plan"), which provides for the issuance of incentive share awards in the form of non-qualified and incentive stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards and performance-based stock awards. The awards may be granted by the Company's Board of Directors to its employees, directors and officers and to consultants. The term of the options granted is ten years, the exercise price is the Company's closing price at the date of grant and the vesting period is usually four years. The Company also granted RSUs under the 2016 Plan that vest over four years.

Under the 2016 Plan, the number of shares authorized for issuance is automatically increased by a number equal to 5% of the total number of shares of the Company's capital stock outstanding on December 31st of the preceding calendar year, or a lesser number of shares determined by the Board annually beginning from January 1, 2017 until January 1, 2026. As of December 31, 2023, there were 2,368,160 shares available for issuance under the 2016 Plan. The increase as of January 1, 2024 was 1,807,235 shares.

The Company has issued restricted stock awards ("RSAs") under certain legacy option plans that generally vested two to four years based on service conditions. As of December 31, 2023, all RSAs were fully vested.

Pursuant to its 2016 Employee Stock Purchase Plan ("ESPP"), the Company may grant or provide for the grant of rights to purchase shares of its Common Stock. The number of shares of its Common Stock reserved for issuance under the ESPP will automatically increase on January 1st of each calendar year by the lesser of 1% of the total number of shares of the Company's Common Stock outstanding on December 31st of the preceding calendar year and 30,000 shares, subject to the ability of the Company's Board of Directors to take action to reduce the size of the increase in any given year. There were no awards issued under ESPP. As of December 31, 2023, the Company had reserved 9,748 shares for future grants under the ESPP.

Stock option activities during the year ended December 31, 2023 are presented below:

	Options Outstanding			
	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2022	3,352,803	$ 5.32	7.8	$ —
Granted	330,266	$ 2.39		$ —
Exercised	(1,500)	$ 3.15		$ 1
Forfeited/Cancelled/Expired	(516,353)	$ 4.94		$ 1
Outstanding at December 31, 2023	3,165,216	$ 5.04	5.9	$ 429
Vested and expected to vest at December 31, 2023	3,165,216	$ 5.04	5.9	$ 429
Exercisable at December 31, 2023	2,176,275	$ 4.01	4.0	$ 115

The aggregate intrinsic value of options at December 31, 2023 is based on the Company's closing stock price on that date of $3.24 per share.

The weighted average grant date fair value of the options granted during 2023 was $1.97. The fair value of vested options during the year ended December 31, 2023 was $5.1 million.

Restricted stock awards and restricted stock unit award activities during the year ended December 31, 2023 are presented below:

	Shares	Weighted Avg Grant Date Fair Value
Outstanding at December 31, 2022	129,666	$ 27.11
Granted	200,000	$ 2.39
Forfeited/Cancelled	(27,341)	$ 39.53
Vested and Issued as Common Stock	(102,325)	$ 23.79
Outstanding at December 31, 2023	200,000	$ 2.39

As of December 31, 2023, there was $1.8 million of total unrecognized compensation expense related to unvested stock options, restricted stock awards and restricted stock units, which the Company expects to recognize over the weighted average remaining period of approximately 1.7 years.

Stock-based Compensation

The Company estimates the fair value of stock options with performance and service conditions using the Black-Scholes valuation model.

The assumptions used to estimate the options fair value were as follows:

	Year Ended December 31,	
	2023	2022
Risk-free interest rate	3.54% - 5.54%	2.65% - 4.20%
Expected volatility	75.40% - 116.96%	81.81% - 85.86%
Expected term (in years)	0.12 - 7.00	5.50 - 7.00
Expected dividend yield	0%	0%

In July 2023, in connection with the resignation of its former chief executive officer, the Company amended the terms of certain of his awards. As a result, the Company reversed $0.6 million previously recognized stock-based compensation expense related to his forfeited and unvested awards.

The tables below summarize the total stock-based compensation expense (reversal) included in the Company's consolidated statements of operations for the periods presented (in thousands):

	Year Ended December 31,	
	2023	2022
Research and development	$ 1,013	$ 1,794
General and administrative	(75)	1,311
Total stock-based compensation	$ 938	$ 3,105

11. Income Taxes

Loss before income taxes consisted of the following components (in thousands):

	Year Ended December 31,	
	2023	2022
United States	$ (68,182)	$ (32,228)
Foreign	(863)	(4,689)
Total	$ (69,045)	$ (36,917)

Significant components of the Company's deferred tax assets and liabilities were as follows (in thousands):

	December 31,	
	2023	2022
Deferred tax assets:		
Net operating loss carryforwards	$ 46,591	$ 42,525
Capitalized research and development	21,431	19,103
Stock-based compensation	2,083	3,192
Depreciation and amortization	856	929
Lease accounting	13,899	13,660
Other	1,907	1,452
Total deferred tax assets before valuation allowance	86,767	80,861
Less: valuation allowance	(75,166)	(68,818)
Total deferred tax assets after valuation allowance	11,601	12,043
Deferred tax liabilities:		
Right-of-use asset	(11,510)	(12,043)
In-process research and development	(3,077)	(3,077)
Other	(91)	-
Total deferred tax liabilities	(14,678)	(15,120)
Net deferred tax liability	$ (3,077)	$ (3,077)

The Company's net operating loss carryforwards at December 31, 2023 are $167.6 million and $118.9 million for federal and state income tax purposes, respectively. Federal and state net operating loss carryforwards are available to offset future taxable income, if any, and will begin to expire in 2026 and 2028, respectively. The federal net operating loss carryforwards generated after 2017 of $113.1 million will carryforward indefinitely and can be used to offset up to 80% of future annual taxable income.

The Company's net operating loss carryforwards may be subject to a substantial annual limitation as a result of ownership changes that have occurred or could occur in the future pursuant to Internal Revenue Code Sections 382 and 383. These ownership changes may limit or eliminate the amount of net operating loss carryforwards that can be utilized to offset future taxable income. If eliminated, the related asset would be removed from deferred tax assets with a corresponding reduction in the valuation allowance. In general, an 'ownership change' as defined by the tax code results from a transaction or series of transactions over a three-year period resulting in an ownership change of more than 50 percent of the outstanding stock of a company by certain stockholders or public groups. The Company has not undergone an ownership change analysis pursuant to Internal Revenue Code Section 382 as of December 31, 2023.

Realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. Management assesses the available positive and negative evidence to estimate if sufficient future taxable income will be generated to use existing deferred tax assets. Based on the weight of available evidence, including the Company's history of operating losses, management has determined that it is more likely than not that the Company's net deferred tax assets will not be realized. Accordingly, a valuation allowance has been established by the Company to fully offset these net deferred tax assets. The Company increased its valuation allowance by approximately $6.3 million during the year ending December 31, 2023:

	December 31,	
	2023	2022
U.S. federal statutory income tax rate	21.0 %	21.0 %
Adjustments for tax effects of:		
State income taxes, net of federal tax	2.9 %	7.3 %
Stock-based compensation	(1.6)%	(0.2)%
Change in valuation allowance	(9.3)%	(28.6)%
Debt extinguishment	(1.2)%	0.0 %
Change in rate	(3.3)%	0.0 %
Fair value adjustment on convertible debt	(6.6)%	0.0 %
Other	(1.9)%	0.5 %
Effective income tax rate	(0.0)%	0.0 %

The Company files income tax returns in the U.S. federal jurisdiction, state of California and certain foreign jurisdictions. As of December 31, 2023, the Company is no longer subject to U.S. federal income tax examinations for tax years ended on or before December 31, 2019 or to California state income tax examinations for tax years ended on or before December 31, 2018. However, to the extent allowed by law, the tax authorities may have the right to examine prior periods where net operating losses or tax credits were generated and carried forward, and make adjustments up to the amount of the net operating loss or credit carryforward.

The Company did not have a liability for unrecognized tax benefits at December 31, 2023 and 2022.

The Company's policy is to classify interest and penalties on uncertain tax positions as a component of tax expense. As of December 31, 2023 and 2022, the Company has no accrued interest or penalties related to uncertain tax positions.

Deferred income taxes have not been provided for undistributed earnings of the Company's consolidated foreign subsidiary because the parent entity would not be required to include the distribution into income as the amount would be tax free.

The Tax Cuts and Jobs Act subjects a U.S. stockholder to tax on GILTI earned by certain foreign subsidiaries. The FASB Staff Q&A, Topic 740 No. 5. Accounting for Global Intangible Low-Taxed Income, states that an entity can make an accounting policy election either to recognize deferred taxes for temporary basis differences expected to reverse as GILTI in future years or to provide for the tax expense related to GILTI in the year the tax is incurred as a period expense only. The Company has elected to account for GILTI in the year the tax is incurred.

12. Commitments and Contingencies

Operating Leases

The Company leases office and research and development space under a non-cancelable operating lease in Marina del Rey, CA. The lease commenced on January 1, 2012 and in April 2020, the Company amended the lease ("2020 Lease Amendment") which, among other things, extended the lease term through December 31, 2031. Base annual rent for calendar year 2022, the first year under the Lease Amendment extended term, was approximately $1.9 million, and base rent increases by 3% annually and will be $2.5 million by the end of the amended term. In addition, the Company received a six-month rent abatement in 2020. In accordance with authoritative guidance, the Company re-measured the lease liability in April 2020 to be $11.7 million using an incremental borrowing rate of 12.89% and related right of use asset was $11.0 million.

Concurrent with the Company's execution of the 2020 Lease Amendment, an irrevocable letter of credit in the amount of $1.2 million was delivered to the landlord. Starting on February 1, 2022, and each year thereafter, the letter of credit will be reduced by 20% of the then outstanding amount. As of December 31, 2023, the letter of credit was $0.7 million.

On October 28, 2021, the Company entered into a lease for office and research and development space under a non-cancellable lease in Los Angeles, California (the "2021 Lease"). The 2021 Lease payment start date was May 1, 2022 and the total lease term is for 16 years and runs through 2038. Monthly rent for 2022 and 2023 are fully or partially abated while the lessor and the Company complete planned tenant improvements to the facility. Base monthly rent will be approximately $0.25 million in 2024. The Company is entitled to receive an allowance for tenant improvements of up to $7.3 million, of which the Company received $5.4 million during the year ended December 31, 2023. The Company is responsible for construction costs over such allowance. Out of pocket expenses to be incurred by the Company are considered noncash lease payments, and included in the lease liability and the right-of-use asset when the amount can be reasonably estimated. As of November 16, 2022, the Company finalized the budget to complete the construction of the 2021 Lease. Accordingly, the Company re-measured the lease liability and related right-of-use asset as of November 30, 2022, using an incremental borrowing rate of 11.8%. The re-measured lease liability of the 2021 Lease as of November 16, 2022 was $37.0 million, and the related right of use asset was $33.8 million. During the year ended December 31, 2023, the budget was modified and the Company re-measured the lease liability. As a result, the lease liability and related right-of-use asset increased by approximately $2.7 million, using an incremental borrowing rate of 14.27%.

In connection with the 2021 Lease, the Company delivered an irrevocable standby letter of credit in the total amount of $5.0 million to the landlord in 2022.

Future minimum annual lease payments under the Company's noncancelable operating leases as of December 31, 2023, are as follows (in thousands):

	Operating Leases
2024	$ 9,899
2025	5,307
2026	5,724
2027	5,452
2028	5,616
Thereafter	43,181
Total minimum lease payments	75,179
Plus: estimated short-term variable lease payments	5,386
Less: amount representing interest	(31,729)
Present value of operating lease obligations	38,064
Less: current portion	(9,481)
Noncurrent operating lease obligations	$ 28,583

Rent expense was $7.4 million and $6.3 million for the years ended December 31, 2023 and 2022, respectively. Total cash payments for operating leases as included in the consolidated statements of cash flows during the years ended December 31, 2023 and 2022 were $3.5 million and $2.7 million, respectively.

Legal Proceedings

From time to time, the Company may be involved in disputes, including litigation, relating to claims arising out of operations in the normal course of business. Any of these claims could subject the Company to costly legal expenses and, while management generally believes that there is adequate insurance to cover many different types of liabilities, the Company's insurance carriers may deny coverage or policy limits may be inadequate to fully satisfy any damage awards or settlements. If this were to happen, the payment of any such awards could have a material adverse effect on the consolidated results of operations and financial position. Additionally, any such claims, whether or not successful, could damage the Company's reputation and business. The Company is currently not a party to any legal proceedings, the adverse outcome of which, in management's opinion, individually or in the aggregate, would have a material adverse effect on its consolidated results of operations or financial position.

13. Grants and Awards

MTEC Grant

On June 15, 2020, the Company entered into a Research Project Award agreement (the "MTEC Agreement") with the Medical Technology Enterprise Consortium ("MTEC"), pursuant to which the Company received a $15.0 million grant and entered into a three-year program administered by the U.S. Department of Defense through MTEC managed by the Naval Medical Research Command with funding from the Defense Health Agency and Joint Warfighter Medical Research Program. On September 29, 2022, the MTEC Agreement was modified to increase the total award by $1.3 million to $16.3 million and extend the term into the third quarter of 2024. The MTEC funds are to partially fund a Phase 1b/2a, randomized, double-blind, placebo-controlled, dose escalation clinical study of the Company's therapeutic phage-based candidate, AP-SA02, for the treatment of complicated *Staphylococcus aureus* bacteremia infections. The MTEC Agreement specifies that the grant is paid to the Company over the term of the award through a cost reimbursable model, based on agreed upon cost share percentages, and the grant money received is not refundable to MTEC.

Upon license or commercialization of intellectual property developed with the funding from the MTEC Agreement, additional fees will be due to MTEC. The Company will elect whether to (a) pay a fixed royalty amount, which is subject to a cap based upon total funding received, or (b) pay an additional assessment fee, which would also be subject to a cap based upon a percentage of total funding received.

The MTEC Agreement is effective through October 30, 2024. The MTEC Agreement may be terminated in whole or in part, 30 calendar days following written notice from the Company to MTEC. In addition, MTEC has the right to terminate the MTEC Agreement upon material breach by the Company.

The Company determined that the MTEC Agreement is not in the scope of ASC 808 or ASC 606. Applying ASC 606 by analogy the Company recognizes proceeds received under the MTEC Agreement as grant revenue in the statement of operations when related costs are incurred. The Company recognized $4.5 million and $5.5 million in grant revenue from the MTEC Agreement during the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023 and 2022, the Company had $1.5 million and $1.9 million as awards receivable from MTEC, respectively.

CFF Therapeutics Development Award

On March 13, 2020, the Company entered into an award agreement (the "Award Agreement") with Cystic Fibrosis Foundation ("CFF"), pursuant to which the Company received a Therapeutics Development Award of $5.0 million (the "CFF Award"). The CFF Award has funded a portion of the Company's Phase 1b/2a clinical trial of the *Pseudomonas aeruginosa* ("*P. aeruginosa*") phage candidate, AP-PA02, as a treatment for airway infections in people with cystic fibrosis ("CF").

The CFF Award is payable to the Company incrementally in installments upon the achievement of certain milestones related to the development program and progress of the Phase 1b/2a clinical trial of AP-PA02, as set forth in the Award Agreement. The first payment under the Award Agreement, in the amount of $1.0 million, became due upon signing the Award Agreement and was received in April 2020. The last milestone in the amount of $0.3 million was achieved in December 2023 and was received in January 2024.

If the Company ceases to use commercially reasonable efforts directed to the development of AP-PA02, or any other Product (as defined in the Award Agreement), for a period of 360 days (an "Interruption") and fails to resume the development of the Product after receiving from CFF notice of an Interruption, then the Company must either repay the amount of the CFF Award actually received by the Company, plus interest, or grant to CFF (1) an exclusive (even as to the Company), worldwide, perpetual, sublicensable license under technology developed under the Award Agreement that covers the Product for use in treating infections in CF patients (the "CF Field"), and (2) a non-exclusive, worldwide, perpetual, sublicensable license under certain background intellectual property covering the Product, to the extent necessary to commercialize the Product in the CF Field.

Upon commercialization by the Company of any Product, the Company will owe a fixed royalty amount to CFF, which is to be paid in installments determined, in part, based on commercial sales volumes of the Product. The Company will be obligated to make an additional fixed royalty payment upon achieving specified sales milestones. The Company may also be obligated to make a payment to CFF if the Company transfers, sells or licenses the Product in the CF Field, or if the Company enters into a change of control transaction.

The term of the Award Agreement commenced on March 10, 2020 and expires on the earlier of the date on which the Company has paid CFF all of the fixed royalty payments set forth therein, the effective date of any license granted to CFF following an Interruption, or upon earlier termination of the Award Agreement. Either CFF or the Company may terminate the Award Agreement for cause, which includes the Company's material failure to achieve certain development milestones. The Company's payment obligations survive the termination of the Award Agreement.

The Company concluded that the CFF Award is in the scope of ASC 808. Accordingly, as discussed in Note 3, "*Significant Accounting Policies"*, the Company recognizes the award upon achievement of certain milestones as credits to research and development expenses. During year ended December 31, 2023 and 2022, the Company recognized $0.3 and $1.0 million as credits to research and development expenses related to the CFF Award, respectively. In addition, the Company concluded under the guidance in ASC 730 that it does not have an obligation to repay funds received once related research and development expenses are incurred.

14. Employee Retirement Plan

The Company's employees participate in an employee retirement plan under Section 401(k) of the Internal Revenue Code of 1986, as amended. All of the Company's employees who meet minimum eligibility requirements are eligible to participate in the plan. The Company did match contributions of $0.2 million and zero to the 401(k) plan for the years ended December 31, 2023 and 2022.

Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

Item 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We have established disclosure controls and procedures designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms and is accumulated and communicated to management, including the principal executive officer (our Chief Executive Officer) and principal financial officer (our Vice President, Corporate Controller), to allow timely decisions regarding required disclosure.

Our management, under the supervision and with the participation of our Chief Executive Officer and our Vice President, Corporate Controller, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this Annual Report on Form 10-K.

Management recognizes that any disclosure controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives. Our disclosure controls and procedures have been designed to provide reasonable assurance of achieving their objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs. Based on such evaluation, our Chief Executive Officer (principal executive officer) and our Vice President, Corporate Controller (principal financial officer) have concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2023.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Exchange Act Rules 13a-15(f) and 15(d) -15(f) as a process designed by, or under the supervision of, our Chief Executive Officer and Vice President, Corporate Controller to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. generally accepted accounting principles.

Because of inherent limitations, internal controls over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risks that controls may become inadequate because of changes in conditions or that the degree of compliance with the policies or procedures may deteriorate.

As of December 31, 2023, our management assessed the effectiveness of our internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework (2013) (the "2013 Framework"). In adopting the 2013 Framework, management assessed the applicability of the principles within each component of internal control and determined whether or not they have been adequately addressed within the current system of internal control and adequately documented. Based on this assessment, management, under the supervision and with the participation of our Chief Executive Officer and Vice President, Corporate Controller, concluded that, as of December 31, 2023, our internal control over financial reporting was effective based on those criteria.

Attestation Report of the Registered Public Accounting Firm

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. We were not required to have, nor have we, engaged our independent registered public accounting firm to perform an audit of internal control over financial reporting as we are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting identified in management's evaluation pursuant to Rules 13a-15(f) or 15d-15(f) of the Exchange Act during our fourth fiscal quarter ended December 31, 2023 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. OTHER INFORMATION

Trading Arrangements

None of the Company's directors or officers adopted, modified, or terminated a Rule 10b5-1 trading arrangement or a non-Rule 10b5-1 trading arrangement during the Company's fiscal quarter ended December 31, 2023.

Item 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

None.

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item will be contained in our definitive proxy statement on Schedule 14A to be filed with the Securities and Exchange Commission in connection with our 2024 annual meeting of stockholders (the "2024 Proxy Statement"), which we expect to file not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, and is incorporated in this report by reference. To the extent that we do not file the 2024 Proxy Statement by such date, we will file an amendment to this Annual Report on Form 10-K that includes the information required by this Item 10.

Item 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference from the information contained in the 2024 Proxy Statement, which we expect to file not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K. To the extent that we do not file the 2024 Proxy Statement by such date, we will file an amendment to this Annual Report on Form 10-K that includes the information required by this Item 11.

Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this item is incorporated by reference from the information contained in the 2024 Proxy Statement, which we expect to file not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K. To the extent that we do not file the 2024 Proxy Statement by such date, we will file an amendment to this Annual Report on Form 10-K that includes the information required by this Item 12.

Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this item is incorporated by reference from the information contained in the 2024 Proxy Statement, which we expect to file not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K. To the extent that we do not file the 2024 Proxy Statement by such date, we will file an amendment to this Annual Report on Form 10-K that includes the information required by this Item 13.

Item 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item is incorporated by reference from the information contained in the 2024 Proxy Statement, which we expect to file not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K. To the extent that we do not file the 2024 Proxy Statement by such date, we will file an amendment to this Annual Report on Form 10-K that includes the information required by this Item 14.

PART IV

Item 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a)(1) Financial Statements

Our Financial Statements are listed in the "Index to Audited Consolidated Financial Statements" of Armata Pharmaceuticals, Inc. in Part II, Item 8 of this Annual Report on Form 10-K.

(a)(2) Financial Statement Schedules

All financial statement schedules have been omitted because they are not required, not applicable, or the required information is included in the consolidated financial statements or notes thereto included in Part II, Item 8 of this Annual Report on Form 10-K.

(a)(3) Exhibits

The following exhibits are filed herewith or incorporated herein by reference:

Exhibit Number	Description of Document
3.1	Amended and Restated Articles of Incorporation of the Company, as amended (incorporated by reference to Exhibit 3.1 to the Company's Quarterly Report on Form 10-Q, filed with the SEC on November 16, 2015).
3.2	Articles of Amendment to Articles of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the registrant's Current Report on Form 8-K (File No. 001-37544), filed with the SEC on April 24, 2017).
3.3	Articles of Amendment to Articles of Incorporation of the Company (incorporated by reference to Exhibit 3.2 to the Company's Quarterly Report on Form 10-Q, filed on November 8, 2018).
3.4	Articles of Amendment to Amended and Restated Articles of Incorporation of the registrant (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K (File No. 001-37544), filed with the SEC on May 10, 2019).
3.5	Amended and Restated Bylaws of the registrant (incorporated by reference to Exhibit 3.5 to the Quarterly Report on Form 10-Q (File No. 001-37544), filed with the SEC on August 14, 2019).
3.6	Articles of Merger, dated as of May 9, 2019 (incorporated by reference to Exhibit 3.2 to the Current Report on Form 8-K (File No. 001-37544), filed with the SEC on May 10, 2019).
3.7	Articles of Amendment to Articles of Incorporation of the registrant, dated as of December 10, 2019 (incorporated herein by reference to Exhibit 3.1 to the Current Report on Form 8-K (File No. 001-37544), filed with the SEC on December 11, 2019).
3.8	Amendment to Amended and Restated Bylaws of the registrant (December 10, 2019) (incorporated herein by reference to Exhibit 3.2 to the Current Report on Form 8-K (File No. 001-37544), filed with the SEC on December 11, 2019).
3.9	Amendment to Amended and Restated Bylaws of the registrant (February 24, 2020) (incorporated herein by reference to Exhibit 3.1 to the Current Report on Form 8-K (File No. 001-37544), filed with the SEC on February 26, 2020).
3.10	Articles of Amendment to Articles of Incorporation of the Company (effective March 26, 2020) (incorporated herein by reference to Exhibit 3.1 to the Current Report on Form 8-K (File No. 001-37544), filed with the SEC on March 30, 2020).
4.1	Reference is made to Exhibits 3.1 through 3.8.
4.2	Form of Common Stock Certificate (incorporated by reference to Exhibit 4.4 to the Company's Registration Statement on Form S-8 (File No. 333-217563), filed on May 1, 2017).

4.3	Form of Common Stock Warrant issued to purchasers in March 2015 private placement (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, filed with the SEC on March 19, 2015).
4.4	Form of Warrant to Purchase Shares of Common Stock issued in connection with the Company's acquisition of certain assets of Novolytics Limited in February 2016 (incorporated by reference to Exhibit 4.13 to the Company's Annual Report on Form 10-K, filed with the SEC on March 30, 2016).
4.5	Form of Warrant to Purchase Common Stock issued to purchasers in May 2017 (incorporated by reference to Exhibit 4.18 to the Company's Registration Statement on Form S-1 (File No. 333-217169)).
4.6	Form of Common Stock Warrant (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, filed with the SEC on January 29, 2020).
4.7	Registration Rights Agreement, dated January 26, 2021, by and between the Company and Innoviva (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K, filed with the SEC on January 27, 2021)
4.8	Form of Common Stock Warrant (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, filed with the SEC on January 27, 2021)
4.9	Description of the Company's securities registered under Section 12 of the Exchange Act.
4.10	Form of Common Stock Warrant (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, filed with the SEC on February 11, 2022)
10.1+	Targeted Genetics Corporation 2009 Stock Incentive Plan (incorporated by reference to Exhibit 10.12 to the Company's Registration Statement on Form 10 (File No. 000-23930), filed December 16, 2013, as amended).
10.2+	AmpliPhi Biosciences Corporation 2012 Stock Incentive Plan (incorporated by reference to Exhibit 10.13 to the Company's Registration Statement on Form 10 (File No. 000-23930), filed December 16, 2013, as amended).
10.3+	Form of Stock Option Agreement under AmpliPhi Biosciences Corporation 2012 Stock Incentive Plan (incorporated by reference to Exhibit 10.14 to the Company's Registration Statement on Form 10 (File No. 000-23930), filed December 16, 2013, as amended).
10.4+	AmpliPhi Biosciences Corporation 2013 Stock Incentive Plan (incorporated by reference to Exhibit 10.21 to the Company's Registration Statement on Form 10 (File No. 000-23930), filed December 16, 2013, as amended).
10.5+	Form of Grant Notice and Stock Option Agreement under AmpliPhi Biosciences Corporation 2013 Stock Incentive Plan (incorporated by reference to Exhibit 10.16 to the Company's Annual Report on Form 10-K, filed with the SEC on March 30, 2016).
10.6+	Armata Pharmaceuticals, Inc. 2016 Equity Incentive Plan, as amended (incorporated by reference to Exhibit 99.1 to the registrant's Registration Statement on Form S-8, filed with the SEC on June 10, 2019).
10.7+	Form of Stock Option Grant Notice, Option Agreement and Notice of Exercise under the Armata Pharmaceuticals, Inc. 2016 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.9 to the Quarterly Report on Form 10-Q, filed with the SEC on August 14, 2019).

10.8+	Armata Pharmaceuticals, Inc. 2016 Employee Stock Purchase Plan (incorporated herein by reference to Exhibit 10.10 to the Quarterly Report on Form 10-Q, filed with the SEC on August 14, 2019).
10.9+	Form of Indemnity Agreement with the Company's Directors and Executive Officers (incorporated by reference to Exhibit 99.2 to the Company's Current Report on Form 8-K, filed with the SEC on January 19, 2016).
10.10+	Form of Director Appointment Letter (incorporated by reference to Exhibit 10.4 to the registrant's Current Report on Form 8-K, filed with the SEC on May 10, 2019).
10.11*	Research Collaboration and Option to License Agreement, effective as of May 24, 2017, by and between Synthetic Genomics, Inc. and Merck Sharp & Dohme Corp. (incorporated herein by reference to Exhibit 10.12 to the Quarterly Report on Form 10-Q, filed with the SEC on August 14, 2019).
10.12*	Asset Purchase Agreement, dated as of February 14, 2018, by and between C3J Therapeutics, Inc., Synthetic Genomics, Inc. and Synthetic Genomics Vaccines, Inc., as amended by Amendment to Asset Purchase Agreement, made and entered into as of December 20, 2018 (incorporated herein by reference to Exhibit 10.12 to the Quarterly Report on Form 10-Q, filed with the SEC on August 14, 2019).
10.13	Registration Rights Agreement, dated February 12, 2020, by and between the Registrant and Innoviva, Inc. (incorporated herein by reference to Exhibit 4.1 to the Current Report on Form 8-K (File No. 001-37544), filed with the SEC on February 13, 2020).
10.14	Registration Rights Agreement, dated January 26, 2021, by and between the Registrant and Innoviva Strategic Opportunities LLC (incorporated herein by reference to Exhibit 10.3 to the Current Report on Form 8-K (File No. 001-37544), filed with the SEC on January 27, 2021).
10.15*	Letter Agreement, dated as of March 10, 2020, by and between Armata Pharmaceuticals, Inc. and the Cystic Fibrosis Foundation (incorporated herein by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q, filed with the SEC on May 14, 2020).
10.16	Registration Rights Agreement, dated October 28, 2021, by and among the Company, Innoviva, and CFF (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, filed with the SEC on October 29, 2021).
10.17+	Lease Agreement, dated October 28, 2021, by and between the Company and 5005 McConnell Avenue, LLC (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on November 2, 2021).
10.18	Assignment and First Amendment of Office Lease, dated as of April 2020, by and among Armata Pharmaceuticals, Inc., C3 Jian, Inc. and Marina Business Center, LLC (incorporated herein by reference to Exhibit 10.3 to the Quarterly Report on Form 10-Q, filed with the SEC on May 14, 2020).
10.19	Amended and Restated Investor Rights Agreement, dated February 9, 2022, by and among the Company and Innoviva (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, filed with the SEC on February 11, 2022).
10.20	Registration Rights Agreement, dated February 9, 2022, by and among the Company and Innoviva (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K, filed with the SEC on February 11, 2022).
10.21	Advisory Agreement, dated March 28, 2022, between the Company and Mr. Martin (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on March 25, 2022).

10.22	Secured Convertible Credit and Security Agreement, dated January 10, 2023 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on January 10, 2023).
10.23	Registration Rights Agreement, dated as of February 9, 2023, by and between the Company and Innoviva Strategic Opportunities LLC (incorporated by reference to Exhibit 4.21 to the Company's Registration Statement on Form S-3, filed with the SEC on February 13, 2023).
10.24	Credit and Security Agreement, dated as of July 10, 2023, by and between the Company and Innoviva Strategic Opportunities LLC (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on July 11, 2023).
10.25	First Amendment to Security Convertible Credit and Security Agreement, dated as of July 10, 2023, by and between the Company and Innoviva Strategic Opportunities LLC (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, filed with the SEC on July 11, 2023).
10.26+	Offer Letter of Employment, by and between the Company and Dr. Deborah Birx (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K, filed with the SEC on July 11, 2023).
10.27+	Separation and Release Agreement, dated as of July 14, 2023, by and between the Company and Brian Varnum (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on July 19, 2023).
10.28	Employment Agreement, dated August 30, 2023, by and between the Company and Richard Rychlik.
10.29	Credit and Security Agreement, dated March 4, 2024, by and among the Company and Innoviva Strategic Opportunities, LLC (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on March 4, 2024).
10.30	First Amendment to Credit and Security Agreement, dated March 4, 2024, by and among the Company and Innoviva Strategic Opportunities, LLC (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, filed with the SEC on March 4, 2024).
10.31	Second Amendment to Secured Convertible Credit and Security Agreement, dated March 4, 2024, by and among the Company and Innoviva Strategic Opportunities, LLC (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K, filed with the SEC on March 4, 2024).
21.1	Subsidiaries of the Company.
23.1	Consent of Independent Registered Public Accounting Firm.
24.1	Power of Attorney (contained on the signature page).
31.1	Certification of Chief Executive Officer Pursuant to Rule 13a-14(a)/15d-14(a).
31.2	Certification of Chief Financial Officer Pursuant to Rule 13a-14(a)/15d-14(a).
32.1	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350.
32.2	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350.
97	Armata Pharmaceuticals, Inc. Policy for the Recovery of Erroneously Awarded Compensation, adopted on October 2, 2023.

101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

+ **Indicates management contract or compensatory plan or arrangement.**

* **Indicates that certain identified information in the exhibit has been omitted because it is both (i) not material, and (ii) would likely cause competitive harm if publicly disclosed.**

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this Annual Report to be signed on its behalf by the undersigned, thereunto duly authorized.

ARMATA PHARMACEUTICALS, INC.

Date: March 21, 2024

By:/s/ Deborah Birx

Name: Deborah Birx, M.D.
Title: Chief Executive Officer
(Principal Executive Officer)

SIGNATURES AND POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Deborah Birx, and Richard Rychlik, and each of them, as his or her true and lawful attorneys-in-fact and agents, each with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K and to file the same, with all exhibits thereto and all documents in connection therewith, with the U.S. Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, 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 such attorneys-in-fact and agents or any of them, or his or her or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Deborah Birx Deborah Birx, M.D.	Chief Executive Officer and Director (Principal Executive Officer)	March 21, 2024
/s/ Richard Rychlik Richard Rychlik	Vice President, Corporate Controller (Principal Financial and Accounting Officer)	March 21, 2024
/s/ Jules Haimovitz Jules Haimovitz	Director	March 21, 2024
/s/ Odysseas D. Kostas, M.D Odysseas D. Kostas, M.D.	Director	March 21, 2024
/s/ Robin Kramer Robin Kramer	Chair of the Board of Directors	March 21, 2024
/s/ Joseph M. Patti, Ph.D. Joseph M. Patti, Ph.D.	Director	March 21, 2024
/s/ Todd C. Peterson, Ph.D. Todd C. Peterson, Ph.D.	Director	March 21, 2024
/s/ Sarah J. Schlesinger, M.D. Sarah J. Schlesinger, M.D.	Director	March 21, 2024

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