



Dear Fellow Shareholders,

Thank you for the opportunity to share Armata Pharmaceutical, Inc.'s ("Armata" or the "Company") progress since last year's Annual Shareholder Meeting. Since that time, we have been acutely focused on the critical development of our two clinical-stage phage product candidates, which we believe have the potential to help address the growing global health crisis of bacterial antimicrobial resistance.

Our first candidate is a multi-phage cocktail (AP-PA02) that we are developing as an inhaled treatment for chronic pulmonary *Pseudomonas aeruginosa* infection in people with cystic fibrosis and non-cystic fibrosis bronchiectasis ("NCFB"). Our second candidate, also a multi-phage cocktail (AP-SA02), 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 allows us to address the broadest range of unmet patient needs while also generating sustained long-term value for the Company. The positive results of studies that we have completed to date support the initiation of pivotal trials—the next critical step for Armata as we work to advance the clinical development of these novel pathogen-specific therapeutics towards registration and commercialization.

We have achieved significant progress towards these goals across three crucial areas:

1. With the completion of our new research and development and manufacturing facility in Los Angeles, we now expect to be able to fully commercialize in the United States by utilizing our state-of-the-art capabilities in developing and manufacturing phage therapeutics, including our proprietary processes, validated release assays, high-throughput semi-automated fill and finish, storage and shipment of drug product. All of our active pharmaceutical ingredients are sourced in the United States with no offsite manufacturing. In parallel, we have significantly improved the efficiency of all aspects of our production, increasing phage titers while maintaining high purity of drug product. Additionally, we have increased shelf life at 4°C.
2. We accelerated patient enrollment in our two parallel Phase 2 clinical trials. Our NCFB *Pseudomonas* trial ("Tailwind") completed enrollment in the second half of 2024, which was ahead of plan, and we released promising topline results in December of 2024. Tailwind was the second patient population for AP-PA02, which was first evaluated in patients with cystic fibrosis in the Phase 1b/2a SWARM-*P.a.* trial that successfully concluded in 2023.

We also accelerated enrollment in our *Staphylococcus* bacteremia trial ("DiSArm"), announcing full enrollment in November 2024, with the last patient visit having taken place in January 2025. During the execution of the trial, we were able to dose escalate to 5e10 PFU every six hours (2E11 PFU every 24 hours) for five days without clinically significant adverse events. In parallel with dose escalation, the evolution of two distinct blinded subsets of subjects

receiving phage has been observed. One subset, comprising approximately half of the treated group, has evidence of persistence of detectable phage in the blood consistent with *in vivo* phage amplification. This suggests that, despite the best available antibiotic treatment for greater than five days, reservoirs of active *Staphylococcus aureus* bacteria remained that our phages targeted, infected and killed before recirculating in the intravascular space. As of now, we anticipate database lock and receipt of topline data in the next few weeks, where we can explore the two aforementioned subsets in an unblinded manner. Topline results are also expected to inform the optimal dose of AP-SA02 to be evaluated in the larger definitive efficacy study.

3. Our research and development team has completed the engineering of both the *Pseudomonas* and *Staphylococcus* production hosts, resulting in higher titers and maintaining high purity. We believe this positions us well for the execution of future pivotal trials. We believe our 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.

Finally, we are happy to report that we completed all prespecified actions outlined in last year's proxy letter on time or ahead of plan.

In parallel, our leadership team is focused on managing costs and ensuring that our resources are focused on efficient clinical trial execution backed by rigorous core science.

I am personally proud to be part of the highly committed team at Armata. Our continued strong progress is the result of the passion and dedication of each employee to achieve our mission of meeting the global challenge of antibiotic resistance by developing high-impact, best-in-class phage therapeutics for all patients in need. Despite these uncertain times, we remain laser focused on demonstrating the important role that phages can have in combatting serious bacterial infections in the blood stream and lungs.

I speak for the entire Armata team when I say that I am optimistic about what the future holds for the Company. I would like to thank you, our shareholders, for continuing to support our efforts and sharing in our lofty goals.

Sincerely,

Deborah Birx, M.D.
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, 2024
- 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**

(310) 665-2928

(Address of principal executive offices, including zip code)

(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, 2024, 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 28, 2024 (the last business day of the Registrant's most recently completed second quarter) as quoted on the NYSE American, was approximately \$30.3 million.

As of February 28, 2025, 36,183,067 shares of the Registrant's common stock were outstanding.

Document Incorporated by Reference

Portions of the registrant's Definitive Proxy Statement relating to the 2025 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, 2024, are incorporated by reference into Part III of this Annual Report on Form 10-K.

TABLE OF CONTENTS
ARMATA PHARMACEUTICALS, INC.

| | <u>Page No.</u> |
|--|------------------------|
| PART I | |
| Item 1. Business | 6 |
| Item 1A. Risk Factors | 40 |
| Item 1B. Unresolved Staff Comments | 62 |
| Item 1C. Cybersecurity | 62 |
| Item 2. Properties | 63 |
| Item 3. Legal Proceedings | 63 |
| Item 4. Mine Safety Disclosures | 64 |
| PART II | |
| Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities | 64 |
| Item 6. Reserved | 64 |
| Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations | 64 |
| Item 7A. Quantitative and Qualitative Disclosures About Market Risk | 75 |
| Item 8. Financial Statements and Supplementary Data | 75 |
| Item 9. Changes In and Disagreements With Accountants on Accounting and Financial Disclosure | 103 |
| Item 9A. Controls and Procedures | 103 |
| Item 9B. Other Information | 104 |
| Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections | 105 |
| PART III | |
| Item 10. Directors, Executive Officers and Corporate Governance | 106 |
| Item 11. Executive Compensation | 106 |
| Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters | 106 |
| Item 13. Certain Relationships and Related Transactions and Director Independence | 106 |
| Item 14. Principal Accountant Fees and Services | 106 |
| PART IV | |
| Item 15. Exhibits and Financial Statement Schedules | 107 |
| Item 16. Form 10-K Summary | 112 |
| Signatures and Power of Attorney | 113 |

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 Los Angeles 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 \$21.6 million DoD award;
- 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 ongoing conflicts between Ukraine and Russia and in the Middle East, the recent and potential future bank failures or other geopolitical events;
- the potential economic and regulatory impacts on the biotechnology, pharmaceutical and drug manufacturing industries;
- the effects of artificial intelligence on our business and the industry as a whole; 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 having completed three Phase 2 trials focused on the development of high-purity, 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 a potentially safer and effective alternative to antibiotics and an essential response to the 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 specific targeted bacteria while uniquely preserving the normal human microbiome or “healthy bacteria”. This is in direct contrast to traditional broad-spectrum antibiotics which can alter the human microbiome increasing susceptibility to opportunistic pathogens, such as *Clostridium difficile* (“*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 clinical-stage phage therapeutics of high purity, and believe we are uniquely positioned to address the growing worldwide threat of antibiotic-resistant bacterial infections. We have completed three critical Phase 2 trials, utilizing two distinct phage cocktails against two different bacterial pathogens with the potential to treat chronic pulmonary disease complicated by bacterial infection, as well as acute systemic bacterial infection. We believe we are on a critical pathway towards pivotal Phase 3 clinical studies.

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 late-stage clinical development. We have improved our manufacturing processes by significantly increasing phage titers and improving production efficiency with the goal of ensuring commercial viability. We believe that we are uniquely advancing two lead candidates, referred to as AP-PA02 and AP-SA02, to address both chronic and acute bacterial infections.

Our first lead phage candidate, inhaled AP-PA02, is focused primarily on the treatment of chronic pulmonary infections due to *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 and multiple ascending dose 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 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. AP-PA02 exposures were generally consistent across 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 (higher AP-PA02 exposures) 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 us a Therapeutics Development Award of \$5.0 million. We received the full award’s amount, including the final payment of \$0.3 million, in January 2024. 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 non-cystic fibrosis Bronchiectasis (“NCFB”) patients with similar chronic pulmonary disease with infections due to *P. 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, NCFB. On December 19, 2024, Armata announced encouraging results from the completed “Tailwind” study – a Phase 2 multicenter, double-blind, randomized, placebo-controlled study to

evaluate the safety, phage kinetics, and efficacy of inhaled AP-PA02 in subjects with NCFB and chronic pulmonary *P. aeruginosa* infection. Data indicated that inhaled AP-PA02 provides a durable reduction of *P. aeruginosa* in the lung, with a favorable safety and tolerability profile. The Tailwind study was conducted in two cohorts running in parallel: subjects in one cohort (cohort A) received inhaled AP-PA02 as monotherapy, while subjects in another cohort (cohort B) received inhaled AP-PA02 in combination with inhaled anti-pseudomonal antibiotic treatment. Subjects in both cohorts were dosed at home by nebulization with study drug administered every 12 hours for 10 days and were followed for approximately four weeks after receiving their last dose of study drug. The primary efficacy endpoint was the reduction in *P. aeruginosa* colony forming units (“CFUs”) in lung sputum at one week following completion of dosing (day 17) compared to baseline. Per the statistical analysis plan, efficacy analysis of each independent cohort showed no significant difference between subjects treated with AP-PA02 and placebo due to small numbers of subjects in each cohort. Notably, a post-hoc intent-to-treat analysis (n=33 active and n=15 placebo; all subjects from both cohorts) demonstrated a statistically significant reduction of *P. aeruginosa* CFUs in the lung at day 17 (AP-PA02 vs. placebo; P=0.05). The reduction in *P. aeruginosa* CFUs persisted two weeks following completion of dosing with AP-PA02 when compared with placebo at day 24 (AP-PA02 vs. placebo; P=0.015). Additionally, paired analysis of *P. aeruginosa* CFU density at baseline compared to day 10 (P=0.03), day 11 (P=0.01), day 17 (P=0.003) and day 24 (P=0.018) was significant in the AP-PA02-treated cohort. We believe the data suggest that AP-PA02 alone is as effective as the combination therapy of phage and antibiotics in reducing *P. aeruginosa* CFUs in the lung. Additionally, approximately one-third of subjects treated with phage monotherapy exhibited at least a 2-log CFU reduction in *P. aeruginosa* compared to no reduction in placebo treated subjects. Safety data indicate that inhaled AP-PA02 was well-tolerated with treatment-emergent adverse events mild and self-limiting. There was one possibly related serious adverse event that was linked to an acute pulmonary event requiring hospitalization that was responsive to antibiotics. We believe the safety and tolerability of AP-PA02 offers a promising profile for treating chronically infected NCFB patients.

Results from the Phase 2 Tailwind study demonstrate the potential of Armata’s high-purity phage cocktail, AP-PA02, as a new monotherapy treatment alternative for chronic pulmonary disease caused by *P. aeruginosa* infection, including drug-resistant bacteria, and indicate the potential for phage therapy to reduce reliance on chronic antibiotic use. The Phase 2 Tailwind study represents the second successful clinical trial for AP-PA02, Armata’s lead pulmonary candidate, which was first evaluated in people with cystic fibrosis in the Phase 1b/2a SWARM-*P.a.* trial that completed in 2023. We believe the learnings on dose-schedule regimens gained from the two completed Phase 2 studies position us to define a safe and promising biologic correlation for a Phase 3 definitive trial which will aim to evaluate inhaled AP-PA02 as an alternative to antibiotics in chronic pulmonary *P. aeruginosa* infection.

In parallel to developing novel phage therapeutics that target chronic bacterial infections, we have an acute bacterial infection clinical development plan focused on *Staphylococcus aureus* (“*S. aureus*”) bacteremia, a difficult-to-treat and often life-threatening human infection 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 *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 received a \$15.0 million award and entered into a multi-year program administered by the U.S Department of Defense through MTEC and managed by the Naval Medical Research Command (“NMRC”) – Naval Advanced Medical Development (“NAMC”) 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. In July 2024, the MTEC Agreement was modified to increase the total award by \$5.3 million to \$21.6 million and extend the term into the third quarter of 2025. We are using the award to partially fund a Phase 1b/2a, multicenter, 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* (the “diSArm study”).

On November 17, 2021, we announced that we had received approval from the FDA to proceed with our IND application for AP-SA02. On November 12, 2024, we announced completion of enrollment of the Phase 1b/2a diSArm study of intravenous AP-SA02 as a potential treatment for *S. aureus* bacteremia. The last patient final follow-up visit

was completed on January 14, 2025. During the Phase 2a portion of diSArm, Armata focused on evaluating clinical safety of higher intravenous doses of AP-SA02 and accelerating enrollment to arrive at topline data expeditiously. The manufacture of highly purified phages using Armata's proprietary methods enabled dose escalation to 5E10 PFU every six hours (2E11 PFU every 24 hours) for five days without clinically significant adverse events. In parallel with dose escalation, the evolution of two distinct blinded subsets of subjects receiving phage has been observed. One subset, comprising approximately half of the treated group, has evidence of persistence of detectable phage in the blood providing early evidence of *in vivo* phage amplification and resultant release of phage progeny. The Company anticipates topline data from the diSArm study in the first half of 2025 where it can explore the two aforementioned subsets in an unblinded manner. Topline results are also expected to inform the optimal dose of AP-SA02 to be evaluated in a larger definitive efficacy study. 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. We are committed to developing a definitive efficacy trial focused on phage as an alternative to broad-spectrum antibiotics and/or antibiotic sparing to decrease the utilization of broad-spectrum antibiotics and their detrimental impact on the normal human microbiome.

On August 1, 2022, we announced FDA approval to proceed with our IND application for AP-SA02 in a second indication, prosthetic joint infections ("PJI") with *S. aureus*. We had planned to initiate a Phase 1b/2a trial; however, in light of the growing concerns of both PJI and wound infections, we are considering 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 our mission to evaluate phage-based therapeutics in randomized controlled clinical trials that evaluate safety and efficacy required to support potential regulatory approval and commercialization of our phage products as alternatives to traditional antibiotics, providing a potential method of treating patients suffering from drug-resistant and difficult-to-treat bacterial infections.

In parallel to the critical pathway Phase 2 trials, Armata has also focused on the validation of the lot release assays to ensure consistency and potency as well as improvement in cGMP manufacturing efficiencies and extension of phage shelf life using specific excipients.

Recent Financing

2025 Credit Agreement

On March 12, 2025, the Company entered into a credit and security agreement (the "2025 Credit Agreement") for a loan in an aggregate amount of \$10.0 million (the "2025 Loan") with Innoviva Strategic Opportunities LLC, a wholly owned subsidiary of Innoviva, Inc. (NASDAQ: INVA), our principal stockholder and a related party (collectively, "Innoviva"). The 2025 Loan bears interest at an annual rate of 14.0% and matures on March 12, 2026. Principal and accrued interest are payable at maturity. Repayment of the 2025 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 2025 Credit Agreement, the Company entered into amendments to (i) its existing convertible loan (the "Convertible Loan") and secured credit and security agreement, dated January 10, 2023, with Innoviva (the "Convertible Credit Agreement"), (ii) its existing secured term loan facility (the "2023 Loan") and credit and security agreement, dated July 10, 2023, with Innoviva (the "2023 Credit Agreement") and (iii) its existing secured term loan facility (the "2024 Loan") and credit and security agreement, dated March 4, 2024, with Innoviva (the "2024 Credit Agreement"), which, among other things, extended the maturity date of each loan to March 12, 2026.

2024 Credit Agreement

On March 4, 2024, the Company entered into the 2024 Credit Agreement for the 2024 Loan in an aggregate amount of \$35.0 million with Innoviva. The 2024 Loan bears interest at an annual rate of 14.0% and was scheduled to mature on June 4, 2025. Principal and accrued interest are payable at maturity. Repayment of the 2024 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 Credit Agreement, the Company amended certain provisions of the Convertible Loan and Convertible Credit Agreement and the 2023 Loan and 2023 Credit Agreement, to, among other things, conform certain terms relating to permitted indebtedness and permitted liens.

On March 12, 2025, the Company executed an amendment to the 2024 Credit Agreement which, among other things, extended the 2024 Loan maturity date to March 12, 2026.

2023 Credit Agreement

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

On November 12, 2024, the Company executed an amendment to the 2023 Credit Agreement, which, among other things, extended the 2023 Loan maturity date to January 10, 2026. On March 12, 2025, the Company executed a subsequent amendment to the 2023 Credit Agreement which, among other things, extended the 2023 Loan maturity date to March 12, 2026.

Convertible Credit Agreement

On January 10, 2023, the Company received the Convertible Loan in the aggregate 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 Company's entry into the 2023 Credit Agreement, to, among other changes, extend the maturity of the Convertible Loan to January 10, 2025. Subsequently, on November 12, 2024, the Company executed another amendment to the Convertible Credit Agreement, which, among other things, extended the Convertible Credit Agreement maturity date to January 10, 2026. Then, on March 12, 2025, the Company executed a subsequent amendment to the Convertible Credit Agreement which, among other things, extended the Convertible Loan maturity date to March 12, 2026.

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 (the "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 \$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.

| Program | Product | Discovery | Preclinical | IND-Cleared | Phase 2 | Partner |
|--|---------|------------|-------------|-------------|------------|---|
| <i>Pseudomonas aeruginosa</i> Respiratory Infections | AP-PA02 | CF | | | SWARM-P.a. | CYSTIC FIBROSIS FOUNDATION Unpartnered |
| | | NCFB | | | Tallwind | |
| <i>Staphylococcus aureus</i> | AP-SA02 | Bacteremia | | | diSArm | U.S. DoD* Unpartnered |
| | | PJI | | inFLEXion | | |

SWARM-P.a. NCT04596315; diSArm NCT05184764; Tallwind NCT05616221

* Department of Defense (DoD) award received through the Medical Technology Enterprise Consortium (MTEC) and managed by the Naval Medical Research Command (NMRC) – Naval Advanced Medical Development (NAMD) with funding from the Defense Health Agency and Joint Warfighter Medical Research Program.

CF: cystic fibrosis; NCFB: non-CF bronchiectasis; PJI: prosthetic joint infection

Strategy

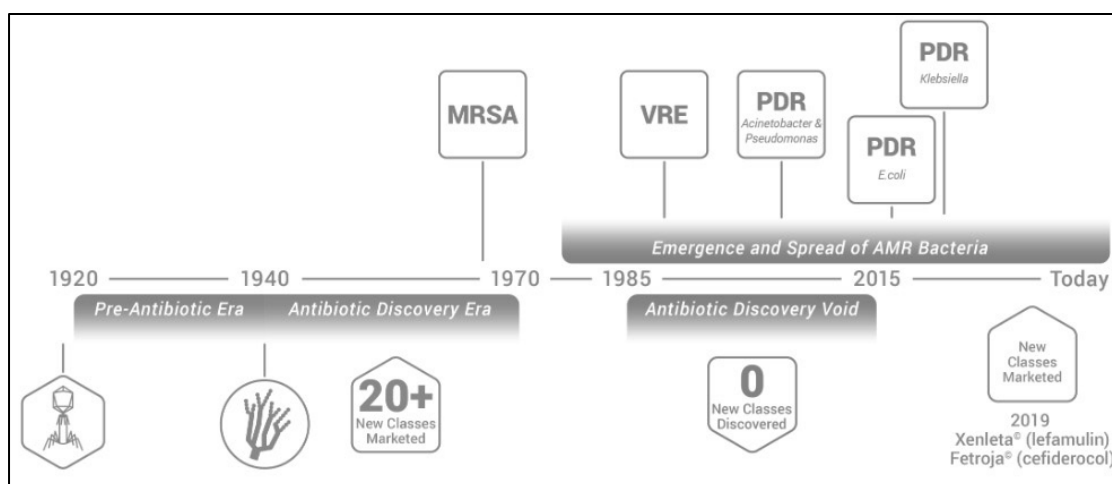
Our strategy is to demonstrate the safety, tolerability and definitive efficacy of multiple phage products in randomized controlled clinical trials required for FDA approval and to support commercialization in both acute and chronic indications of high unmet medical need, including bacterial infections 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.
- Advance clinical trials of AP-SA02 in patients with bacteremia due to acute infection with *S. aureus*, including methicillin-resistant *S. aureus* (“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.
- Develop other bacteriophage therapeutics, potentially including AP-PA03, for the treatment of other antibiotic-resistant and difficult-to-treat *P. aeruginosa* infections such as acute bacterial pneumonia.

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”, 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*.



MRSA: methicillin-resistant *Staphylococcus aureus*; VRE: vancomycin resistant enterococci; PDR: pandrug-resistant; AMR: antimicrobial resistance

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 controlled clinical trials to test promising novel therapeutics as alternatives to traditional 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 *P. 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.

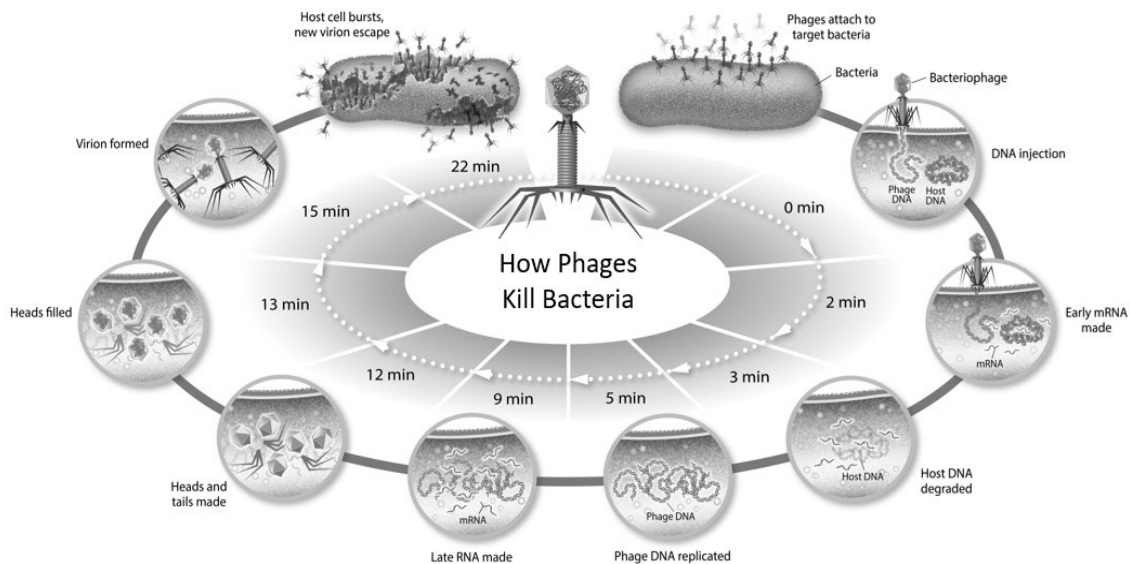
Hospital-acquired (nosocomial) infections are a major healthcare problem throughout the world, affecting developed countries as well as resource-poor countries. The WHO reports that hospital-acquired infections are among the major causes of death and increased morbidity among hospitalized patients. In the United States 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 normal human 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 *C. 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.

More 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: No approved therapy for NCFB *P. aeruginosa**

NCFB is a chronic progressive pulmonary disease with 422,000 prevalent cases and 90,000 incident cases in the United States, expanding at a compound annual growth rate of 3.5%. NCFB is a condition characterized by recurrent respiratory infections that lead to a vicious cycle of impaired mucociliary clearance, chronic infection, bronchial inflammation, structural damage, and progressive lung function loss. *P. aeruginosa* is the most prevalent pathogen responsible for these recurrent infections. Approximately 30% of NCFB patients are colonized with *P. aeruginosa*, resulting in enhanced disease progression and poorer outcomes, including decreased lung function and lower quality of life, more frequent acute exacerbations, 7-fold increase in hospitalizations, and 3-fold increase in death. The average annual healthcare costs for an NCFB patient colonized with *P. aeruginosa* exceeds \$200,000, 175% higher compared to non-colonized patients. 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 FDA-approved medications for the treatment of NCFB patients with chronic *P. aeruginosa* respiratory infection, including inhaled antibiotics or therapeutics that address antibiotic resistance and reduce exacerbations. Advantages of bacteriophages include exquisite specificity for the target bacterial pathogen (e.g., *P. aeruginosa*), minimal risks of dysbiosis compared to broad-spectrum antibiotics (e.g., to lung and gut microbiomes), mitigation of antimicrobial resistance, and lower risk of off-target effects.

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 United States develop bacteremia each year. *S. aureus* is the most commonly identified pathogen in both hospital- and community-acquired bloodstream infections. Annually in the United States 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 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. Until 2024, daptomycin (approved in 2006; based on clinical cure rates of less than 50%) and vancomycin were the only two FDA-approved antibiotics with label indications in the United States 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. In April 2024, the FDA approved Zevtera (ceftobiprole medocartil sodium for injection) for the treatment of adults with SAB.

Prosthetic Joint Infection and Wound Infection

The total number of 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. Engineering the host is critical to decreasing drug product contaminants.



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. We believe 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.

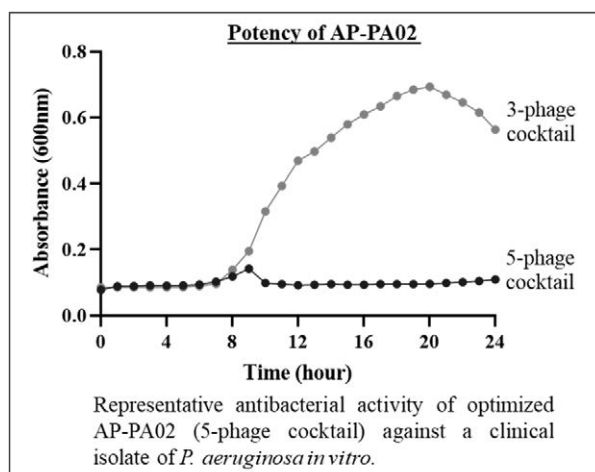
Human exposure through treatment of single patients with AP-PA01 under the expanded access program has been helpful in demonstrating the promise and safety of phage therapy. Feedback from the pre-IND meeting has been insightful for the regulatory path required for phage therapeutics in general, and specifically 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 do not 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. 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.



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 have developed AP-PA02 as a sterile liquid formulation, suitable for delivery by inhalation. Through the end of 2024, clinical trial material of AP-PA02 was manufactured under cGMP at our production facility in Marina del Rey, California. As of 2025, clinical trial material of AP-PA02 is being manufactured under cGMP at our production facility in Los Angeles, California to support the required regulatory filing(s) for clinical entry both inside and outside the United States.

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 *P. 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. Pharmacokinetics (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. Moreover, 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.

With positive outcomes from this first clinical study, SWARM-*P.a.*, we initiated a follow-on Phase 2 study investigating AP-PA02 in NCFB patients chronically infected with *P. aeruginosa*.

Clinical Development of AP-PA02 in Non-Cystic Fibrosis Bronchiectasis: Completed Phase 2 Study

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”). On December 19, 2024, Armata announced encouraging results from the completed “Tailwind” study – a Phase 2 multicenter, double-blind, randomized, placebo-controlled study to evaluate the safety, phage kinetics, and efficacy of inhaled AP-PA02 in subjects with NCFB and chronic pulmonary *P. aeruginosa* infection. Data indicated that inhaled AP-PA02 provides a durable reduction of *P. aeruginosa* in the lung, with a favorable safety and tolerability profile.

The Tailwind study was conducted in two cohorts running in parallel: subjects in one cohort (cohort A) received inhaled AP-PA02 as monotherapy, while subjects in another cohort (cohort B) received inhaled AP-PA02 in combination with inhaled anti-pseudomonal antibiotic treatment. Subjects in both cohorts were dosed at home by nebulization with study drug administered every 12 hours for 10 days and were followed for approximately four weeks after receiving their last dose of study drug. The primary efficacy endpoint was the reduction in *P. aeruginosa* colony forming units (“CFUs”) in lung sputum at one week following completion of dosing (day 17) compared to baseline. Per the statistical analysis plan, efficacy analysis of each independent cohort showed no significant difference between subjects treated with AP-PA02 and placebo due to small numbers of subjects in each cohort. Notably, a post-hoc intent-to-treat analysis (n=33 active and n=15 placebo; all subjects from both cohorts) demonstrated a statistically significant reduction of *P. aeruginosa* CFUs in the lung at day 17 (AP-PA02 vs. placebo; P=0.05). The reduction in *P. aeruginosa* CFUs persisted two weeks following completion of dosing with AP-PA02 when compared with placebo at day 24 (AP-PA02 vs. placebo; P=0.015). Additionally, paired analysis of *P. aeruginosa* CFU density at baseline compared to day 10 (P=0.03), day 11 (P=0.01), day 17 (P=0.003) and day 24 (P=0.018) was significant in the AP-PA02-treated cohort. We believe the data suggest that AP-PA02 alone is as effective as the combination therapy of phage and antibiotics in reducing *P. aeruginosa* CFUs in the lung. Additionally, approximately one-third of subjects treated with phage monotherapy exhibited at least a 2-log CFU reduction in *P. aeruginosa* compared to no reduction in placebo treated subjects.

The relationship between phage dose and microbiological impact on *P. aeruginosa* confirms the findings in the cystic fibrosis SWARM-*P.a.* Phase 2a trial.

Safety data from the Tailwind study indicate that inhaled AP-PA02 was well-tolerated with treatment-emergent adverse events mild and self-limiting. There was one possibly related serious adverse event that was linked to an acute pulmonary event requiring hospitalization that was responsive to antibiotics. We believe the safety and tolerability of AP-PA02 offers a promising profile for treating chronically infected NCFB patients.

Results from the Phase 2 Tailwind study demonstrate the potential of Armata’s high-purity phage cocktail, AP-PA02, as a new monotherapy treatment alternative for chronic pulmonary disease caused by *P. aeruginosa* infection,

including drug-resistant bacteria, and indicate the potential for phage therapy to reduce reliance on chronic antibiotic use.

The Phase 2 *Tailwind* study represents the second successful clinical trial for AP-PA02, Armata's lead pulmonary candidate, which was first evaluated in people with cystic fibrosis in the Phase 1b/2a SWARM-*P.a.* trial that completed in 2023. We believe the learnings on dose-schedule regimens gained from the two completed Phase 2 studies position us to define a safe and promising biologic correlation for a Phase 3 definitive study which will aim to evaluate inhaled AP-PA02 as an alternative to antibiotics in chronic pulmonary *P. aeruginosa* infection.

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; intranasal 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. Through the end of 2024, clinical trial material of AP-SA02 was manufactured under cGMP at our production facility in Marina del Rey, California. As of 2025, clinical trial material of AP-SA02 is being manufactured under cGMP at our production facility in Los Angeles, California to support the required regulatory filing(s) for clinical entry both inside and outside the United States.

We combine our proprietary approach and expertise in identifying, characterizing and developing both naturally occurring and engineered bacteriophages with our proprietary phage-specific host-engineered cGMP manufacturing capabilities to advance high-quality bacteriophage product candidates for late-stage clinical development. We believe a key advantage of our phage manufacturing expertise is the purity profiles of our phage products, including AP-SA02, our phage product candidate targeting *S. aureus*; this has enabled us to pursue treatment of complicated *S. aureus* bacteremia, where repetitive intravenous dosing is required. Throughout the past 12 months, improvements in our proprietary upstream manufacturing processes have resulted in a ten-fold increase in phage titer. Additionally, significant improvements in recovery throughout our processes has resulted in five-fold more doses from a single production run. We have improved our overall production efficiency with the goal of ensuring commercial viability. The Los Angeles site's approximately 10,000 square foot cGMP facility enables us to bring more efficient manufacturing processes on line and allows for full commercialization from the current facility, streamlining the timeline from potential successful pivotal trial to a Biologics License Application ("BLA").

Clinical Development of AP-SA02 in Bacteremia: Completed Phase 1b/2a Study

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 administered by the U.S Department of Defense through MTEC and managed by the Naval Medical Research Command (NMRC) – Naval Advanced Medical Development (NAMD) 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. In July 2024, the MTEC Agreement was modified to increase the total award by \$5.3 million to \$21.6 million and extend the term into the third quarter of 2025.

On November 12, 2024, we announced completion of enrollment of the Phase 1b/2a diSArm study of intravenous AP-SA02 as a potential treatment for *S. aureus* bacteremia. The last patient final follow-up visit was completed on January 14, 2025. During the Phase 2a portion of diSArm, Armata focused on evaluating clinical safety of higher intravenous doses of AP-SA02 and accelerating enrollment to arrive at topline data expeditiously. The manufacture of highly purified phages using Armata's proprietary methods enabled dose escalation to 5E10 PFU every six hours (2E11 PFU every 24 hours) for five days without clinically significant adverse events. In parallel with dose escalation, the evolution of two distinct blinded subsets of subjects receiving phage has been observed. One subset, comprising approximately half of the treated group, has evidence of persistence of detectable phage in the blood providing early

evidence of *in vivo* phage amplification and resultant release of phage progeny. The Company anticipates topline data from the diSArm study in the first half of 2025 where it can explore the two aforementioned subsets in an unblinded manner. Topline results are also expected to inform the optimal dose of AP-SA02 to be evaluated in a larger definitive efficacy study.

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. We are committed to developing a definitive efficacy trial focused on phage as an alternative to broad-spectrum antibiotics and/or antibiotic sparing to decrease the utilization of broad-spectrum antibiotics and their detrimental impact on the normal human microbiome.

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; however, in light of the growing concerns of both PJI and wound infection, we are considering 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*.

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

Through the end of 2024, we produced, tested and released 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 and is licensed by the California Department of Public Health for drug manufacturing. In the fourth quarter of 2024, manufacturing was fully relocated to our new research and development and manufacturing facility, and corporate headquarters, located in Los Angeles, California.

Our Los Angeles facility consists of approximately 56,500 square feet of office, research and development and manufacturing space. Office space and research laboratories have been occupied since the third quarter of 2023, and construction of the cGMP manufacturing space (~10,000 square feet) was completed in the third quarter of 2024. Our Los Angeles 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 (Quality Assurance and Quality Control) and manufacturing and facilities personnel trained under cGMPs.

We operate in-house process development activities through the production, purification, formulation, and release of our therapeutic phage cocktails for use in human clinical trials. 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 manufacturing facility is capable of producing sterile drug products, utilizing ISO-certified cleanrooms. 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.

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, 2024, we owned or had exclusive license rights to a total of 152 patents and applications: 11 U.S. patents, 12 U.S. patent applications, 73 foreign patents, and 56 foreign patent applications, with nominal expiration on various dates between 2024 and 2045. 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 BiomX, Inc. (merged with Adaptive Phage Therapeutics in 1Q

2024), Intralytix, Inc., Locus Biosciences, Inc., TechnoPhage, SA, 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 award and entered into a multi-year program administered by the U.S Department of Defense through MTEC and managed by the Naval Medical Research Command (NMRC) – Naval Advanced Medical Development (NAMD) 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. In July 2024, the MTEC Agreement was modified to increase the total award by \$5.3 million to \$21.6 million and extend the term into the third quarter of 2025. We are using the award to partially fund a Phase 1b/2a, multicenter, 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* (“diSArm” study). The MTEC Agreement specifies that the award 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 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 August 15, 2025. 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.

Facilities

Our corporate headquarters are located in Los Angeles, California, with an address of 5005 McConnell Avenue, Los Angeles, CA 90066 (the “McConnell Facility”). On October 28, 2021, we entered into a lease for approximately 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 occupied since the third quarter of 2023, with cGMP manufacturing space (~10,000 square feet) fully constructed and occupied in the second half of 2024.

We also 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 approximately 35,500 square feet of office, research and development and manufacturing space (the “Marina del Rey Lease”). The Marina del Rey Lease expires on December 31, 2031. The facility includes 19,500 square feet of BSL2 laboratory space and approximately 3,000 square feet of cGMP laboratory space. We are actively seeking a sub-tenant to take over the remaining term of the Marina del Rey 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 potentially 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,

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, 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"), 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 the Health Information Technology for Economic and Clinical Health Act of 2009 ("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 and covered subcontractors 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), other healthcare professionals (such as physician assistants and nurse practitioners), 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 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 has substantially changed healthcare financing and delivery by both governmental and private insurers.

Since its enactment, there have been a number of amendments and legal and political challenges to certain aspects of the ACA. For example, on August 16, 2022, the Inflation Reduction Act of 2022 (IRA) was signed into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how such challenges and any additional healthcare reform measures will impact the ACA.

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 2032 unless additional Congressional action is taken. 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.

The current administration is pursuing policies to reduce regulations and expenditures across government including at HHS, the FDA, the Centers for Medicare & Medicaid Services ("CMS") and related agencies. These actions may propose policy changes that may create additional uncertainty for our business.

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.

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. Further, coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we seek regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. Additionally, we may develop companion diagnostic tests for use with our current and future product candidates. We will be required to obtain coverage and reimbursement for these tests separately and apart from the coverage and reimbursement we may seek for our current and future potential product candidates.

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 February 28, 2025, we had 60 full-time employees. Of the 60 full-time employees, 52 were engaged in research and development activities and 8 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.

Compensation and Benefits

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.

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, trade restrictions, 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 DoD 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 interim, “topline,” and preliminary data, or 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 and are subject to audit and verification procedures that could result in material changes in the final data.
- 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 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 face potential risks associated with future changes in laws and policies, including the availability of government funding for grants, staffing and funding of regulatory agencies.
- The use or anticipated use of artificial intelligence (“AI”) technologies, including generative AI, by us or third parties, may increase or create new operational risks.
- 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 consolidated financial statements as of December 31, 2024 and December 31, 2023 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, 2024, we had unrestricted cash and cash equivalents of \$9.3 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 term loans, which comprise of \$60.0 million of principal and \$9.4 million of accrued interest, mature in January 2026 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 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 2025, 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;
- the costs of lawsuits involving us or our product candidates; and
- the continued availability of government funding for grants.

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, political, 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, 2024, our accumulated deficit was \$327.7 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 this 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 award and have entered into a multi-year program administered by the U.S Department of Defense through MTEC and managed by the Naval Medical Research Command (NMRC) – Naval Advanced Medical Development (NAMD) 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. In July 2024, the MTEC Agreement was modified to increase the total award by \$5.3 million to \$21.6 million and extend the term into the third quarter of 2025. We are using the award to partially fund a Phase 1b/2a, multicenter, 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* (“diSArm” study).

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 have historically included and may continue to 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 interim, “top-line,” and preliminary data, or 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 and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose interim, top-line or preliminary data from our preclinical studies and clinical trials, based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data when we publicly disclose such data. As a result, any interim, top-line or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Preliminary or top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim, top-line and preliminary data should be viewed with caution until the final data are available. In addition, preliminary or interim data from ongoing clinical trials are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available or as patients from our clinical trials continue other treatments for their disease. Adverse differences between any preliminary or interim data we disclose and final data could significantly harm our business prospects.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. Any information we determine not to disclose may ultimately be deemed significant by investors or others with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the interim, top-line or preliminary data that we report differ from final results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, product candidates may be harmed, which could significantly harm our business, financial condition, results of operations and prospects.

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;
- changes in the FDA and foreign regulatory approval processes, staffing, resources or perspectives that may delay or prevent the approval of future products and result in lost market opportunity;
- changes in regulations or judicial decisions, or new interpretations of existing laws, regulations or judicial decisions, related to health care availability, pricing or marketing practices, compliance with employment practices, method of delivery, payment for health care products and services, compliance with health information and data privacy and security laws and regulations, tracking and reporting payments and other transfers of value made to physicians and teaching hospitals, extensive anti-bribery and anti-corruption prohibitions, product serialization and labeling requirements and used product take-back requirements;
- 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 continuing to develop novel manufacturing processes for our phage product candidates at our facility in Los Angeles, California. Construction of the new manufacturing facility in Los Angeles, California was completed 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, changes in regulatory review practices for a submitted product application, or changes in regulatory staffing and funding 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, as well as similar state laws governing the collection, use, and disclosure of health-related information. 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 negative consequences – including criminal penalties, regulatory fines, reputational damage, and other harmful effects – 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 governing the use, security, and disclosure of such information.

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 also 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 collection, use, disclosure, transfer, or other processing of personal data regarding individuals in the European Union (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 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 is independent of the EU. From January 1, 2021, companies have had to comply with both the GDPR and 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.

We face potential risks associated with future changes in laws and policies, including the availability of government funding for grants, staffing and funding of regulatory agencies.

In the United States, changes in the U.S. government between administrations have resulted in potential changes in regulations, fiscal policy, social programs, domestic and foreign relations and international trade policies. Our ability to respond to these developments or comply with any resulting new legal or regulatory requirements, including those involving economic and trade sanctions, could increase our costs of doing business, reduce our financial flexibility and otherwise have a material adverse effect on our business, financial condition and results of our operations.

Our operations, including research, development, and clinical programs and trials, are largely dependent on government grants (for example, the MTEC Agreement, which is paid over the term of the award), meaning any substantial policy shift or executive action that restricts or diminishes the availability of these funds could materially harm our business.

The use or anticipated use of artificial intelligence (“AI”) technologies, including generative AI, by us or third parties, may increase or create new operational risks.

AI technologies offer numerous potential benefits, such as creating or increasing operational efficiencies, and we expect an increase in the use of AI and generative AI by us, third parties on our behalf, and other market actors, including our competitors. However, the deployment of such technologies also poses certain risks, including that the algorithms may be flawed, misused or otherwise function in an unexpected manner; data sets may be insufficient, of poor quality, or contain biased information; and inappropriate or controversial data practices by data scientists, engineers, and end-users could impair results. The relative newness of the technology, the speed at which it is being adopted, and the paucity of laws, regulations or standards expressly and specifically governing its use increases these risks. If the analyses that AI-based applications assist in producing are deficient or inaccurate, we could be subjected to competitive harm, potential legal liability and brand or reputational harm. Our competitors may also adopt AI or generative AI more quickly or more effectively than we do, which could cause competitive harm. Furthermore, use of AI-based software may lead to the release of confidential information which may impact our ability to realize the benefits of our intellectual property.

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 (“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

There is a high rate of failure inherent in drug discovery and development, and failure can occur at any point in the process, including in later stages after substantial investment.

New product candidates that appear promising in development or prior to being acquired may fail to reach the market or may have only limited commercial success because of efficacy or safety concerns, inability to obtain or maintain necessary regulatory approvals or payor reimbursement or coverage, failure to obtain placement on guidelines or recommendations published by third-party organizations that are commensurate with clinical data, the application of pricing controls, limited scope of approved uses, label changes, changes in the relevant treatment standards or the availability of newer better, or more cost-effective competitive products, difficulty or excessive costs to manufacture, insufficient infrastructure to support detection, diagnostic or other requisites for treatment, ineffectiveness in reaching healthcare professionals, including digitally given the increase in virtual engagements, or infringement of the patents or intellectual property rights of others. We may also fail to allocate research and development resources efficiently, fail to pursue or invest sufficiently in product candidates or indications that may have been successful, or fail to optimally balance trial design, conduct, and speed to accomplish desired outcomes.

Regulatory agencies establish high hurdles for the efficacy and safety of new products and indications. Delay, uncertainty, unpredictability, and inconsistency in drug approval processes across markets and agencies can result in delays in product launches, lost market opportunities, impairment of inventories, and other negative impacts. In addition, it can be very difficult to predict revenue growth rates of, or variability in demand for, new products and indications,

which in some cases leads to difficult meeting product demand or, on the other hand, excess inventory and related financial charges.

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.

Current and future healthcare reform measures may affect our results of operations.

In the United States, federal and state legislatures, health agencies and third-party payors continue to focus on containing the cost of health care. Legislative and regulatory proposals, enactments to reform health care insurance programs and increasing pressure from social sources could significantly influence the manner in which our future products may be prescribed, purchased and reimbursed, which may adversely affect our results of operations.

In the European Union and some other international markets, the government provides health care at low cost to consumers and regulates pharmaceutical prices, patient eligibility or reimbursement levels to control costs for the government-sponsored health care system. Many countries have announced or implemented measures, and may in the future implement new or additional measures, to reduce health care costs to limit the overall level of government expenditures. These measures vary by country and may include, among other things, patient access restrictions, suspensions on price increases, prospective and possible retroactive price reductions and other recoupments and increased mandatory discounts or rebates, recoveries of past price increases and greater importation of drugs from lower-cost countries. These measures may adversely affect our future revenue and business operations.

Our business is subject to increasing government price controls and other public and private restrictions on pricing, reimbursement, and access for our drugs, which could have a material adverse effect on our results of operations, reputation or business.

Public and private payors continue to take aggressive steps to control their expenditures for pharmaceuticals by placing restrictions on pricing and reimbursement for, and patient access to, medicines. Governments and private payors worldwide have intensified their scrutiny of, and actions intended to address, pricing, reimbursement, and access to pharmaceutical products and are demanding greater commercial and clinical value from pharmaceutical companies in the form of strong product differentiation and demonstrated value. The effect of reducing prices and reimbursement would significantly impact potential future revenues and business opportunities. Within the United States, state level transparency initiatives, importation rules, reporting requirements, and mandated programs, may also increase administrative costs, in some cases, compromise confidential business practices and otherwise detrimentally impact our business.

Heightened governmental scrutiny over the manner in which drug manufacturers price their marketed products and the practices of pharmacy benefit managers and other supply chain entities has also resulted in several U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, require advance notice of list price increases, establish upper payment limits or other restrictions by drug affordability review boards, allow the importation of drugs from other countries, address pharmacy benefit manager practices, and reform government program reimbursement methodologies for drug products. In particular, the IRA contains provisions designed to limit the prices paid by Medicare for various prescription drugs. While the impact of the IRA on the pharmaceutical industry cannot yet be fully determined, it is likely to be significant.

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, 2024, Innoviva owns 69.3% 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

80.0% 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. Furthermore, any sales by Innoviva of a substantial number of shares of our Common Stock, or the expectation of such sales, could cause a significant reduction in the market price of our Common Stock.

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, 2024 and December 31, 2024, the high and low sales prices of our Common Stock as reported on NYSE varied between \$1.85 and \$4.18 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, 2024, 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 3,755,965 shares of our Common Stock at a weighted-average exercise price of \$3.74 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 loan 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 (including tariffs, embargoes, sanctions or other trade restrictions), significant natural disasters (including as a result of climate change) or other events that disrupt macroeconomic conditions. Pandemics, such as the COVID-19 pandemic, have in the past impacted and may in the future impact our business, operations and financial condition and results. 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 in the Middle East) 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, trade restrictions (including tariffs, embargoes and sanctions), 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.

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 by successful cyber-attacks.

Our operations could be disrupted if our information systems—or those of our vendors—fail, if we or our vendors are unsuccessful in implementing necessary upgrades, or if we or our vendors are subject to successful 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 and others, in digital form. Data maintained in digital form is subject to risk of cyber-attacks, which 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 (as discussed below in Item 1C), such attacks are increasing in frequency and sophistication, and the possibility of a future data compromise, and risks associated with intrusion, tampering, and theft, cannot be eliminated entirely. We have experienced cyber-attacks in various forms, including phishing and other attempts to compromise our systems, but none of these has resulted in a material incident. 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. Further, our cybersecurity controls may not function as intended or our logging may be insufficient to fully investigate an incident.

A system failure, accident or security breach may also result in a material disruption of our independent drug development programs. For example, the loss of clinical trial data from ongoing or future clinical trials for any of our product candidates could result in delays in regulatory approval efforts and significantly increase costs to recover or reproduce the data. Our information security systems are also subject to laws and regulations requiring that we take measures to protect the privacy and security of certain information we gather and use in our business. For example, federal and state laws, including, without limitation, state security breach notification laws, state health information privacy laws and federal and state consumer protection laws, govern the collection, use, disclosure and storage of personal information. To the extent that any disruption or security breach were to result in a loss of or damage to data or applications, or inappropriate disclosure of confidential or proprietary information or personal health information, we could incur substantial liability, our reputation would be damaged and the further development of our product candidates could be delayed.

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. A compromise of the security or integrity of any of these systems could adversely affect our security posture.

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. 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.

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.

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 ("Board of Directors") and management. Our Board of Directors delegated oversight of Cybersecurity to the Audit Committee. Members of our Board of Directors 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. Members of our Board of Directors 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 square feet of office, research and development and manufacturing space under a non-cancellable 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 occupied since the third quarter of 2023, with cGMP manufacturing space (~10,000 square feet) fully constructed and occupied in the second half of 2024.

We also 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 approximately 35,500 square feet of laboratory and office space. The Marina del Rey Lease expires on December 31, 2031. The facility includes 19,500 square feet of BSL2 laboratory space, and approximately 3,000 square feet of cGMP laboratory space. We are actively seeking a sub-tenant to take over the remaining term of the Marina del Rey 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 existing office and laboratory space is sufficient to meet our needs for the foreseeable future. Additionally, we believe the newly constructed McConnell Facility, offering expanded manufacturing capacity, will allow us to pursue contract manufacturing opportunities for phage and potentially other advanced biologics.

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 February 28, 2025, there were 70 holders of record of our Common Stock. As of such date, there were 36,183,067 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 high-purity, pathogen-specific bacteriophage therapeutics for the treatment of antibiotic-resistant and difficult-to-treat bacteria using our proprietary bacteriophage-based technology. We see bacteriophages as a potentially safer and effective alternative to antibiotics and an essential response to the 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 specific targeted bacteria while uniquely preserving the normal human microbiome or “healthy bacteria”. 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 clinical-stage phage therapeutics of high purity, and believe we are uniquely positioned to address the growing worldwide threat of antibiotic-resistant bacterial infections. We have completed three critical Phase 2 trials, utilizing two distinct phage cocktails against two different bacterial pathogens with the potential to treat chronic pulmonary disease complicated by bacterial infection, as well as acute systemic bacterial infection. We believe we are on a critical pathway towards pivotal Phase 3 clinical studies.

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 cGMP manufacturing capabilities to advance a target pipeline of high-quality bacteriophage product candidates for late-stage clinical development. We have improved our manufacturing processes by significantly increasing phage titers and improving production efficiency with the goal of ensuring commercial viability. We believe that we are uniquely advancing two lead candidates, referred to as AP-PA02 and AP-SA02, to address both chronic and acute bacterial infections.

Our first lead phage candidate, inhaled AP-PA02, is focused primarily on the treatment of chronic pulmonary infections due to *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 and multiple ascending dose clinical trial to evaluate the safety and tolerability of inhaled AP-PA02 in subjects with cystic fibrosis 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 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. AP-PA02 exposures were generally consistent across 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 (higher AP-PA02 exposures) 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 CFF, which granted us a Therapeutics Development Award of \$5.0 million. We received the full award’s amount, including the final payment of \$0.3 million, in January 2024. 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 non-cystic fibrosis Bronchiectasis (“NCFB”) patients with similar chronic pulmonary disease with infections due to *P. 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”). On December 19, 2024, Armata announced encouraging results from the completed “Tailwind” study – a Phase 2 multicenter, double-blind, randomized, placebo-controlled study to evaluate the safety, phage kinetics, and efficacy of inhaled AP-PA02 in subjects with NCFB and chronic pulmonary *P. aeruginosa* infection. Data indicated that inhaled AP-PA02 provides a durable reduction of *P. aeruginosa* in the lung, with a favorable safety and tolerability profile. The Tailwind study was conducted in two cohorts running in parallel: subjects in one cohort (cohort A) received inhaled AP-PA02 as monotherapy, while subjects in another cohort (cohort B) received inhaled AP-PA02 in combination with inhaled anti-pseudomonal antibiotic treatment. Subjects in both cohorts were dosed at home by nebulization with study drug

administered every 12 hours for 10 days and were followed for approximately four weeks after receiving their last dose of study drug. The primary efficacy endpoint was the reduction in *P. aeruginosa* colony forming units ("CFUs") in lung sputum at one week following completion of dosing (day 17) compared to baseline. Per the statistical analysis plan, efficacy analysis of each independent cohort showed no significant difference between subjects treated with AP-PA02 and placebo due to small numbers of subjects in each cohort. Notably, a post-hoc intent-to-treat analysis (n=33 active and n=15 placebo; all subjects from both cohorts) demonstrated a statistically significant reduction of *P. aeruginosa* CFUs in the lung at day 17 (AP-PA02 vs. placebo; P=0.05). The reduction in *P. aeruginosa* CFUs persisted two weeks following completion of dosing with AP-PA02 when compared with placebo at day 24 (AP-PA02 vs. placebo; P=0.015). Additionally, paired analysis of *P. aeruginosa* CFU density at baseline compared to day 10 (P=0.03), day 11 (P=0.01), day 17 (P=0.003) and day 24 (P=0.018) was significant in the AP-PA02-treated cohort. We believe the data suggest that AP-PA02 alone is as effective as the combination therapy of phage and antibiotics in reducing *P. aeruginosa* CFUs in the lung. Additionally, approximately one-third of subjects treated with phage monotherapy exhibited at least a 2-log CFU reduction in *P. aeruginosa* compared to no reduction in placebo treated subjects. Safety data indicate that inhaled AP-PA02 was well-tolerated with treatment-emergent adverse events mild and self-limiting. There was one possibly related serious adverse event that was linked to an acute pulmonary event requiring hospitalization that was responsive to antibiotics. We believe the safety and tolerability of AP-PA02 offers a promising profile for treating chronically infected NCFB patients.

Results from the Phase 2 Tailwind study demonstrate the potential of Armata's high-purity phage cocktail, AP-PA02, as a new monotherapy treatment alternative for chronic pulmonary disease caused by *P. aeruginosa* infection, including drug-resistant bacteria, and indicate the potential for phage therapy to reduce reliance on chronic antibiotic use. The Phase 2 Tailwind study represents the second successful clinical trial for AP-PA02, Armata's lead pulmonary candidate, which was first evaluated in people with cystic fibrosis in the Phase 1b/2a SWARM-*P.a.* trial that completed in 2023. We believe the learnings on dose-schedule regimens gained from the two completed Phase 2 studies position us to define a safe and promising biologic correlation for a Phase 3 definitive trial which will aim to evaluate inhaled AP-PA02 as an alternative to antibiotics in chronic pulmonary *P. aeruginosa* infection.

In parallel to developing novel phage therapeutics that target chronic bacterial infections, we have an acute bacterial infection clinical development plan focused on *Staphylococcus aureus* ("*S. aureus*") bacteremia, a difficult-to-treat and often life-threatening human infection 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 *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 received a \$15.0 million award and entered into a multi-year program administered by the U.S Department of Defense through MTEC and managed by the Naval Medical Research Command (NMRC) – Naval Advanced Medical Development (NAMD) 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. In July 2024, the MTEC Agreement was modified to increase the total award by \$5.3 million to \$21.6 million and extend the term into the third quarter of 2025. We are using the award to partially fund a Phase 1b/2a, multicenter, 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* ("diSArm" study).

On November 17, 2021, we announced that we had received approval from the FDA to proceed with our IND application for AP-SA02. On November 12, 2024, we announced completion of enrollment of the Phase 1b/2a diSArm study of intravenous AP-SA02 as a potential treatment for *S. aureus* bacteremia. The last patient final follow-up visit was completed on January 14, 2025. During the Phase 2a portion of diSArm, Armata focused on evaluating clinical safety of higher intravenous doses of AP-SA02 and accelerating enrollment to arrive at topline data expeditiously. The manufacture of highly purified phages using Armata's proprietary methods enabled dose escalation to 5E10 PFU every six hours (2E11 PFU every 24 hours) for five days without clinically significant adverse events. In parallel with dose escalation, the evolution of two distinct blinded subsets of subjects receiving phage has been observed. One subset,

comprising approximately half of the treated group, has evidence of persistence of detectable phage in the blood providing early evidence of *in vivo* phage amplification and resultant release of phage progeny. The Company anticipates topline data from the diSArm study in the first half of 2025 where it can explore the two aforementioned subsets in an unblinded manner. Topline results are also expected to inform the optimal dose of AP-SA02 to be evaluated in a larger definitive efficacy study. 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. We are committed to developing a definitive efficacy trial focused on phage as an alternative to broad-spectrum antibiotics and/or antibiotic sparing to decrease the utilization of broad-spectrum antibiotics and their detrimental impact on the normal human microbiome.

On August 1, 2022, we announced FDA approval to proceed with our IND application for AP-SA02 in a second indication, prosthetic joint infections (“PJI”) with *S. aureus*. We had planned to initiate a Phase 1b/2a trial; however, in light of the growing concerns of both PJI and wound infections, we are considering 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 our mission to evaluate phage-based therapeutics in randomized controlled clinical trials that evaluate safety and efficacy required to support potential regulatory approval and commercialization of our 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.

| Program | Product | Discovery | Preclinical | IND-Cleared | Phase 2 | Partner |
|--|---------|------------|-------------|-------------|------------|----------------------------|
| <i>Pseudomonas aeruginosa</i> Respiratory Infections | AP-PA02 | CF | | | SWARM-P.a. | CYSTIC FIBROSIS FOUNDATION |
| | | NCFB | | | Tailwind | Unpartnered |
| <i>Staphylococcus aureus</i> | AP-SA02 | Bacteremia | | | diSArm | U.S. DoD* |
| | | PJI | | inFLEXion | | Unpartnered |

SWARM-P.a. NCT04596310; diSArm NCT03184764; Tailwind NCT03616221

* Department of Defense (DoD) award received through the Medical Technology Enterprise Consortium (MTEC) and managed by the Naval Medical Research Command (NMRC) - Naval Advanced Medical Development (NAMC) with funding from the Defense Health Agency and Joint Warfighter Medical Research Program.

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, 2024, we had an accumulated deficit of \$327.7 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 of and seeking to obtain regulatory approval for 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 of \$9.3 million as of December 31, 2024 will not be sufficient to enable us to complete all necessary development of any potential product candidates and fund our operations for the next twelve months from the date the consolidated financial statements included elsewhere in this Annual Report on Form 10-K are

issued. These circumstances raise substantial doubt about the Company's ability to continue as a going concern. 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

MTEC Agreement Modification

In July 2024, we extended the MTEC Agreement to August 2025 and increased the amount of the award by \$5.3 million to a total of \$21.6 million. We will recognize an increase in grant revenue from the third quarter of 2024 until the full amount of the amended award is utilized.

2025 Credit Agreement

On March 12, 2025, the Company entered the 2025 Credit Agreement for the 2025 Loan in an aggregate amount of \$10.0 million. The 2025 Loan bears interest at an annual rate of 14.0% and matures on March 12, 2026. Principal and accrued interest are payable at maturity. Repayment of the 2025 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 2025 Credit Agreement, the Company entered into amendments to (i) the Convertible Loan and Convertible Credit Agreement, (ii) the 2023 Loan and 2023 Credit Agreement, and (iii) the 2024 Loan and 2024 Credit Agreement, which, among other things, extended the maturity date of the Convertible Loan, 2023 Loan and 2024 Loan, respectively, to March 12, 2026.

2024 Credit Agreement

On March 4, 2024, the Company entered into the 2024 Credit Agreement for the 2024 Loan in an aggregate amount of \$35.0 million. The 2024 Loan bears interest at an annual rate of 14.0% and was scheduled to mature on June 4, 2025. Principal and accrued interest are payable at maturity. Repayment of the 2024 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 Credit Agreement, the Company amended certain provisions of the Convertible Loan and Convertible Credit Agreement and the 2023 Loan and 2023 Credit Agreement to, among other things, conform certain terms relating to permitted indebtedness and permitted liens.

On March 12, 2025, the Company executed an amendment to the 2024 Credit Agreement which, among other things, extended the 2024 Loan maturity date to March 12, 2026.

2023 Credit Agreement

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

On November 12, 2024, the Company executed an amendment to the 2023 Credit Agreement, which, among other things, extended the 2023 Loan maturity date to January 10, 2026. On March 12, 2025, the Company executed a

subsequent amendment to the 2023 Credit Agreement which, among other things, extended the 2023 Loan maturity date to March 12, 2026.

Results of Operations

Comparison of years ended December 31, 2024 and 2023

The following table summarizes our results of operations for the years ended December 31, 2024 and 2023 (dollars in thousands):

| | Year Ended December 31, | | Change | |
|--|-------------------------|--------------------|------------------|----------------|
| | 2024 | 2023 | Amount | % |
| Grant revenue | \$ 5,174 | \$ 4,529 | \$ 645 | 14.2% |
| Operating expenses | | | | |
| Research and development | 34,426 | 33,770 | 656 | 1.9% |
| General and administrative | 13,184 | 11,649 | 1,535 | 13.2% |
| Total operating expenses | 47,610 | 45,419 | 2,191 | 4.8% |
| Loss from operations | (42,436) | (40,890) | (1,546) | 3.8% |
| Other income (expense) | | | | |
| Interest income | 697 | 179 | 518 | 289.4% |
| Interest expense | (10,742) | (2,626) | (8,116) | 309.1% |
| Change in fair value of the Convertible Loan | 31,399 | (21,845) | 53,244 | (243.7%) |
| Gain (loss) on debt and the Convertible Loan extinguishments | 2,166 | (3,863) | 6,029 | (156.1%) |
| Total other income (expense), net | 23,520 | (28,155) | 51,675 | (183.5%) |
| Net loss | <u>\$ (18,916)</u> | <u>\$ (69,045)</u> | <u>\$ 50,129</u> | <u>(72.6%)</u> |

Grant Revenue

We recognized \$5.2 million and \$4.5 million of grant revenue for the years ended December 31, 2024 and 2023, respectively, which represents MTEC's share of the clinical development costs incurred for our AP-SA02 program for the treatment of *S. aureus* bacteremia.

Research and Development

The following table summarizes our research and development expenses for the years ended December 31, 2024 and 2023 (dollars in thousands):

| | Year Ended December 31, | | Change | |
|---|-------------------------|------------------|---------------|-------------|
| | 2024 | 2023 | Amount | % |
| External costs: | | | | |
| Clinical trial expenses | \$ 10,278 | \$ 9,982 | \$ 296 | 3.0% |
| Other research and development costs, including consulting, laboratory supplies and other | 3,418 | 4,665 | (1,247) | (26.7%) |
| Total external costs | 13,696 | 14,647 | (951) | (6.5%) |
| Internal costs: | | | | |
| Personnel-related costs | 10,925 | 9,665 | 1,260 | 13.0% |
| Facilities and overhead costs | 9,805 | 9,458 | 347 | 3.7% |
| Total research and development expense: | <u>\$ 34,426</u> | <u>\$ 33,770</u> | <u>\$ 656</u> | <u>1.9%</u> |

Research and development expenses increased by \$0.6 million, from \$33.8 million for the year ended December 31, 2023 to \$34.4 million for the year ended December 31, 2024.

Clinical trial costs increased by \$0.3 million, from \$10.0 million for the year ended December 31, 2023, to \$10.3 million for the year ended December 31, 2024. The increase is primarily due to a \$2.2 million increase in the AP-PA02 NCFB study as the study is at an active stage with significant developments during the year ended December 31, 2024, offset by a \$1.9 million decrease in other clinical trial expenses, based on the progress of our clinical trials.

Other external research and development costs decreased by \$1.3 million from \$4.7 million for the year ended December 31, 2023 to \$3.4 million for the year ended December 31, 2024. We recognized zero and \$0.3 million credits to research and development expenses related to the CFF grant for the years ended December 31, 2024 and 2023, respectively. Our consultant expenses decreased by \$0.9 million, spending on outsource service contracts decreased by \$0.4 million, laboratory supplies decreased by \$0.2 million.

Our external research and development expenses by project for the years ended December 31, 2024 and 2023 were as follows (in thousands):

| | | Year Ended December 31, | |
|----------------|-------------------------------------|-------------------------|------------------|
| | | 2024 | 2023 |
| Product | Project name | | |
| AP-PA02 | Non-Cystic Fibrosis Bronchiectasis | \$ 6,840 | \$ 4,922 |
| AP-PA02 | Cystic Fibrosis | 236 | 1,692 |
| AP-SA02 | Bacteremia | 4,177 | 4,789 |
| AP-SA02 | Prosthetic Joint Infection | 35 | 202 |
| | Expenses not allocated by projects* | 2,408 | 3,042 |
| | Total external costs | \$ 13,696 | \$ 14,647 |

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

Personnel-related costs, including employee payroll and related expenses, increased by \$1.3 million, from \$9.7 million for the year ended December 31, 2023 to \$11.0 million for the year ended December 31, 2024, largely due to an increase of \$0.9 million in incentive compensation expense, whereas no such expense was incurred during the year ended December 31, 2023, an increase of \$0.7 million in severance expense, offset by a decrease of \$0.3 million in employee stock-based compensation expenses, which was primarily due to the full vesting of awards issued in prior periods.

Facilities and overheads increased by \$0.3 million from \$9.5 million for the year ended December 31, 2023 to \$9.8 million for the year ended December 31, 2024, largely as a result of an increase in lease expense of \$1.0 million, partially offset by a decrease of \$0.7 million in expensed noncapitalizable lab equipment, lab equipment maintenance and other research and development costs.

General and Administrative

General and administrative expenses were \$13.1 million and \$11.7 million for the years ended December 31, 2024 and 2023, respectively. The increase of \$1.4 million is primarily related to an increase of \$2.1 million in personnel related costs, including \$2.3 million in stock-based compensation expense, mainly related to the awards granted in March 2024, an increase of \$0.7 million in salaries, an increase of \$0.2 million in incentive compensation expense, offset by a \$1.1 million decrease in severance expense. The increase in general and administrative expenses was also attributable to an increase of \$0.5 million in lease expenses, an increase of \$0.8 million in other facilities, general, administrative and overhead expenses, partially offset by a decrease of \$2.0 million in legal, accounting and other consulting expenses.

Interest Income

Interest income for the years ended December 31, 2024 and 2023 was \$0.7 million and \$0.2 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 \$10.7 million and \$2.6 million for the years ended December 31, 2024 and 2023, respectively, which relates to the interest and the amortization of debt discount and issuance costs for the 2023 Loan and 2024 Loan received from Innoviva in July 2023 and March 2024, respectively. Interest expense is accrued at each period end and is payable at the loan maturity. Refer to Note 8, “*Term Debt*”, in our consolidated financial statements included elsewhere in this Annual Report on Form 10-K for additional details.

Change in Fair Value of Convertible Loan

We recognized a fair value of the Convertible Loan gain of \$31.4 million for the year ended December 31, 2024 and the Convertible Loan loss of \$21.8 million for the year ended December 31, 2023. The Convertible Loan 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 Loan*”, in our consolidated financial statements included elsewhere in this Annual Report on Form 10-K for additional details.

Gain (Loss) on Debt and Convertible Loan Extinguishments

We recognized a gain of \$2.2 million on debt extinguishment for the year ended December 31, 2024, which relates to the amendments to the 2023 Loan and Convertible Loan on November 12, 2024. The gain was estimated as the difference between the carrying value of the 2023 Loan and Convertible Loan before the modification and the fair value of the 2023 Loan and Convertible Loan after the modification. Refer to Note 8, “*Term Debt*” and Note 7, “*Convertible Loan*”, in our consolidated financial statements included elsewhere in this Annual Report on Form 10-K for additional details. We recognized a loss of \$3.9 million on the Convertible Loan extinguishment for the year ended December 31, 2023, which relates to the amendment to the Convertible Loan on July 10, 2023. Refer to Note 7, “*Convertible Loan*”, 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 \$9.3 million as of December 31, 2024, will not be sufficient to fund our operations for the next 12 months from the date the consolidated financial statements included elsewhere in this Annual Report on Form 10-K are issued. 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.

On March 12, 2025, the Company entered the 2025 Credit Agreement for the 2025 Loan in an aggregate amount of \$10.0 million. The 2025 Loan bears interest at an annual rate of 14.0% and matures on March 12, 2026. Principal and accrued interest are payable at maturity. Repayment of the 2025 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 2025 Credit Agreement, the Company entered into amendments to (i) the Convertible Loan and Convertible Credit Agreement, (ii) the 2023 Loan and 2023 Credit Agreement, and (iii) the 2024 Loan and 2024 Credit Agreement, which, among other things, extended the maturity date of the Convertible Loan, 2023 Loan and 2024 Loan, respectively, to March 12, 2026.

In July 2024, we amended the MTEC Agreement and increased the amount of the award by \$5.3 million to a total of \$21.6 million. We will recognize grant revenue from the third quarter of 2024 until the full amount of the amended award is utilized.

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 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 the 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 loan 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, | |
|--|-------------------------|-------------------|
| | 2024 | 2023 |
| Net cash used in operating activities | \$ (37,551) | \$ (47,423) |
| Net cash used in investing activities | (1,879) | (8,134) |
| Net cash provided by financing activities | 34,958 | 53,988 |
| Net decrease in cash, cash equivalents and restricted cash | <u>\$ (4,472)</u> | <u>\$ (1,569)</u> |

Cash Flows Used in Operating Activities

Net cash used in operating activities was \$37.6 million and \$47.4 million for the years ended December 31, 2024 and 2023, respectively.

Cash used in operating activities in the year ended December 31, 2024 was primarily due to our net loss for the period of \$18.9 million, adjusted by non-cash net changes of \$16.5 million and a net change of \$2.1 million in our net operating assets and liabilities. The non-cash items consist of \$31.4 million related to a gain from change in fair value of our Convertible Loan, \$2.2 million extinguishment gain related to the extension of our Convertible Loan and 2023 Loan maturity to January 10, 2026, \$10.8 million of non-cash interest expense on outstanding balances of the 2023 Loan and the 2024 Loan, \$1.3 million related to depreciation and amortization expense, \$2.1 million related to change in right-of-use asset, \$2.9 million related to stock-based compensation expense. The changes in our net operating assets and liabilities were primarily due to a decrease of \$5.0 million in operating lease liability, mainly related to payments for our new leased facility construction, which was completed in 2024, and rent payments, \$3.8 million decrease in accounts payable and accrued liabilities, partially offset by a decrease of \$5.1 million in prepaid expenses and other assets and an increase of \$1.5 million in accrued compensation.

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 the Convertible Loan, \$3.9 million related to the Convertible Loan extinguishment loss, \$2.6 million of non-cash interest expense on the Convertible 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, 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 Flows Used in Investing Activities

Net cash used in investing activities was \$1.9 million and \$8.1 million for the years ended December 31, 2024 and 2023, 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 the construction of our manufacturing facility was completed as of December 31, 2024.

Cash Flows from Financing Activities

Cash provided by financing activities for the year ended December 31, 2024 was \$34.9 million, which consisted primarily of net proceeds from the issuance of the 2024 Loan.

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

Off-Balance Sheet Arrangements

As of December 31, 2024, we did not have any off-balance sheet arrangements.

Critical Accounting Policies and Use of Estimates

Management's discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements as of December 31, 2024 and December 31, 2023, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an ongoing basis, we evaluate estimates and assumptions, including but not limited to those related to the fair value estimate of the Convertible Loan, stock-based compensation expense, accruals for research and development costs, impairment of goodwill and intangible assets and impairment of long-lived assets. We base our 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 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. Payments made under these arrangements in advance of the performance of the related services are recorded as prepaid expenses and other current assets until the services are rendered. To date, there have been no material differences between estimates of such expenses and the amounts actually incurred.

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 and November 2024. 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 Loan*", 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 2026.

As of December 31, 2024, we estimated the fair value of the Convertible Loan to be \$32.9 million. For the year ended December 31, 2024, we recognized a change in fair value gain of \$31.4 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 (Ernst & Young, LLP; San Diego, CA; PCAOB ID: 42) | 77 |
| Consolidated Balance Sheets as of December 31, 2024 and 2023 | 79 |
| Consolidated Statements of Operations for the Years Ended December 31, 2024 and 2023 | 80 |
| Consolidated Statements of Stockholders' Deficit for the Years Ended December 31, 2024 and 2023 | 81 |
| Consolidated Statements of Cash Flows for the Years Ended December 31, 2024 and 2023 | 82 |
| Notes to Consolidated Financial Statements for the Years Ended December 31, 2024 and 2023 | 83 |

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, 2024 and 2023, and the related consolidated statements of operations, stockholders' deficit, 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, 2024 and 2023, 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 2024, the Company incurred \$34.5 million for research and development costs and as of December 31, 2024, the Company recorded \$1.1 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 20, 2025

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

| | <u>December 31, 2024</u> | <u>December 31, 2023</u> |
|---|--------------------------|--------------------------|
| Assets | | |
| Current assets | | |
| Cash and cash equivalents | \$ 9,291 | \$ 13,523 |
| Prepaid expenses and other current assets | 1,273 | 2,265 |
| Other receivables | 744 | 3,363 |
| Total current assets | <u>11,308</u> | <u>19,151</u> |
| Restricted cash | 5,480 | 5,720 |
| Property and equipment, net | 13,241 | 12,559 |
| Operating lease right-of-use asset | 41,687 | 44,717 |
| In-process research and development | 10,256 | 10,256 |
| Goodwill | 3,490 | 3,490 |
| Other assets | 975 | 2,470 |
| Total assets | <u>\$ 86,437</u> | <u>\$ 98,363</u> |
| Liabilities and stockholders' deficit | | |
| Current liabilities | | |
| Accounts payable and accrued liabilities | \$ 2,055 | \$ 5,689 |
| Accrued compensation | 2,280 | 768 |
| Term debt, current | 38,954 | — |
| Current portion of operating lease liabilities | 4,431 | 9,481 |
| Other current liabilities | 529 | 523 |
| Total current liabilities | <u>48,249</u> | <u>16,461</u> |
| Convertible Loan, non-current | 32,897 | 58,633 |
| Term debt, non-current | 22,539 | 23,674 |
| Operating lease liabilities, net of current portion | 27,694 | 28,583 |
| Deferred tax liability | 3,077 | 3,077 |
| Total liabilities | <u>134,456</u> | <u>130,428</u> |
| Commitments and contingencies (Note 12) | | |
| Stockholders' deficit | | |
| Common Stock, \$0.01 par value; 217,000,000 shares authorized; 36,183,067 and 36,122,932 shares issued and outstanding at December 31, 2024 and December 31, 2023, respectively | 362 | 361 |
| Additional paid-in capital | 279,354 | 276,393 |
| Accumulated deficit | (327,735) | (308,819) |
| Total stockholders' deficit | <u>(48,019)</u> | <u>(32,065)</u> |
| Total liabilities and stockholders' deficit | <u>\$ 86,437</u> | <u>\$ 98,363</u> |

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 | |
|--|-------------------|-------------------|
| | 2024 | 2023 |
| Grant revenue | \$ 5,174 | \$ 4,529 |
| Operating expenses | | |
| Research and development | 34,426 | 33,770 |
| General and administrative | 13,184 | 11,649 |
| Total operating expenses | <u>47,610</u> | <u>45,419</u> |
| Operating loss | (42,436) | (40,890) |
| Other income (expense) | | |
| Interest income | 697 | 179 |
| Interest expense | (10,742) | (2,626) |
| Change in fair value of the Convertible Loan | 31,399 | (21,845) |
| Gain (loss) on debt and the Convertible Loan extinguishments | 2,166 | (3,863) |
| Total other income (expense), net | <u>23,520</u> | <u>(28,155)</u> |
| Net loss | \$ (18,916) | \$ (69,045) |
| Per share information: | | |
| Net loss per share, basic | <u>\$ (0.52)</u> | <u>\$ (1.91)</u> |
| Weighted average shares outstanding, basic | <u>36,160,848</u> | <u>36,075,555</u> |
| Net loss per share, diluted | <u>\$ (0.89)</u> | <u>\$ (1.91)</u> |
| Weighted average shares outstanding, diluted | <u>59,059,971</u> | <u>36,075,555</u> |

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

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

| | Stockholders' Deficit | | | | |
|---|-----------------------|---------------|----------------------------------|------------------------|-----------------------------------|
| | Common Stock | | Additional Paid-in Capital | Accumulated Deficit | Total Stockholders' Deficit |
| | Shares | Amount | | | |
| Balances, December 31, 2022 | 36,144,706 | \$ 361 | \$ 275,493 | \$ (239,774) | \$ 36,080 |
| Forfeiture of restricted stock awards | (27,341) | — | — | — | — |
| Withholdings for taxes related to net share settlement of equity awards | (25,933) | — | (43) | — | (43) |
| Exercise of stock options | 1,500 | — | 5 | — | 5 |
| Issuance of Common Stock upon vesting of restricted stock units | 30,000 | — | — | — | — |
| Stock-based compensation expense | — | — | 938 | — | 938 |
| Net loss | — | — | — | (69,045) | (69,045) |
| Balances, December 31, 2023 | <u>36,122,932</u> | <u>\$ 361</u> | <u>\$ 276,393</u> | <u>\$ (308,819)</u> | <u>\$ (32,065)</u> |

| | Stockholders' Deficit | | | | |
|--|-----------------------|---------------|----------------------------------|------------------------|-----------------------------------|
| | Common Stock | | Additional Paid-in Capital | Accumulated Deficit | Total Stockholders' Deficit |
| | Shares | Amount | | | |
| Balances, December 31, 2023 | 36,122,932 | \$ 361 | \$ 276,393 | \$ (308,819) | \$ (32,065) |
| Exercise of stock options | 37,282 | 1 | 129 | — | 130 |
| Withholdings for taxes related to net share settlement of equity awards | (4,222) | — | — | — | — |
| Issuance of Common Stock upon release of restricted stock units, net of tax withholdings | 27,075 | — | (61) | — | (61) |
| Stock-based compensation expense | — | — | 2,893 | — | 2,893 |
| Net loss | — | — | — | (18,916) | (18,916) |
| Balances, December 31, 2024 | <u>36,183,067</u> | <u>\$ 362</u> | <u>\$ 279,354</u> | <u>\$ (327,735)</u> | <u>\$ (48,019)</u> |

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, | |
|--|--------------------------------|------------------|
| | 2024 | 2023 |
| Operating activities: | | |
| Net loss | \$ (18,916) | \$ (69,045) |
| Adjustments required to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization expense | 1,325 | 972 |
| Stock-based compensation expense | 2,893 | 938 |
| Change in fair value of the Convertible Loan | (31,399) | 21,845 |
| Non-cash interest expense | 10,758 | 2,573 |
| Non-cash interest income | — | (22) |
| Gain (loss) on debt and Convertible Loan extinguishments | (2,166) | 3,863 |
| Change in right-of-use asset | 2,053 | 1,018 |
| Loss from disposal of property and equipment | — | 81 |
| Changes in operating assets and liabilities: | | |
| Prepaid expenses and other assets | 5,106 | 4,826 |
| Accounts payable and accrued liabilities | (3,755) | 39 |
| Accrued compensation | 1,512 | (1,060) |
| Operating lease liability | (4,962) | (13,451) |
| Net cash used in operating activities | (37,551) | (47,423) |
| Investing activities: | | |
| Purchases of property and equipment | (1,879) | (8,144) |
| Proceeds from sale of property and equipment | — | 10 |
| Net cash used in investing activities | (1,879) | (8,134) |
| Financing activities: | | |
| Proceeds from issuance of the Convertible Loan, net of issuance costs | — | 29,101 |
| Proceeds from issuance of term debt, net of issuance costs | 34,889 | 24,925 |
| Payments for taxes related to net share settlement of equity awards | (61) | (43) |
| Proceeds from exercise of stock options | 130 | 5 |
| Net cash provided by financing activities | 34,958 | 53,988 |
| Net decrease in cash, cash equivalents and restricted cash | (4,472) | (1,569) |
| Cash, cash equivalents and restricted cash, beginning of period | 19,243 | 20,812 |
| Cash, cash equivalents and restricted cash, end of period | <u>\$ 14,771</u> | <u>\$ 19,243</u> |
| Supplemental disclosure of cash flow information: | | |
| Right-of-use asset obtained in exchange for operating lease liability | \$ 977 | \$ 2,700 |
| Property and equipment included in accounts payable and accrued liabilities | \$ 89 | \$ 217 |

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

| | Year Ended December 31, | |
|--|--------------------------------|------------------|
| | 2024 | 2023 |
| Cash and cash equivalents | \$ 9,291 | \$ 13,523 |
| Restricted cash | 5,480 | 5,720 |
| Cash, cash equivalents and restricted cash | <u>\$ 14,771</u> | <u>\$ 19,243</u> |

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 69.3% of the Company’s outstanding equity as of December 31, 2024. 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 seats of the Company’s Board of Directors (“Board of Directors”) during the year ended December 31, 2024, 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 Company’s Board of Directors 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, 2024, the Company had an accumulated deficit of \$327.7 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 \$9.3 million as of December 31, 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:

2025 Credit Agreement

On March 12, 2025, the Company entered into a credit and security agreement (the “2025 Credit Agreement”) for a loan in an aggregate amount of \$10.0 million (the “2025 Loan”) with Innoviva Strategic Opportunities LLC, a wholly owned subsidiary of Innoviva, Inc. (NASDAQ: INVA), our principal stockholder and a related party (collectively, “Innoviva”). The 2025 Loan bears interest at an annual rate of 14.0% and matures on March 12, 2026. Principal and accrued interest are payable at maturity. Repayment of the 2025 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 2025 Credit Agreement, the Company entered into amendments to (i) its existing convertible loan (the “Convertible Loan”) and secured credit and security agreement, dated January 10, 2023, with Innoviva (the “Convertible Credit Agreement”), (ii) its existing secured term loan facility (the “2023 Loan”) and credit and security agreement, dated July 10, 2023, with Innoviva (the “2023 Credit Agreement”) and (iii) its existing secured term loan facility (the “2024 Loan”) and credit and security agreement, dated March 4, 2024, with Innoviva (the “2024 Credit Agreement”), which, among other things, extended the maturity date of each loan to March 12, 2026.

2024 Credit Agreement

On March 4, 2024, the Company entered into 2024 Credit Agreement for the 2024 Loan in an aggregate amount of \$35.0 million. The 2024 Loan bears interest at an annual rate of 14.0% and was scheduled to mature on June 4, 2025. On March 12, 2025, the Company executed an amendment to the 2024 Credit Agreement which, among other things, extended the 2024 Loan maturity date to March 12, 2026. Principal and accrued interest are payable at maturity. Repayment of the 2024 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 Credit Agreement, the Company amended certain provisions of the Convertible Loan and Convertible Credit Agreement and the 2023 Loan and 2023 Credit Agreement to, among other things, conform certain terms relating to permitted indebtedness and permitted liens.

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 Loan, 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.

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 restricted cash. As of December 31, 2024 and 2023, cash, cash equivalents and restricted cash were invested primarily in money market funds and U.S. treasury securities through highly rated financial institutions in accordance with the Company's investment policy, to a concentration limit per issuer or sector.

Other receivables represent amounts due from the Medical Technology Enterprise Consortium ("MTEC") (Note 13, "Grants and Awards") and reimbursement for tenant improvements (Note 12, "Commitments and Contingencies").

Cash and Cash Equivalents

Cash and cash equivalents consist primarily of cash deposits and marketable securities with original maturities of less than three months.

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, "Commitments and Contingencies").

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 Loan 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. The Convertible Loan 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, 2024 or 2023.

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, 2024, the Company performed the annual evaluation of its IPR&D assets for impairment. The Company considered the development timelines for its *S. aureus* development program and noted no qualitative factors that would indicate potential impairment of its IPR&D asset. The Company also performed a quantitative analysis for impairment analysis and based on this analysis, the fair value of this bacteriophage program was greater than its carrying value as of December 31, 2024. Consequently, no impairment was noted for the IPR&D asset.

As of December 31, 2023, 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.

No impairment loss was recognized as of December 31, 2024 and 2023.

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, 2024 and 2023.

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 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, 2024 and 2023, the Company recognized as other receivables in its consolidated balance sheets \$0.7 million and \$1.5 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, 2024 and 2023, 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 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 adopted ASU 2023-07 standard in the fourth quarter of 2024 for annual and retrospective reporting periods with all interim disclosures to begin in the first quarter of fiscal year 2025. Refer to Note 15. "Segment Reporting".

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 (loss) per share ("EPS") computation. The Company adopted this ASU as of January 1, 2024, which did not have an impact on its consolidated financial statements or related disclosures.

Recent Accounting Pronouncements Not Yet Adopted

On 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 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.

In November 2024, the FASB issued Accounting Standards Update ASU 2024-03 Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): *Disaggregation of Income Statement Expenses*. The guidance in ASU 2024-03 requires public business entities to disclose in the notes to the financial statements, among other things, specific information about certain costs and expenses including purchases of inventory; employee compensation; and depreciation, amortization and depletion expenses for each caption on the income statement where such expenses are included. ASU 2024-03 is effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027. Early adoption is permitted, and the amendments may be applied prospectively to reporting periods after the effective date or retrospectively to all periods presented in the financial statements. The Company is currently evaluating the provisions of this guidance and assessing the potential impact on the Company’s consolidated financial statement disclosures.

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.

| | December 31, 2024 | | | |
|--|-------------------|----------|---------|---------|
| | Total | Level 1 | Level 2 | Level 3 |
| Investments in money market fund – financial assets, included in cash and cash equivalents | \$ 4,955 | \$ 4,955 | \$ — | \$ — |
| Convertible Loan– financial liabilities | 32,897 | — | — | 32,897 |

| | December 31, 2023 | | | |
|---|-------------------|---------|---------|-----------|
| | Total | Level 1 | Level 2 | Level 3 |
| Convertible Loan– financial liabilities | \$ 58,633 | \$ — | \$ — | \$ 58,633 |

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 the fair value of its Convertible Loan using the following inputs for the years ended December 31, 2024 and 2023:

| | <u>December 31, 2024</u> | <u>December 31, 2023</u> |
|---------------------------------------|--------------------------|--------------------------|
| Discount rate | 15.67%-28.28% | 21.01%-45.88% |
| Probabilities of settlement scenarios | 0%-75% | 0%-85% |
| Volatility | 83.30%-111.60% | 101.1%-123.6% |
| Expected term (in years) | 0.10-1.20 | 0.20-1.50 |
| Risk-free rate | 4.08%-5.33% | 4.62%-5.39% |

The following table presents a summary of the changes in the fair value of its Convertible Loan for the years ended December 31, 2024 and 2023 (in thousands):

| | <u>December 31, 2024</u> | <u>December 31, 2023</u> |
|---|--------------------------|--------------------------|
| Convertible Loan at the beginning of the period | \$ 58,633 | \$ — |
| Net issuance of the Convertible Loan ⁽¹⁾ | — | 29,226 |
| Initial recognition of modified Convertible Loan ⁽¹⁾ | — | 35,031 |
| Change in fair value | (31,399) | 21,845 |
| Amount exchanged ⁽²⁾ | — | (31,332) |
| Loss on the Convertible Loan extinguishment | 5,663 | 3,863 |
| Convertible Loan at the end of the period | <u>\$ 32,897</u> | <u>\$ 58,633</u> |

(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, “Convertible Loan”).

5. Net Loss per Share

The computation of basic EPS is based on the weighted-average number of the Company’s Common Stock outstanding. The computation of diluted EPS is based on the weighted-average number of the Company’s Common Stock outstanding and potential dilutive Common Stock. Diluted EPS is computed using the more dilutive of the treasury stock method, which reflects the potential dilution that would occur if securities or other contracts to issue Common Stock were exercised or converted to the Company’s Common Stock. Common Stock options, warrants and unvested restricted stock units were not included in dilutive EPS as their impact would be antidilutive.

The following table sets forth the computation of basic and diluted net loss per share attributable to common stockholders for the years ended December 31, 2024 and 2023 (in thousands, except share and per share data):

| | Year Ended December 31, | |
|---|-------------------------|--------------------|
| | 2024 | 2023 |
| Numerator: | | |
| Net loss attributable to common stockholders, basic | \$ (18,916) | \$ (69,045) |
| Gain from change in fair value of the Convertible Loan | (31,399) | — |
| Gain on debt and the Convertible Loan extinguishments | (2,166) | — |
| Net loss attributable to common stockholders, diluted | <u>\$ (52,481)</u> | <u>\$ (69,045)</u> |
| Denominator: | | |
| Weighted average shares outstanding, basic | 36,160,848 | 36,075,555 |
| Shares issuable upon the conversion of the Convertible Loan | 22,899,123 | — |
| Weighted average common shares outstanding, diluted | <u>59,059,971</u> | <u>36,075,555</u> |
| Net loss per share, basic | <u>\$ (0.52)</u> | <u>\$ (1.91)</u> |
| Net loss per share, diluted | <u>\$ (0.89)</u> | <u>\$ (1.91)</u> |

The following outstanding securities as of December 31, 2024 and 2023 have been excluded from the computation of diluted weighted average shares outstanding, as they would have been anti-dilutive:

| | December 31, 2024 | December 31, 2023 |
|--|-------------------|-------------------|
| Outstanding stock options | 3,755,965 | 3,165,216 |
| Unvested restricted stock units | 220,000 | 200,000 |
| Shares issuable upon the conversion of the Convertible Loan ⁽¹⁾ | — | 21,293,861 |
| Outstanding warrants | 19,365,847 | 19,365,847 |
| Total | <u>23,341,812</u> | <u>44,024,924</u> |

(1) The Company determined the number of shares issuable upon the conversion of the Convertible Loan as of December 2023, based on the Convertible Loan principal amount of \$30.0 million, accrued and unpaid interest of \$2.4 million, calculated at an annual interest rate of 8%, converted at \$1.52 per share.

6. Balance Sheet Details

Property and Equipment, net

Property and equipment as of December 31, 2024 and 2023 consisted of the following (in thousands):

| | December 31, 2024 | December 31, 2023 |
|--------------------------------|-------------------|-------------------|
| Laboratory equipment | \$ 21,316 | \$ 19,678 |
| Furniture and fixtures | 831 | 817 |
| Office and computer equipment | 438 | 438 |
| Leasehold improvements | 3,802 | 3,447 |
| Total | <u>26,387</u> | <u>24,380</u> |
| Less: accumulated depreciation | <u>(13,146)</u> | <u>(11,821)</u> |
| Property and equipment, net | <u>\$ 13,241</u> | <u>\$ 12,559</u> |

Depreciation and amortization expense totaled \$1.3 million and \$1.0 million for the years ended December 31, 2024 and 2023, respectively. Property and equipment not in use was \$8.3 million and \$8.1 million as of December 31, 2024 and 2023, respectively, and is 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, 2024 and 2023 consisted of the following (in thousands):

| | December 31, 2024 | December 31, 2023 |
|---|--------------------------|--------------------------|
| Tenant improvement allowance receivable (Note 12) | \$ — | \$ 1,835 |
| Grant and award receivable (Note 13) | 744 | 1,528 |
| | <u>\$ 744</u> | <u>\$ 3,363</u> |

Accounts Payable and Accrued Liabilities

Accounts payable and accrued liabilities as of December 31, 2024 and 2023 consisted of the following (in thousands):

| | December 31, 2024 | December 31, 2023 |
|---------------------------------|--------------------------|--------------------------|
| Accounts payable | \$ 766 | \$ 1,585 |
| Accrued clinical trial expenses | 828 | 3,021 |
| Other accrued expenses | 461 | 1,083 |
| | <u>\$ 2,055</u> | <u>\$ 5,689</u> |

7. Convertible Loan

On January 10, 2023, the Company received the Convertible Loan in the aggregate 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 Company's entry into the 2023 Credit Agreement to, among other changes, extend the maturity of the Convertible Loan to January 10, 2025. Then, on March 12, 2025, the Company executed a subsequent amendment to the Convertible Credit Agreement which, among other things, extended the Convertible Loan maturity date to March 12, 2026. 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 \$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 2023 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 losses of \$23.6 million from July 10, 2023 to December 31, 2023 as the change in fair value of the Convertible Loan post modification.

On November 12, 2024, the Company amended the terms of the Convertible Credit Agreement and 2023 Credit Agreement, to, among other changes, extend the maturity of both loans to January 10, 2026. The Company concluded that the amendments were a combined transaction and an extinguishment for accounting purposes. The Company estimated fair value of the combined transaction, the 2023 Loan and the Convertible Loan, before and after modification and calculated an extinguishment gain of \$2.2 million, which was recognized as other income (expense) in the consolidated statement of operations for the year ended December 31, 2024. After this amendment, the Company continued to account for the Convertible Loan at fair value on its consolidated balance sheet, with changes in fair value recorded as other income (expense) in the consolidated statements of operations during each reporting period. The Company recognized \$31.4 million as the change in fair value of the Convertible Loan for the year ended December 31, 2024.

On March 12, 2025, the Company executed an amendment to the Convertible Credit Agreement which, among other things, extended the Convertible Loan maturity date to March 12, 2026.

8. Term Debt

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

On November 12, 2024, the Company executed an amendment to the 2023 Credit Agreement, which, among other things, extended the 2023 Loan maturity date to January 10, 2026. On March 12, 2025, the Company executed a subsequent amendment to the 2023 Credit Agreement which, among other things, extended the 2023 Loan maturity date to March 12, 2026.

The 2023 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 2023 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 2023 Credit Agreement, certain bankruptcy or insolvency events, and a material deviation from the Company's operating budget.

The 2023 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. The Company recognized \$2.4 million and \$0.9 million debt issuance costs and debt discount for the years ended December 31, 2024 and 2023, respectively, using the effective interest method. The Company recognized \$6.7 million and \$2.6 million of accrued interest expense for the years ended December 31, 2024 and 2023, respectively. The 2023 Loan's annual effective interest rate was 48.76% and 27.31% as of December 31, 2024 and 2023, respectively.

On March 4, 2024, the Company entered into the 2024 Credit Agreement for the 2024 Loan in an aggregate amount of \$35.0 million. The 2024 Loan bears interest at an annual rate of 14.0% and was scheduled to mature on June 4, 2025. On March 12, 2025, the Company executed an amendment to the 2024 Credit Agreement which, among other

things, extended the 2024 Loan maturity date to March 12, 2026. Principal and accrued interest are payable at maturity. Repayment of the 2024 Loan is guaranteed by the Company's domestic subsidiaries, and the 2024 Loan is secured by substantially all of the assets of the Company and the subsidiary guarantors.

The 2024 Loan was initially recognized at cash proceeds of \$35.0 million net of debt issuance costs of \$0.1 million, and subsequently is recognized at the amortized cost. Debt issuance costs are amortized using the effective interest method to interest expense over the term of the 2024 Loan. The Company recognized \$4.1 million of accrued interest expense for the year ended December 31, 2024. The 2024 Loan's annual effective interest rate was 14.25% as of December 31, 2024.

The 2023 Credit Agreement and the 2024 Credit Agreement contain 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 2023 Credit Agreement and the 2024 Credit Agreement also include 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 2023 Credit Agreement and the 2024 Credit Agreement, certain bankruptcy or insolvency events, and a material deviation from the Company's operating budget.

9. Stockholders' Deficit

Warrants

As of December 31, 2024 outstanding warrants to purchase shares of Common Stock were as follows:

| Shares | Exercise Price | Expiration Date |
|------------|----------------|-------------------|
| 993,139 | \$ 2.87 | February 11, 2025 |
| 7,717,661 | \$ 2.87 | March 27, 2025 |
| 1,867,912 | \$ 3.25 | January 26, 2026 |
| 4,285,935 | \$ 3.25 | March 16, 2026 |
| 1,807,396 | \$ 5.00 | February 8, 2027 |
| 2,692,604 | \$ 5.00 | March 30, 2027 |
| 1,200 | \$ 1,680.00 | None |
| 19,365,847 | | |

Shares Reserved for Future Issuance

As of December 31, 2024 and 2023, the Company had reserved shares of its Common Stock for future issuance as follows:

| | December 31, 2024 | December 31, 2023 |
|--|-------------------|-------------------|
| Stock options outstanding | 3,755,965 | 3,165,216 |
| Unvested restricted stock units | 220,000 | 200,000 |
| Shares issuable under the Employee Stock Purchase Plan | 11,890 | 9,748 |
| Shares available for future grants under the 2016 Plan | 3,405,908 | 2,368,160 |
| Warrants outstanding | 19,365,847 | 19,365,847 |
| Shares issuable upon the conversion of the Convertible Loan ⁽¹⁾ | 22,899,123 | 21,293,861 |
| Total shares reserved | 49,658,733 | 46,402,832 |

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 of Directors annually beginning from January 1, 2017 until January 1, 2026. As of December 31, 2024, there were 3,405,908 shares available for issuance under the 2016 Plan.

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, 2024, 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, 2024, the Company had reserved 11,890 shares for future grants under the ESPP.

Stock option activities during the year ended December 31, 2024 are presented below:

| | Shares | Options Outstanding | | |
|--|-------------|--|--|--|
| | | Weighted Average Exercise Price | Weighted Average Remaining Contractual Term (Years) | Aggregate Intrinsic Value (in thousands) |
| Outstanding at December 31, 2023 | 3,165,216 | \$ 5.04 | 5.9 | \$ 429 |
| Granted | 1,859,054 | \$ 3.34 | | \$ — |
| Exercised | (37,282) | \$ 3.38 | | \$ 24 |
| Forfeited/Cancelled/Expired | (1,231,023) | \$ 6.48 | | \$ 4 |
| Outstanding at December 31, 2024 | 3,755,965 | \$ 3.74 | 7.5 | \$ 4 |
| Vested and expected to vest at December 31, 2024 | 3,755,965 | \$ 3.74 | 7.5 | \$ 4 |
| Exercisable at December 31, 2024 | 2,059,396 | \$ 4.04 | 6.4 | \$ 2 |

The aggregate intrinsic value of options at December 31, 2024 is based on the Company’s closing stock price on that date of \$1.85 per share.

The weighted average grant date fair value of the options granted during 2024 and 2023 was \$2.54 and \$1.97, respectively. The fair value of vested options during the year ended December 31, 2024 and 2023 was \$2.8 million and \$5.1 million, respectively.

Restricted stock awards and restricted stock unit award activities during the year ended December 31, 2024 are presented below:

| | Shares | Weighted Avg Grant Date Fair Value |
|----------------------------------|----------|--|
| Outstanding at December 31, 2023 | 200,000 | \$ 2.39 |
| Granted | 90,000 | \$ 3.38 |
| Vested | (50,000) | \$ 2.39 |
| Cancelled | (20,000) | \$ 3.38 |
| Outstanding at December 31, 2024 | 220,000 | \$ 2.73 |

As of December 31, 2024, there was \$2.6 million of total unrecognized compensation expense related to unvested stock options and restricted stock units, which the Company expects to recognize over the weighted average remaining period of approximately 1.9 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, | |
|--------------------------|-------------------------|----------------|
| | 2024 | 2023 |
| Risk-free interest rate | 3.54%-4.25% | 3.54%-5.54% |
| Expected volatility | 89.40%-92.50% | 75.40%-116.96% |
| Expected term (in years) | 5.1-7.0 | 0.1-7.0 |
| Expected dividend yield | 0% | 0% |

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, | |
|--------------------------------|-------------------------|----------|
| | 2024 | 2023 |
| Research and development | \$ 663 | \$ 1,013 |
| General and administrative | 2,230 | (75) |
| Total stock-based compensation | \$ 2,893 | \$ 938 |

11. Income Taxes

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

| | Year Ended December 31, | |
|---------------|-------------------------|-------------|
| | 2024 | 2023 |
| United States | \$ (18,020) | \$ (68,182) |
| Foreign | (896) | (863) |
| Total | \$ (18,916) | \$ (69,045) |

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

| | December 31, | |
|--|--------------|------------|
| | 2024 | 2023 |
| Deferred tax assets: | | |
| Net operating loss carryforwards | \$ 53,618 | \$ 46,591 |
| Capitalized research and development | 24,045 | 21,431 |
| Stock-based compensation | 1,804 | 2,083 |
| Depreciation and amortization | 762 | 856 |
| Lease accounting | 13,505 | 13,899 |
| Interest expense carryforward | 1,292 | — |
| Other | 2,086 | 1,907 |
| Total deferred tax assets before valuation allowance | 97,112 | 86,767 |
| Less: valuation allowance | (84,217) | (75,166) |
| Total deferred tax assets after valuation allowance | 12,895 | 11,601 |
| Deferred tax liabilities: | | |
| Right-of-use asset | (10,763) | (11,510) |
| In-process research and development | (3,077) | (3,077) |
| Debt basis differences | (1,991) | — |
| Other | (141) | (91) |
| Total deferred tax liabilities | (15,972) | (14,678) |
| Net deferred tax liability | \$ (3,077) | \$ (3,077) |

The Company's net operating loss carryforwards at December 31, 2024 are \$195.3 million, \$139.2 million and \$12.0 for federal, state and foreign 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 2029, respectively. The federal net operating loss carryforwards generated after 2017 of \$140.8 million will carryforward indefinitely and can be used to offset up to 80% of future annual taxable income. The Company's foreign net operating loss carryforwards do not expire.

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, 2024.

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 \$9.1 million during the year ending December 31, 2024:

| | December 31, | |
|--|--------------|--------|
| | 2024 | 2023 |
| U.S. federal statutory income tax rate | 21.0 % | 21.0 % |
| Adjustments for tax effects of: | | |
| State income taxes, net of federal tax | 9.6 % | 2.9 % |
| Stock-based compensation | (3.7)% | (1.6)% |
| Non-deductible debt items | 25.3 % | (7.8)% |
| Change in valuation allowance | (49.7)% | (9.3)% |
| Change in rate | 0.5 % | (3.3)% |
| Return to provision | (1.6)% | (0.7)% |
| Permanent differences and other | (1.4)% | (1.2)% |
| 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, 2024, the Company is no longer subject to U.S. federal income tax examinations for tax years ended on or before December 31, 2020 or to California state income tax examinations for tax years ended on or before December 31, 2019. 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, 2024 and 2023.

The Company's policy is to classify interest and penalties on uncertain tax positions as a component of tax expense. As of December 31, 2024 and 2023, 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, with the lease term through December 31, 2031. Annual base rent is from \$1.9 million and increases by 3% annually and will be \$2.5 million by the end of the term. The Company also maintains an irrevocable letter of credit in connection with this lease, which had a balance of \$0.5 million as of December 31, 2024 and is reducing 20% annually through the end of the lease term.

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, CA (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 was fully or partially abated while the lessor and the Company completed planned tenant improvements to the facility. Base monthly rent is approximately \$0.3 million in 2024. The Company was responsible for construction costs over the tenant improvements allowance of \$7.2 million. The construction was completed as of December 31, 2024, and the Company received the

full allowance. Out-of-pocket expenses to be incurred by the Company were considered noncash lease payments, and included in the lease liability and right-of-use asset.

In connection with the execution of the 2021 Lease, the Company delivered an irrevocable standby letter of credit in the 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, 2024, are as follows (in thousands):

| | Operating Leases |
|--|---------------------|
| 2025 | \$ 4,716 |
| 2026 | 5,293 |
| 2027 | 5,452 |
| 2028 | 5,616 |
| 2029 | 5,784 |
| Thereafter | 37,996 |
| Total minimum lease payments | 64,857 |
| Less: amount representing interest | (32,732) |
| Present value of operating lease obligations | 32,125 |
| Less: current portion | (4,431) |
| Noncurrent operating lease obligations | \$ 27,694 |

Operating lease expenses were \$8.4 million and \$7.4 million for the years ended December 31, 2024 and 2023, respectively. Variable costs related to operating expenses and taxes, which are recognized as incurred, were \$1.7 million and \$1.0 million for the years ended December 31, 2024 and 2023, respectively.

The following table summarizes supplemental cash flow information related to the Company's operating leases for the years ended December 31, 2024 and 2023 (in thousands):

| | Year Ended December 31, | |
|---|-------------------------|-----------|
| | 2024 | 2023 |
| Cash paid for amounts included in the measurement of lease liabilities: | | |
| Operating cash flows from operating leases | \$ 9,010 | \$ 18,839 |

The following table summarizes the weighted-average remaining lease term and weighted-average discount rate related to the Company's operating leases as of December 31, 2024 and 2023:

| | December 31, 2024 | December 31, 2023 |
|--|-------------------|-------------------|
| Weighted-average remaining lease term, years | 11.74 | 12.79 |
| Weighted-average discount rate, % | 13.9 | 13.9 |

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 an agreement (the "MTEC Agreement") with MTEC, pursuant to which the Company received a \$15.0 million award and entered into a multi-year program administered by the DoD through MTEC and managed by the Naval Medical Research Command ("NMRC") – Naval Advanced Medical Development ("NAMD") 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. In July 2024, the MTEC Agreement was modified to increase the total award by \$5.3 million to \$21.6 million and extend the term into the third quarter of 2025. The Company is using the award 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 *S. aureus* bacteremia infections. The MTEC Agreement specifies that the award will be paid to the Company over the term of the award through a cost reimbursable model, based on agreed upon cost share percentages, and the 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 August 15, 2025. 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 \$5.2 million and \$4.5 million in grant revenue from the MTEC Agreement during the years ended December 31, 2024 and 2023, respectively. As of December 31, 2024 and 2023, the Company had \$0.7 million and \$1.5 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 up to \$5.0 million (the "CFF Award"). The CFF Award was used to fund 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 *Pseudomonas* 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 CFF Award was 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 total amount of the CFF award was recognized through December 2023 and no additional payments are expected.

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, 2024 and 2023, the Company recognized zero and \$0.3 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 to the 401(k) plan for the years ended December 31, 2024 and 2023.

15. Segment Reporting

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 determination of a single business segment is consistent with the consolidated financial information regularly provided to the Company’s chief operating decision maker (“CODM”). The Company’s CODM is its Chief Executive Officer, who reviews financial information on an aggregate basis for purposes of assessing performance, making operating decisions, allocating resources and evaluating financial performance. The long-lived assets of \$14.0 million, which represents 99.3% of the Company’s total long-lived assets, are maintained in the United States.

The following table includes certain segment information for the years ended December 31, 2024 and 2023.

| | Year Ended December 31, | |
|--|-------------------------|-------------|
| | 2024 | 2023 |
| Grant revenue | \$ 5,174 | \$ 4,529 |
| Operating expenses | | |
| Research and development expenses: | | |
| AP-PA02: Non-Cystic Fibrosis Bronchiectasis | 6,840 | 4,922 |
| AP-PA02: Cystic Fibrosis | 236 | 1,692 |
| AP-SA02: Bacteremia | 4,177 | 4,789 |
| AP-SA02Prosthetic Joint Infection | 35 | 202 |
| Expenses not allocated by projects | 2,408 | 3,042 |
| Total external research and development expenses | 13,696 | 14,647 |
| Research and development personnel expenses | 10,764 | 9,408 |
| Other research and development expenses | 9,966 | 9,715 |
| Total research and development expenses | 34,426 | 33,770 |
| General and administrative expenses: | | |
| General and administrative personnel expenses | 4,935 | 2,480 |
| Other general and administrative expenses | 8,249 | 9,169 |
| Total general and administrative expenses | 13,184 | 11,649 |
| Total operating expenses | 47,610 | 45,419 |
| Operating loss | (42,436) | (40,890) |
| Other income (expense), net | 23,520 | (28,155) |
| Net loss | \$ (18,916) | \$ (69,045) |

16. Subsequent Events

On March 12, 2025, the Company entered into the 2025 Credit Agreement for the 2025 Loan in an aggregate amount of \$10.0 million. The 2025 Loan bears interest at an annual rate of 14.0% and matures on March 12, 2026. Principal and accrued interest are payable at maturity. Repayment of the 2025 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 2025 Credit Agreement, the Company entered into amendments to (i) the Convertible Loan and Convertible Credit Agreement, (ii) the 2023 Loan and 2023 Credit Agreement, and (iii) the 2024 Loan and 2024 Credit Agreement, which, among other things, extended the maturity date of the Convertible Loan, 2023 Loan and 2024 Loan, respectively, to March 12, 2026.

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 Senior Vice President, Finance and Principal Financial Officer), to allow timely decisions regarding required disclosure.

Our management, under the supervision and with the participation of our Chief Executive Officer and our Senior Vice President, Finance and Principal Financial Officer, 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 Senior Vice President, Finance and Principal Financial Officer have concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2024.

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 Senior Vice President, Finance and Principal Financial Officer 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, 2024, 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 Senior Vice President, Finance and Principal Financial Officer, concluded that, as of December 31, 2024, 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, 2024 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, 2024.

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 2025 annual meeting of stockholders (the “2025 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 2025 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.

We have adopted a written code of business conduct and ethics (the “Code of Business Conduct”) that applies to all directors, officers and employees of Armata, including any principal executive officer, principal financial officer or principal accounting officer of Armata. The Code of Business Conduct is available on our internet website at www.armatapharma.com. If we ever were to amend or waive any provision of the Code of Business Conduct that applies to our principal executive officer, principal financial officer, principal accounting officer or any person performing similar functions, we intend to satisfy our disclosure obligations with respect to any such waiver or amendment by posting such information on our internet website set forth above rather than filing a Form 8-K.

The Company has an insider trading policy governing the purchase, sale and other dispositions of the Company’s securities that applies to all Company personnel, including directors, officers, employees, and other covered persons. The Company also follows procedures for the repurchase of its securities. The Company believes that its insider trading policy and repurchase procedures are reasonably designed to promote compliance with insider trading laws, rules and regulations, and listing standards applicable to the Company. A copy of the Company’s insider trading policy is filed as Exhibit 19.1 to this Form 10-K.

Item 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference from the information contained in the 2025 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 2025 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 2025 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 2025 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 2025 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 2025 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 2025 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 2025 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 10.11 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+ Employment Agreement, dated August 30, 2023, by and between the Company and Richard Rychlik (incorporated by reference to Exhibit 10.28 to the Company's Annual Report on Form 10-K, filed with the SEC on March 21, 2024).
- 10.28 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).
- 10.29 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).
- 10.30 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).
- 10.31+ Employment Letter Agreement by and between Mina Pastagia, M.D. and Armata Pharmaceuticals, Inc., dated as of September 22, 2020 (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, filed with the SEC on July 25, 2024).

- 10.32+ Amendment No. 1, dated as of July 22, 2024, to that certain Employment Letter Agreement by and between Mina Pastagia, M.D. and Armata Pharmaceuticals, Inc., dated as of September 22, 2020 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on July 25, 2024).
- 10.33+ Employment Letter Agreement, dated July 31, 2024, by and between Armata Pharmaceuticals, Inc. and David House (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on August 15, 2024).
- 10.34+ Confidential Separation and Release Agreement by and between Armata Pharmaceuticals, Inc. and Richard Rychlik dated as of September 30, 2024 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on October 3, 2024).
- 10.35 Second Amendment to Credit and Security Agreement, dated as of November 12, 2024, by and among the Issuer, Innoviva Sub and the other parties thereto (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on November 15, 2024).
- 10.36 Third Amendment to Secured Convertible Credit and Security Agreement, dated as of November 12, 2024, by and among the Issuer, Innoviva Sub and the other parties thereto (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, filed with the SEC on November 15, 2024).
- 10.37+ Separation and Release Agreement, by and between Armata Pharmaceuticals, Inc. and Mina Pastagia, M.D., dated as of December 2, 2024 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on December 4, 2024).
- 10.38+ Employment Letter Agreement, dated June 1, 2024, by and between Armata Pharmaceuticals, Inc. and Pierre Kyme.
- 10.39 Credit and Security Agreement, dated March 12, 2025, 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 12, 2025).
- 10.40 First Amendment to Credit and Security Agreement, dated as of March 12, 2025, by and among the Issuer, Innoviva Sub and the other parties thereto (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, filed with the SEC on March 12, 2025).
- 10.41 Third Amendment to Credit and Security Agreement, dated as of March 12, 2025, by and among the Issuer, Innoviva Sub and the other parties thereto (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K, filed with the SEC on March 12, 2025).
- 10.42 Fourth Amendment to Secured Convertible Credit and Security Agreement, dated March 12, 2025, by and among the Company and Innoviva Strategic Opportunities, LLC (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K, filed with the SEC on March 12, 2025).
- 19.1 Armata Pharmaceuticals, Inc. Amended and Restated Insider Trading Policy and Guidelines with Respect to Certain Transaction in Securities, Effective as of December 16, 2024 and as Amended Through December 16, 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).

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| 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 20, 2025

By: /s/ Deborah Birx

Name: Deborah Birx, M.D.

Title: Chief Executive Officer and Director
(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 David D. House, 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 |
|---|---|----------------|
| <u>/s/ Deborah Birx</u> Deborah Birx, M.D. | Chief Executive Officer and Director (Principal Executive Officer) | March 20, 2025 |
| <u>/s/ David D. House</u> David D. House | Senior Vice President, Finance and Principal Financial Officer | March 20, 2025 |
| <u>/s/ Jules Haimovitz</u> Jules Haimovitz | Director | March 20, 2025 |
| <u>/s/ Odysseas D. Kostas, M.D</u> Odysseas D. Kostas, M.D. | Director | March 20, 2025 |
| <u>/s/ Robin Kramer</u> Robin Kramer | Chair of the Board of Directors | March 20, 2025 |
| <u>/s/ Joseph M. Patti, Ph.D.</u> Joseph M. Patti, Ph.D. | Director | March 20, 2025 |
| <u>/s/ Todd C. Peterson, Ph.D.</u> Todd C. Peterson, Ph.D. | Director | March 20, 2025 |
| <u>/s/ Sarah J. Schlesinger, M.D.</u> Sarah J. Schlesinger, M.D. | Director | March 20, 2025 |

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