

**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, 2020**

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.)

**4503 Glencoe Avenue  
Marina del Rey, CA 90292**

(Address of principal executive offices, including zip code)

**(858) 829-0829**

(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

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.

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, 2020, the aggregate market value of voting stock held by non-affiliates of the Registrant, based on the closing price of the Common Stock on June 30, 2020 (the last business day of the Registrant's most recently completed second quarter) as quoted on the NYSE American, was approximately \$37.7 million.

As of March 17, 2021, 24,940,442 shares of the Registrant's Common Stock were outstanding.

**TABLE OF CONTENTS**  
**ARMATA PHARMACEUTICALS INC.**

	<u>Page No.</u>
<b>PART I</b>	
Item 1. Business	5
Item 1A. Risk Factors	44
Item 1B. Unresolved Staff Comments	70
Item 2. Properties	70
Item 3. Legal Proceedings	70
Item 4. Mine Safety Disclosures	70
<b>PART II</b>	
Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	70
Item 6. Selected Financial Data	72
Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations	72
Item 7A. Quantitative and Qualitative Disclosures About Market Risk	81
Item 8. Financial Statements and Supplementary Data	81
Item 9. Changes In and Disagreements With Accountants on Accounting and Financial Disclosure	108
Item 9A. Controls and Procedures	108
Item 9B. Other Information	109
<b>PART III</b>	
Item 10. Directors, Executive Officers and Corporate Governance	110
Item 11. Executive Compensation	120
Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	128
Item 13. Certain Relationships and Related Transactions and Director Independence	131
Item 14. Principal Accountant Fees and Services	135
<b>PART IV</b>	
Item 15. Exhibits and Financial Statement Schedules	136
Item 16. Form 10-K Summary	137
Signatures	141

## 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 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 (“FDA”) and other regulatory agencies;
- our ability to leverage the experience of our management team and to attract and retain management and keep management and other key personnel;
- the capacities and performance of our suppliers, manufacturers, contract research organizations (“CROs”) and other third parties over whom we have limited control;
- our ability to staff and maintain our Marina del Rey production facility under fully compliant current Good Manufacturing Practices (cGMP);
- the actions of our competitors and success of competing drugs or other therapies that are or may become available;
- our expectations with respect to future growth and investments in our infrastructure, and our ability to effectively manage any such growth;
- the size and potential growth of the markets for any of our product candidates, and our ability to capture share in or impact the size of those markets;
- the benefits of our product candidates;
- potential market growth and market and industry trends;
- maintaining collaborations with third parties including our partnership with Merck, known as MSD outside of the United States and Canada, the Cystic Fibrosis Foundation, and the U.S. Department of Defense (“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 for 2021 and 2022;
- our ability to be a leader in the development of phage-based therapeutics;
- the expected use of proceeds from the \$15 million DoD grant;
- the effects of government regulation and regulatory developments, and our ability and the ability of the third parties with whom we engage to comply with applicable regulatory requirements;
- the accuracy of our estimates regarding future expenses, revenues, capital requirements and need for additional financing;
- our expectations regarding future planned expenditures;
- our ability to achieve and maintain effective internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act;
- our ability to obtain, maintain and successfully enforce adequate patent and other intellectual property protection of any of our products and product candidates;

- our ability to protect our intellectual property, including pending and issued patents;
- our ability to operate our business without infringing the intellectual property rights of others;
- our ability to advance our clinical development programs, which could be impacted by the COVID-19 pandemic;
- the expected impact of the COVID-19 pandemic on our operations and any statements of assumptions underlying any of the items mentioned; 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.

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

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

## **PART I**

### **Item 1. BUSINESS**

#### **Overview**

We are a clinical-stage biotechnology company focused on the development of pathogen-specific bacteriophage therapeutics for the treatment of antibiotic-resistant and difficult-to-treat bacterial infections using our proprietary bacteriophage-based technology. Bacteriophages or “phages” have a powerful and highly differentiated mechanism of action that enables binding to and killing specific bacteria, in contrast to traditional broad-spectrum antibiotics. We

believe that phages represent a promising means to treat bacterial infections, especially those that have developed resistance to current standard of care therapies, including the so-called multidrug-resistant or “superbug” strains of bacteria. We are a leading developer of phage therapeutics that are uniquely positioned to address the growing worldwide threat of antibiotic-resistant bacterial infections.

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 current good manufacturing practice regulations (“cGMP”) compliant manufacturing capabilities to advance a broad pipeline of high-quality bacteriophage product candidates. We believe that synthetic phage, engineered using advances in sequencing and synthetic biology techniques, represent a promising means to advance phage therapy, including phage-based diagnostics and improving upon the ability of natural phage to treat bacterial infections, especially those that have developed resistance to current antibiotic therapies, including the multidrug-resistant or “superbug” bacterial pathogens.

We are developing and advancing our lead clinical phage candidate for *Pseudomonas aeruginosa* (“*P. aeruginosa*”), AP-PA02. On October 14, 2020, we received the approval to proceed from the FDA for our Investigational New Drug application for AP-PA02. We plan to continue to advance 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 and tolerability of inhaled AP-PA02 in subjects with cystic fibrosis (“CF”) and chronic pulmonary *P. aeruginosa* infection, provided that the impacts of COVID-19 do not impede our ability to enroll subjects in this clinical trial. This study is supported by the Cystic Fibrosis Foundation (“CFF”), which granted us a Therapeutics Development Award of up to \$5.0 million (“CFF Award”).

We are also developing a phage product candidate for *Staphylococcus aureus* (“*S. aureus*”) for the treatment of *S. aureus* bacteremia, AP-SA02. On June 15, 2020, we entered into an agreement (the “MTEC Agreement”) with the Medical Technology Enterprise Consortium (“MTEC”), pursuant to which we will receive a \$15.0 million grant and entered into a three-year program administered by the DoD through MTEC with funding from the Defense Health Agency and Joint Warfighter Medical Research Program. We expect to use the grant to partially fund a Phase 1/2, multicenter, randomized, double-blind, placebo-controlled dose escalation study that will assess the safety, tolerability, and efficacy of AP-SA02 for the treatment of adults with complicated *S. aureus* bacteremia in 2021. However, the COVID-19 outbreak may delay or prohibit the enrollment of patients in our clinical trials.

In partnership with Merck & Co., known as Merck Sharp & Dohme outside of the United States and Canada (“Merck”), we are developing proprietary synthetic phage candidates to target undisclosed infectious disease agents. Our proprietary phage engineering platform serves to enhance the clinical and commercial prospects of phage therapy. These attributes 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.

In addition to our more advanced pipeline programs, we have phage discovery efforts underway to target other major pathogens of infectious disease (including *Enterococcus faecium*, *S. aureus*, *Klebsiella pneumoniae*, *Acinetobacter baumannii*, *P. aeruginosa*, and *Enterobacter species*, or “ESKAPE pathogens”) and preventable infectious disease of the microbiome.

We are committed to conducting randomized controlled clinical trials required for FDA approval in order to move toward commercialization of alternatives to traditional antibiotics and provide a potential method of treating patients suffering from drug-resistant bacterial infections.

## **Corporate History and Reorganization**

Armata was created as a result of a business combination of AmpliPhi Biosciences Corporation, a bacteriophage development stage company (“AmpliPhi”) with C3J Therapeutics, Inc. (“C3J”), where Ceres Merger Sub, Inc., a wholly-owned subsidiary of AmpliPhi, merged with and into C3J (the “Merger”). On May 9, 2019, immediately prior to the closing of the Merger, AmpliPhi changed its name to Armata Pharmaceuticals, Inc.

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

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

### **Business Update Regarding COVID-19**

On January 30, 2020, the World Health Organization ("WHO") announced a global health emergency because of a new strain of coronavirus originating in Wuhan, China (the "COVID-19 outbreak") and the risks to the international community as the virus spreads globally beyond its point of origin. In March 2020, the WHO classified the COVID-19 outbreak as a pandemic, based on the rapid increase in exposure globally.

The COVID-19 pandemic has directly and indirectly impacted our business, results of operations and financial condition and is expected to continue to impact our business. For example, the COVID-19 pandemic has resulted in delays in our clinical trials due to the implementation of COVID-19 protocols at investigator sites, which resulted in longer than anticipated site identification and initiation activities. In addition, while we currently do not anticipate any interruptions in our supply chain, it is possible that the COVID-19 pandemic and response efforts may have a future impact on our third-party suppliers and partners. It is possible that due to the increasing emphasis on the development of vaccines for COVID-19, certain basic supply chain materials such as resins, vessels, vials and stoppers may be in high demand by the pharmaceutical companies developing vaccines and our ability to obtain these materials for our development activities could be negatively impacted. We have experienced some delays of this nature in the fourth quarter of 2020 and in early 2021.

The full extent of the COVID-19 pandemic impact will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning COVID-19, the actions taken to contain it or treat its impact, the development and distribution of vaccines and the economic impact on local, regional, national and international markets. Management continues to actively monitor the developments regarding the pandemic and the impact that the pandemic could have on our financial condition, liquidity, ability to enroll patients in our contemplated clinical trials, manufacturing and research and development operations, suppliers to our operations and suppliers to our outside clinical trial organizations, biotech industry overall, and importantly the health and safety of our workforce. Given the continuing evolution of the COVID-19 outbreak and the global responses to curb its spread, we are not able to estimate the effects of the COVID-19 outbreak on our results of operations, financial condition, or liquidity for fiscal year 2021 or 2022. Any recovery from negative impacts to our business and related economic impact due to the COVID-19 outbreak may also be slowed or reversed by a number of factors, including but not limited to multiple variants of the COVID-19 virus, a resurgence in COVID-19 infections, and the seasonal flu.

### **Recent Developments**

On January 26, 2021, we entered into a securities purchase agreement (the "2021 Securities Purchase Agreement") with Innoviva Strategic Opportunities LLC, a wholly-owned subsidiary of Innoviva, Inc. (Nasdaq: INVA) (collectively, "Innoviva"), pursuant to which we agreed to issue and sell to Innoviva, in a private placement, up to 6,153,847 newly issued shares (the "Shares") of our common stock, par value \$0.01 per share ("common stock") and warrants (the "Common Warrants") to purchase up to 6,153,847 shares of common stock, with an exercise price per share of \$3.25 (the "2021 Private Placement"). Each Share was sold together with one Common Warrant, and the per-unit purchase price is \$3.25. The 2021 Private Placement occurred in two tranches.

On January 26, 2021 and concurrently with entering into the 2021 Securities Purchase Agreement, we completed the first tranche (the “First Closing”) of the 2021 Private Placement. At the First Closing, Innoviva purchased 1,867,912 Shares and Common Warrants to purchase 1,867,912 shares of common stock, in compliance with any and all applicable laws and without the requirement for the prior receipt of the stockholders’ approval under the listing requirements of the NYSE American, for an aggregate purchase price of approximately \$6.1 million.

We received shareholder approval for the second closing (“Second Closing”) on March 16, 2021, and the Second Closing was completed on March 17, 2021, when Innoviva purchased 4,286,935 shares of Shares and Common Warrants for an aggregate purchase price of \$13.9 million.

We received aggregate gross proceeds from the 2021 Private Placement of approximately \$20.0 million, before deducting transaction expenses, and excluding proceeds (if any) received in connection with the exercise of any warrants.

As part of the First Closing, we entered into an amended and restated investor rights agreement (the “A&R IRA”), which amended and restated in its entirety that certain Investor Rights Agreement, dated February 12, 2020, with Innoviva, Inc. Pursuant to the A&R IRA, for so long as Innoviva and its affiliates hold at least 12.5% of the outstanding shares of common stock on a fully-diluted basis, Innoviva shall have the right to designate two (2) directors to our board of directors and for so long as Innoviva and its affiliates hold at least 8%, but less than 12.5%, of the outstanding shares of common stock on a fully-diluted basis, Innoviva shall have the right to designate one (1) director, subject to certain conditions and qualifications set forth in the A&R IRA. The A&R IRA also provides Innoviva with certain subscription rights in the event of any new issuances.

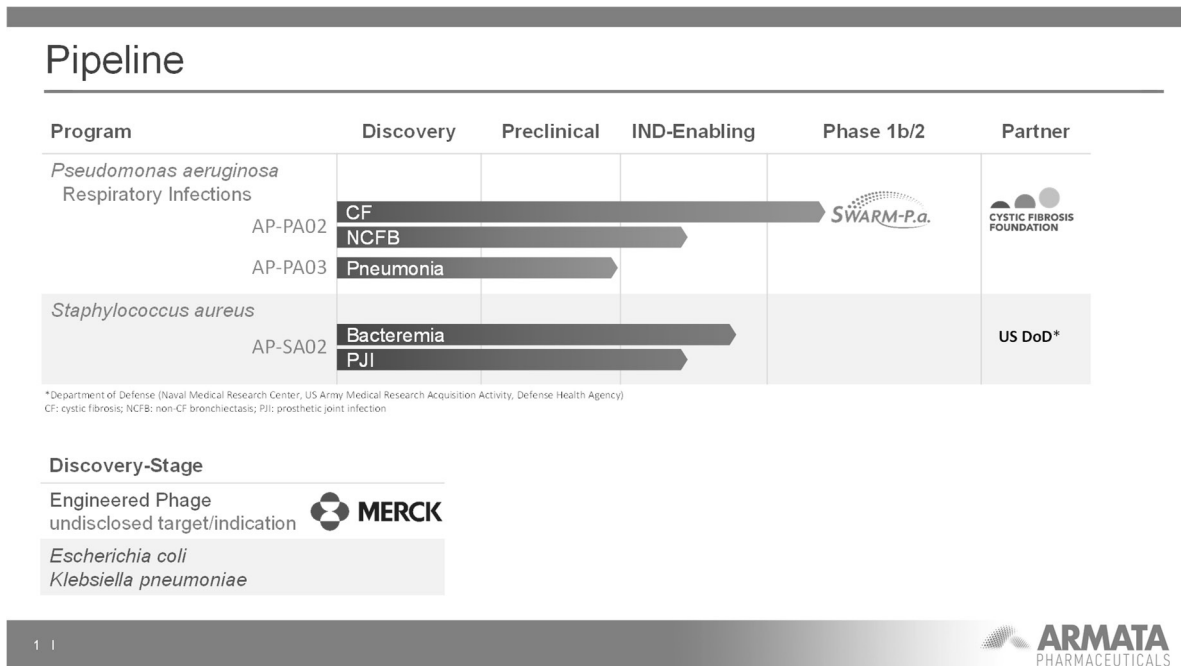
As part of the First Closing, we also entered into a registration rights agreement (the “Registration Rights Agreement”) with Innoviva. Pursuant to the Registration Rights Agreement, we must file a registration statement on Form S-1 or Form S-3 (the “Shelf Registration Statement”) covering the resale of the securities issued and sold pursuant to the 2021 Securities Purchase Agreement with the U.S. Securities and Exchange Commission (the “Commission”) on a continuous basis pursuant to Rule 415 promulgated under the Securities Act of 1933, as amended (the “Securities Act”), or if Rule 415 is not available for offers and sales of such securities, by such other means of distribution of such securities as Innoviva may reasonably specify. We must use commercially reasonable efforts to cause the Shelf Registration Statement to be declared effective under the Securities Act as promptly as possible after the filing thereof, but in any event (i) no later than the fifteenth (15th) day following the filing of the Shelf Registration Statement in the event of no “review” by the Commission, (ii) no later than the sixtieth (60th) day following the filing of the Shelf Registration Statement in the event of “limited review” by the Commission, or (iii) in the event of a “review” by the Commission, the one hundred and twentieth (120th) day following the filing of the Shelf Registration Statement, subject to certain exceptions.

We also entered into a Voting Agreement with Innoviva (the “Voting Agreement”), pursuant to which Innoviva agreed not to vote or take any action by written consent with respect to shares of common stock held by Innoviva or any of its subsidiaries which represent, in the aggregate, more than 49.5% of the total number of shares of common stock issued and outstanding as of any given record date for voting (such shares, the “Excess Shares”) on the matters related to the election of directors or removal of directors from our board of directors (“Board Matters”) presented at any meeting of the our stockholders (or any adjournment or postponement thereof) or for their action by written consent, in each case, unless the board of directors authorizes Innoviva to vote such Excess Shares with respect to Board Matters.



## Pipeline

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



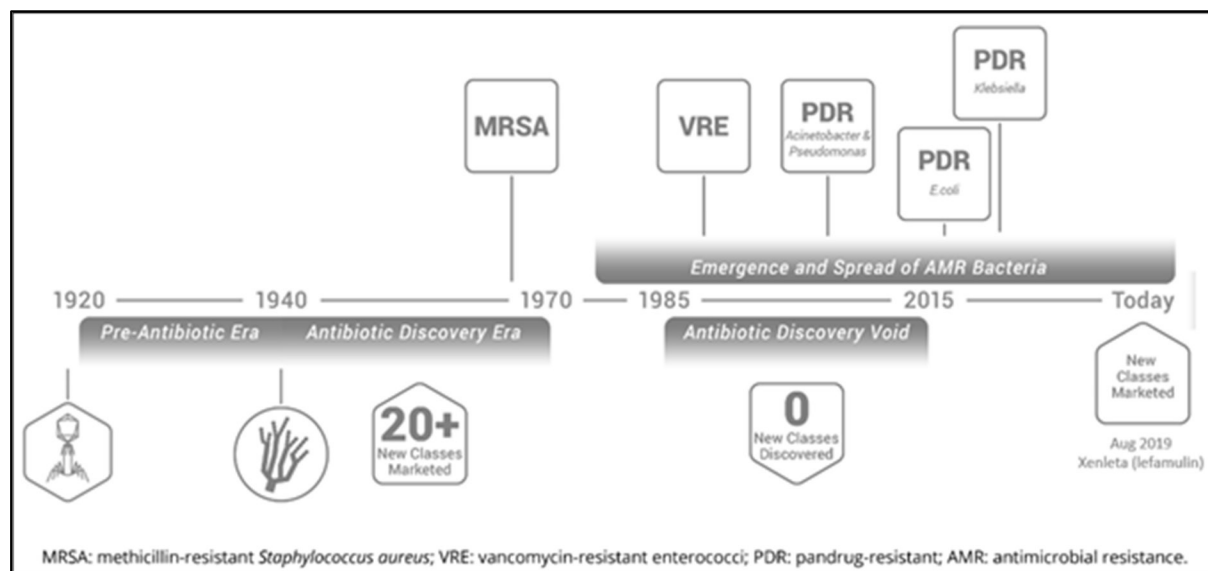
## Strategy

Our strategy is to demonstrate safety, tolerability and efficacy of multiple phage products in randomized controlled clinical trials required for FDA approval and to support commercialization in multiple 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 enables discovery of optimal product candidates, efficient process development and manufacturing, 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 chronic pulmonary *P. aeruginosa* infections.
- Develop bacteriophage therapeutics, including AP-PA02 and AP-PA03, for the treatment of other antibiotic-resistant and difficult-to-treat *P. aeruginosa* infections such as non-cystic fibrosis bronchiectasis (“NCFB”) and hospitalized pneumonia.
- Initiate and advance clinical trials of AP-SA02 in patients with complicated *S. aureus* bacteremia.
- Develop AP-SA02 for the treatment of other antibiotic-resistant and difficult-to-treat *S. aureus* infections such as periprosthetic joint infections. Because a study in PJI may use a different route of administration from the bacteremia study, it is possible, pending FDA concurrence, that we could initiate a study in this indication prior to obtaining safety data from the AP-SA02 bacteremia study.
- Advance our partnership with Merck to develop synthetic phage utilizing our phage engineering platform to improve natural phage characteristics, such as host range, biofilm disruption and antimicrobial activity.
- Develop phage-based diagnostics to drive clinical success and market adoption.

## The Need for New Anti-Infective Therapies

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



The dramatic and continuous emergence of antibiotic-resistant bacteria, and the lack of new antibiotics in the pipeline, has prompted calls to action from many of the world’s major health bodies such as The Centers for Disease Control and Prevention (the “CDC”), and 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 EMA.

The IDSA and 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 US\$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 United States alone is calculated at US\$21 billion to US\$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.

## **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. According to an April 2020 report from PEW Charitable Trusts, only 41 new antibiotics (all small molecules that act systemically) with the potential to treat serious or life-threatening bacterial infections are in global clinical development. This is compared with more than 1,100 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.

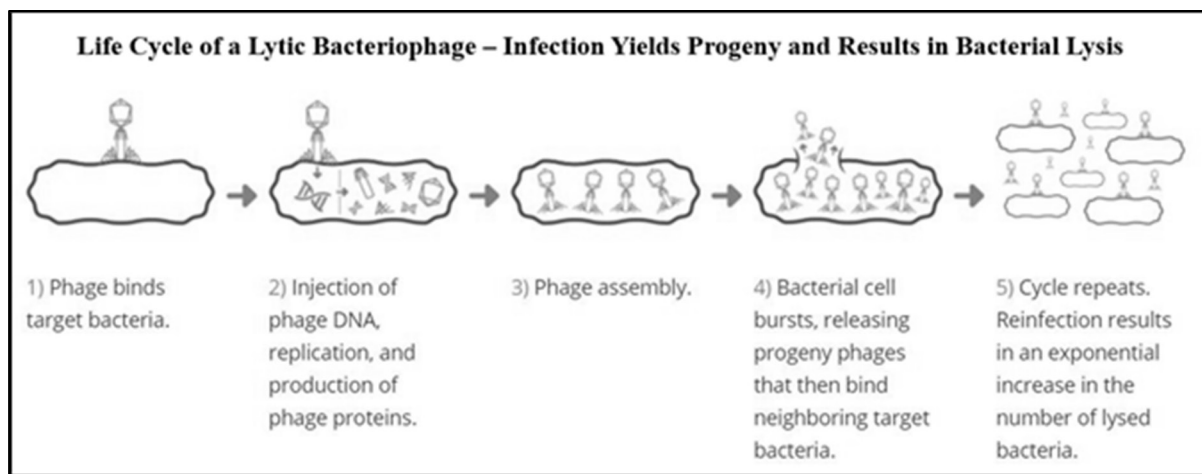
Hospital-acquired (nosocomial) infections are a major healthcare problem throughout the world, affecting developed countries as well as resource-poor countries. The WHO reports that hospital-acquired infections are among the major causes of death and increased morbidity among hospitalized patients and estimates that more than 1.4 million people per year worldwide suffer from infectious complications from a hospital stay. In 2016, the CDC reported that in the United States, approximately 4% of all patients admitted to a hospital will be affected by a hospital-acquired infection during their stay, typically requiring extended stays and additional care.

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 method of treating bacterial infection.

## **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.



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

- Highly specific/selective bactericidal agents, sparing the microbiome. Since each strain of phage generally exploits 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 beneficial bacteria through the use of antibiotics. Such risks could include serious opportunistic infections such as *Clostridium difficile* infection and vancomycin-resistant *enterococcal* (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 infectious diseases

caused by many pathogenic bacterial species. However, the safety and effectiveness of these therapies have not been conclusively established due to the lack of randomized controlled clinical studies.

Recently, Western medicine has seen a rise in the clinical evaluation of phages. In the United Kingdom, two early-stage clinical trials of *P. aeruginosa* phage cocktails showed no adverse effects in patients. One study (Phase 1/2a) demonstrated efficacy in a small trial of 12 patients with chronic multidrug-resistant *P. aeruginosa* otitis treated with a cocktail of six natural phages. Since 2016, there have been a number of Compassionate Use cases in which patients suffering from various serious or life-threatening infections have been treated with phage therapy under physician-sponsored Emergency Investigational New Drug (“Emergency IND”) 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. Phage 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 (“USDA”). 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 threat of antimicrobial resistance, we believe it is essential that phage safety and efficacy is demonstrated by conducting rigorous well-powered clinical trials required for FDA approval, in order to move toward commercialization of alternatives to traditional antibiotics and bring a potential solution to all patients suffering from drug-resistant bacterial infections.

## **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 30,000 people in the United States (70,000 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 55% of CF patients by age 25, and are strongly associated with worsening lung function, frequent pulmonary exacerbations, and increased mortality. In 2018, the median survival age was 47 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 \$400 million in 2020.

### *Non-Cystic Fibrosis Bronchiectasis*

NCFB is a chronic respiratory disease affecting more than 110,000 people in the United States and 200,000 people in Europe, characterized by recurrent respiratory infections that lead to a vicious cycle of impaired mucociliary clearance, chronic infection, bronchial inflammation, and progressive lung function loss. *P. aeruginosa* is the most prevalent pathogen responsible for these recurrent infections. It is found in approximately 30% of cases and is associated with enhanced disease progression, including poorer lung function and lower quality of life, more frequent exacerbations, 7-fold increase in hospitalizations, and 3-fold increase in death. NCFB patients frequently become chronically colonized with multidrug-resistant strains of *P. aeruginosa* because of the need for repeated courses of antibiotic treatment. There are currently no approved antibiotics to manage chronic *P. aeruginosa* infection in NCFB patients.

### *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 hospitalization 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 (excess of \$40,000 per patient), and accounts for around 50% of all intensive care unit antibiotics.

### *Staphylococcus aureus Infections*

#### *Bacteremia*

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

## Prosthetic Joint Infection

The total number of prosthetic joint infection (“PJI”)-related revision surgeries is expected to more than double from 70,000 in 2020 to 144,000 in 2040 in the United States and European Union Five (France, Germany, Italy, Spain, 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 (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 phage were administered by intravenous or intraarticular routes and shown to be generally well tolerated.

## Platform Technologies

### Proprietary 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 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, with the potential to create supercharged synthetic phages that, once marketing authorization is obtained, can be deployed in the clinic as highly effective weapons in the fight against multidrug-resistant bacterial infections. Engineering natural phages may broaden their host range, minimize resistance and improve efficacy through the expression of beneficial moieties such as biofilm-degrading enzymes and antimicrobial peptides.



#### *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:*

In partnership with Synthetic Genomics, we employ next-generation sequencing and a proprietary sequencing database and software for the analyses of our phages.



#### *Engineering Phage to Confer Desirable Properties:*

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



#### *Formulation Development and Chemistry, Manufacturing, and Controls (CMC):*

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 and testing and release of clinical trial material.

## Preclinical and Clinical Development Programs

### Overview

We are committed to developing novel phage therapies, with drug development expertise and product development capabilities that span bench to clinic, including in-house phage-specific cGMP manufacturing. Our phage discovery

platform in which we screen panels of clinically-relevant isolates against our extensive phage library utilizing proprietary methods that identify phage combinations with superior attributes, together with our phage-specific cGMP compliant manufacturing facilities, uniquely enables us to efficiently identify optimal product candidates. Our microbiological surveillance and synthetic biology capabilities drive long-term product life cycle management.

Our therapeutic phage candidates aim to address areas of significant unmet medical need, by targeting key drug-resistant bacteria, including those on the World Health Organization's global priority pathogens list, and the priority pathogens list issued by the Centers for Disease Control and Prevention. 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 pneumonias in hospitalized patients; *S. aureus*, with its heteroresistant and methicillin-resistant *S. aureus* (MRSA) strains, has been implicated in systemic (e.g., bacteremia) as well as prosthetic-related 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.

We believe our cGMP-facility has the capacity to produce our proprietary bacteriophage therapeutics for our clinical trials through a potential biologics license application filing and potential approval.

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

#### *Historical Background*

AP-PA02 is being developed as a replacement for its predecessor 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-SA01 through any expanded access program.

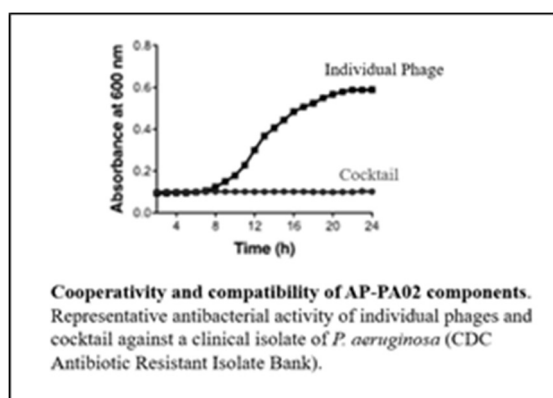
In August 2018, we held a Type B pre-IND meeting with the U.S. FDA regarding a proposed Phase 1/2 clinical study of AP-PA01 for the treatment of *P. aeruginosa* respiratory infections (ventilated-associated pneumonia). Feedback from the FDA in September 2018 included: agreement on product specifications, 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 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 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. A series of selection criteria and different methods were deployed, including bioinformatics and comparative genomics, in order to identify optimal attributes for a product candidate. We have engaged in preclinical studies to determine pharmacological and toxicological parameters to confirm therapeutic potential in the clinic. 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 natural *P. aeruginosa* phages originating from distinct families and subfamilies, targeting multiple receptor classes, functioning with compatibility (i.e., the phages don't interfere with one another) and cooperativity (i.e., the phages work together for a better outcome), and further characterized by being highly potent and having a broad host range and overlap. AP-PA02 demonstrates broad coverage against approximately 90% of tested clinical isolates.



Preclinical highlights of AP-PA02 include:

- Significantly reduced *P. aeruginosa* biofilm mass *in vitro* within 4 hours of a low-dose application;
- Persisted in the lung after intranasal instillation;
- Systemic exposure after intranasal instillation is limited;
- 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 and intravenous administration. Clinical trial material of AP-PA02 is manufactured under cGMP at our production facility in Marina del Rey, California, to support the required regulatory filing(s) for clinical entry in the United States. Potency of drug substance currently supports doses up to approximately  $1 \times 10^{11}$  PFU (plaque forming units) per mL, and endotoxin levels are well within specifications for an intravenous product.

## *Clinical Development of AP-PA02 in Cystic Fibrosis*

AP-PA02 product candidate is currently in clinical development. On October 14, 2020, Armata received approval for the study to proceed from the FDA for its Investigational New Drug (“IND”) to initiate the “SWARM-*P.a.*” study – a Phase 1b/2a, multi-center, double-blind, randomized, placebo-controlled, single ascending dose (“SAD”) and multiple ascending dose (“MAD”) clinical trial to evaluate the safety and tolerability of inhaled AP-PA02 in subjects with CF and chronic pulmonary *P. aeruginosa* infection. Primary Endpoints (SAD and MAD) will include incidence and severity of treatment-emergent, adverse events. Secondary Endpoints (MAD) will include changes in *P. aeruginosa* colony-forming units (CFU). We will look at clinical parameters as a part of exploratory endpoints for the SAD and MAD cohorts. The study is designed to include a total of approximately 48 subjects in multiple U.S.-based sites. We anticipate generating topline data from the MAD portion of the study in 2022.

The SWARM-*P.a.* study is supported by the CFF, which in March 2020 granted us a Therapeutics Development Award of up to \$5.0 million.

With positive outcomes from this first study, SWARM-*P.a.*, we plan to initiate follow-on studies that will investigate the efficacy of AP-PA02 in chronically-infected patients and patients with primary/early intermittent infections. Our ultimate goal is to bring AP-PA02 to the CF community at large as a new FDA-approved novel therapy to treat airway *P. aeruginosa* infections and improve the long-term health of people with CF.

### *Exploring Additional Clinical Indications for Our P. aeruginosa Phage Product Candidates*

In addition to pursuing lung infections in CF patients, we have begun charting the appropriate clinical and regulatory paths for other respiratory infections with high unmet clinical need, such as in NCFB patients as well as acute pneumonias in hospitalized patients.

We intend to optimize *P. aeruginosa* phage product candidates for the treatment of each of these indications. Our clinical candidate for pneumonia, AP-PA03, took advantage of our collection of relevant *P. aeruginosa* clinical isolates and our expanded phage library. AP-PA03 is comprised of a cocktail of natural *P. aeruginosa* phages originating from distinct genera, targeting multiple receptor classes, functioning with compatibility and cooperativity, and further characterized by being highly potent and having a broad host coverage against approximately 90% of tested clinical isolates. We expect AP-PA03 to enter process development in the first half of 2021. We do not anticipate clinical development of AP-PA02 for NCFB until such time that we can evaluate the results of the CF SWARM-*P.a.* study.

We plan to obtain regulatory approval to initiate clinical studies for NCFB and/or for pneumonia in 2021 or 2022.

## ***Staphylococcus aureus Phage Product Candidate, AP-SA02***

### *Historical Background*

AP-SA02 is being developed as a more advanced version of its predicate 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).

- More recently, 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 comprising natural lytic phages that target the problematic pathogen, *S. aureus*.

Preclinical highlights of AP-SA02 include:

- Coverage of more than 90% of clinical isolates tested, including against drug-resistant isolates (MRSA: methicillin-resistant *S. aureus* and VRSA: vancomycin-resistant *S. aureus*);
- Efficiency of plating and plaque morphology reflect strongly potent component phages. Potency further demonstrated by the failure of attempts to obtain phage-resistant bacteria;
- Component phages are stable and retain infectivity after exposure to relevant biological fluids (blood and plasma);
- Penetrates pre-existing biofilms;
- Additive, indifferent, or synergistic effects in combination with vancomycin; no antagonistic effects noted; and
- Maintains activity in the presence of current standard-of-care anti-staphylococcal antibiotics.

We have developed AP-SA02 as a sterile solution, suitable for delivery by intravenous administration. Feasibility batches of AP-SA02 have been completed meeting all intended specifications. Verification batches are advancing with quality control data expected to support regulatory filings. Potency of drug substance supports doses up to at least  $1 \times 10^9$  PFU (plaque forming units) per phage, and endotoxin levels are well within specifications for an intravenous product. Clinical trial material of AP-SA02 will be manufactured under cGMP at our production facility in Marina del Rey, California, to support the required regulatory filing(s) for clinical entry in the United States and ex-U.S.

#### *Clinical Development of AP-SA02 in Bacteremia*

We plan to file an IND application with the FDA in 2021, and, upon regulatory clearance, initiate a first-in-man Phase 1b/2a, multicenter, 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 complicated bacteremia due to *S. 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. We anticipate conducting the study at sites in the United States and also at sites abroad.

The Phase 1b/2a study will be partially funded by a \$15.0 million award from the DoD through the Medical Technology Enterprise Consortium (“MTEC”) with funding from the Defense Health Agency and Joint Warfighter Medical Research Program.

Data from this Phase 1b/2a study will be invaluable for a follow-on trial that will be designed to demonstrate of efficacy of AP-SA02 in treating *S. aureus* bacteremia. We anticipate findings from this 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.

#### *Additional Clinical Indications for AP-SA02*

Improved patient outcomes are needed for other *Staphylococcal* infections, in settings such as prosthetic joint infection (“PJI”), for which antimicrobial resistance is a growing concern. We believe AP-SA02 could also have a meaningful impact in this indication, particularly PJIs caused by methicillin-resistant *S. aureus* (“MRSA”).

#### ***Merck Partnered Program***

Proprietary synthetic phage candidates designed to target an undisclosed infectious disease agent are being developed in partnership with Merck, a collaboration that reflects the pharmaceutical industry’s growing interest in phage therapy. Pursuant to the terms of the Amended and Restated Research Collaboration and Option to License Agreement between Armata and Merck (the “Research and Option Agreement”) we are engaged in the research and development of engineered phage, or a combination of two or more engineered phages, that infect specific bacteria, pursuant to the criteria set forth in the research plan. We intend for the phage to be engineered for a wide host range, and to express anti-biofilm and antimicrobial payloads. We will be entitled to milestone payments tied to the achievement of product development and regulatory milestones, and royalty payments based on net sales of products developed pursuant to the Research and Option Agreement. We are responsible for our costs and expenses in connection with the research program. Unless the Research and Option Agreement is terminated by Merck, it will continue in full force and effect until one or more products developed thereunder has received marketing authorization and, thereafter, until expiration of all royalty obligations thereunder. Upon expiration of the Research and Option Agreement, Merck’s licenses pursuant to the Research and Option Agreement will become fully paid-up, perpetual licenses. An amendment to the Research and Option Agreement with a revised research plan was agreed to by the parties in December 2019.

#### ***Engineered Phage-Based Diagnostic***

We are developing a diagnostic test that, once fully developed, will help us to rapidly and accurately identify patients for future clinical trials and we believe will be useful in the commercialization of our phage product candidates. These tests are designed to drive early use of our therapeutic phage in a treatment paradigm by identifying patients who are most likely to benefit. For example, those patients who are infected with a bacterial isolate that is sensitive to our particular therapeutic phage, and to monitor response to treatment with our particular therapeutic phage. The test is designed to be highly sensitive and to identify colonized patients even before a diagnosis of infection has been given by the treating physician.

#### ***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. An outbreak of ventilator-associated pneumonia caused by a new emerging hypervirulent *K. pneumoniae* strain led to the death of five patients in the intensive care unit of a hospital in China (Lancet Infect. Dis.; Volume 18:1, Jan 2018).

Furthermore, our team of microbiologists and synthetic biologists hunt for natural phages and evaluate the suitability of these phages for engineering using our proprietary synthetic phage platform. We continue to make advancements in the engineering of super fit phage, incorporating the best attributes from a phage family to expand host range and increase burst size, and improving bactericidal and biofilm activity through the expression of heterologous proteins.

## **Manufacturing**

We produce clinical quantities of each of our bacteriophage product candidates at our cGMP-compliant manufacturing facility in Marina del Rey, California. This facility, which serves as our headquarters, has approximately 35,500 square feet of laboratory and office space, including 5,600 square feet of cGMP laboratory space, designed to produce clinical quantities of each of our product candidates and to perform in-house Quality Control testing. We operate in-house process development activities through to production, purification, formulation, and release of our therapeutic phage cocktails for use in human clinical trials. Our facility is licensed by the California Department of Public Health (“CDPH”) for drug manufacturing, and is subject to periodic, unannounced inspections for compliance with cGMP and other state and federal laws and regulations. The facility is subject to periodic inspections by the City of Los Angeles and Los Angeles County for fire hazard and waste management and is in compliance with all applicable regulations. Our facility is staffed with an independent Quality Unit and Manufacturing and Facilities personnel trained under cGMPs. We believe this facility will be sufficient to meet our manufacturing needs through our Phase 3 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 Marina del Rey facility is capable of manufacturing sterile drug products, utilizing ISO-certified cleanrooms and ISO 5-certified biological safety cabinets. The facility also houses an ISO 5-certified closed system isolator. We may further optimize future formulations of our product candidates which may or may not require assurance of sterility.

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

Although our facility is capable of manufacturing our phage product candidates, we rely on, and may continue to rely on, third-party contract manufacturers for the manufacture of certain raw materials, components, or packaging of the product candidates that may be developed for clinical testing, as well as for commercialization.

## **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 (“U.S. PTO”) to determine priority of invention.

### ***Bacteriophage Patent Portfolio***

As of January 14, 2021, we owned or had exclusive license rights to a total of 121 patents and applications: 11 U.S. patents, 7 U.S. non-provisional patent applications, 2 U.S. provisional applications, 62 foreign patents, and 39 foreign patent applications, with nominal expiration on various dates between 2024 and 2041. 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, bacteriophage combinations, the sequential use of bacteriophages in combination with conventional antibiotics, genetic sequence variations, methods to reduce antibiotic resistance, methods to design therapeutic combination panels of bacteriophage, disinfection methods using bacteriophages, and bacteriophage mutants having increased bacterial host spectra.

### **Competition**

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

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

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

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

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

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

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

## **Sales and Marketing**

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

We have not yet established a sales, marketing or product distribution infrastructure because our lead candidates are still in early clinical development. Subject to receiving marketing approvals, or earlier we intend to either partner the commercial rights to our products with existing companies that have the wherewithal and resources to commercialize explore 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**

### ***License Agreements***

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

Pursuant to the terms of the Research and Option Agreement, we are engaged in generating broad host range synthetic bacteriophage candidate(s) targeting an undisclosed infectious disease agent(s), pursuant to the criteria set forth in the research plan.

We granted to Merck an exclusive, worldwide license in our patent rights, and our interest in any joint patent rights, with the right to grant and authorize sublicenses, for any and all uses of any product candidates, or products, developed through the research plans set forth in the Research and Option Agreement in a specific field of use. Further, we granted

to Merck an exclusive, worldwide license, with the right to grant and authorize sublicenses, in our background intellectual property and know-how, solely to make, have made, use, import, offer to sell and sell (but not genetically modify) the product candidates, or products, developed through the research plans set forth in the Research and Option Agreement in the specific field of use.

We will be entitled to milestone payments tied to the achievement of product development and regulatory milestones, and royalty payments based on net sales of products developed pursuant to the Research and Option Agreement.

Each party to the Research and Option Agreement is responsible for its costs and expenses in connection with the research program. Unless the Research and Option Agreement is terminated by Merck, it will continue in full force and effect until one or more products developed thereunder has received marketing authorization and, thereafter, until expiration of all royalty obligations thereunder. Upon termination of the Research and Option Agreement, Merck's licenses pursuant to the Research and Option Agreement will become fully paid-up, perpetual licenses.

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

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

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

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

#### ***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 will receive a \$15.0 million grant and entered into a three-year program administered by the DoD through MTEC with funding from the Defense Health Agency and Joint Warfighter Medical Research Program. We plan to use the grant to partially fund a Phase 1b/2, randomized, double-blind, placebo-controlled, dose escalation clinical study of Armata's therapeutic phage-based candidate, AP-SA02, for the treatment of complicated *S. aureus* bacteremia infections. The MTEC Agreement specifies that the grant will be paid to us through a cost reimbursable model, based on agreed upon cost share percentages, and the grant money received is not refundable to MTEC.

Upon license or commercialization of intellectual property developed with the funding from the MTEC Agreement, additional fees will be due to MTEC. We 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 will be effective through January 25, 2024. The MTEC Agreement may be terminated in whole or in part, 30 calendar days following the written notice from either party. In addition, MTEC has the right to terminate the MTEC Agreement upon material breach by Armata.

#### *CFF Therapeutics Development Award*

On March 13, 2020, we entered into an award agreement (the “Agreement”) with CFF, pursuant to which we received a Therapeutics Development Award of up to \$5.0 million (the “Award”). The Award will be used to fund a portion of our Phase 1b/2 clinical trial of the *P. aeruginosa* phage candidate, AP-PA02, as a treatment for *P. aeruginosa* airway infections in people with CF.

The first payment under the Agreement, in the amount of \$1.0 million, became due upon signing the Agreement and was received in April 2020. The remainder of the Award will be paid to us incrementally in installments upon the achievement of certain milestones related to the development program and progress of the Phase 1b/2 clinical trial of AP-PA02, as set forth in the Agreement.

If we cease to use commercially reasonable efforts directed to the development of AP-PA02, or any other Product (as defined in the 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 we must either repay the amount of the Award actually received by the Company, plus interest, or grant to CFF (1) an exclusive (even as to Armata), worldwide, perpetual, sublicensable license under technology developed under the 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 our commercialization of any Product, we 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. We will be obligated to make an additional fixed royalty payment upon achieving specified sales milestones. We may also be obligated to make a payment to CFF if we transfer, sell or license the Product in the CF Field, or if we enter into a change of control transaction.

The term of the Agreement commenced on March 10, 2020 and expires on the earlier of the date on which we have 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 Agreement. Either CFF or Armata may terminate the agreement for cause, which includes our material failure to achieve certain development milestones. Our payment obligations survive the termination of the Agreement.

#### **Facilities**

Our corporate headquarters are located in Marina del Rey, California, where we currently lease 35,500 square feet of laboratory and office space. The lease expires on December 31, 2031. The facility includes 19,500 square feet of BSL2 laboratory space dedicated to phage product development. The facility includes approximately 3,000 square feet of cGMP laboratory space, designed to produce clinical quantities of our phage product candidates for human trials and to perform in-house Quality Control (“QC”) testing. The manufacturing space consists of two ISO-certified cleanrooms capable of production, purification, drug product formulation and aseptic filling of drug product. The QC laboratory contains qualified analytical instruments to support the testing and release of clinical trial material. The facility is licensed by the California Department of Public Health (“CDPH”) for drug manufacturing, and is subject to periodic, unannounced inspections for compliance with cGMP and other state and federal laws and regulations. Armata’s 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.

In addition, we lease a 5,000 square foot facility located in Sydney, Australia. The 4,000 square feet of laboratory space provides capabilities to support phage product development and manufacturing process development. The facility is also set up to provide microbiological support of clinical trials.

We occupy approximately 1,000 square feet of leased office space pursuant to a month-to-month sublease, located at 3579 Valley Centre Drive, Suite 100, San Diego, California 92130.

We believe that our facilities are adequate for our current and near-term needs.

## **Legal Proceedings**

In addition, 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 ("PREA"), 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 "GAIN Act"). The FDA will determine that a product will fill an unmet medical need if it will provide a therapy where none exists or provide a therapy that may be potentially superior to existing therapies based on efficacy or safety factors. We intend to request Fast Track designation for our product candidates if applicable.

Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a new drug or biological may request the FDA to designate the drug or biologic as a Fast Track product at any time during the clinical development of the product. Unique to a Fast Track product, the FDA may consider for review sections of the marketing application on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the application, the FDA agrees to accept sections of the application and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application.

Any product submitted to the FDA for marketing, including under a Fast Track program, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review, accelerated approval, and, as of 2018, for antibacterial and antifungal therapies, approval under the Limited Population Pathway. Any product is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or if there is a significant improvement in the treatment, diagnosis or prevention of a disease compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug or biological product designated for priority review in an effort to facilitate the review. Additionally, a product may be eligible for accelerated approval. Drug or biological products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval, which means that they may be approved on the basis of adequate and well-controlled clinical trials establishing that the product has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity or mortality, 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 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 U.S. PTO. 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 U.S. PTO, 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 (“PMA”) 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;
- 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, and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services

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

- the federal transparency requirements under the Affordable Care Act, including the provision commonly referred to as the Physician Payments Sunshine Act, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually to the U.S. Department of Health and Human Services information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members;
- federal government price reporting laws, which require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs; and
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

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

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

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

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

If any of the physicians or other healthcare providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs, which may also adversely affect our business.

#### *Additional Regulation*

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

#### *U.S. Foreign Corrupt Practices Act*

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

#### *U.S. Healthcare Reform*

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

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

The Tax Cuts and Jobs Act of 2017 ("TCJA"), includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." Additionally, on January 22,

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

In addition, the Budget Control Act of 2011 and the Bipartisan Budget Act of 2015 led to aggregate reductions of Medicare payments to providers of up to 2% per fiscal year that will remain in effect through 2027 unless additional Congressional action is taken. Further, on January 2, 2013, the American Taxpayer Relief Act was signed into law, which, among other things, reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. More recently, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which have resulted in several recent Congressional inquiries and proposed bills designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for pharmaceutical products. Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

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

#### *Government Regulation Outside of the United States*

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

#### *Clinical Trials*

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

## *Approval Process*

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

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

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

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

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

Marketing authorization is valid for five years in principle and the marketing authorization may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or the competent authority of the authorizing member state. To this end, the marketing authorization holder must provide the EMA or the competent authority with a consolidated version of the file in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least six months before the marketing authorization ceases to be valid. Once renewed, the marketing authorization is valid for an unlimited period, unless the European

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

### *Orphan Designation*

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

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

In the European Union, orphan drug designation entitles the sponsor to financial incentives such as reduction of fees or fee waivers and to ten years of market exclusivity granted following medicinal product approval. Market exclusivity precludes the EMA or a national regulatory authority from validating another MAA, and the European Commission or a national regulatory authority from granting another marketing authorization, for a same or similar medicinal product and a same therapeutic indication, for that time period. This 10-year period may be reduced to six years if the orphan drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity. The orphan exclusivity may be lost vis-à-vis another medicinal product in cases the manufacturer is unable to assure sufficient quantity of the medicinal product to meet patient needs or if that other product is proved to be clinically superior to the approved orphan product. A drug is clinically superior if it is safer, more effective or makes a major contribution to patient care. Orphan drug designation must be requested before submitting a MAA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process, and it does not afford any regulatory exclusivity until a marketing authorization is granted.

### *Expedited Development and Approval*

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

- the accelerated approval: the EMA may reduce the maximum timeframe for the evaluation of an MAA from 210 days to 150 days when the future medicinal product is of major interest from the point of view of public health, in particular from the viewpoint of therapeutic innovation; and
- the conditional marketing authorization: as part of its marketing authorization process, the European Commission may grant marketing authorizations on the basis of less complete data than is normally required.

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

- the risk/benefit balance of the medicinal product is positive;

- it is likely that the applicant will be in a position to provide the comprehensive clinical data;
- unmet medical needs will be addressed; and
- the benefit to public health of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent in the fact that additional data is still required.

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

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

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

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

### *Pediatrics*

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

The pediatric data are generated through the implementation of a pediatric investigation plan (“PIP”) that is proposed by the company after completion of the PK studies in adults and agreed upon by the EMA, typically after some modifications. The PIP lists all the studies to conduct and measures to take in order to prove the safety and efficacy of the future medicinal product when used in children. The EMA may agree to modify the PIP at the company’s request. The scope of the PIP is the adult therapeutic indication or the condition of which the adult application is part or even the



mechanism of action of the active substance, at the EMA's quasi-discretion. This very broad discretion enables the EMA to require companies to develop children indications that are different from the adult indications.

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

#### *Post-Marketing Requirements*

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

#### *Supplementary Protection Certificate and Regulatory Exclusivities*

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

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

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

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

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

A medicinal product that contains a new active substance (reference medicinal product) is granted eight years of data exclusivity followed by two years of market protection. Data exclusivity prevents other companies from referring to the non-clinical and clinical data in marketing authorization dossier of the reference medicinal product for submission of generic MAA purposes, and market protection prevents other companies from placing generics on the market. Pursuant to the concept of global marketing authorization, any further development of that medicinal product (e.g., new indication, new form, change to the active substance) by the marketing authorization holder does not trigger any new or

additional protection. The authorization of any new development is considered as “falling” into the initial marketing authorization with regard to regulatory protection; hence, the new development only benefits from the regulatory protection that remains when it is authorized. The only exception is a new therapeutic indication that is considered as bringing a significant clinical benefit in comparison to the existing therapies. Such new indication will add one-year of market protection to the global marketing authorization, provided that it is authorized within the first eight years of authorization (i.e., during the data exclusivity period). Moreover, a new therapeutic indication of a “well-established substance” benefits from one-year data exclusivity but limited to the non-clinical and clinical data supporting the new indication. Any active substance approved for at least ten years in the EEA qualifies as well-established substance.

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

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

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

#### *Other Healthcare Laws and Compliance Requirements Outside of the United States*

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

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

#### ***Pricing and Reimbursement***

Although none of our product candidates has been commercialized for any indication, if they are approved for marketing, commercial success of our product candidates will depend, in part, upon the availability of third-party reimbursement from payors at the federal, state and private levels. Third-party payors include government healthcare

programs, such as Medicare and Medicaid, private health insurers and managed-care plans. We anticipate third-party payors will provide reimbursement for our products. However, these third-party payors are increasingly challenging the price and examining the cost effectiveness of medical products and services. In addition, significant uncertainty exists as to the reimbursement status of newly approved healthcare products. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost effectiveness of our products. Our product candidates may not be considered cost effective. It is time consuming and expensive for us to seek reimbursement from third-party payors. Reimbursement may not be available or sufficient to allow us to sell our products on a competitive and profitable basis.

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

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

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

### **Employees and Human Capital**

As of March 1, 2021, we had 59 full-time employees and three part-time employees. Of the 59 full-time employees, 52 were engaged in research and development activities and seven 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.

### ***Diversity and Inclusion***

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

### ***Workforce Health and Safety***

In response to the COVID-19 pandemic in 2020, we instituted a remote work protocol to help ensure the safety of our employees, our community, and to adhere to federal, state, and local requirements and the CDC recommendations of social distancing and limited public exposure in connection with the COVID-19 pandemic. We did not implement any furlough, layoff, or salary reductions during this time. We continue to evaluate our ability to operate in light of recent resurgences of COVID-19 and the advisability of continuing operations based on federal, state and local guidance, evolving data concerning the pandemic and the best interests of our employees, third parties with whom we collaborate, and our stockholders.

### ***Compensation and Benefits***

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.

## **Corporate History and Reorganization**

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

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

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

## **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. If any of the following risks actually occur, our business, financial condition, results of operations, and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock would likely decline. In addition, the global economic climate and effects of the COVID-19 pandemic may amplify many of the risks described below or their impact on us.*

### **Summary of Risk Factors**

Our ability to execute on our business strategy is subject to a number of risks, which are discussed more fully below in this section. You should carefully consider these risks before making an investment in our common stock. These risks include, among others, the following:

- Public health crises such as pandemics or similar outbreaks could materially and adversely affect our preclinical and clinical trials, business, financial condition and results of operations;
- 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 to raise additional capital to support our operations;
- 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;
- We have never generated any revenue from product sales and may never be profitable,
- Maintaining and improving our financial controls and the requirements of being a public company may strain our resources, divert management's attention and affect our ability to attract and retain qualified board members;

- If we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate financial statements on a timely basis could be impaired and our public reporting may be unreliable;
- 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 may not be entitled to forgiveness of our recently received Paycheck Protection Program Loan, and our application for the Paycheck Protection Program Loan could in the future be determined to have been impermissible or could result in damage to our reputation;
- If we are unable to obtain FDA approval of our products, we will not be able to commercialize our products in the United States;
- Results from preclinical studies and Phase 1 or 2 clinical trials of our product candidates or from single-patient expanded access treatments may not be predictive of the results of later stage clinical trials;
- We 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;
- 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;
- We have not completed formulation development of our product candidates;
- Our product candidates must undergo rigorous clinical testing, such clinical testing may fail to demonstrate safety and efficacy and any of our product candidates could cause undesirable side effects, which would substantially delay or prevent regulatory approval or commercialization;
- 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 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 are subject to significant regulatory approval requirements, which could delay, prevent or limit our ability to market our product candidates;
- Failure to comply with health and data protection laws and regulations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity and could negatively affect our operating results and business;
- A variety of risks associated with our international operations could materially adversely affect our business;
- We depend upon key personnel who may terminate their employment with us at any time and we may need to hire additional qualified personnel in order to obtain financing, pursue collaborations or develop and market our product candidates;
- We must manage a geographically dispersed organization;
- We rely on third parties to conduct our clinical trials, and their failure to perform their obligations in a timely or competent manner may delay development and commercialization of our product candidates;
- We are dependent on patents, trade secrets and other forms of non-patent intellectual property protection. If we fail to adequately protect this intellectual property or if we otherwise do not have exclusivity for the marketing of our products, our ability to commercialize products could suffer;

- If we are sued for infringing intellectual property rights of third parties or if we are forced to engage in an interference proceeding, it will be costly and time-consuming, and an unfavorable outcome in that litigation or interference would have a material adverse effect on our business;
- If our competitors are able to develop and market products that are more effective, safer or more affordable than ours, or obtain marketing approval before we do, our commercial opportunities may be limited;
- There is a substantial risk of product liability claims in our business. If we do not obtain sufficient liability insurance, a product liability claim could result in substantial liabilities;
- 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;
- The uncertainty associated with pharmaceutical reimbursement and related matters may adversely affect our business;
- Innoviva may exert a substantial influence on actions requiring stockholder vote, potentially in a manner that you do not support;
- The price of our common stock has been and may continue to be volatile; and
- We have never paid dividends on our common stock, and we do not anticipate paying any cash dividends on our common stock in the foreseeable future.

#### **Risks Related to Our Financial Condition and Need for Additional Capital**

***Public health crises such as pandemics or similar outbreaks could materially and adversely affect our preclinical and clinical trials, business, financial condition and results of operations.***

In March 2020, the World Health Organization declared COVID-19 a global pandemic and the United States declared a national emergency with respect to COVID-19. In response to the COVID-19 pandemic, “shelter in place” orders and other public health guidance measures have been implemented across much of the United States and Europe, including in the locations of our principal place of business, clinical trial sites, and locations of our key vendors and partners. Our clinical development program and preclinical study timelines have been and may continue to be negatively affected by COVID-19, which could materially and adversely affect our business, financial condition and results of operations. For example, the COVID-19 pandemic has resulted in delays in our clinical trial due to the implementation of COVID-19 protocols resulted in longer than anticipated initiation activities at clinical sites. In addition, while we currently do not anticipate any interruptions in our supply chain, it is possible that the COVID-19 pandemic and response efforts may have an impact in the future on our and/or our third-party suppliers and partners. It is possible that due to the increasing emphasis on the development of vaccines for COVID-19, certain basic supply chain materials such as resins, vessels, vials and stoppers may be in high demand by the pharmaceutical companies developing vaccines and our ability to obtain these materials for our development activities could be negatively impacted. We have experienced some delays of this nature in recent months

Further, due to “shelter in place” orders and other public health guidance measures, we have implemented a remote working policy. Our increased reliance on personnel working from home may negatively impact productivity, or disrupt, delay or otherwise adversely impact our business. For example, with our personnel working from home, some of our research activities that require our personnel to be in our laboratories may be delayed.

As a result of the COVID-19 pandemic, or similar pandemics, and related “shelter in place” orders and other public health guidance measures, we have and may in the future experience disruptions that could materially and adversely impact our clinical trials, business, financial condition and results of operations. Potential disruptions include but are not limited to:

- delays or difficulties in enrolling patients in our clinical trials;

- delays or difficulties in initiating or expanding clinical trials, including delays or difficulties with clinical site initiation and recruiting clinical site investigators and clinical site staff;
- increased rates of patients withdrawing from our clinical trials following enrollment as a result of contracting COVID-19 or other health conditions or being forced to quarantine;
- interruption of key clinical trial activities, such as clinical trial site data monitoring and efficacy, safety and translational data collection, processing and analyses, due to limitations on travel imposed or recommended by federal, state or local governments, employers and others or interruption of clinical trial subject visits, which may impact the collection and integrity of subject data and clinical study endpoints;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- delays or disruptions in preclinical experiments and IND-enabling studies due to restrictions of on-site staff and unforeseen circumstances at contract research organizations, or CROs, and vendors;
- interruption or delays in the operations of the FDA and comparable foreign regulatory agencies;
- interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems;
- delays in receiving approval from local regulatory authorities to initiate our planned clinical trials;
- limitations on employee or other resources that would otherwise be focused on the conduct of our clinical trials and pre-clinical work, including because of sickness of employees or their families, the desire of employees to avoid travel or contact with large groups of people, an increased reliance on working from home, school closures or mass transit disruptions;
- changes in regulations as part of a response to the COVID-19 pandemic which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- delays in necessary interactions with regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government or contractor personnel; and
- refusal of the FDA to accept data from clinical trials in affected geographies outside the United States.

These and other factors arising from the COVID-19 global pandemic could worsen in countries that are already afflicted with COVID-19, could continue to spread to additional countries or could return to countries where the pandemic has been partially contained, such as the current resurgence of cases in the United States, each of which could further adversely impact our ability to conduct clinical trials and our business generally, and could materially and adversely affect our business, financial condition and results of operations.

The COVID-19 global pandemic continues to rapidly evolve. The extent to which the outbreak may affect our clinical trials, business, financial condition and results of operations will depend on future developments, which are highly uncertain and cannot be predicted at this time, such as the ultimate geographic spread of the disease, the duration of the outbreak, travel restrictions and actions to contain the outbreak or treat its impact, such as social distancing and quarantines or lock-downs in the United States and other countries, business closures or business disruptions, the effectiveness of actions taken in the United States and other countries to contain and treat the disease, and the development, approval and distribution of an effective vaccine. Future developments in these and other areas present material uncertainty and risk with respect to our clinical trials, business, financial condition and results of operations.

***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 to raise additional capital to support our operations.***

The audited financial statements and accompanying notes thereto included disclosures and an opinion from our independent registered public accounting firm stating that our recurring losses and negative cash flows from operations raise substantial doubt about our ability to continue as a going concern. Our financial statements as of December 31, 2020 and 2019 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. At December 31, 2020, we had cash and cash equivalents of \$9.6 million, and we have had recurring losses from operations and negative operating cash flows since inception.

We will need to raise additional capital to support our operations and product development activities. In the near term, we expect to continue to fund our operations, if at all, primarily through equity and debt financings. Our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions, including the current recession, and the recent disruptions to, and volatility in, financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic. 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.

On March 27, 2020, we completed a private placement (“2020 Private Placement”) transaction in which we sold to Innoviva a total of 8,710,800 newly issued shares of the Company’s common stock and warrants to purchase 8,710,800 shares of common stock, with an exercise price per share of \$2.87. The 2020 Private Placement was closed in two tranches for total aggregate gross proceeds of \$25.0 million.

On January 26, 2021, we entered into the 2021 Securities Purchase Agreement in connection with the 2021 Private Placement. See the section entitled “Business—Recent Developments” for a description of the 2021 Private Placement.

While we believe that our existing resources including the proceeds from the 2021 Private Placement will be sufficient to fund our planned operations into the first quarter of 2022, we cannot provide assurances that our estimates are 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. Developing drugs and conducting clinical trials is expensive. Our future funding requirements will depend on many factors, including:

- the costs and timing of our research and development activities;
- the progress and cost of our clinical trials and other research and development activities;
- manufacturing costs associated with our targeted phage therapies strategy and other research and development activities;
- the terms and timing of any collaborative, licensing, acquisition or other arrangements that we may establish;
- whether and when we receive future Australian tax rebates, if any;
- the costs and timing of seeking regulatory approvals;



- the costs of filing, prosecuting, defending and enforcing any patent applications, claims, patents and other intellectual property rights; and
- the costs of lawsuits involving us or our product candidates.

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

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

As of December 31, 2020, our accumulated deficit was \$179.7 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. For the years ended December 31, 2020 and 2019, we had losses from operations of \$21.6 million and \$19.8 million, respectively. Additional information regarding our results of operations may be found in our consolidated financial statements and in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included in Item 2 in this report.

***We have never generated any revenue from product sales and may never be profitable.***

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.

***Maintaining and improving our financial controls and the requirements of being a public company may strain our resources, divert management’s attention and affect our ability to attract and retain qualified board members.***

As a public company, we are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and the rules of the NYSE American. The requirements of these rules and regulations increase our legal and financial compliance costs, make some activities more difficult, time-consuming or costly and place strain on our personnel, systems and resources. The Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and financial condition.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. Ensuring that we have adequate internal financial and accounting controls and procedures in place is a costly and time-consuming effort that needs to be re-evaluated frequently.

We currently do not have an internal audit group, and we may need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. Implementing any appropriate changes to our internal controls may require specific compliance training for our directors, officers and employees, entail substantial costs to modify our existing accounting systems, and take a significant period of time to complete. Such changes may not, however, be effective in maintaining the adequacy of our internal controls, and any failure to maintain that adequacy, or consequent inability to produce accurate financial statements on a timely basis, could increase our operating costs and could materially impair our ability to operate our business. Moreover, effective internal controls are necessary for us to produce reliable financial reports and are important to help prevent fraud.

In accordance with NYSE American rules, we are required to maintain a majority independent board of directors. The various rules and regulations applicable to public companies make it more difficult and more expensive for us to maintain directors’ and officers’ liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to maintain coverage. If we are unable to maintain adequate directors’ and officers’ insurance, our ability to recruit and retain qualified officers and directors will be significantly curtailed.

***If we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate financial statements on a timely basis could be impaired and our public reporting may be unreliable.***

We are required to maintain internal control over financial reporting adequate to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our consolidated financial statements in accordance with generally accepted accounting principles. We do not expect that our internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system’s objectives will be met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or

by management override of the controls. Over time, controls may become inadequate because changes in conditions or deterioration in the degree of compliance with policies or procedures may occur. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected. Material weaknesses in our internal controls have been identified in the past, and we cannot assure you that significant deficiencies or material weaknesses in our internal control over financial reporting will not be identified in the future.

If we are unable to maintain effective controls and procedures, or identify any future material weaknesses, the accuracy and timing of our financial reporting may be adversely affected, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports and we may experience a loss of public confidence, which could have an adverse effect on our business, financial condition and the market price of our common stock.

***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 the “MTEC Agreement”, pursuant to which we have started to receive a \$15 million grant and have entered into a three-year program administered by the DoD through MTEC with funding from the Defense Health Agency and Joint Warfighter Medical Research Program. We plan to use the grant to partially fund a Phase 1b/2, randomized, double-blind, placebo-controlled, dose escalation clinical study of Armata's therapeutic phage-based candidate, AP-SA02, for the treatment of complicated *S. aureus* bacteremia infections.

As an organization, we are relatively new to government contracting and new to the regulatory compliance obligations that such contracting entails. If we fail to maintain compliance with those obligations, we may be subject to potential liability and may result in the termination of our government contracts, including the MTEC Agreement.

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

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

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

***We may not be entitled to forgiveness of our recently received Paycheck Protection Program Loan, and our application for the Paycheck Protection Program Loan could in the future be determined to have been impermissible or could result in damage to our reputation.***

In April 2020, we received loan proceeds of approximately \$0.7 million (the “PPP Loan”) pursuant to the Paycheck Protection Program under the Coronavirus Aid, Relief, and Economic Security Act (the “CARES Act”) administered by the U.S. Small Business Administration (the “SBA”). We used the PPP Loan to retain current employees, maintain payroll and make lease and utility payments. The PPP Loan is evidenced by a promissory note, which contains customary events of default relating to, among other things, payment defaults and breaches of representations and warranties. The PPP Loan is scheduled to mature in April 2022 (the “Maturity Date”), bears interest at a rate of 1.00%

per annum, and is subject to the standard terms and conditions applicable to loans administered by the SBA under the CARES Act.

Commencing in August 2021, we are required to pay regular monthly payments in an amount equal to one month's accrued interest under the PPP Loan. All interest which accrues during the initial six months of the loan period will be deferred and payable on the Maturity Date. The amounts outstanding under the PPP Loan may be prepaid by us at any time prior to maturity without penalty. Under the CARES Act, as amended in June 2020, loan forgiveness is generally available for the sum of documented payroll costs, covered rent payments, covered mortgage interest and covered utilities during the 24-week period beginning on the date of the first disbursement of the PPP Loan. The amount of the PPP Loan eligible to be forgiven may be reduced in certain circumstances, including as a result of certain headcount or salary reductions. We will be required to repay any portion of the outstanding principal that is not forgiven, along with accrued interest, and we cannot provide any assurance that we will be eligible for loan forgiveness, that we will apply for forgiveness, or that any amount of the PPP Loan will ultimately be forgiven by the SBA.

In order to apply for the PPP Loan, we were required to certify, among other things, that the current economic uncertainty made the PPP Loan request necessary to support our ongoing operations. We made this certification in good faith after analyzing, among other things, the maintenance of our workforce, our need for additional funding to continue operations, and our ability to access alternative forms of capital in the current market environment to offset the effects of the COVID-19 pandemic. Following this analysis, we believe that we satisfied all eligibility criteria for the PPP Loan, and that our receipt of the PPP Loan is consistent with the broad objectives of the CARES Act. The certification described above did not contain any objective criteria and is subject to interpretation.

On April 23, 2020, the SBA issued guidance stating that it is unlikely that a public company with substantial market value and access to capital markets will be able to make the required certification in good faith. The lack of clarity regarding loan eligibility under the Paycheck Protection Program has resulted in significant media coverage and controversy with respect to public companies applying for and receiving loans. If, despite our good-faith belief that given our circumstances we satisfied all eligible requirements for the PPP Loan, we are later determined to have violated any applicable laws or regulations that may apply to us in connection with the PPP Loan or it is otherwise determined that we were ineligible to receive the PPP Loan, we may be required to repay the PPP Loan in its entirety and/or be subject to additional penalties, which could also result in adverse publicity and damage to our reputation. Should we be audited or reviewed by federal or state regulatory authorities as a result of filing an application for forgiveness of the PPP Loan or otherwise, such audit or review could result in the diversion of management's time and attention and legal and reputational costs. If we were to be audited or reviewed and receive an adverse determination or finding in such audit or review, we could be required to return the full amount of the PPP Loan. Any of these events could have a material adverse effect on our business, results of operations and financial condition.

## **Risks Related to Our Business**

***We have limited operating history, have incurred significant operating losses since inception and expects to incur significant operating losses for the foreseeable future. We may never become profitable or, if achieved, be able to sustain profitability.***

To date, we have funded our operations primarily through private placement offerings of equity securities. As of December 31, 2020, we had cash and cash equivalents of \$9.6 million. We have incurred significant operating losses since our inception and expect to incur significant losses for the foreseeable future as we continue our development programs for our product candidates.

We currently generate no revenue from product sales, and may never be able to commercialize our product candidates, or other future product candidates. We do not currently have the required approvals to market our product candidates and we may never receive them. We may not be profitable even if we or any of our future development partners succeed in commercializing any of our product candidates. Because of the numerous risks and uncertainties associated with developing and commercializing our product candidates, we are unable to predict the extent of any future losses or when it will become profitable, if at all.

***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 candidate AP-PA02, for which we received FDA clearance of our IND application. 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 if we 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.

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

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

In addition, we have used our bacteriophage technology in the area of targeted medicine under single-patient expanded access guidelines, which permit the use of phage therapy outside of clinical trials, in the United States and Australia. Despite prior single-patient expanded access successes, no assurance can be given that we will have similar single-patient expanded access treatment successes in the future. Single-patient expanded access is a term that is used to refer to the use of an investigational drug or therapy outside of a clinical trial to treat a patient with a serious or immediately life-threatening disease or condition who has no comparable or satisfactory alternative treatment options.

Regulators often allow single-patient expanded access on a case-by-case basis for an individual patient or for defined groups of patients with similar treatment needs. In some countries, such as Australia, the treating physician can administer treatment under single-patient expanded access guidelines without pre-approval from the applicable regulatory authority.

In September 2018, we received the official minutes from our August 2018 Type B pre-IND meeting with the FDA regarding our AP-SA01 bacteriophage therapy product candidate. The FDA expressed general agreement with our proposed clinical trial designs and, based on the current FDA feedback, no additional clinical or nonclinical data are required to proceed with human clinical trials. Subsequent to the Type B meeting, we have changed the bacteriophage product candidate to AP-SA02. While we believe the FDA comments and stances related to AP-SA01 will apply to AP-SA02, there can be no assurances that is the case.

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.

***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.

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

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

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

- delays in the development of manufacturing capabilities for our product candidates to enable their consistent production at clinical trial scale;
- failures in our internal manufacturing operations that result in our inability to consistently and timely produce bacteriophages in sufficient quantities to support our clinical trials;
- the availability of financial resources to commence and complete our planned clinical trials;
- delays in reaching a consensus with clinical investigators on study design;
- delays in reaching a consensus with regulatory agencies on trial design or in obtaining regulatory approval to commence a trial;
- delays in obtaining clinical materials;
- slower than expected patient recruitment for participation in clinical trials;
- failure by clinical trial sites, other third parties, or us to adhere to clinical trial agreements;
- delays in reaching agreement on acceptable clinical trial agreement terms with prospective sites or obtaining institutional review board approval;
- changes in local regulations as part of a response to the COVID-19 outbreak, which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether; and
- adverse safety events experienced during our clinical trials.

If we do not successfully commence or complete our clinical trials on schedule, the price of our common stock may decline.

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;
- delays or difficulties in enrolling patients in our clinical trials as a result of impacts associated with the COVID-19 pandemic; and

- competition for patients from clinical trials for other treatments.

We may experience difficulties in enrolling patients in our clinical trials, which 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.

***We have not completed formulation development of our product candidates.***

The development of our bacteriophage product candidates requires that we isolate, select and combine a number of bacteriophages that target the desired bacteria for that product candidate. The selection of bacteriophages for any of our product candidates is based on a variety of factors, including without limitation the ability of the selected phages, in combination, to successfully kill the targeted bacteria, the degree of cross-reactivity of the individual phages with the same part of the bacterial targets, the ability of the combined phages to satisfy regulatory requirements, our ability to manufacture sufficient quantities of the phages, intellectual property rights of third parties, and other factors. While we have selected initial formulations of AP-SA02 for the treatment of *S. aureus* infections, and the initial formulations of AP-PA02 for the treatment of *P. aeruginosa* infections in CF patients. There can be no assurance that these initial formulations will be the final formulations of AP-SA02 or AP-PA02 for commercialization if approved. If we are unable to complete formulation development of our product candidates in the time frame that we have anticipated, then our product development timelines, and the regulatory approval of our product candidates, could be delayed.

***Our product candidates must undergo rigorous clinical testing, such clinical testing may fail to demonstrate safety and efficacy and any of our product candidates could cause undesirable side effects, which would substantially delay or prevent regulatory approval or commercialization.***

Before we can obtain regulatory approval for a product candidate, we must undertake extensive clinical testing in humans to demonstrate safety and efficacy to the satisfaction of the FDA or other regulatory agencies. Clinical trials of new drug candidates sufficient to obtain regulatory marketing approval are expensive and take years to complete.

We cannot be certain of successfully completing clinical testing within the time frame we have planned, or at all. We may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent us from receiving regulatory approval or commercializing our product candidates, including the following:

- our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and/or preclinical testing or to abandon programs;
- the results obtained in earlier stage clinical testing may not be indicative of results in future clinical trials;
- clinical trial results may not meet the level of statistical significance required by the FDA or other regulatory agencies;
- we, or regulators, may suspend or terminate our clinical trials if the participating patients are being exposed to unacceptable health risks; and
- our product candidates may have unintended or undesirable effects on patients that may delay or preclude regulatory approval of our product candidates or limit their commercial use, if approved.

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

We are developing novel manufacturing processes for our product candidates at our facility in Marina Del Rey (near Los Angeles), California. The manufacturing processes for our product candidates, and the scale up of such processes for clinical trials, is 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 Marina Del Rey 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.

***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 U.S. 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 may need to license additional intellectual property rights.***

The development and commercialization of phage-based antibacterial agents may require us to obtain rights to intellectual property from third parties. We may also determine that it is necessary or advisable to license other intellectual property from third parties. There can be no assurance that such intellectual property rights would be available on commercially reasonable terms, if at all.

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

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

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

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

***Failure to comply with health and data protection laws and regulations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity and could negatively affect our operating results and business.***

We and any potential collaborators may be subject to federal, state and foreign data protection laws and regulations (i.e., laws and regulations that address privacy and data security). In the United States, numerous federal and state laws and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), that govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations or the operations of our collaborators. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under the HIPAA, as amended by HITECH. Depending on the facts and circumstances, we could be subject to criminal penalties if we knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

International data protection laws, including Regulation 2016/679, known as the General Data Protection Regulation (GDPR) may also apply to health-related and other personal information obtained outside of the United States. The GDPR went into effect on May 25, 2018. The GDPR introduced new data protection requirements in the European Union, as well as potential fines for noncompliant companies of up to the greater of €20 million or 4% of annual global revenue. The regulation imposes numerous new requirements for the collection, use and disclosure of personal information, including more stringent requirements relating to consent and the information that must be shared with data subjects about how their personal information is used, the obligation to notify regulators and affected individuals of personal data breaches, extensive new internal privacy governance obligations and obligations to honor expanded rights of individuals in relation to their personal information (e.g., the right to access, correct and delete their data). In addition, the GDPR includes restrictions on cross-border data transfer. The GDPR will increase our responsibility and liability in relation to personal data that we process, and we may be required to put in place additional mechanisms to ensure compliance with the new EU data protection rules. Further, the United Kingdom's vote in favor of

exiting the EU, often referred to as Brexit, has created uncertainty with regard to data protection regulation in the United Kingdom. In particular, it is unclear whether the United Kingdom will enact data protection legislation equivalent to the GDPR and how data transfers to and from the United Kingdom will be regulated.

In addition, California recently enacted legislation that has been dubbed the first “GDPR-like” law in the United States. Known as the California Consumer Privacy Act, it creates new individual privacy rights for consumers (as that word is broadly defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA requires covered companies to provide new disclosures to California consumers, provide such consumers new ways to opt-out of certain sales of personal information, and allow for a new cause of action for data breaches. The CCPA may impact (possibly significantly) our business activities and exemplifies the vulnerability of our business to the evolving regulatory environment related to personal data and protected health information.

Compliance with U.S. and international data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure to comply with U.S. and international data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals’ privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend and could result in adverse publicity that could harm our business.

***A variety of risks associated with our international operations could materially adversely affect our business.***

In addition to our U.S. operations, we have operations and a subsidiary in Australia and a subsidiary company in the United Kingdom. We face risks associated with our international operations, including possible unfavorable regulatory, pricing and reimbursement, political, tax and labor conditions, which could harm our business. We are subject to numerous risks associated with international business activities, including:

- compliance with differing or unexpected regulatory requirements for the development, manufacture and, if approved, commercialization of our product candidates;
- difficulties in staffing and managing foreign operations;
- foreign government taxes, regulations and permit requirements;
- U.S. and foreign government tariffs, trade restrictions, price and exchange controls and other regulatory requirements;
- anti-corruption laws, including the Foreign Corrupt Practices Act;
- economic weakness, including inflation, natural disasters, war, events of terrorism or political instability in particular foreign countries;
- fluctuations in currency exchange rates, which could result in increased operating expenses and reduced revenues, and other obligations related to doing business in another country;
- compliance with tax, employment, immigration and labor laws, regulations and restrictions for employees living or traveling abroad;
- workforce uncertainty in countries where labor unrest is more common than in the United States;

- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- changes in diplomatic and trade relationships; and
- challenges in enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States.

These and other risks associated with our international operations may materially adversely affect our business, financial condition and results of operations.

***We depend upon key personnel who may terminate their employment with us at any time and we may need to hire additional qualified personnel in order to obtain financing, pursue collaborations or develop and market our product candidates***

Our success depends on our continued ability to attract, retain and motivate highly qualified management, clinical, manufacturing, and scientific personnel and on our ability to develop and maintain important relationships with leading academic institutions, clinicians and scientists. Our success will depend on our ability to retain and motivate personnel and hire additional qualified personnel when required, including personnel with expertise in clinical trials, government regulation, cGMP manufacturing, and other areas. Competition for qualified personnel in the biotechnology field is intense. We face competition for personnel from other biotechnology and pharmaceutical companies, universities, public and private research institutions and other organizations. We also face competition from other more well-funded and well-established businesses, and we may also be viewed as a riskier choice from a job stability perspective due to our relative newer status than longer existing biotech and pharmaceutical companies. If we are unable to attract and retain key personnel and advisors, it may negatively affect our ability to successfully develop, test, commercialize and market our products and product candidates.

***We must manage a geographically dispersed organization.***

While we are a small company, we currently have operations in the United States and Australia. In the future, we may also locate facilities in other locations based on proximity to personnel with the expertise needed to research, develop and manufacture phage-based therapeutics, costs of operations or other factors. Managing our organization across multiple locations and multiple time zones may reduce our efficiency, increase our expenses and increase the risk of operational difficulties in the execution of our plans.

***Because the Merger resulted in an ownership change under Section 382 of the Internal Revenue Code for Armata, Armata's pre-Merger net operating loss carryforwards and certain other tax attributes will be subject to limitations. The net operating loss carryforwards and other tax attributes of C3J may also be subject to limitations as a result of ownership changes.***

If a corporation undergoes an “ownership change” within the meaning of Section 382 of the Internal Revenue Code of 1986, as amended, such corporation’s net operating loss carryforwards and certain other tax attributes arising from before the ownership change are subject to limitations on use after the ownership change. In general, an ownership change occurs if there is a cumulative change in the corporation’s equity ownership by certain stockholders that exceeds fifty percentage points over a rolling three-year period. Similar rules may apply under state tax laws. The Merger resulted in an ownership change for AmpliPhi and, accordingly, AmpliPhi’s net operating loss carryforwards and certain other tax attributes may be subject to limitations (or disallowance) on their use after the Merger. C3J’s net operating loss carryforwards may also be subject to limitation as a result of prior shifts in equity ownership and/or the Merger. Additional ownership changes in the future could result in additional limitations on our net operating loss carryforwards. Consequently, even if we achieve profitability, we may not be able to utilize a material portion of our net operating loss carryforwards and other tax attributes, which could have a material adverse effect on cash flow and results of operations.

As of December 31, 2020, we had federal net operating loss carryforwards of approximately \$110.5 million

## **Risks Related to Our Reliance on Third Parties**

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

We use third parties, such as clinical research organizations, to assist in conducting our clinical trials. 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 clinical research operations could also be negatively impacted by delays resulting from the COVID-19 pandemic. We are not able to predict the impact on the timing and costs of our planned clinical trials as a result of COVID-19.

## **Risks Related to Our Intellectual Property**

***We are dependent on patents and proprietary technology. If we fail to adequately protect this intellectual property or if we otherwise do not have exclusivity for the marketing of our products, our ability to commercialize products could suffer.***

Our commercial success will depend in part on our ability to obtain and maintain patent protection sufficient to prevent others from marketing our product candidates, as well as to defend and enforce these patents against infringement and to operate without infringing the proprietary rights of others. Protection of our product candidates from unauthorized use by third parties will depend on having valid and enforceable patents cover our product candidates or their manufacture or use, or having effective trade secret protection. If our patent applications do not result in issued patents, or if our patents are found to be invalid, we will lose the ability to exclude others from making, using or selling the inventions claimed therein. We have a limited number of patents and pending patent applications.

The patent positions of biotechnology companies can be uncertain and involve complex legal and factual questions. This is due to inconsistent application of policy and changes in policy relating to examination and enforcement of biotechnology patents to date on a global scale. The laws of some countries may not protect intellectual property rights to the same extent as the laws of countries having well-established patent systems, and those countries may lack adequate rules and procedures for defending our intellectual property rights. Also, changes in either patent laws or in interpretations of patent laws may diminish the value of our intellectual property. We are not able to guarantee that all of our patent applications will result in the issuance of patents and we cannot predict the breadth of claims that may be allowed in our patent applications or in the patent applications we may license from others.

Central provisions of The Leahy-Smith America Invents Act, or the America Invents Act went into effect on September 16, 2012 and on March 16, 2013. The America Invents Act includes a number of significant changes to U.S. patent law. These changes include provisions that affect the way patent applications are being filed, prosecuted and litigated. For example, the America Invents Act enacted proceedings involving post-issuance patent review procedures, such as *inter partes* review (“IPR”), and post-grant review, that allow third parties to challenge the validity of an issued patent in front of the United States Patent and Trademark Office (“U.S. PTO”) Patent Trial and Appeal Board. Each proceeding has different eligibility criteria and different patentability challenges that can be raised. IPRs permit any person (except a party who has been litigating the patent for more than a year) to challenge the validity of the patent on the grounds that it was anticipated or made obvious by prior art. Patents covering pharmaceutical products have been subject to attack in IPRs from generic drug companies and from hedge funds. If it is within six months of the issuance of the challenged patent, a third party can petition the U.S. PTO for post-grant review, which can be based on any invalidity grounds and is not limited to prior art patents or printed publications.

In post-issuance proceedings, U.S. PTO rules and regulations generally tend to favor patent challengers over patent owners. For example, unlike in district court litigation, claims challenged in post-issuance proceedings are given their broadest reasonable meaning, which increases the chance a claim might be invalidated by prior art or lack support in the patent specification. As another example, unlike in district court litigation, there is no presumption of validity for an issued patent, and thus, a challenger's burden to prove invalidity is by a preponderance of the evidence, as opposed to the heightened clear and convincing evidence standard. As a result of these rules and others, statistics released by the U.S. PTO show a high percentage of claims being invalidated in post-issuance proceedings. Moreover, with few exceptions, there is no standing requirement to petition the U.S. PTO for inter partes review or post-grant review. In other words, companies that have not been charged with infringement or that lack commercial interest in the patented subject matter can still petition the U.S. PTO for review of an issued patent. Thus, even where we have issued patents, our rights under those patents may be challenged and ultimately not provide us with sufficient protection against competitive products or processes.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- we might not be the first to file patent applications for our inventions;
- others may independently develop similar or alternative product candidates to any of our product candidates that fall outside the scope of our patents;
- our pending patent applications may not result in issued patents;
- our issued patents may not provide a basis for commercially viable products or may not provide us with any competitive advantages or may be challenged by third parties;
- others may design around our patent claims to produce competitive products that fall outside the scope of our patents;
- we may not develop additional patentable proprietary technologies related to our product candidates; and
- we are dependent upon the diligence of our appointed agents in national jurisdictions, acting for and on our behalf, which control the prosecution of pending domestic and foreign patent applications and maintain granted domestic and foreign patents.

An issued patent does not guarantee us the right to practice the patented technology or commercialize the patented product. Third parties may have blocking patents that could be used to prevent us from commercializing our patented products and practicing our patented technology. Our issued patents and those that may be issued in the future may be challenged, invalidated or circumvented, which could limit our ability to prevent competitors from marketing the same or related product candidates or could limit the length of the term of patent protection of our product candidates. Moreover, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any of our product candidates can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of the patent. Patent term extensions may not be available for these patents.

***We rely on trade secrets and other forms of non-patent intellectual property protection. If we are unable to protect our trade secrets, other companies may be able to compete more effectively against us.***

We rely on trade secrets to protect certain aspects of our technology, including our proprietary processes for manufacturing and purifying bacteriophages. Trade secrets are difficult to protect, especially in the pharmaceutical industry, where much of the information about a product must be made public during the regulatory approval process. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside

scientific collaborators and other advisors may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third party illegally obtained and is using our trade secret information is expensive and time-consuming, and the outcome is unpredictable. In addition, courts outside the United States may be less willing to or may not protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

***If we are sued for infringing intellectual property rights of third parties or if we are forced to engage in an interference proceeding, it will be costly and time-consuming, and an unfavorable outcome in that litigation or interference would have a material adverse effect on our business.***

Our ability to commercialize our product candidates depends on our ability to develop, manufacture, market and sell our product candidates without infringing the proprietary rights of third parties. Numerous United States and foreign patents and patent applications, which are owned by third parties, exist in the general field of anti-infective products or in fields that otherwise may relate to our product candidates. If we are shown to infringe, we could be enjoined from use or sale of the claimed invention if we are unable to prove that the patent is invalid. In addition, because patent applications can take many years to issue, there may be currently pending patent applications, unknown to us, which may later result in issued patents that our product candidates may infringe, or which may trigger an interference proceeding regarding one of our owned or licensed patents or applications. There could also be existing patents of which we are not aware that our product candidates may inadvertently infringe or which may become involved in an interference proceeding.

The biotechnology and pharmaceutical industries are characterized by the existence of a large number of patents and frequent litigation based on allegations of patent infringement. For so long as our product candidates are in clinical trials, we believe our clinical activities fall within the scope of the exemptions provided by 35 U.S.C. Section 271(e) in the United States, which exempts from patent infringement liability activities reasonably related to the development and submission of information to the FDA. As our clinical investigational drug product candidates progress toward commercialization, the possibility of a patent infringement claim against us increases. While we attempt to ensure that our active clinical investigational drugs and the methods we employ to manufacture them, as well as the methods for their use we intend to promote, do not infringe other parties' patents and other proprietary rights, we cannot be certain they do not, and competitors or other parties may assert that we infringe their proprietary rights in any event.

We may be exposed to future litigation based on claims that our product candidates, or the methods we employ to manufacture them, or the uses for which we intend to promote them, infringe the intellectual property rights of others. Our ability to manufacture and commercialize our product candidates may depend on our ability to demonstrate that the manufacturing processes we employ and the use of our product candidates do not infringe third-party patents. If third-party patents were found to cover our product candidates or their use or manufacture, we could be required to pay damages or be enjoined and therefore unable to commercialize our product candidates, unless we obtained a license. A license may not be available to us on acceptable terms, if at all.

## **Risks Related to Our Industry**

***If our competitors are able to develop and market products that are more effective, safer or more affordable than ours, or obtain marketing approval before we do, our commercial opportunities may be limited.***

Competition in the biotechnology and pharmaceutical industries is intense and continues to increase. Some companies that are larger and have significantly more resources than we do are aggressively pursuing antibacterial development programs, including traditional therapies and therapies with novel mechanisms of action. In addition, other companies are developing phage-based products for non-therapeutic uses, and may elect to use their expertise in phage development and manufacturing to try to develop products that would compete with ours.

We also face potential competition from academic institutions, government agencies and private and public research institutions engaged in the discovery and development of drugs and therapies. Many of our competitors have significantly greater financial resources and expertise in research and development, preclinical testing, conducting clinical trials, obtaining regulatory approvals, manufacturing, sales and marketing than we do. Smaller or early-stage

companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established pharmaceutical companies.

Our competitors may succeed in developing products that are more effective, have fewer side effects and are safer or more affordable than our product candidates, which would render our product candidates less competitive or noncompetitive. These competitors also compete with us to recruit and retain qualified scientific and management personnel, establish clinical trial sites and patient registration for clinical trials, as well as to acquire technologies and technology licenses complementary to our programs or advantageous to our business. Moreover, competitors that are able to achieve patent protection, obtain regulatory approvals and commence commercial sales of their products before we do, and competitors that have already done so, may enjoy a significant competitive advantage.

The Generating Antibiotics Incentives Now Act is intended to provide incentives for the development of new, qualified infectious disease products. These incentives may result in more competition in the market for new antibiotics, and may cause pharmaceutical and biotechnology companies with more resources than we have to shift their efforts towards the development of products that could be competitive with our product candidates.

***There is a substantial risk of product liability claims in our business. If we do not obtain sufficient liability insurance, a product liability claim could result in substantial liabilities.***

Our business exposes us to significant potential product liability risks that are inherent in the development, manufacturing and marketing of human therapeutic products. Regardless of merit or eventual outcome, product liability claims may result in:

- delay or failure to complete our clinical trials;
- withdrawal of clinical trial participants;
- decreased demand for our product candidates;
- injury to our reputation;
- litigation costs;
- substantial monetary awards against us; and
- diversion of management or other resources from key aspects of our operations.

If we succeed in marketing products, product liability claims could result in an FDA investigation of the safety or efficacy of our products, our manufacturing processes and facilities or our marketing programs. An FDA investigation could also potentially lead to a recall of our products or more serious enforcement actions, or limitations on the indications, for which they may be used, or suspension or withdrawal of approval.

We have product liability insurance that covers our clinical trials up to a \$10.0 million annual per claim and aggregate limit. We intend to expand our insurance coverage to include the sale of commercial products if marketing approval is obtained for our product candidates or any other compound that we may develop. However, insurance coverage is expensive and we may not be able to maintain insurance coverage at a reasonable cost or at all, and the insurance coverage that we obtain may not be adequate to cover potential claims or losses.



***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.

***The uncertainty associated with pharmaceutical reimbursement and related matters may adversely affect our business.***

Market acceptance and sales of any one or more of our product candidates will depend on reimbursement policies and may be affected by future healthcare reform measures in the United States and in foreign jurisdictions. Government authorities and third-party payers, such as private health insurers and health maintenance organizations, decide which drugs they will cover and establish payment levels. We cannot be certain that reimbursement will be available for any of our product candidates. Also, we cannot be certain that reimbursement policies will not reduce the demand for, or the price paid for, our products. If reimbursement is not available or is available on a limited basis, we may not be able to successfully commercialize any product candidates that we develop.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the “MMA”), changed the way Medicare covers and pays for pharmaceutical products. The legislation established Medicare Part D, which expanded Medicare coverage for outpatient prescription drug purchases by the elderly but provided authority for limiting the number of drugs that will be covered in any therapeutic class. The MMA also introduced a new reimbursement methodology based on average sales prices for physician-administered drugs.

The United States and several foreign jurisdictions are considering, or have already enacted, a number of legislative and regulatory proposals to change the healthcare system in ways that could affect its ability to sell its products profitably. Among policy makers and payers in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access to healthcare. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. We expect to experience pricing pressures in connection with the sale of any products that we develop due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, and additional legislative proposals.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively, the “ACA”), became law in the United States, which substantially

changed the way healthcare is financed by both governmental and private insurers. While we cannot predict what impact on federal reimbursement policies this legislation will have in general or on our business specifically, the ACA and any amendments thereto may result in downward pressure on pharmaceutical reimbursement, which could negatively affect market acceptance of, and the price we may charge for, our products that receive regulatory approval. We also cannot predict the impact of ACA and its amendments on us as many of the ACA, as amended, requires the promulgation of detailed regulations implementing the statutory provisions, which have not yet been fully implemented.

### **Risks Related to Our Common Stock**

***Innoviva may exert a substantial influence on actions requiring stockholder vote, potentially in a manner that you do not support.***

Following the second closing of the 2021 Private Placement, Innoviva holds approximately 59.6% of our outstanding shares and 14,864,647 warrants to purchase shares of our common stock. If Innoviva were to exercise the warrants held by them, they would hold approximately 74.7% of our issued and outstanding shares of common stock. Innoviva's large ownership stake may allow it to exert a substantial influence on actions requiring a stockholder vote, potentially in a manner that you do not support, including amendments to our articles of incorporation, adoption of measures that could delay or prevent a change in control or impede a merger, takeover, or other business combination involving us, and approval of other major corporate transactions. In addition, Innoviva's stock ownership may discourage a potential acquirer from making a tender offer or otherwise attempting to obtain control of us, which in turn could reduce our stock price or prevent our stockholders from realizing a premium over our stock price. Accordingly, our stockholders other than Innoviva may be unable to influence management and exercise control over our business.

***The price of our common stock has been and may continue to be volatile.***

As of December 31, 2020, we had outstanding common warrants to purchase an aggregate of 10,547,618 shares of our common stock at a weighted-average exercise price of \$4.53 per share. As of December 31, 2020, in-the-money warrants included warrants issued to Innoviva during 2020 Private Placement which have an exercise price of \$2.87 per share. We also have outstanding options to exercise 1,668,926 shares of our common stock at a weighted-average exercise price of \$6.30 per share. Although we cannot determine when these warrants or options will ultimately be exercised, it is reasonable to assume that such warrants and options will be exercised only if the exercise price is below the market price of our common stock. To the extent any of our outstanding warrants or options are exercised, additional shares of our common stock will be issued that will generally be eligible for resale in the public market (subject to limitations under Rule 144 under the Securities Act for certain of our warrants and with respect to shares held by our affiliates), which will result in dilution to our security holders. The issuance of additional securities could also have an adverse effect on the market price of our common stock.

***We have never paid dividends on our common stock, and we do not anticipate paying any cash dividends on our common stock in the foreseeable future.***

We have never declared or paid cash dividends on our common stock. We do not anticipate paying any cash dividends on our common stock in the foreseeable future. We currently intend to retain all available funds and any future earnings to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be our stockholders' sole source of gain for the foreseeable future.

### **General Risk Factors**

***Our business and operations might be adversely affected by security breaches, including any cybersecurity incidents.***

We depend on the efficient and uninterrupted operation of our computer and communications systems, which we use for, among other things, sensitive company data, including our financial data, intellectual property and other proprietary business information.

While certain of our operations have business continuity and disaster recovery plans and other security measures intended to prevent and minimize the impact of IT-related interruptions, our IT infrastructure and the IT infrastructure of our consultants, contractors and vendors are vulnerable to damage from cyberattacks, computer viruses, unauthorized access, electrical failures and natural disasters or other catastrophic events. We could experience failures in our information systems and computer servers, which could result in an interruption of our normal business operations and require substantial expenditure of financial and administrative resources to remedy. System failures, accidents or security breaches can cause interruptions in our operations and can result in a material disruption of our targeted phage therapies, bacteriophage product candidates and other business operations. The loss of data from completed or future studies or clinical trials could result in delays in our research, development or regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liabilities and the development of our product candidates could be delayed or otherwise adversely affected.

Even though we believe we carry commercially reasonable business interruption and liability insurance, we might suffer losses as a result of business interruptions that exceed the coverage available under our insurance policies or for which we do not have coverage. For example, we are not insured against terrorist attacks or cyberattacks. Any natural disaster or catastrophic event could have a significant negative impact on our operations and financial results. Moreover, any such event could delay the development of our product candidates.

***Interruptions in the availability of server systems or communications with Internet or cloud based services, or failure to maintain the security, confidentiality, accessibility or integrity of data stored on such systems, could harm our business.***

We rely upon a variety of Internet service providers, third-party hosting facilities and cloud computing platform providers to support our business. Failure to maintain the security, confidentiality, accessibility or integrity of data stored on such systems could damage our reputation in the market, cause us to lose revenue or market share, increase our service costs, cause us to incur substantial costs, subject us to liability for damages and/or fines and divert our resources from other tasks, any one of which could materially adversely affect our business, financial condition, results of operations and prospects. Any damage to, or failure of, such systems, or communications to and between such systems, could result in interruptions in our operations. If our security measures or those of our third-party data center hosting facilities, cloud computing platform providers, or third-party service partners, are breached, and unauthorized access is obtained to our data or our information technology systems, we may incur significant legal and financial exposure and liabilities.

We do not have control over the operations of the facilities of our cloud service providers and our third-party providers may be vulnerable to damage or interruption from natural disasters, cybersecurity attacks, terrorist attacks, power outages and similar events or acts of misconduct. In addition, any changes in our cloud service providers' service levels may adversely affect our ability to meet our requirements and operate our business.

***If securities or industry analysts do not publish research or publish unfavorable research about our business, our stock price and trading volume could decline.***

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. We currently have three securities analysts and may never obtain additional research coverage by other securities and industry analysts. If no additional securities or industry analysts commence coverage of our company, the trading price for our stock could be negatively impacted. If we obtain additional securities or industry analyst coverage and if one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, demand for our stock could decrease, which could cause our stock price and trading volume to decline.

***Sales of a substantial number of shares of our common stock in the public market by our existing stockholders could cause our stock price to decline.***

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that sales may have on the prevailing market price of our common stock.

***Future sales and issuances of our common stock or rights to purchase common stock by us, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to decline.***

We are generally not restricted from issuing additional common stock, including any securities that are convertible into or exchangeable for, or that represent the right to receive, common stock. The market price of our common stock could decline as a result of sales of common stock or securities that are convertible into or exchangeable for, or that represent the right to receive, common stock or the perception that such sales could occur.

We expect that significant additional capital will be needed in the future to continue our planned operations, including conducting clinical trials, commercialization efforts, expanded research and development activities and costs associated with operating as a public company. To the extent we raise additional capital by issuing equity or convertible securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

Pursuant to our 2016 Equity Incentive Plan (the “2016 Plan”), our management is authorized to grant stock options and other equity-based awards to our employees, directors and consultants. The number of shares available for future grant under the 2016 Plan will automatically increase on January 1<sup>st</sup> of each year by up to 5% of all shares of our capital stock outstanding as of December 31<sup>st</sup> of the preceding calendar year, subject to the ability of our board of directors to take action to reduce the size of the increase in any given year. In addition, we may grant or provide for the grant of rights to purchase shares of our common stock pursuant to our 2016 Employee Stock Purchase Plan (“ESPP”). The number of shares of our common stock reserved for issuance under the ESPP will automatically increase on January 1<sup>st</sup> of each calendar year by the lesser of 1% of the total number of shares of our common stock outstanding on December 31<sup>st</sup> of the preceding calendar year and 30,000 shares, subject to the ability of our board of directors to take action to reduce the size of the increase in any given year. Currently, we plan to register the increased number of shares available for issuance under the 2016 Plan and ESPP each year. Increases in the number of shares available for future grant or purchase may result in additional dilution, which could cause our stock price to decline.

***Provisions of Washington law and our current articles of incorporation and bylaws may discourage another company from acquiring us and may prevent attempts by our stockholders to replace or remove our current management.***

Provisions of Washington law and our current articles of incorporation and bylaws may discourage, delay or prevent a merger or acquisition that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace or remove our board of directors. These provisions include:

- authorizing the issuance of “blank check” preferred stock without any need for action by stockholders;
- requiring supermajority stockholder voting to effect certain amendments to our articles of incorporation and bylaws; and

- establishing advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings.

In addition, because we are incorporated in Washington, we are governed by the provisions of Chapter 23B.19 of the Washington Business Corporation Act, which, among other things, restricts the ability of stockholders owning 10% or more of our outstanding voting stock from merging or combining with us. These provisions could discourage potential acquisition attempts and could reduce the price that investors might be willing to pay for shares of our common stock in the future and result in the market price being lower than it would without these provisions.

Although we believe these provisions collectively provide for an opportunity to receive higher bids by requiring potential acquirers to negotiate with our board of directors, they would apply even if an offer may be considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management

***Foreign governments tend to impose strict price controls, which may adversely affect our future profitability.***

In some foreign countries, particularly in the European Union, prescription drug pricing 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 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 profitability will be negatively affected.

***We may incur significant costs complying with environmental laws and regulations, and failure to comply with these laws and regulations could expose us to significant liabilities.***

Our research and development activities use biological and hazardous materials that are dangerous to human health and safety or the environment. We are subject to a variety of federal, state and local laws and regulations governing the use, generation, manufacture, storage, handling and disposal of these materials and wastes resulting from these materials. We are also subject to regulation by the Occupational Safety and Health Administration (“OSHA”), state and federal environmental protection agencies and to regulation under the Toxic Substances Control Act. OSHA, state governments or federal Environmental Protection Agency, may adopt regulations that may affect our research and development programs. We are unable to predict whether any agency will adopt any regulations that could have a material adverse effect on our operations. We have incurred, and will continue to incur, capital and operating expenditures and other costs in the ordinary course of our business in complying with these laws and regulations.

Although we believe our safety procedures for handling and disposing of these materials comply with federal, state and local laws and regulations, we cannot entirely eliminate the risk of accidental injury or contamination from the use, storage, handling or disposal of hazardous materials. In the event of contamination or injury, we could be held liable for any resulting damages, and any liability could significantly exceed our insurance coverage.

***Taxing authorities could reallocate our taxable income among our subsidiaries, which could increase our overall tax liability.***

We are organized in the United States, and we currently have subsidiaries in the United Kingdom and Australia. If we succeed in growing our business, we expect to conduct increased operations through our subsidiaries in various tax jurisdictions pursuant to transfer pricing arrangements between us and our subsidiaries. If two or more affiliated companies are located in different countries, the tax laws or regulations of each country generally will require that transfer prices be the same as those between unrelated companies dealing at arm’s length and that appropriate documentation is maintained to support the transfer prices. While we believe that we operate in compliance with applicable transfer pricing laws and intend to continue to do so, our transfer pricing procedures are not binding on applicable tax authorities.

If tax authorities in any of these countries were to successfully challenge our transfer prices as not reflecting arm's length transactions, they could require us to adjust our transfer prices and thereby reallocate our income to reflect these revised transfer prices, which could result in a higher tax liability to us. In addition, if the country from which the income is reallocated does not agree with the reallocation, both countries could tax the same income, resulting in double taxation. If tax authorities were to allocate income to a higher tax jurisdiction, subject our income to double taxation or assess interest and penalties, it would increase our consolidated tax liability, which could adversely affect our financial condition, results of operations and cash flows.

#### **Item 1B. UNRESOLVED STAFF COMMENTS**

None.

#### **Item 2. PROPERTIES**

Our corporate headquarters are located in Marina del Rey, California, where we currently lease 35,500 square feet of laboratory and office space. The lease expires on December 31, 2031. The facility includes 19,500 square feet of BSL2 laboratory space dedicated to phage product development. The facility includes approximately 3,000 square feet of cGMP laboratory space, designed to produce clinical quantities of our phage product candidates for human trials and to perform in-house Quality Control ("QC") testing.

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. The facility is also set up to provide microbiological support of clinical trials.

We occupy approximately 1,000 square feet of leased office space pursuant to a month-to-month sublease, located at 3579 Valley Centre Drive, Suite 100, San Diego, California 92130.

We believe that our existing office and laboratory space is sufficient to meet our needs for the foreseeable future and that suitable additional space will be available when and if needed.

#### **Item 3. LEGAL PROCEEDINGS**

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

#### **Item 4. MINE SAFETY DISCLOSURES**

Not applicable.

## **PART II**

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

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

## **Holders of Common Stock**

As of March 5, 2021, there were 115 holders of record of our common stock. As of such date, there were 20,622,065 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.

## **Recent Sales of Unregistered Securities**

### ***2020 Private Placement***

On January 27, 2020, we entered into a Securities Purchase Agreement with Innoviva (the “2020 Securities Purchase Agreement”), pursuant to which we agreed to issue and sell to Innoviva, in the 2020 Private Placement, 8,710,800 newly issued shares of our common stock and warrants to purchase 8,710,800 shares of common stock, with an exercise price per share of \$2.87. Each share of common stock was sold together with one common warrant granting the warrant holder the right to purchase an additional share of common stock (“Common Unit”) at \$2.87 per share. The 2020 Private Placement occurred in two tranches. The first closing occurred on February 12, 2020, at which time Innoviva purchased 993,139 Common Units in exchange for an aggregate gross cash payment of approximately \$2.8 million. On March 27, 2020, the second closing occurred subsequent to shareholder approval, at which time Innoviva purchased 7,717,661 Common Units in exchange for aggregate gross proceeds of \$22.2 million.

### ***Registration Rights Agreement and Investor Rights Agreement***

As part of the First Closing of the 2020 Private Placement, we entered into a registration rights agreement (the “2020 Registration Rights Agreement”) and an investor rights agreement (the “Investor Rights Agreement”) with Innoviva. Pursuant to the 2020 Registration Rights Agreement, we filed a registration statement on Form S-3 on April 1, 2020, which was declared effective on April 8, 2020, covering the resale of the securities issued and sold pursuant to the 2020 Securities Purchase Agreement with the Commission on a continuous basis pursuant to Rule 415 promulgated under the Securities Act of 1933, as amended (the “Securities Act”).

The Investor Rights Agreement provides that for so long as Innoviva and its affiliates hold at least 12.5% of the outstanding shares of Common Stock on a fully-diluted basis, Innoviva shall have the right to designate two (2) directors to our board of directors, and for so long as Innoviva and its affiliates hold at least 8% but less than 12.5% of the outstanding shares of Common Stock on a fully-diluted basis, Innoviva shall have the right to designate one (1) director, subject to certain qualifications and conditions in the Investor Rights Agreement. The Investor Rights Agreement also provides for participation rights for Innoviva to participate in future offerings of equity securities by Armata. The Investor Rights Agreement was subsequently amended and restated by the A&R IRA.

### ***2021 Private Placement***

On January 26, 2021, we entered into the 2021 Securities Purchase Agreement with Innoviva, pursuant to which we agreed to issue and sell to Innoviva, in the 2021 Private Placement, 6,153,847 newly issued shares of our common stock and warrants to purchase 6,153,847 shares of common stock, with an exercise price per share of \$3.25. Each share of common stock was sold together with one common warrant granting the warrant holder the right to purchase an additional share of common stock at \$3.25 per share. See the section entitled “Business—Recent Developments” for a description of the 2021 Private Placement, which is incorporated by reference herein.

## Item 6. SELECTED FINANCIAL DATA

The selected consolidated financial data set forth below as of December 31, 2020 and 2019, and for the years ended December 31, 2020 and 2019, are derived from our audited consolidated financial statements included elsewhere in this report. This information should be read in conjunction with those consolidated financial statements, the notes thereto, and with “*Management’s Discussion and Analysis of Financial Condition and Results of Operations.*”

	For the year ended December 31,	
	2020	2019
<b>Statement of Operations Data:</b>		
Grant revenue	\$ 823,000	\$ —
Loss from operations	\$ (21,587,000)	\$ (19,752,000)
Net loss	\$ (22,181,000)	\$ (19,479,000)
Net loss per share, basic	\$ (1.35)	\$ (2.49)
Shares used in computing net loss per share, basic	16,415,012	7,827,197
Net loss per share, diluted	\$ (1.35)	\$ (2.55)
Shares used in computing net loss per share, diluted	16,415,012	8,009,909
<b>Balance Sheet Data:</b>		
Cash and cash equivalents	\$ 9,649,000	\$ 6,033,000
Working capital	4,141,000	1,776,000
Total assets	39,516,000	25,451,000
Total liabilities	20,659,000	10,858,000
Accumulated deficit	(179,702,000)	(157,521,000)
Total stockholders’ equity	\$ 18,857,000	\$ 14,593,000

## 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. Some of the information contained in this discussion and analysis are set forth elsewhere in this Annual Report, 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.

Our predecessor, C3 Jian, Inc., was incorporated under the laws of the state of California on November 4, 2005. On February 26, 2016, as part of a reorganization transaction, C3 Jian, Inc. merged with a wholly owned subsidiary of C3J, and as part of this process, C3 Jian, Inc. was converted to a limited liability company organized under the laws of the State of California named C3 Jian, LLC. On May 9, 2019, C3J completed a reverse merger with AmpliPhi, where Ceres Merger Sub, Inc., a wholly-owned subsidiary of AmpliPhi, merged with and into C3J. Following the completion of the Merger, and a \$10.0 million concurrent private placement financing, the former C3J stockholders owned approximately 76% of our common stock and the former AmpliPhi stockholders owned approximately 24% of our common stock.

Immediately prior to the Merger, AmpliPhi completed a 1-for-14 reverse stock split and changed its name to Armata Pharmaceuticals, Inc. Our common stock is traded on the NYSE American exchange under the symbol “ARMP.” We are headquartered in Marina Del Rey, CA, in a 35,500 square-foot research and development facility built for product development with capabilities spanning from bench to clinic. In addition to microbiology, synthetic biology, formulation, chemistry and analytical laboratories, the facility is equipped with two licensed GMP drug manufacturing suites enabling the production, testing and release of clinical material.



Statements contained in this Annual Report that are not statements of historical fact are forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. Such forward-looking statements include, without limitation, statements concerning product development plans, commercialization of our products, the expected market opportunity for our products, the use of bacteriophages and synthetic phages to kill bacterial pathogens, having resources sufficient to fund our operations into the first quarter of 2022, future funding sources, general and administrative expenses, clinical trial and other research and development expenses, costs of manufacturing, costs relating to our intellectual property, capital expenditures, the expected benefits of our targeted phage therapies strategy, the potential market for our products, tax credits and carry-forwards, and litigation-related matters. Words such as “believe,” “anticipate,” “plan,” “expect,” “intend,” “will,” “goal,” “potential” and similar expressions are intended to identify forward-looking statements, though not all forward-looking statements necessarily contain these identifying words. These statements are subject to risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth below under Item 1A, “Risk Factors” and elsewhere in this Annual Report on Form 10-K. These forward-looking statements speak only as of the date on which they were made, and we undertake no obligation to update any forward-looking statements.

## Overview

We are a clinical-stage biotechnology company focused on the development of pathogen-specific bacteriophage therapeutics for the treatment of antibiotic-resistant and difficult-to-treat bacterial infections using our proprietary bacteriophage-based technology. Bacteriophages or “phages” have a powerful and highly differentiated mechanism of action that enables binding to and killing specific bacteria, in contrast to traditional broad-spectrum antibiotics. We believe that phages represent a promising means to treat bacterial infections, especially those that have developed resistance to current standard of care therapies, including the so-called multidrug-resistant or “superbug” strains of bacteria. We are a leading developer of phage therapeutics which are uniquely positioned to address the growing worldwide threat of antibiotic-resistant bacterial infections.

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 cGMP manufacturing capabilities to advance a broad pipeline of high-quality bacteriophage product candidates. We believe that synthetic phage, engineered using advances in sequencing and synthetic biology techniques, represent a promising means to advance phage therapy, including phage-based diagnostics and improving upon the ability of natural phage to treat bacterial infections, especially those that have developed resistance to current antibiotic therapies, including the multidrug-resistant or “superbug” bacterial pathogens.

We are developing and advancing our lead clinical phage candidate for *P. aeruginosa*. On October 14, 2020, Armata received the approval to proceed from the FDA for its Investigational New Drug application for AP-PA02. We plan to continue to advance 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 and tolerability of inhaled AP-PA02 in subjects with CF and chronic pulmonary *P. aeruginosa* infection, provided that the impacts of COVID-19 do not impede our ability to enroll subjects in this clinical trial. This study is supported by the CFF, which granted us a Therapeutics Development Award of up to \$5.0 million.

We are also developing a phage product candidate for *S. aureus* for the treatment of *S. aureus* bacteremia. On June 15, 2020, we entered into an agreement (the “MTEC Agreement”) with the Medical Technology Enterprise Consortium (“MTEC”), pursuant to which we will receive a \$15.0 million grant and entered into a three-year program administered by the DoD through MTEC with funding from the Defense Health Agency and Joint Warfighter Medical Research Program. We expect to use the grant to partially fund a Phase 1/2, multi-center, randomized, double-blind, placebo-controlled dose escalation study, provided that COVID-19 disease has been reduced to the point that clinical trials in patients are enrolling, that will assess the safety, tolerability, and efficacy of this development program in 2021, using our phage-based candidate, AP-SA02, for the treatment of adults with complicated *S. aureus* bacteremia.

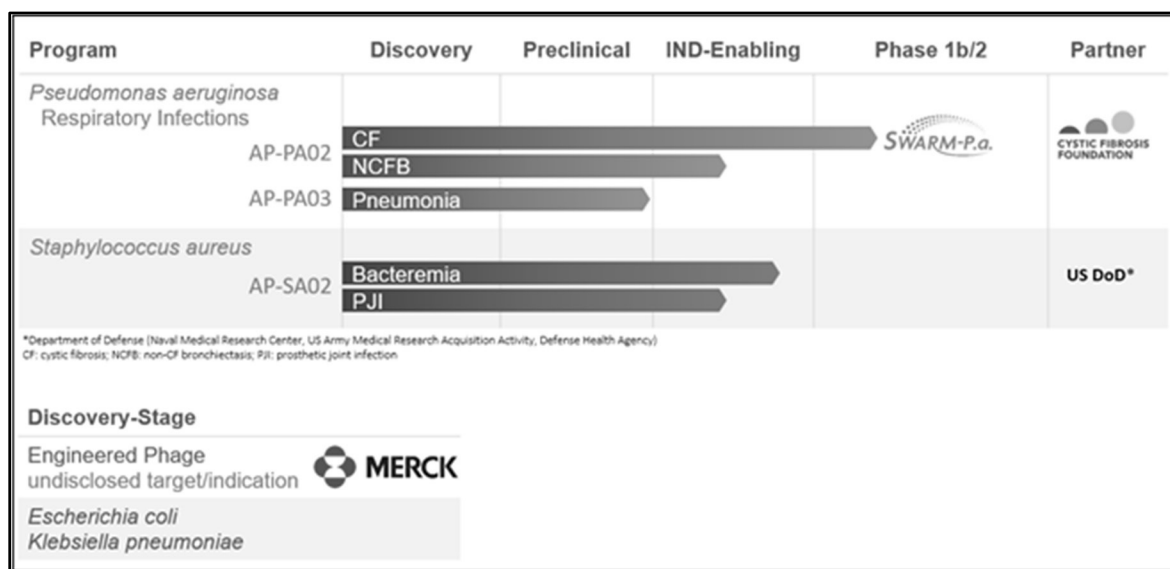
In partnership with Merck & Co., known as Merck Sharp & Dohme outside of the United States and Canada (“Merck”), we are developing proprietary synthetic phage candidates to target undisclosed infectious disease agents. Our proprietary phage engineering platform serves to enhance the clinical and commercial prospects of phage therapy.

These attributes 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.

In addition to our more advanced pipeline programs, we have phage discovery efforts underway to target other major pathogens of infectious disease (including ESKAPE pathogens) and preventable infectious disease of the microbiome.

We are committed to conducting randomized controlled clinical trials required for FDA approval in order to move toward commercialization of alternatives to traditional antibiotics and provide a potential method of treating patients suffering from drug-resistant bacterial infections.

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



We have generally 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, 2020, we had an accumulated deficit of \$179.7 million. We anticipate that a substantial portion of our capital resources and efforts in the foreseeable future will be focused on completing the development and seeking to obtain regulatory approval of our product candidates.

We currently expect to use our existing cash and cash equivalents for the continued research and development of our product candidates, including through our targeted phage therapies strategy, and for working capital and other general corporate purposes. We expect to continue to incur significant and increasing operating losses at least for the next several years. 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 will not be sufficient to enable us to complete all necessary development of any potential product candidates. Accordingly, we will be required to obtain further funding through one or more other public or private equity offerings, debt financings, collaboration, strategic financing, grants or government contract awards, licensing arrangements or other sources. Our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, financial markets in the United States and worldwide resulting from the ongoing

COVID-19 pandemic. 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.

### **Business Update Regarding COVID-19**

On January 30, 2020, the World Health Organization (“WHO”) announced a global health emergency because of a new strain of coronavirus originating in Wuhan, China (the “COVID-19 outbreak”) and the risks to the international community as the virus spreads globally beyond its point of origin. In March 2020, the WHO classified the COVID-19 outbreak as a pandemic, based on the rapid increase in exposure globally.

The COVID-19 pandemic has directly and indirectly impacted our business, results of operations and financial condition and is expected to continue to impact our business. For example, the COVID-19 pandemic has resulted in delays in our clinical trials due to the implementation of COVID-19 protocols at investigator sites, which resulted in longer than anticipated site identification and initiation activities. In addition, while we currently do not anticipate any interruptions in our supply chain, it is possible that the COVID-19 pandemic and response efforts may have a future impact on our third-party suppliers and partners. It is possible that due to the increasing emphasis on the development of vaccines for COVID-19, certain basic supply chain materials such as resins, vessels, vials and stoppers may be in high demand by the pharmaceutical companies developing vaccines and our ability to obtain these materials for our development activities could be negatively impacted. We have experienced some delays of this nature in the fourth quarter of 2020.

The full extent of the COVID-19 pandemic impact will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning COVID-19, the actions taken to contain it or treat its impact, the development and distribution of vaccines and the economic impact on local, regional, national and international markets. Management continues to actively monitor the developments regarding the pandemic and the impact that the pandemic could have on our financial condition, liquidity, ability to enroll patients in our contemplated clinical trials, manufacturing and research and development operations, suppliers to our operations and suppliers to our outside clinical trial organizations, biotech industry overall, and importantly the health and safety of our workforce. Given the continuing evolution of the COVID-19 outbreak and the global responses to curb its spread, we are not able to estimate the effects of the COVID-19 outbreak on its results of operations, financial condition, or liquidity for fiscal year 2021 or 2022. Any recovery from negative impacts to our business and related economic impact due to the COVID-19 outbreak may also be slowed or reversed by a number of factors, including the current widespread resurgence in COVID-19 infections, combined with the seasonal flu.

### **Recent Events**

On January 26, 2021, we entered into the 2021 Securities Purchase Agreement in connection with the 2021 Private Placement. See the section entitled “Business—Recent Developments” for a description of the 2021 Private Placement, which is incorporated herein by reference.

The Company received aggregate gross proceeds from the 2021 Private Placement of approximately \$20.0 million, before deducting transaction expenses, and excluding proceeds (if any) received in connection with the exercise of any warrants.

### **Results of Operations**

As a result of the Merger, C3J was considered the accounting acquirer of AmpliPhi because C3J’s shareholders retained a majority control of ownership of the combined company subsequent to the Merger; therefore, the historical financial statements presented herein prior to the closing of the Merger are the historical financial statements of C3J.

## *Comparison of year ended December 31, 2020 and 2019*

### *Grant Revenue*

We recognized \$0.8 million of grant revenue during the year ended December 31, 2020, which represents MTEC's share of the costs incurred for our AP-SA02 program for the treatment of *S. aureus* bacteremia infections. We invoice MTEC on a monthly basis for eligible costs incurred under the grant agreement.

### *Research and Development*

Research and development expenses for the year ended December 31, 2020 and 2019 were \$14.4 million and \$9.8 million, respectively. The net increase of \$4.6 million was partially due to a \$2.3 million increase of clinical trial and laboratory supply expenses in connection with our clinical trial of the AP-PA02 program, a \$1.6 million increase in payroll and related expenses due to increased headcount during 2020, a \$0.4 million increase in regulatory costs, a \$0.4 million net increase in facility and maintenance costs and a reduction of \$0.3 million in research and development consulting expenses. Also included in research and development expenses for the year ended December 31, 2020 was \$1.0 million of CFF Award accounted for as offset to research and development expenses. Research and development expenses for the year ended December 31, 2019 included a credit of \$1.3 million for Australian tax rebates received in 2019.

### *General and Administrative*

General and administrative expenses for the year ended December 31, 2020 and 2019 were \$8.0 million and \$9.3 million, respectively. The net decrease of \$1.3 million was primarily due to a \$1.2 million decrease in share-based compensation, a \$1.0 million decrease of professional expenses due to merger related expenses in the year ended December 31, 2019, offset by a \$0.3 million increase in insurance costs, and a \$0.4 million increase in payroll, incentive compensation and related expenses.

### *Loss on sale of assets*

Loss on sale of available-for-sale assets of \$0.7 million during the year ended December 31, 2019 represented the excess of carrying value of Slovenia net assets sold over proceeds received. The loss primarily related to fixed assets sold and accordingly, there was no impact on cash and cash equivalents from this transaction.

### *Other Income (Expense)*

For the year ended December 31, 2020 and 2019, we recorded noncash interest expense of \$0.6 million and \$0.9 million as a result of interest accretion on the time-based cash payments due in connection with the SGI asset acquisition. The decrease of \$0.3 million was primarily related to a reduced balance due to SGI as a result of a cash payment of \$1.0 million in January 2019 and \$1.0 million in January 2020.

For the year ended December 31, 2019, we recorded a noncash gain of \$1.1 million upon the settlement of the derivative liability as a result of the issuance of equity in connection with the SGI asset acquisition coinciding with the closing of the Merger. See Note 11 to our consolidated financial statements.

### *Income Taxes*

There was no income tax expense or benefit for the year ended December 31, 2020 or December 31, 2019.

### *Operating activities*

Net cash used in operating activities for the year ended December 31, 2020 was \$18.3 million, as compared to \$15.6 million for the year ended December 31, 2019. The increase of \$2.7 million was due to a \$2.7 million increase in net loss, \$1.3 million net decrease in non-cash adjustments to cash used in operating activities, offset by a \$1.3 million net decrease in operating assets and liabilities.

### *Investing activities*

Net cash used in investing activities of \$0.8 million for the year ended December 31, 2020 was related to purchases of property and equipment. Cash provided by investing activities was \$2.9 million for the year ended December 31, 2019, primarily due to \$3.0 million of cash acquired in connection with the Merger, offset in part by net capital equipment purchases of \$0.1 million.

### *Financing activities*

Net cash provided by financing activities was \$23.2 million for the year ended December 31, 2020, which was primarily comprised of \$22.9 million net proceeds raised from the 2020 Private Placement transaction with Innoviva, \$0.7 million proceeds from the PPP loan, and \$0.2 million proceeds received from warrant and employee stock option exercises, offset by a payment of \$0.6 million in deferred consideration related to the time-based payment obligation in connection with the SGI asset acquisition.

Net cash of \$9.0 million provided by financing activities for the year ended December 31, 2019 was comprised of net cash proceeds of \$10.0 million from a common stock sale coinciding with the Merger, offset by a payment of \$1.0 million in deferred consideration related to the time-based payment obligation in connection with the SGI asset acquisition.

## **Liquidity, Capital Resources and Financial Condition**

We have prepared our consolidated financial statements on a going concern basis, which assumes that we will realize our assets and satisfy our liabilities in the normal course of business. However, we have incurred net losses since our inception and have negative operating cash flows. These circumstances raise substantial doubt about our ability to continue as a going concern. The accompanying 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 our ability to continue as a going concern. Management plans to raise additional capital through equity offerings, debt financings, or other capital sources, including potential collaborations, licenses and other similar arrangements. 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 January 26, 2021, we entered into the 2021 Securities Purchase Agreement in connection with the 2021 Private Placement. See the section entitled “Business—Recent Developments” for a description of the 2021 Private Placement, which is incorporated herein by reference.

Management believes our existing cash resources and including the proceeds from the 2021 Private Placement of \$20.0 million will be sufficient to fund our planned operations into the first quarter of 2022, but not one year from the issuance of the 2020 financial statements. For the foreseeable future, our ability to continue our operations is dependent upon our ability to obtain additional capital.

## **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 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 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 financings;
- collaborative arrangements, government grants or strategic financings;
- licensing arrangements; and
- public or private debt.

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. Moreover, if we are unable to obtain additional funds on a timely basis, there will be substantial doubt about our ability to continue as a going concern and increased risk of insolvency and loss of investment by our stockholders. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of such securities could result in dilution to our existing stockholders. Our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic.

### **Critical Accounting Policies and Use of Estimates**

Our significant accounting policies are described in Note 3 to the consolidated financial statements included in this Annual Report.

Our management's discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements as of December 31, 2020 and December 31, 2019, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, and expenses and the related disclosure of contingent assets and liabilities. On an on-going basis, we evaluate our estimates and judgments, including those related to impairment assessment of our grants and awards, indefinite lived intangible

assets, and stock-based compensation. We base our estimates on historical experience, known trends and events, and various other factors that we believe are 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.

#### *Grants and Awards*

We determined that grants and awards are out of the scope of ASC Topic 606, *Revenue from Contracts with Customers* (“ASC 606”) because the funding entities do not meet the definition of a “customer”, as defined by ASC 606, as there is no transfer of control of goods or services. With respect to each grant or award, we determine if it has a collaboration in accordance with ASC Topic 808, *Collaborative Arrangements* (“ASC 808”). To the extent the grant or award is within the scope of ASC 808, we recognize amounts received as a contra-expense or grant revenue in the consolidated statement of operations when the related research and development expenses are incurred. For grant and awards outside the scope of ASC 808, we apply ASC 606 or International Accounting Standards No. 20, *Accounting for Government Grants and Disclosure of Government Assistance*, by analogy, and revenue is recognized when we incur expenses related to the grants for the amount we are entitled to under the provisions of the contract.

We also consider 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 we are obligated to repay funds received regardless of the outcome of the related research and development activities, then we are required to estimate and recognize that liability. Alternatively, if we are not required to repay the funds, then payments received are recorded as revenue or contra-expense as the expenses are incurred.

Deferred grant or award liability represents award funds received or receivable for which the allowable expenses have not yet been incurred as of the balance sheet date.

#### *Valuation of Goodwill and Intangible Assets with Indefinite Lives*

Our goodwill represents the excess of the cost over the fair value of net assets acquired from our business combination. The determination of the value of goodwill and intangible assets arising from the business combination requires extensive use of accounting estimates and judgments to allocate the purchase price to the fair value of the net tangible and intangible assets acquired, including capitalized in-process research and development, or IPR&D. Intangible assets acquired in a business combination that are used for IPR&D activities are considered indefinite lived until the completion or abandonment of the associated research and development efforts. Upon commercialization of the relevant research and development project, we will amortize the acquired in-process research and development over its estimated useful life or expense the acquired in-process research and development should the research and development project be unsuccessful with no future alternative use.

Goodwill and IPR&D are not amortized; however, they are assessed for impairment using fair value measurement techniques on an annual basis or more frequently if facts and circumstance warrant such a review. The goodwill or IPR&D are considered to be impaired if we determine that the carrying value of the reporting unit or IPR&D exceeds its respective fair value, respectively.

#### *Impairment of Goodwill*

We perform our goodwill impairment analysis at the reporting unit level. For the years ended December 31, 2020 and 2019, our company has one reporting unit. We perform our annual impairment analysis by either doing a qualitative assessment of a reporting unit’s fair value from the last quantitative assessment to determine if there is potential impairment, or comparing a reporting unit’s estimated fair value to its carrying amount. If a quantitative assessment is performed the evaluation includes management estimates of cash flow projections based on internal future projections and/or use of a market approach by looking at market values of comparable companies. Our market capitalization is also considered as a part of this analysis.

In accordance with our accounting policy, we completed the annual evaluation for impairment of goodwill as of December 31, 2020 using the qualitative method and determined that no impairment existed.

#### *Impairment Review of In-process Research and Development (“IPR&D”)*

We test our IPR&D asset 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. Significant management judgment is required in the forecast of future operating results that are used in our impairment analysis. The estimates management use are consistent with the plans and estimates that it uses to manage its business. Significant assumptions utilized the 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. Our analysis indicated no impairment existed.

### *Stock-Based Compensation*

Compensation expense related to stock options granted is measured at the grant date based on the estimated fair value of the award and is recognized on an accelerated attribution method over the requisite service period. We determine the estimated fair value of each stock option on the date of grant using the Black-Scholes valuation model which uses assumptions regarding a number of complex and subjective variables. The risk-free interest rate is based on the U.S. Treasury yield for a period consistent with the expected term of the option in effect at the time of the grant. Expected volatility is based on an analysis of the historical volatility of Armata and peer companies' common stock. The expected term represents the period that we expect our stock options to be outstanding. The expected term assumption is estimated using the simplified method set forth in the U.S. Securities and Exchange (the "SEC") Staff Accounting Bulletin 110, which is the mid-point between the option vesting date and the expiration date. For stock options granted to parties other than employees or directors, we elect, on a grant by grant basis, to use the expected term or the contractual term of the option award. We have never declared or paid dividends on our common stock and have no plans to do so in the foreseeable future. Forfeitures are recognized as a reduction of stock-based compensation expense as they occur. Changes in these assumptions may lead to variability with respect to the amount of stock compensation expense we recognize related to stock options.

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.

### **Recent Accounting Pronouncements**

Refer to *Note 3* of the notes to the consolidated financial statements contained elsewhere in this Annual Report.

### **Off-Balance Sheet Arrangements**

As of December 31, 2020, we did not have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. In addition, we do not engage in trading activities involving non-exchange traded contracts. Therefore, we are not materially exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in these relationships.



**Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

We are a smaller reporting company as defined by Rule 12b-2 of 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	83
Consolidated Balance Sheets as of December 31, 2020 and 2019	85
Consolidated Statements of Operations for the Years Ended December 31, 2020 and 2019	86
Consolidated Statements of Stockholders' Equity for the Years Ended December 31, 2020 and 2019	87
Consolidated Statements of Cash Flows for the Years Ended December 31, 2020 and 2019	88
Notes to Consolidated Financial Statements for the Years Ended December 31, 2020 and 2019	89

## 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, 2020 and 2019, the related consolidated statements of operations, stockholders' equity, and cash flows for the years then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2020 and 2019, 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 negative cash flows from operations 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 account or disclosure to which it relates.

#### *Valuation of in-process research and development intangible assets*

<i>Description of the Matter</i>	At December 31, 2020, the Company's in-process research and development ("IPR&D") intangible assets were \$10.3 million. As discussed in Note 3 to the consolidated financial statements, IPR&D assets are intangible assets with indefinite lives and are not subject to amortization. Such assets are
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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. The Company tests IPR&D assets for impairment as of December 31 of each year or more frequently if indicators of impairment are present.

Auditing the impairment test was complex and highly judgmental due to the significant estimation required to determine the fair value of the IPR&D intangible assets. In particular, the fair value estimates required the use of valuation methodologies that were sensitive to significant assumptions such as changes in the discount rate, timing of clinical studies and regulatory approvals, the probability of success of research and development programs and forecasted sales and anticipated growth rates.

*How We  
Addressed the  
Matter in Our  
Audit*

To test the estimated fair value of the Company's IPR&D intangible assets, we performed audit procedures that included, among others, assessing the Company's use of appropriate valuation methodologies with the assistance of a valuation specialist, performing sensitivity analyses to determine which assumptions had the greatest impact on the overall determination of fair value, and testing the completeness and accuracy of the underlying data. Our audit procedures over the most significant assumptions included comparing the assumptions to current industry, market and economic trends, to historical results of the Company's business and other guideline companies within the same industry and to other relevant factors. For example, to evaluate the probability of success of research and development programs, we considered the phase of development of the IPR&D project and third-party data regarding clinical trial success rates.

/s/ Ernst & Young LLP

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

San Diego, California  
March 18, 2021

**Armata Pharmaceuticals Inc.  
Consolidated Balance Sheets**

	<u>December 31, 2020</u>	<u>December 31, 2019</u>
<b>Assets</b>		
<b>Current assets</b>		
Cash and cash equivalents	\$ 9,649,000	\$ 6,033,000
Awards receivable	561,000	—
Prepaid expenses and other current assets	636,000	622,000
<b>Total current assets</b>	<u>10,846,000</u>	<u>6,655,000</u>
Restricted cash	1,200,000	700,000
Property and equipment, net	2,047,000	2,187,000
Operating lease right-of-use asset	10,790,000	2,028,000
In-process research and development	10,256,000	10,256,000
Goodwill	3,490,000	3,490,000
Other assets	887,000	135,000
<b>Total assets</b>	<u>\$ 39,516,000</u>	<u>\$ 25,451,000</u>
<b>Liabilities and stockholders' equity</b>		
<b>Current liabilities</b>		
Accounts payable and accrued liabilities	\$ 1,929,000	\$ 1,278,000
Accrued compensation	563,000	1,323,000
Deferred asset acquisition consideration	1,940,000	970,000
Current portion of operating lease liabilities	1,551,000	1,308,000
PPP Loan	722,000	—
<b>Total current liabilities</b>	<u>6,705,000</u>	<u>4,879,000</u>
Operating lease liabilities, net of current portion	10,877,000	1,555,000
Deferred asset acquisition consideration, net of current portion	—	1,347,000
Deferred tax liability	3,077,000	3,077,000
<b>Total liabilities</b>	<u>20,659,000</u>	<u>10,858,000</u>
<b>Stockholders' equity</b>		
Common stock, \$0.01 par value; 217,000,000 shares authorized; 18,688,461 and 9,922,758 shares issued and outstanding at December 31, 2020 and 2019, respectively	187,000	99,000
Additional paid-in capital	198,372,000	172,015,000
Accumulated deficit	(179,702,000)	(157,521,000)
<b>Total stockholders' equity</b>	<u>18,857,000</u>	<u>14,593,000</u>
<b>Total liabilities and stockholders' equity</b>	<u>\$ 39,516,000</u>	<u>\$ 25,451,000</u>

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

**Armata Pharmaceuticals Inc.**  
**Consolidated Statements of Operations**

	Year Ended December 31,	
	2020	2019
<b>Grant revenue</b>	\$ 823,000	\$ —
<b>Operating expenses</b>		
Research and development	14,444,000	9,824,000
General and administrative	7,966,000	9,265,000
Loss on sale of assets (Note 6)	—	663,000
Total operating expenses	22,410,000	19,752,000
<b>Loss from operations</b>	(21,587,000)	(19,752,000)
<b>Other income (expense)</b>		
Interest income	28,000	96,000
Interest expense	(628,000)	(931,000)
Other income (expense)	6,000	(9,000)
Change in fair value of derivative liabilities	—	1,117,000
<b>Total other income (expense), net</b>	(594,000)	273,000
<b>Net loss</b>	(22,181,000)	(19,479,000)
Per share information:		
Net loss per share, basic	\$ (1.35)	\$ (2.49)
Weighted average shares outstanding, basic	16,415,012	7,827,197
Net loss per share, diluted	\$ (1.35)	\$ (2.55)
Weighted average shares outstanding, diluted	16,415,012	8,009,909

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

**Armata Pharmaceuticals Inc.**  
**Consolidated Statements of Stockholders' Equity**

	Stockholders' Equity				
	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
<b>Balances, December 31, 2018</b>	5,069,633	\$ 51,000	\$ 145,685,000	\$ (138,042,000)	\$ 7,694,000
Forfeiture of restricted stock awards	(44,255)	—	(39,000)	—	(39,000)
Issuance of common stock and conversion of deferred consideration for asset acquisition	516,976	5,000	1,457,000	—	1,462,000
Issuance of common stock in connection with reverse merger	2,389,135	23,000	10,686,000	—	10,709,000
Sale of common stock, net of issuance costs	1,991,269	20,000	9,955,000	—	9,975,000
Stock-based compensation	—	—	4,271,000	—	4,271,000
Net loss	—	—	—	(19,479,000)	(19,479,000)
<b>Balances, December 31, 2019</b>	<u>9,922,758</u>	<u>\$ 99,000</u>	<u>\$ 172,015,000</u>	<u>\$ (157,521,000)</u>	<u>\$ 14,593,000</u>

	Stockholders' Equity				
	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
<b>Balances, December 31, 2019</b>	9,922,758	\$ 99,000	\$ 172,015,000	\$ (157,521,000)	\$ 14,593,000
Sale of common stock, net of issuance costs	8,710,800	87,000	22,723,000	—	22,810,000
Exercises of warrants	14,464	—	81,000	—	81,000
Return of restricted stock awards for tax withholdings	(2,511)	—	(8,000)	—	(8,000)
Forfeiture of restricted stock awards	(4,010)	—	—	—	—
Exercise of stock options	27,382	1,000	86,000	—	87,000
Issuance of stock awards, net of tax withholding	19,578	—	—	—	—
Stock-based compensation	—	—	3,475,000	—	3,475,000
Net loss	—	—	—	(22,181,000)	(22,181,000)
<b>Balances, December 31, 2020</b>	<u>18,688,461</u>	<u>\$ 187,000</u>	<u>\$ 198,372,000</u>	<u>\$ (179,702,000)</u>	<u>\$ 18,857,000</u>

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

**Armata Pharmaceuticals Inc.**  
**Consolidated Statements of Cash Flows**

	<b>Year Ended December 31,</b>	
	<b>2020</b>	<b>2019</b>
<b>Operating activities:</b>		
Net loss	\$ (22,181,000)	\$ (19,479,000)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation	1,114,000	1,351,000
Stock-based compensation	3,475,000	4,271,000
Non-cash interest expense	628,000	918,000
Payment of accreted interest for deferred consideration for asset acquisition	(432,000)	—
Change in fair value of derivative liability	—	(1,117,000)
Loss on sale of assets (Note 6)	—	663,000
Changes in operating assets and liabilities:		
Award receivable	(467,000)	—
Accounts payable and accrued liabilities	544,000	(1,374,000)
Accrued compensation	(760,000)	(853,000)
Operating lease right-of-use asset and liability, net	803,000	(310,000)
Prepaid expenses and other current assets	(994,000)	348,000
<b>Net cash used in operating activities</b>	<b>(18,270,000)</b>	<b>(15,582,000)</b>
<b>Investing activities:</b>		
Purchases of property and equipment	(824,000)	(224,000)
Proceeds from sale of property and equipment	—	93,000
Cash acquired in reverse merger transaction	—	3,008,000
<b>Net cash (used in) provided by investing activities</b>	<b>(824,000)</b>	<b>2,877,000</b>
<b>Financing activities:</b>		
Principal payment of deferred consideration for asset acquisition	(568,000)	(1,000,000)
Proceeds from Paycheck Protection Program Loan	717,000	—
Proceeds from sale of common stock, net of offering costs	22,893,000	9,975,000
Proceeds from exercise of employee stock options	87,000	—
Proceeds from exercise of warrants	81,000	—
<b>Net cash provided by financing activities</b>	<b>23,210,000</b>	<b>8,975,000</b>
Net increase (decrease) in cash, cash equivalents and restricted cash	4,116,000	(3,730,000)
Cash, cash equivalents and restricted cash, beginning of period	6,733,000	10,463,000
Cash, cash equivalents and restricted cash, end of period	<b>\$ 10,849,000</b>	<b>\$ 6,733,000</b>
<b>Supplemental schedule of non-cash investing and financing activities:</b>		
Unpaid offering costs	\$ 65,000	\$ 116,000
Property and equipment included in accounts payable	\$ 150,000	\$ 36,000
Issuance of common stock in reverse merger transaction	\$ —	\$ 10,709,000
Conversion of deferred asset acquisition consideration upon reverse merger	\$ —	\$ 1,463,000
	<b>Year Ended December 31,</b>	
	<b>2020</b>	<b>2019</b>
Cash and cash equivalents	\$ 9,649,000	\$ 6,033,000
Restricted cash	1,200,000	700,000
Cash, cash equivalents and restricted cash	<b>\$ 10,849,000</b>	<b>\$ 6,733,000</b>

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”, and together with its subsidiaries referred to herein as, the “Company”) is a clinical-stage biotechnology company focused on the development of pathogen-specific bacteriophage therapeutics for the treatment of antibiotic-resistant infections using its proprietary bacteriophage-based technology. The Company was created as a result of a business combination between C3J Therapeutics, Inc. (“C3J”) and AmpliPhi Biosciences Corporation (“AmpliPhi”) that closed on May 9, 2019, where Ceres Merger Sub, Inc., a wholly owned subsidiary of AmpliPhi, merged with and into C3J (the “Merger”), with C3J surviving the Merger as a wholly owned subsidiary of AmpliPhi. In the Merger, each share of C3J common stock outstanding immediately prior to the Merger was converted into the right to receive approximately .6906 shares of AmpliPhi common stock. The shares were then adjusted further to account for a reverse split of AmpliPhi common stock at a reverse split ratio of 1-for-14. All share and per share amounts have been retrospectively adjusted to give effect to the exchange of C3J common stock and the reverse split of AmpliPhi common stock.

Immediately prior to the closing of the Merger, AmpliPhi changed its name to Armata Pharmaceuticals, Inc. Armata’s common stock is traded on the NYSE American exchange under the ticker symbol “ARMP.”

Immediately following the Merger, certain existing C3J shareholders purchased \$10.0 million in Armata common stock. After the Merger and such concurrent private placement, the former C3J security holders owned approximately 76% of the aggregate number of shares of Armata’s common stock and the security holders of AmpliPhi as of immediately prior to the Merger owned approximately 24% of the aggregate number of shares of Armata’s common stock. In addition, upon closing of the Merger, five of the seven members of the board of directors were appointed by C3J.

In connection with the Merger, C3J was considered the accounting acquirer of AmpliPhi because C3J’s shareholders retained a majority control of ownership of the Company subsequent to the Merger. In addition, the seven-member board of directors of the combined company include five members established by C3J. Therefore, the historical financial statements presented herein prior to the closing of the Merger are the historical financial statements of C3J.

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

## **2. Liquidity**

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. However, the Company has incurred net losses since its inception and has negative operating cash flows. These circumstances raise substantial doubt about the Company’s ability to continue as a going concern. The accompanying 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.

On March 27, 2020, the Company completed a private placement transaction and sold to Innoviva Inc. (“Innoviva”) 8,710,800 newly issued shares of the Company’s common stock and warrants to purchase 8,710,800 shares of common stock, with an exercise price per share of \$2.87 (the “2020 Private Placement”). Each share of common stock was sold together with one common warrant granting the warrant holder the right to purchase an additional share of common stock at \$2.87 per share. The 2020 Private Placement was closed in two tranches raising total gross proceeds of \$25.0 million.

On January 26, 2021, the Company entered into a securities purchase agreement (the “Securities Purchase Agreement”) with Innoviva, pursuant to which the Company agreed to issue and sell to Innoviva, in a private placement, up to 6,153,847 newly issued shares of common stock, par value \$0.01 per share (the “Shares”), and warrants (the “Common Warrants”) to purchase up to 6,153,847 shares of our common stock, with an exercise price per share of \$3.25 (the “2021 Private Placement”).

The 2021 Private Placement closed in two tranches. On January 26, 2021 and concurrently with entering into the Securities Purchase Agreement, the Company completed the first tranche (the “First Closing”) of the 2021 Private Placement. At the First Closing, Innoviva purchased 1,867,912 Shares and Common Warrants to purchase 1,867,912 shares of common stock, for an aggregate purchase price of approximately \$6.1 million.

At the closing of the second tranche (the “Second Closing”), which was approved by the Company’s stockholders, Innoviva purchased 4,285,935 Shares and Common Warrants to purchase 4,285,935 shares of common stock for an aggregate purchase price of \$13.9 million. The Second Closing was completed on March 17, 2021.

Management plans to raise additional capital through equity offerings, debt financings, or other capital sources, including potential collaborations, licenses and other similar arrangements. 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. 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 resulting from the ongoing COVID-19 pandemic. 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. For the foreseeable future, the Company’s ability to continue its operations is dependent upon its ability to obtain additional capital.

### **3. Significant Accounting Policies**

#### ***Basis of Presentation***

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries including C3J, Biocontrol Limited and AmpliPhi Australia Pty Ltd. All significant intercompany accounts and transactions have been eliminated.

#### ***Use of Estimates***

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States (“U.S. GAAP”) requires management to make estimates and assumptions that affect the amounts reported in its consolidated financial statements and accompanying notes. On an ongoing basis, management evaluates these estimates and judgments, which are based on historical and anticipated results and trends and on various other assumptions that management believes to be reasonable under the circumstances. By their nature, estimates are subject to an inherent degree of uncertainty and, as such, actual results may differ from management’s estimates.

#### ***Cash and Cash Equivalents***

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

### ***Fair Value of Financial Instruments***

Financial instruments include cash equivalents, prepaid expenses and other assets, restricted cash, accounts payable, accrued expenses and deferred asset acquisition consideration. The carrying amount of cash equivalents prepaid expenses and other assets, restricted cash, accounts payable and accrued expenses are generally considered to be representative of their respective fair values because of the short-term nature of those instruments. Based on the Level 3 inputs of borrowing rates currently available to the Company, the Company believes the fair value of deferred asset acquisition consideration approximates its carrying value.

### ***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:

	<b>Estimated Useful Lives</b>
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 book values of the assets to future net undiscounted cash flows that the assets or the asset groups are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the book value of the assets exceed their fair value, which is measured based on the estimated discounted future net cash flows arising from the assets or asset groups. No impairment losses on long-lived assets have been recorded through December 31, 2020.

### ***In-Process Research and Development (“IPR&D” and Acquired IPR&D)***

IPR&D assets are intangible assets with indefinite lives and are not subject to amortization. The Company’s IPR&D assets represent a capitalized in-process bacteriophage development programs for S. aureus infections that the Company acquired through the Merger. 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. Significant 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. Significant 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.

During the fourth quarter ended December 31, 2020, 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. In addition, the Company performed a quantitative analysis of the fair value of its *S. aureus* phage program as of December 31, 2020, using a net present value model of projected income and expenses and a discount rate of 16.7%. Based on this analysis, the fair value of this phage program was greater than its carrying value as of December 31, 2020. Consequently, no impairment was noted for the IPR&D asset.

### ***Goodwill***

Goodwill, which has an indefinite useful life, represents the excess of purchase consideration over the fair value of net assets acquired. The Company's goodwill as of December 31, 2020 is associated with AmpliPhi's business prior to the Merger. 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. There was no impairment of goodwill during the year ended December 31, 2020.

### ***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. Forfeitures are recognized as a reduction of stock-based compensation expense as 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.

### ***Revenue Recognition***

The Company recognizes revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which it expects to be entitled in exchange for those goods or services. To determine revenue recognition for contracts with customers, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies its performance obligations. At contract inception, the Company assesses the goods or services agreed upon within each contract and assess whether each good or service is distinct and determine those that are performance obligations. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. During the years ended December 31, 2020 and 2019 the company did not recognize revenue or deferred revenue from contracts with customers.

### ***Grants and Awards***

In applying the provisions of ASC Topic 606, *Revenue from Contracts with Customers* ("ASC 606"), Armata has determined that grants and awards are out of the scope of ASC 606 because the funding entities do not meet the

definition of a “customer”, as defined by ASC 606, as there is not considered to be a transfer of control of goods or services. With respect to each grant or award, the Company determines if it has a collaboration in accordance with ASC Topic 808, *Collaborative Arrangements* (“ASC 808”). To the extent the grant or award is within the scope of ASC 808, the Company recognizes amounts received as a contra-expense or grant revenue on the consolidated statement of operations when the related research and development expenses are incurred. 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 grants for the amount the Company is entitled to under the provisions of the contract.

Armata 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 Armata is required to estimate and recognize that liability. Alternatively, if Armata is not required to repay the funds, then payments received are recorded as revenue or contra-expense as the expenses are incurred.

Deferred grant or award liability represents award funds received or receivable for which the allowable expenses have not yet been incurred as of the balance sheet date.

### ***Research and Development Costs***

Research and development (“R&D”) costs consist primarily of direct and allocated salaries, incentive compensation, stock-based compensation and other personnel-related costs, facility costs, and third-party services. Third party services include studies and clinical trials conducted by clinical research organizations. R&D activities are expensed as incurred. The Company records accruals for estimated ongoing clinical trial expenses. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the studies, including the phase or completion of events, invoices received and contracted costs. Judgments and estimates are made in determining the accrued balances at the end of the reporting period.

Research and development expenses are partially offset by the benefit of tax incentive payments for qualified research and development expenditures from the Australian tax authority (“AU Tax Rebates”). The Company does not record AU Tax Rebates until payment is received due to the uncertainty of receipt. During the year ended December 31, 2019, the Company received AU Tax Rebates of approximately \$1.3 million related to calendar year 2018, and such rebates have been recorded as an offset to research and development expense in the Company’s consolidated statements of operations. During the year ended December 31, 2020, the Company applied for AU Tax Rebates for the calendar year 2019 and received \$0.7 million in January 2021 which will be recognized in the first quarter of 2021 as an offset to research and development expenses.

### ***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.

### ***Derivative Liabilities***

Derivative liabilities are accounted for in accordance with the applicable accounting guidance provided in ASC 815 – *Derivatives and Hedging* based on the specific terms of the agreements. Derivative liabilities are recorded at fair value at each reporting period with any change in fair value recognized as a component of change in fair value of asset acquisition derivative liability in the consolidated statements of operations. The Company has a zero derivative liability balance at December 31, 2020 as the liability of \$1.1 million at December 31, 2018 was settled upon the Merger in May 2019.

### ***Basic and Diluted Net Loss per Share***

Net earnings or loss per share (“EPS”) is calculated in accordance with the applicable accounting guidance provided in ASC 260, *Earnings per Share*. Basic EPS is calculated by dividing net income or loss by the weighted-average number of common shares outstanding. Diluted net loss per share is computed in accordance with the treasury stock method and reflects the potential dilution that would occur if securities or other contracts to issue common stock were exercised or converted to common stock. The calculation of diluted loss per share requires that, to the extent the average market price of the underlying shares for the reporting period exceeds the exercise price of the warrants, and the presumed exercise of such securities are dilutive to net loss per share for the period, an adjustment to net loss available to common stockholders used in the calculation is required to remove the change in fair value of the warrants from the numerator for the period. Likewise, an adjustment to the denominator is required to reflect the related dilutive shares, if any, under the treasury stock method.

### ***Settlement of Zero-coupon Debt Instrument***

The Company’s deferred purchase consideration arrangement with Synthetic Genomics (Note 12) does not have a stated interest rate. Upon repayment of deferred purchase consideration, the Company classifies the portion attributable to accreted interest as a cash outflow for operating activities, and the portion relating to principal as a cash outflow for financing activities.

### ***Recent Accounting Pronouncements Not Yet Adopted***

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

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (“ASC 740”)*, which simplifies the accounting for income taxes by eliminating certain exceptions to the guidance in ASC 740 related to the approach for intra-period tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. The new guidance also simplifies aspects of the accounting for franchise taxes and enacted changes in tax laws or rates and clarifies the accounting for transactions that result in a step-up in the tax basis of goodwill. The guidance is effective for calendar-year public business entities in 2021 and interim periods within that year. Early adoption is permitted. The Company does not expect adoption of this new guidance will have a material impact on its consolidated financial statements or related disclosures.

In August 2020, the FASB issued ASU No. 2020-06, *Debt - Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging - Contracts in Entity's Own Equity (Subtopic 815-40)* ("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 202-06 modifies how particular convertible instruments and certain contracts that may be settled in cash or shares impact the diluted EPS computation. The amendments in ASU 2020-06 are effective for smaller reporting companies as defined by the SEC for fiscal years beginning after December 15, 2023, including interim periods within those fiscal years. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020. The Company is currently evaluating the impact of ASU 2020-06 on its financial statements and does not expect the adoption of this ASU to have a material impact on the Company's consolidated financial statements.

### **Recently Adopted Accounting Standards**

In November 2018, FASB issued ASU 2018-18, *Clarifying the Interaction between Topic 808 and Topic 606*. The objective of the standard is to clarify the interaction between Topic 808, *Collaborative Arrangements*, and Topic 606, *Revenue from Contracts with Customers*. Currently, Topic 808 does not provide comprehensive recognition or measurement guidance for collaborative arrangements, and the accounting for those arrangements is often based on an analogy to other accounting literature or an accounting policy election. Similarly, aspects of Topic 606 have resulted in uncertainty in practice about the effect of the revenue standard and credit loss standard on the accounting for collaborative arrangements. The standard became effective for the Company for fiscal periods beginning on January 1, 2020. The adoption of this ASU did not have an impact on the Company's financial condition, results of operations, cash flows, or financial statement disclosures.

### **4. Fair Value of Financial Assets and Liabilities – Derivative Instruments**

The guidance regarding fair value measurements prioritizes the inputs used in measuring fair value and establishes a three-tier value hierarchy that distinguishes among the following:

- Level 1—Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access.
- Level 2—Valuations based on quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active and models for which all significant inputs are observable, either directly or indirectly.
- Level 3—Valuations based on inputs that are unobservable and significant to the overall fair value measurement.

The Company estimates the fair values of derivative liabilities utilizing Level 3 inputs. No derivative liabilities have been transferred between the classification levels. Estimating the fair values of derivative liabilities requires the use of significant and subjective inputs that may, and are likely to, change over the duration of the instrument with related changes in internal and external market factors.

There were no assets or liabilities that require recurring fair value measurements as of December 31, 2020 or 2019.

The following table sets forth a summary of changes in the fair value of the Company's derivative liabilities during the year ended December 31, 2019:

	<b>Asset Acquisition Derivative Liability</b>
Balance, December 31, 2018	\$ 1,117,000
Changes in estimated fair value	(1,117,000)
Balance, December 31, 2019	\$ —

The Company estimated the fair value of this derivative by forecasting the timing and likelihood of the events occurring and discounting the probability adjusted payments using an appropriate discount based on market interest rates and its own non-performance risk as required by ASC 820 – *Fair Value Measurement*. There is no longer a potential payment requirement associated with the derivative liability subsequent to the Merger. Accordingly, the fair value of the derivative liability was reduced to zero with the associated change recorded in other income.

## 5. The Merger

On May 9, 2019, the Company completed the Merger (see Note 1). On the date of the Merger, AmpliPhi had, and the Company currently has, IPR&D related to the *S. aureus* development program, a phage product candidate for the treatment of *S. aureus* infections. The product candidate was utilized in clinical applications through single-patient expanded access guidelines established by U.S. and Australian regulatory agencies. Further, AmpliPhi provided a workforce that is considered to have the necessary skills, knowledge, and experience to perform a process, that when applied to IPR&D is critical to the ability to convert it into outputs. Based on this evaluation, the Company determined that the Merger should be accounted for as a business combination pursuant to Financial Accounting Standards Board Accounting Standards Codification Topic 805, *Business Combinations* (“ASC 805”).

In connection with the Merger, the Company allocated the total purchase consideration of \$10.7 million in stock to the net assets and liabilities acquired, including identifiable intangible assets and related deferred tax liability, based on their respective fair values at the acquisition date. The Company recognizes deferred tax liabilities for indefinite-lived intangible assets in accordance with ASC 740, *Income Taxes*.

The following table summarizes the allocation of the purchase price to the fair value of the respective assets and liabilities acquired, which was finalized in the quarter ended December 31, 2019.

Cash and cash equivalents	\$ 3,008,000
Prepaid expenses	257,000
Property and equipment	708,000
Right of use asset	271,000
In-process research and development (1)	10,256,000
Total assets	14,500,000
Accounts payable	(4,004,000)
Other long term liabilities	(199,000)
Deferred tax liability	(3,077,000)
Net assets acquired	7,220,000
Purchase price	10,710,000
Goodwill (2)	\$ 3,490,000

(1) IPR&D relates to a bacteriophage product candidate for the treatment of *S. aureus* infections in patients with bacteremia. The valuation of this asset was prepared by an independent third party based on estimated discounted cash flows based on probability-weighted future development expenditures and revenue streams provided by the Company’s management.

(2) Goodwill represents the excess of the purchase price over the valuation of the fair value of tangible and identified intangible assets, less liabilities, acquired.

In addition, the Company incurred and expensed costs directly related to the Merger totaling approximately \$1.1 million which are included in general and administrative expenses in the consolidated statement of operations.

Since the closing date of the Merger, the results of AmpliPhi’s operations have been included in the Company’s consolidated financial statements. Selected amounts related to AmpliPhi’s business included in the Company’s consolidated statements of operations from the period of May 9, 2019, the date of the Merger, to December 31, 2019 and



for the year ended December 31, 2020 are summarized in the table below. Amounts shown do not include the offset to research and development expenses related to AU Tax rebates discussed in Note 3.

	Year Ended December 31, 2020	May 9, 2019 9 through December 31, 2019
Research and development expenses	\$ 583,000	\$ 1,321,000
General and administrative expenses	1,205,000	1,917,000
Sale of Slovenia	—	663,000
Net loss	<u>\$ 1,788,000</u>	<u>\$ 3,901,000</u>

## 6. Loss on Sale of Assets

The Company produces clinical quantities of each of its bacteriophage product candidates at its cGMP-compliant manufacturing facilities. With the completion of the Merger in May 2019, the Company had two manufacturing sites, one in Marina del Rey, California and additionally in Ljubljana, Slovenia. Each manufacturing site had clean rooms, in-use equipment and experienced manufacturing personnel.

On November 8, 2019, the Company entered into an agreement to sell the Slovenia subsidiary to an un-related third-party buyer (“Buyer”) and on December 6, 2019, the sale transaction was completed. The agreement requires that the Buyer maintain the ability of the Slovenia facility to manufacture the Company’s products. If the Company requires such products, the Buyer and the Company would negotiate a supply agreement governing the purchase and sale of such products. In addition, the Company has the right to repurchase the Slovenian subsidiary’s operations at any point in the five year period immediately following the closing. The Company recognized a loss on sale of assets of \$0.7 million, representing the excess of the net assets sold over proceeds received, in the statement of operations for the year ended December 31, 2019.

## 7. Net Loss per Share

Diluted EPS for the year ended December 31, 2019 included a numerator adjustment to remove the gain related to the change in fair value of derivative liabilities \$0.9 million, net of interest. Additionally, diluted EPS for the year ended December 31, 2019 included an adjustment to the weighted-average shares outstanding to appropriately weigh the shares issued for the Synthetic Genomics asset acquisition discussed in Note 12.

	Year Ended December 31,	
	2020	2019
Basic and diluted net loss per share calculation:		
Net loss, basic	\$ (22,181,000)	\$ (19,479,000)
Change in fair value of derivative liabilities, net of interest	—	(938,000)
Net loss, diluted	<u>(22,181,000)</u>	<u>(20,417,000)</u>
Weighted average shares outstanding, basic	16,415,012	7,827,197
Net loss per share, basic	<u>\$ (1.35)</u>	<u>\$ (2.49)</u>
Weighted average shares outstanding, diluted	16,415,012	8,009,909
Net loss per share, diluted	<u>\$ (1.35)</u>	<u>\$ (2.55)</u>

The following outstanding securities at December 31, 2020 and 2019 have been excluded from the computation of diluted weighted average shares outstanding for the years ended December 31, 2020 and 2019, as they would have been anti-dilutive:

	Year Ended December 31,	
	2020	2019
Options	1,668,926	1,275,380
Restricted stock awards	322,756	343,493
Warrants	10,547,618	1,854,007
<b>Total</b>	<b>12,539,300</b>	<b>3,472,880</b>

## 8. Balance Sheet Details

### *Property and Equipment, net*

Property and equipment consisted of the following:

	December 31, 2020	December 31, 2019
Laboratory equipment	\$ 6,547,000	\$ 6,047,000
Furniture and fixtures	719,000	646,000
Office and computer equipment	413,000	323,000
Leasehold improvements	3,423,000	3,329,000
Total	11,102,000	10,345,000
Less: accumulated depreciation	(9,055,000)	(8,158,000)
Property and equipment, net	<u>\$ 2,047,000</u>	<u>\$ 2,187,000</u>

Depreciation expense totaled \$1.1 million and \$1.4 million the years ended December 31, 2020 and 2019, respectively.

### *Accounts Payable and Accrued Liabilities*

Accounts payable and accrued liabilities consisted of the following:

	December 31,	
	2020	2019
Accounts payable	\$ 956,000	\$ 547,000
Accrued clinical trial expenses	248,000	—
Other accrued expenses	725,000	731,000
	<u>\$ 1,929,000</u>	<u>\$ 1,278,000</u>

## 9. Income Taxes

Loss before income taxes consisted of the following components:

	Year Ended December 31,	
	2020	2019
United States	\$ (21,583,000)	\$ (18,341,000)
Foreign	(598,000)	(1,138,000)
Total	<u>\$ (22,181,000)</u>	<u>\$ (19,479,000)</u>

The company has not recognized any current or deferred tax expense on its US and Foreign pre-tax losses for the years ended December 31, 2020 and 2019.

The differences between the Company's effective tax rate and the U.S. federal statutory tax rate were as follows:

	December 31,	
	2020	2019
U.S. federal statutory income tax rate	21.0 %	21.0 %
Adjustments for tax effects of:		
State income taxes, net of federal tax	6.6 %	2.6 %
Stock-based compensation	(0.7)%	(0.5)%
Change in valuation allowance	(28.5)%	(22.7)%
Net operating loss carryforwards and credit expirations	0 %	(3.1)%
Stock issuance costs	0 %	(1.2)%
Gain on derivative liability extinguishment	0 %	1.2 %
Slovenia facility sale	0 %	1.9 %
Permanent differences	0 %	1.3 %
Other	1.6 %	(0.5)%
Effective income tax rate	<u>0.0 %</u>	<u>0.0 %</u>

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

	December 31,	
	2020	2019
Deferred tax assets:		
Net operating loss carryforwards	\$ 31,243,000	\$ 26,291,000
Capitalized research and development	15,789,000	15,262,000
Stock-based compensation	2,087,000	1,358,000
Depreciation and amortization	1,405,000	1,632,000
Lease accounting	3,478,000	801,000
Other	989,000	981,000
Total deferred tax assets before valuation allowance	54,991,000	46,325,000
Less: valuation allowance	(51,972,000)	(45,670,000)
Total deferred tax assets after valuation allowance	<u>3,019,000</u>	<u>655,000</u>
Deferred tax liabilities:		
Right-of-use asset	(3,019,000)	(655,000)
In-process research and development	(3,077,000)	(3,077,000)
Total deferred tax liabilities	<u>(6,096,000)</u>	<u>(3,732,000)</u>
Net deferred tax liability	<u>\$ (3,077,000)</u>	<u>\$ (3,077,000)</u>

The Company's net operating loss carryforwards at December 31, 2020 are \$110.5 million and \$78.7 million for federal and state income tax purposes, respectively. Federal and state net operating loss carryforwards are available to offset future taxable income, if any, and will begin to expire in 2026 to 2028, respectively. The federal NOL's generated in tax years 2018 and forward will carryforward indefinitely.

The ability of the Company to utilize net operating losses carryforwards to reduce future domestic taxable income and domestic income tax is subject to various limitations under the Internal Revenue Code (Code). The utilization of such carryforwards may be limited upon the occurrence of certain ownership changes during any three-year period resulting in an aggregate change of more than 50% in beneficial ownership. The Company previously determined an ownership change occurred on May 9, 2019 as a result of the merger discussed in Note 5. The resulting limitation significantly reduced the Company's ability to utilize its net operating loss and credit carryovers before the expire.

Accordingly, in 2019 the Company reduced its deferred tax assets for the net operating loss and credit carryforwards that were expected to expire unused with a corresponding offset to the valuation allowance recorded against such assets. Future ownership changes under Section 382 may also limit the Company's ability to fully utilize any remaining tax benefits. The Company does not believe that it has experienced another more-than 50% ownership change since the date of the merger. Future equity transactions by the Company, or by 5% of stockholders, could cause a more-than-50% ownership change and, therefore, trigger a limitation on the annual utilization of net operating losses.

The Company has generated federal and state income tax losses in all years since its inception. Accordingly, management has determined that significant negative evidence precludes the Company from recording a net deferred tax asset for financial statement purposes as it is more likely than not that its deferred tax assets will not be realized.

The Company files income tax returns in the U.S. federal jurisdiction, state of California and certain foreign jurisdictions. As of December 31, 2020, the Company is no longer subject to U.S. federal income tax examinations for tax years ended on or before December 31, 2014 or to California state income tax examinations for tax years ended on or before December 31, 2013. 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, 2020 and 2019.

The Company's policy is to classify interest and penalties on uncertain tax positions as a component of tax expense. As of December 31, 2020, the Company has no accrued interest or penalties related to uncertain tax positions.

## **10. Paycheck Protection Program Loan**

In April 2020, the Company received loan proceeds of \$717,000 ("PPP Loan") under the Paycheck Protection Program ("PPP"). The PPP, established as part of the Coronavirus Aid, Relief and Economic Security Act, provides for loans to qualifying businesses for amounts up to 2.5 times the average monthly payroll expenses of the qualifying business, calculated as provided under the PPP. The PPP provides a mechanism for forgiveness of up to the full amount borrowed after twenty-four weeks as long as the borrower uses the loan proceeds during the twenty-four week period after the loan origination for eligible purposes, including payroll costs, certain benefits costs, rent and utilities costs or other permitted purposes, and maintains its payroll levels, subject to certain other requirements and limitations. The amount of loan forgiveness is subject to reduction, among other reasons, if the borrower terminates employees or reduces salaries during the measurement period. The Company is prepared to submit its application for loan forgiveness and anticipates that the loan will be forgiven based on the current guidelines. The Company cannot provide any assurance that it will be eligible for loan forgiveness or that any amount of the PPP loan will ultimately be forgiven.

The PPP Loan is unsecured, evidenced by a promissory note (the "Note") given by the Company as borrower through its bank, serving as the lender. The interest rate on the Note is 1.0% per annum. Payments of principal and interest are deferred until August 2021 (the "Deferral Period"). Any unforgiven portion of the PPP Loan is payable over the two-year term, with payments deferred during the Deferral Period. The Company is permitted to prepay the Note at any time without payment of any premium.

## **11. Commitments and Contingencies**

### ***Operating Leases***

The Company leases office and research and development space under a noncancelable operating lease in Marina Del Rey, CA. The lease commenced January 1, 2012 and in April 2020, the Company amended the lease ("Lease Amendment") which, among other things, extended the lease term through December 31, 2031. Base annual rent for calendar year 2022 under the Lease Amendment will be approximately \$1.9 million, and base rent increases by 3% annually and will be \$2.5 million by the end of the amended term. In addition, the Company received rent abatement for six months starting May 1, 2020, and an allowance for tenant improvements of \$0.8 million to be used during calendar

year of 2021. In accordance with authoritative guidance, the Company remeasured the lease liability to be \$11.7 million and related right of use asset of \$11.0 million as of the Lease Amendment date with an incremental borrowing rate of 12.9%.

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

Future minimum annual lease payments under the Company's noncancelable operating leases as of December 31, 2020, are as follows:

	<b>Operating Leases</b>
2021	\$ 1,638,000
2022	1,893,000
2023	1,950,000
2024	2,008,000
2025	2,069,000
Thereafter	13,783,000
Total minimum lease payments	<u>23,341,000</u>
Less: amount representing interest	<u>(10,913,000)</u>
Present value of operating lease obligations	<u>12,428,000</u>
Less: current portion	<u>(1,551,000)</u>
Noncurrent operating lease obligations	<u>\$ 10,877,000</u>

Rent expense was \$1.9 million and \$1.5 million for the years ended December 31, 2020 and 2019, respectively. Total cash payments for operating leases as included in the consolidated statements of cash flows during the year ended December 31, 2020 and 2019 was \$1.1 million and \$1.7 million, respectively.

### ***License Agreement***

The Company entered into an exclusive license agreement with The Regents of the University of California (the "Regents") on April 24, 2007 including amendments for the use of several patents. As part of the license agreement, the Company issued The Regents 10,540 shares of common stock.

The Company is required to pay the Regents \$5,000 in annual maintenance fees and milestone fees for the first licensed product in both the Human Dental and Human Medical fields of application as follows: 1) filing of an Investigational New Drug application: \$20,000; 2) completing a Phase 1 clinical trial: \$50,000; 3) completing a Phase 2 clinical trial: \$50,000; 4) completing a Phase 3 clinical trial: \$150,000; and 5) first commercial sale of a license product: \$250,000.

Total expenses incurred under the Regents license agreement was \$21,000 for each of the years ended December 31, 2020 and 2019. On October 21, 2020, the Company provided the notice to the Regents to terminate the license agreement, which would become effective 90 days from the date of the termination notice.

### ***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.

## 12. Synthetic Genomics Asset Acquisition

On February 28, 2018, C3J completed an acquisition of certain synthetic phage assets (the "synthetic phage assets") from Synthetic Genomics, Inc. ("SGI") for consideration consisting of \$8.0 million in cash and \$27.0 million in equity. The cash payments consisted of: \$1.0 million paid at closing on February 28, 2018, \$1.0 million at one year from closing, \$1.0 million at two years from closing, and \$5.0 million at three years from closing (the payments due on the one, two, three year anniversary are collectively the "time-based payment obligation"). The equity payment (the "equity payment" and, together with the time-based payment obligation, the "deferred purchase price arrangement") was due upon the earlier of the initial public offering of shares of C3J's common stock pursuant to an effective registration statement under the Securities Act of 1933, as amended, the sale of all or substantially all of C3J's assets to a third party, or a consolidation or merger into a third party. On December 20, 2018, in contemplation of the Merger (see Note 5), the deferred purchase price arrangement was amended. Under the amended agreement, the purchase consideration consisted of (i) closing consideration of \$1.0 million paid on February 28, 2018, (ii) cash payments of \$1.0 million on January 31, 2019, \$1.0 million on January 31, 2020, and \$2.0 million on January 31, 2021, (iii) an issuance of that number of shares of C3J's common stock equal to ten percent of C3J's fully-diluted capitalization, excluding options and restricted stock awards, immediately prior to the closing of the Merger, and (iv) potential milestone payments of up to \$39.5 million related to the development and relevant regulatory approval of products utilizing bacteriophage from the synthetic phage assets acquired from SGI (the "milestone payment obligation").

The equity payment was determined to be a derivative liability in accordance with ASC 815, *Derivatives and Hedging* and was initially recorded at its fair value of \$2.8 million. Throughout 2018 and until May 9, 2019, the derivative liability was adjusted to its fair value based upon a payment probability assessment and marked-to-market at the end of each period (see Note 4). Following the December 20, 2018 amendment to the deferred purchase price arrangement, the Company considered the probability of the reduction to the share issuance consideration in estimating the fair value of the derivative liability. The equity payment was settled on May 9, 2019, the date of the Merger (Note 5). There was no interest expense related to the equity payment for the year ended December 31, 2020 or 2019.

For year ended December 31, 2020 and 2019, the Company recognized \$0.6 million and \$0.9 million of interest expense related to the time-based payment obligations.

## 13. Research Collaboration Arrangement

In connection with the Synthetic Phage Asset Acquisition discussed in Note 12, the Company was assigned a research collaboration agreement ("Research and Option Agreement") with Merck.

In May 2019, the Research and Option Agreement was amended and extended for four years. During the research term, the Company will be entitled to milestone payments tied to the achievement of product development milestone events in the amount of \$1.5 million. The collaboration agreement also provides for the initiation of a second research program should Merck exercise that option during the initial research term and pays the option fee of \$1.5 million. To date, Merck has not exercised its license option nor has the Company reached any milestones or earned any revenue under the Research and Option Agreement. Merck has the right to terminate the agreement at any time with 90 days' notice. Each party to the Research and Option Agreement is responsible for its costs and expenses in connection with the research program.

## 14. Grants and Awards

### MTEC Grant

On June 15, 2020, the Company entered into an Research Project Award agreement (the “MTEC Agreement”) with the Medical Technology Enterprise Consortium (“MTEC”), pursuant to which the Company will receive a \$15.0 million grant and entered into a three-year program administered by DoD through MTEC with funding from the Defense Health Agency and Joint Warfighter Medical Research Program. The Company plans to use the grant to partially fund a Phase 1b/2, randomized, double-blind, placebo-controlled, dose escalation clinical study of Armata's therapeutic phage-based candidate, AP-SA02, for the treatment of complicated *S. aureus* bacteremia infections. The MTEC Agreement specifies that the grant will be paid to the Company through a cost reimbursable model, based on agreed upon cost share percentages, and the grant money received is not refundable to MTEC.

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

The MTEC Agreement will be effective through January 25, 2024. The MTEC Agreement may be terminated in whole or in part, 30 calendar days following the 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 on the statement of operations when related costs are incurred. The Company recognized \$0.8 million in grant revenue from the MTEC Agreement during the year ended December 31, 2020.

### CFF Therapeutics Development Award

On March 13, 2020, the Company entered into an award agreement (the “Agreement”) with CFF, pursuant to which it received a Therapeutics Development Award of up to \$5.0 million (the “Award”). The Award will be used to fund a portion of the Company's Phase 1b/2 clinical trial of the *P. aeruginosa* phage candidate, AP-PA02, as a treatment for *P. aeruginosa* airway infections in people with CF.

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

If the Company ceases to use commercially reasonable efforts directed to the development of AP-PA02, or any other Product (as defined in the 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 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 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 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 Agreement. Either CFF or the Company may terminate the 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 Agreement.

The Company concluded that the CFF Award is in the scope of ASC 808. Accordingly, as discussed in Note 3, award amounts received from CFF upon achievement of certain milestones are recognized as credits to research and development expenses in the period the expenses are incurred. During year ended December 31, 2020, the Company recognized \$1.0 million as credits to research and development expenses related to the CFF Award. 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.

## 15. Stockholders’ Equity

The Company is authorized to issue one class of shares designated as “Common Stock”. The number of shares of common stock authorized to be issued is 217,000,000 shares.

### *Private Investment*

On January 27, 2020, the Company entered into the Securities Purchase Agreement with Innoviva, pursuant to which the Company agreed to issue and sell to Innoviva, in the 2020 Private Placement, 8,710,800 newly issued shares of the Company’s common stock and warrants to purchase 8,710,800 shares of common stock, with an exercise price per share of \$2.87. Each share of common stock was sold together with one common warrant granting the warrant holder the right to purchase an additional share of common stock (“Common Unit”) at \$2.87 per share. The 2020 Private Placement occurred in two tranches. The first closing occurred on February 12, 2020, at which time Innoviva purchased 993,139 Common Units in exchange for an aggregate gross cash payment of approximately \$2.8 million. On March 27, 2020, the second closing occurred subsequent to shareholder approval, at which time Innoviva purchased 7,717,661 Common Units in exchange for aggregate gross proceeds of \$22.2 million.

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

As described in more detail in Note 2, in January 2021, the Company entered into a securities purchase agreement with Innoviva for the 2021 Private Placement.

### *Warrants*

At December 31, 2020, outstanding warrants to purchase shares of common stock are as follows:

Shares Underlying Outstanding Warrants	Exercise Price	Expiration Date
2,246	\$ 567.00	March 31, 2021
597,881	\$ 21.00	May 10, 2022
1,235,491	\$ 5.60	October 16, 2023
993,139	\$ 2.87	February 12, 2025
7,717,661	\$ 2.87	March 27, 2025
1,200	\$ 1,680.00	None
<u>10,547,618</u>		



## 16. Stock-based Compensation

### *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, agents, advisors and independent contractors who provide services to the Company or to a subsidiary of the Company. The exercise price for stock options must not be less than the fair market value of the underlying shares on the date of grant. Stock options expire no later than ten years from the date of grant and generally vest and typically become exercisable over a four-year period following the date of grant. Upon the exercise of stock options, the Company issues the resulting shares from shares reserved for issuance under the 2016 Plan. Under the 2016 Plan, the number of shares authorized for issuance automatically increases annually beginning January 1, 2017 and through January 1, 2026.

In connection with the Merger, the Company assumed the C3J Jian, Inc. Amended 2006 Stock Option Plan (the “Assumed 2006 Plan”) and the C3J Therapeutics, Inc. 2016 Stock Plan (the “Assumed 2016 Plan”). These plans provided for stock option and restricted stock awards (“RSAs”) to C3J employees in years prior to the Merger with AmpliPhi. The number of shares subject to each outstanding stock option and RSA under those assumed plans, along with the exercise price of stock options, were equitably adjusted pursuant to the terms of the plans to reflect the impact of the Merger and the one-for-fourteen reverse stock split, in each case in a manner intended to preserve the then-current intrinsic value of the awards. No additional awards will be made under either plan. The assumed C3J stock options were substantially vested and expensed as of the merger date. Vesting of the assumed C3J RSAs is based on the occurrence of a public liquidity event, or a change in control. In the event of a public liquidity event, service or milestone based vesting schedules begins. Service periods are generally two to four years. In the event of a change in control, 100% vesting occurs upon the closing of such an event. The merger with AmpliPhi constituted a public liquidity event and triggered the start of vesting of RSAs.

In November 2020, the Company made an inducement grant of a restricted stock unit award outside of its 2016 Plan to a new employee for 70,000 shares of the Company’s common stock, of which 40,000 shares will vest six months from the grant date and the remaining 30,000 shares will vest three years from the grant date. In addition, the Company granted this new employee 33,000 shares of its common stock which were immediately vested upon issuance.

### *Stock-based Compensation*

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

The assumptions used in the Black-Scholes model for options granted during the year ended December 31, 2020 are presented below:

	<b>Year Ended December 31, 2020</b>
Risk-free interest rate	0.13% --1.48%
Expected volatility	90.43% -- 94.0%
Expected term (in years)	5.5 – 7.0
Expected dividend yield	0%

The risk-free interest rate is based on the U.S. Treasury yield for a period consistent with the expected term of the option in effect at the time of the grant. Expected volatility is based on an analysis of the historical volatility of Armata and peer companies’ common stock. 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. For stock options granted to parties other than employees or directors, the Company elects, on a grant by grant basis, to use the expected term or the contractual term of the option award. The Company has never declared or paid dividends on its common stock and has no plans to do so in the foreseeable future. Forfeitures are recognized as a reduction of stock-based compensation expense as they occur.

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

	Year Ended December 31,	
	2020	2019
Research and development	\$ 1,252,000	\$ 872,000
General and administrative	2,223,000	3,398,000
Total stock-based compensation	<u>\$ 3,475,000</u>	<u>\$ 4,270,000</u>

	Year Ended December 31,	
	2020	2019
Expense related to RSA's issued prior to Merger and vesting beginning on Merger closing date	\$ 2,081,000	\$ 2,152,000
Acceleration of RSA expense in connection with executive severance	55,000	1,244,000
Expense related to inducement award	166,000	—
Expense related to vesting of stock options issued under the Company's stock plans	1,173,000	874,000
Total stock-based compensation expense	<u>\$ 3,475,000</u>	<u>\$ 4,270,000</u>

Stock option transactions during the year ended December 31, 2020 are presented below:

	Options Outstanding			
	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2019	1,275,380	\$ 7.61	8.81	—
Granted	551,766	3.38	—	—
Exercised	(27,382)	3.15	—	14,000
Forfeited/Cancelled	(130,838)	5.69	—	—
Outstanding at December 31, 2020	<u>1,668,926</u>	<u>\$ 6.30</u>	<u>8.32</u>	<u>\$ —</u>
Vested and expected to vest at December 31, 2020	<u>1,668,926</u>	<u>\$ 6.30</u>	<u>8.32</u>	<u>\$ —</u>
Exercisable at December 31, 2020	<u>439,526</u>	<u>\$ 14.82</u>	<u>6.75</u>	<u>\$ —</u>

Restricted stock award transactions under the Assumed 2016 Plan and restricted stock unit award transactions during the year ended December 31, 2020 are presented below:

	Shares	Weighted Avg Grant Date Fair Value
	Outstanding at December 31, 2019	343,493
Granted	103,000	3.34
Forfeited/Cancelled	(4,010)	16.02
Vested and Issued as Common Stock	(119,727)	12.24
Outstanding at December 31, 2020	<u>322,756</u>	<u>\$ 19.55</u>

The aggregate intrinsic value of options at December 31, 2020 is based on the Company's closing stock price on that date of \$2.98 per share. As of December 31, 2020, there was \$3.4 million of total unrecognized compensation

expense related to unvested stock options and RSAs, excluding unvested RSAs with performance conditions deemed to be improbable for the period ended December 31, 2020, which the Company expects to recognize over the weighted average remaining period of 1.71 years.

***Shares Reserved For Future Issuance***

As of December 31, 2020, the Company had reserved shares of its common stock for future issuance as follows:

	<u>Shares Reserved</u>
Stock options outstanding	1,668,926
Unvested restricted stock units	70,000
Employee stock purchase plan	7,605
Available for future grants under the 2016 Plan	138,814
Warrants outstanding	<u>10,547,618</u>
Total shares reserved	<u>12,432,963</u>

**17. 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. Matching contributions to the 401(k) plan are made for certain eligible employees to meet non-discrimination provisions of the plan. The Company did not make matching contributions to the 401(k) plan for the years ended December 31, 2020 and 2019.

## **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 maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our periodic and current reports that we file with the Commission is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and our principal financial officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives. In reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. In addition, the design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

As of December 31, 2020, our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2020.

#### ***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 Chief 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, 2020, 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). 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 Chief Financial Officer, concluded that, as of December 31, 2020, our internal control over financial reporting was effective based on those criteria.

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 pursuant to SEC rules that permit us to provide only management's report in this Annual Report on Form 10-K.

***Changes in Internal Control Over Financial Reporting.***

An evaluation was also performed under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, of any changes in our internal control over financial reporting that occurred during our last fiscal quarter and that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. There were no changes in our internal control over financial reporting during the quarter ended December 31, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**Item 9B. OTHER INFORMATION**

None.

## PART III

### Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

#### MANAGEMENT

The following table sets forth information about our executive officers and directors as of March 1, 2021.

Name	Age	Position(s)
Todd R. Patrick	58	Chief Executive Officer, Director
Brian Varnum, Ph.D.	61	President & Chief Development Officer
Steve R. Martin	60	Chief Financial Officer
Duane Morris	70	Vice President, Operations
<b>Non-Employee Directors</b>		
Richard J. Bastiani, Ph.D.(3)	78	Chairman of the Board of Directors
Odysseas D. Kostas, M.D. (3)(4)	46	Director
Robin C. Kramer (1)	55	Director
Joseph M. Patti, Ph.D.(2)	56	Director
Todd C. Peterson, Ph.D. (1)	63	Director
Sarah J. Schlesinger, M.D.(2)(4)	61	Director

(1) Member of the Audit Committee.

(2) Member of the Compensation Committee.

(3) Member of the Nominating and Corporate Governance Committee.

(4) Serves as a designee of Innoviva under the Investor Rights Agreement.

**Todd R. Patrick** has served as our Chief Executive Officer and as a director since the consummation of the Merger. He previously served as President and Chief Executive Officer of C3J from 2010 until the consummation of the Merger, and as a member of C3J's board of directors from 2009 until the consummation of the Merger. Before joining C3J, Mr. Patrick was the President and board member of ID Biomedical Corporation from 1994 until 2005, when the company was acquired by GlaxoSmithKline. Prior to ID Biomedical Corporation, Mr. Patrick was the Director of the Office of Intellectual Property Administration at the University of California, Los Angeles ("UCLA"), where he was responsible for the patenting and licensing of intellectual property arising out of UCLA. Mr. Patrick has been involved in several start-ups and has helped raise over \$600 million in equity or debt capital. Mr. Patrick currently serves on the board of directors of CRH Medical Corporation (NYSE: CRHM), where he has served since 2006 and is a member of the audit, corporate governance and nominating, and compensation committees; and AltPep Corporation. He is also on the board of directors of the non-profit Foster Foundation.

Mr. Patrick was selected as a director because of his extensive leadership experience with biotechnology companies and his in-depth understanding of our business, strategy and management team, as well as his experience serving as a public company director and executive officer.

**Brian Varnum, Ph.D.** has served as our President and Chief Development Officer since the Merger. He previously served at C3J as its Vice President of Product Development starting in 2012 and became its Chief Development Officer in 2014, serving in that role until the Merger in May 2019. Dr. Varnum is a biotech veteran with more than 20 years of experience. Dr. Varnum began his career with Amgen Inc. and spent more than 18 years at the biotech pioneer as that company grew from a start-up to a large and successful biotechnology company. He started in discovery research where his team purified novel growth factors and advanced antibodies and small molecules into clinical studies. Dr. Varnum also worked in development, assisting with clinical development of proteins, antibodies and small molecules. In this capacity, he contributed to key regulatory filings, market research and product launch, giving him experience in drug discovery and development from the lab bench to product launch and marketing. After retiring from Amgen Inc. in 2007, Dr. Varnum turned his focus to the start-up landscape, working in several capacities, including assisting investors,

entrepreneurs and start-ups in the assessment of technologies for funding or in-licensing. In these capacities, he established research strategies and plans, and served as Chief Scientific Officer for several companies, securing funding, and executing research contracts with large and mid-sized pharmaceutical companies. Dr. Varnum obtained his Ph.D. from UCLA studying oncogenes, and his drug development research experience includes hematopoietic growth factor discovery, oncology, auto-immune/inflammatory disorders, personalized medicine in inflammatory bowel disease and infectious diseases.

**Steve R. Martin** has served as our Chief Financial Officer since January 2016. Mr. Martin served as Senior Vice President and Chief Financial Officer of Applied Proteomics, Inc., a molecular diagnostics company, from December 2014 to August 2015. From June 2011 to December 2014, Mr. Martin served as Senior Vice President and Chief Financial Officer of Apricus Biosciences, Inc., a publicly traded pharmaceutical company, and served as the Interim Chief Executive Officer of Apricus from November 2012 through March 2013. From 2008 to January 2011, Mr. Martin served as Senior Vice President and Chief Financial Officer of BakBone Software, a publicly traded software company. During his final 10 months with BakBone until the company's acquisition in January 2011, Mr. Martin also served as BakBone's Interim Chief Executive Officer. From 2005 to 2007, Mr. Martin served as Chief Financial Officer of Stratagene Corporation, a publicly traded research products and clinical diagnostics company. Mr. Martin's previous experience also includes serving as Controller with Gen-Probe Incorporated, a publicly traded molecular diagnostics company, as well as 10 years with Deloitte & Touche LLP, a public accounting firm. Mr. Martin currently serves on the board of directors of Ensysce Biosciences, where he has served since 2020. Mr. Martin holds a B.S. degree from San Diego State University and is a certified public accountant (inactive).

**Duane Morris** has served as our Vice President, Operations since the Merger. He previously led the production, quality, facilities and clinical operations areas for C3J from December 2011 to May 2019. Prior to joining C3J, Mr. Morris was the Chief Operating Officer at Response Biomedical Corp. in Vancouver, Canada from February 2007 to October 2010, where he directed the expansion of manufacturing facilities and scale-up of in-vitro diagnostic products. Prior to his tenure at Response Biomedical Corp., Mr. Morris was responsible for all manufacturing and quality control activities for ID Biomedical Corporation from February 2003 until its acquisition by GlaxoSmithKline in 2005. From 2005 to December 2006, Mr. Morris served as general manager of GlaxoSmithKline Biologicals, in which role he was responsible for all North American Operations, which included influenza vaccine production for GlaxoSmithKline. Mr. Morris started his career at Syntex Corporation (now Roche) in Palo Alto, where he spent 21 years in positions of increasing responsibility, ultimately becoming the Director of Pharmaceutical Manufacturing. Mr. Morris earned his B.A. in Management from Saint Mary's College in Moraga, California.

### *Non-Employee Directors*

**Richard J. Bastiani**, Ph.D., has served as a member of the board of directors and our Chairman since the Merger. He has previously served as a member of the board of directors of C3J from 2013 until the consummation of the Merger. Dr. Bastiani is currently retired. He has over 40 years of industry experience and has served on the boards of 14 biotechnology and life science companies throughout his career, including as a director of BioNex Solutions, Inc., a privately-held company that develops and manufactures systems for laboratory automation and liquid handling, since 2014. From 1995 through 2018, he served as a member of the board of directors of Abaxis, Inc., a formerly public diagnostic company providing point of care, automated blood analysis systems and single test products for human and veterinary markets that was acquired by Zoetis Inc. in 2018 for approximately \$2.0 billion. From 1995 to 1998, Dr. Bastiani was President of Dendreon, a biotechnology company dedicated to providing innovative cell therapies for cancer. From 1970 until 1995, Dr. Bastiani held a number of positions with Syva Company, a diagnostic company, including as President from 1991 until Syva Company was acquired by a subsidiary of Hoechst AG of Germany in 1995. From 2007 to 2011, Dr. Bastiani served as chairman of the board of directors of Response Biomedical Corp. In 1996, Dr. Bastiani was appointed to the board of directors of ID Biomedical Corporation, and he served as the chairman of the board of directors from 1998 until the company's 2005 acquisition by GlaxoSmithKline. Dr. Bastiani also served as co-founder and a director of DiscoverRx, a privately held company developing and selling high-throughput screening, protein profile and cell pathway assays and services, and on the board of Pathwork Diagnostics, a privately held molecular diagnostic company focused on cancer diagnostics using proprietary genomic profiling and informatics. Dr. Bastiani also serves on the Board of Fellows of Santa Clara University. He received his Ph.D. in Chemistry from

Michigan State University in 1970, his M.S. in Chemistry from California State University in 1967, and his B.S. in Chemistry from Santa Clara University in 1964.

*Director Qualifications.* Dr. Bastiani was selected as a director because of his extensive leadership experience with biotechnology companies and his in-depth knowledge of the industry, as well as his experience serving on the boards of directors of various public and private companies.

**Odysseas D. Kostas**, M.D. has served as a member of our board of directors since February 2020. He also currently serves as a director of Innoviva, Inc. He is a Partner and Senior Managing Director at Sarissa Capital Management LP. Sarissa Capital focuses on improving the strategies of companies to enhance shareholder value. Prior to joining Sarissa Capital, Dr. Kostas served as a Director at Evercore ISI (formerly ISI), covering the biotechnology and pharmaceutical industries. Previously, he practiced internal medicine as part of the Yale New Haven Health System and was engaged as a consultant to various biotechnology companies. Dr. Kostas also previously served on the board of directors of Enzon Pharmaceuticals. Dr. Kostas has a B.S from Massachusetts Institute of Technology (MIT) and a M.D. from University of Texas Southwestern Medical School. Dr. Kostas has demonstrated leadership in his field, and his knowledge of and experience in our industry contributed to our conclusion that he should serve as a director.

*Director Qualifications.* Mr. Kostas was selected as a director because of his extensive leadership experience with biotechnology companies and his in-depth knowledge of our business, strategy and management team, as well as his experience serving as a public company director.

**Robin C. Kramer** has served as Senior Vice President, Chief Accounting Officer and Head of Global Business Services and Treasury of Biogen, a biopharma company, since January 2021. Ms. Kramer served as Biogen's Vice President, Chief Accounting Officer from November 2018 to December 2020. Prior to joining Biogen, Ms. Kramer served as the Senior Vice President and Chief Accounting Officer of Hertz Global Holdings, Inc., a car rental company, from May 2014 to November 2018. Prior to that, Ms. Kramer was an audit partner at Deloitte & Touche LLP (Deloitte), a professional services firm, from 2007 to 2014, including serving in Deloitte's National Office Accounting Standards and Communications Group from 2007 to 2010. From 2005 to 2007 Ms. Kramer served as Chief Accounting Officer of Fisher Scientific International, Inc., a laboratory supply and biotechnology company, and from 2004 to 2005 Ms. Kramer served as Director, External Reporting, Accounting and Control for the Gillette Company, a personal care company. Ms. Kramer also held partner positions in the public accounting firms of Ernst & Young LLP and Arthur Anderson LLP. Ms. Kramer is a licensed certified public accountant (CPA) in Massachusetts. She is a member of the Massachusetts Society of CPAs and the American Institute of CPAs. She has served as a Board Member of Samsung Bioepis Co., LTD. from July 2020 to Present, and as a Board member of the Center for Women and Enterprise from August 2020 – Present. She previously served as a Board Member for the Massachusetts State Board of Accountancy from September 2011 to December 2015 and Probus Insurance Company Europe DAC, from 2016 to 2018.

*Director Qualifications.* Ms. Kramer was selected as a director because of her years of experience in biotechnology and life sciences research and development and her in-depth knowledge of the industry. She has financial expertise, including a thorough understanding of financial statements, corporate finance and accounting and extensive experience with public companies, all of which makes her a valued member of the board of directors.

**Joseph M. Patti**, Ph.D. has served as a member of the board of directors since the consummation of the Merger. He also currently serves as President and Chief Executive Officer and director of AgilVax, Inc., a private biotechnology company that discovers and develops antibody-based therapeutics to treat metastatic cancer, and as President of JP Biotech Advisors, Inc., which provides strategic growth and drug development advice to emerging biotechnology companies. Dr. Patti is also a director of ECM Biosurgery, a private preclinical biotechnology company focused on collagen-based therapeutics. From November 2012, Dr. Patti served as Aviragen Therapeutics, Inc.'s Executive Vice President of Corporate Development and Strategy until October 2014, when he was appointed the company's President and Chief Executive Officer and director. He served in those roles until February 2018, when Aviragen merged with Vaxart, Inc. Prior to joining Aviragen, Dr. Patti co-founded Inhibitex, Inc. in 1994 and served as its Chief Scientific Officer and Senior Vice President of Research and Development from 2007 until it was acquired by Bristol Myers Squibb in February 2012. He also served as its Chief Scientific Officer and Vice President of Research and Development from 2005 to 2007 and as Vice President, Preclinical Development prior to that. Before co-founding Inhibitex, Dr. Patti



was an Assistant Professor at Texas A&M's Institute of Biosciences and Technology and also served on the faculty at the University of Texas Health Science Center Graduate School of Biomedical Sciences. Dr. Patti received a B.S. in Microbiology from the University of Pittsburgh, a M.S.P.H. from the University of Miami, School of Medicine and a Ph.D. in Biochemistry from the University of Alabama at Birmingham. Dr. Patti was a director of SciStem Therapeutics, Inc., a privately-held biotechnology company from 2012 to 2015. Dr. Patti was a director of Inhibitex from 1998 to 2005.

*Director Qualifications.* Dr. Patti was selected as a director because of his scientific knowledge and background and experience in developing numerous preclinical and clinical bio-pharmaceutical product candidates, as well as his senior management experience over the past decade in developing and implementing the business and financial strategies of emerging, publicly-traded biopharmaceutical companies and serving as a public company director.

**Todd C. Peterson**, Ph.D. has served as a member of the board of directors since October 2019. Dr. Todd Peterson is Founder and Principal at GenApex Bio (GenApex Biotechnology Consulting), a board practice, investment and advisory services LLC based in Coronado, California. He has over 35 years of experience in biotechnology and life sciences research and development across the areas of molecular and cell biology, nucleic acids and genomics product and technology development. His experience encompasses clinical diagnostics, life science research tools and drug discovery technologies, products, and markets. Previously, Dr. Peterson was Chief Scientific Officer at The Allen Institute in Seattle, Washington, overseeing science and technology strategy and growth initiatives across unit Institutes for Brain Science, Cell Science, Immunology, and the Paul G. Allen Frontiers Group. Prior to joining the Allen Institute, Dr. Peterson was Chief Technology Officer at Synthetic Genomics, Inc., a leader in synthetic biology and applied genomics technologies developing a robust portfolio of breakthrough solutions addressing major global issues. Prior to joining SGI, Dr. Peterson led Genomics and Synthetic Biology R&D at Invitrogen/Life Technologies (now Thermo Fisher Scientific), a global leader in life science tools. Prior to Life Technologies, Dr. Peterson held R&D positions with increasing leadership responsibilities and scope at Genicon Sciences, Trega Biosciences, Hybritech and Gen-Probe where he focused on technology research, product development and commercialization. Dr. Peterson was a postdoctoral fellow at the Max Planck Institute in Cologne Germany after receiving his Ph.D. in Microbiology at the University of Southern California School of Medicine. He obtained his M.A. in Biological Sciences and B.A. in Molecular Biology and Biochemistry at the University of California, Santa Barbara.

*Director Qualifications.* Dr. Peterson was selected as a director because of his years of experience in biotechnology and life sciences research and development, his in-depth knowledge of the industry and pre-clinical / early-stage scientific requirements, and his experience and understanding of our bacteriophage platform.

**Sarah J. Schlesinger**, M.D. has served as a member of our board of directors since February 2020. She also currently serves as a member of the Board of Directors of Innoviva, Inc., and serves on its Compensation Committee and the Nominating/Corporate Governance Committee. Dr. Schlesinger is an Associate Professor of Clinical Investigation at Rockefeller University and Senior Attending Physician at Rockefeller University Hospital. Dr. Schlesinger was The Clinical Director of the laboratory of Dr. Ralph Steinman (Nobel Laureate 2011) from 2002 until his death in 2011. Dr. Schlesinger led the Dendritic Cell section of the Division of Retrovirology at the Walter Reed Army Institute of Research and was also a member of the Division of Infectious and Parasitic Disease Pathology at the Armed Forces Institute of Pathology from 1994 to 2002. In 2002, Dr. Schlesinger rejoined Rockefeller University and began working with the International AIDS Vaccine Initiative as a Scientist in Vaccine Research and Design. Dr. Schlesinger has been a member of Rockefeller University Hospital's Institutional Review Board ("IRB") (Ethics Committee) since 2003 and previously served as IRB's vice-chairperson. In 2017 she assumed the position of chairperson of the IRB. She is currently the director of the education and training programs at Rockefeller University Center for Clinical and Translational Science. Dr. Schlesinger currently serves on the board of two non-profit organizations: the AIDS Vaccines Advocacy Coalition, and The Hastings Center, the pre-eminent center for the study of bioethics. Dr. Schlesinger served as an independent corporate director of Ariad Pharmaceuticals from 2013 until its sale to Takeda Pharmaceutical Company Limited in 2017. She also served as an independent corporate director of The Medicines Company from 2018 until its acquisition by Novartis in 2020. Dr. Schlesinger has a B.A. from Wellesley College and a M.D. from Rush Medical College in Chicago, Illinois. She trained in Anatomic Pathology at The New York Hospital where she served as Chief Resident. Dr. Schlesinger has demonstrated leadership in her field and her substantial knowledge of our industry contributed to our conclusion that she should serve as a director.

*Director Qualifications.* Dr. Schlesinger was selected as a director because of her extensive leadership experience with biotechnology companies and her in-depth knowledge of the industry, as well as her experience serving on the boards of directors of various public and private companies.

Our Nominating and Corporate Governance Committee seeks to assemble a board of directors that, as a whole, possesses the appropriate balance of professional and industry knowledge, financial expertise and high-level management experience necessary to oversee and direct our business. To that end, the Nominating and Corporate Governance Committee has identified and evaluated nominees in the broader context of the board of directors' overall composition, with the goal of recruiting members who complement and strengthen the skills of other members and who also exhibit integrity, collegiality, sound business judgment and other qualities that the Nominating and Corporate Governance Committee views as critical to effective functioning of the board of directors. The brief biographies below include information regarding the specific and particular experience, qualifications, attributes or skills of each nominee that led the Nominating and Corporate Governance Committee to recommend that person as a nominee. However, each of the members of the Nominating and Corporate Governance Committee may have a variety of reasons why he or she believes a particular person would be an appropriate nominee for the board of directors, and these views may differ from the views of other members.

## **Board Composition**

Our business and affairs are organized under the direction of our board of directors, which currently consists of six members. The primary responsibilities of our board of directors are to provide oversight, strategic guidance, counseling and direction to our management. Our board of directors meets on a regular basis and on an ad hoc basis as required.

As required under the NYSE American exchange listing standards, a majority of the members of a listed company's board of directors must qualify as "independent," as affirmatively determined by the board of directors. Our board of directors consults with our counsel to ensure that the board of directors' determinations are consistent with relevant securities and other laws and regulations regarding the definition of "independent," including those set forth in pertinent listing standards of the NYSE American exchange, as in effect from time to time.

Consistent with these considerations, after review of all relevant identified transactions or relationships between each director, or any of his or her family members, and us, our senior management and our independent auditors, the board affirmatively determined that Richard J. Bastiani, Ph.D., Odysseas D. Kostas, M.D., Robin C. Kramer, Joseph M. Patti, Ph.D., Todd C. Peterson, Ph.D., and Sarah J. Schlesinger, M.D. and are independent directors within the meaning of the applicable NYSE American exchange listing standards. In making this determination, our board found that none of these directors or nominees for director had a material or other disqualifying relationship with us. The board concluded that Mr. Patrick is not an independent director within the meaning of the applicable NYSE American exchange listing standards. Mr. Patrick is not an independent director under these rules given his role as our Chief Executive Officer.

As required under applicable NYSE American rules, we anticipate that our independent directors will meet in regularly scheduled executive sessions at which only independent directors are present.

Our amended and restated bylaws provide that the board of directors will consist of not less than one nor more than nine members, as fixed from time to time by a resolution of the board of directors. The authorized size of our board of directors is currently eight members.

## **Board Leadership Structure**

Our board of directors has an independent Chairman, Richard J. Bastiani, Ph.D., who has authority, among other things, to call and preside over board meetings, to set meeting agendas and to determine materials to be distributed to the board of directors. Accordingly, the Chairman has substantial ability to shape the work of the board of directors. We have a separate chair for each committee of the board of directors. As a general policy, the board of directors believes that separation of the positions of Chairman and Chief Executive Officer reinforces the independence of the board of

directors from management, creates an environment that encourages objective oversight of management's performance and enhances the effectiveness of the board of directors as a whole. As such, Mr. Patrick serves as our Chief Executive Officer, while Dr. Bastiani serves as our Chairman of our board of directors. We expect and intend the positions of Chairman of the board of directors and Chief Executive Officer to continue to be held by separate individuals in the future.

### **Role of the Board in Risk Oversight**

One of the principal functions of our board of directors is to provide oversight concerning the assessment and management of risk related to our business. The board of directors is involved in risk oversight through direct decision-making authority with respect to fundamental financial and business strategies and major corporate activities.

While the board of directors oversees our risk management, our management is responsible for day-to-day risk management processes, including, without limitation, strategic, operational, financial, regulatory and cyber-security risks that may exist from time to time. The board of directors expects management to consider the risks of, and risk management in, each business decision, to proactively develop and monitor risk management strategies and processes for day-to-day activities and to effectively implement risk management strategies adopted by the board of directors and its committees. In connection with this responsibility, members of management provide regular reports to the board of directors regarding business operations and strategic planning, financial planning and budgeting and regulatory matters, including any material risk to our company related to such matters. Although the board of directors does not have a formal risk oversight policy, the board of directors does, as a whole and through its various committees, oversee the proper functioning of our internal risk management processes. In its risk oversight role, the board of directors evaluates whether management has reasonable controls in place to address material risks we currently face and those we may face in the future.

The board of directors has delegated oversight for specific areas of risk exposure to committees of the board of directors as follows:

- The Audit Committee is primarily responsible for overseeing our financial risk management processes on behalf of the board of directors. The Audit Committee is responsible for discussing our overall risk assessment and risk management policies with management and our independent registered public accounting firm, as well as our plans to monitor and control any financial risk exposure. The Audit Committee is also responsible for primary risk oversight related to our internal control over financial reporting, disclosure controls and procedures, and legal and regulatory compliance. In addition, the Audit Committee reviews all related-person transactions, including the risks related to those transactions impacting our company. Going forward, we expect that the Audit Committee will receive reports from management regarding its assessment of risks at least quarterly.
- The Compensation Committee oversees our compensation programs and reviews the conduct incentivized by those programs, including any impact on risk-taking by our executive officers and employees.
- The Nominating and Corporate Governance Committee oversees the organization, membership and structure of our board of directors and our corporate governance practices. The committee members report to the full board of directors on material developments in their areas of oversight.

We believe this division of responsibilities is the most effective approach for addressing the risks we face and that our board of directors' leadership structure, which also emphasizes the independence of our board of directors in its oversight of our business and affairs, supports this approach.

The board of directors and its committees meet at regularly scheduled and special meetings throughout the year at which management reports to the board concerning the results of our risk management activities, as well as external changes that may change the levels of business risk to which we are exposed. At each regular meeting of our board of directors, the chairperson of each committee reports to the full board regarding the matters reported and discussed at any committee meetings, including any matters related to risk assessment or risk management. Upon the request of the

committees, our principal executive officer and principal financial officer attend meetings of these committees when they are not in executive session, and often report on matters that may not be otherwise addressed at these meetings. In addition, our directors are encouraged to communicate directly with members of management regarding matters of interest, including matters related to risk, at times when meetings are not being held.

## **Board Committees**

The board of directors has an Audit Committee, a Compensation Committee and a Nominating and Corporate Governance Committee. Each of the Audit Committee, Compensation Committee and Nominating and Corporate Governance Committee operates under a written charter, the adequacy of which each respective committee regularly reviews and reassesses. A copy of each charter is available under the heading “Corporate Governance” of the Investor Relations section of our website at <https://investor.armatapharma.com/corporate-governance>. Our board of directors may establish additional committees from time to time in accordance with our Bylaws.

Below is a description of each committee of the board of directors. The board of directors has determined that each member of each committee meets the applicable NYSE American exchange rules and regulations regarding “independence” and each member is free of any relationship that would impair his or her individual exercise of independent judgment with regard to our company.

### ***Audit Committee***

Our Audit Committee currently consists of Robin Kramer (Chair) and Dr. Peterson. The board of directors reviews the NYSE American exchange listing standards definition of independence for Audit Committee members on an annual basis and has determined that each of the members of our Audit Committee satisfies the NYSE American exchange listing requirements and SEC independence requirements.

The primary purpose of the Audit Committee is to oversee our corporate accounting and financial reporting processes and audits of its financial statements. The functions of the Audit Committee include, among other things:

- evaluating the performance, independence and qualifications of our independent auditors and determining whether to retain our existing independent auditors or engage new independent auditors and to present its conclusion to our board of directors;
- reviewing and approving the engagement of our independent auditors to perform audit services and any permissible non-audit services;
- monitoring the rotation of partners of our independent auditors on our audit engagement team as required by law;
- prior to engagement of any independent auditor, and, at least annually thereafter, reviewing relationships that may reasonably be thought to bear on the auditor’s independence, and assessing and otherwise taking the appropriate action to oversee the independence of our independent auditor;
- reviewing our annual and quarterly financial statements and reports, including the disclosures contained under the caption “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” and discussing the statements and reports with our independent auditors and management;
- reviewing with our independent auditors and management significant issues that arise regarding accounting principles and financial statement presentation and matters concerning the scope, adequacy and effectiveness of our internal control over financial reporting;
- reviewing with management and our auditors any earnings announcements and other public announcements regarding material developments;

- establishing procedures for the receipt, retention and treatment of complaints received by us regarding internal accounting controls, accounting or auditing matters and other matters;
- preparing the report that the SEC requires in our annual proxy statement;
- reviewing and providing oversight of any related-person transactions in accordance with our related-person transactions policy and reviewing and monitoring compliance with legal and regulatory responsibilities, including our code of business conduct and ethics;
- reviewing on a periodic basis our investment policy; and
- reviewing and evaluating on an annual basis its own performance, including its compliance with its charter.

### ***Compensation Committee***

Our Compensation Committee consists of Dr. Patti (Chair) and Dr. Schlesinger. Our board of directors has determined that each of the members of our Compensation Committee is a non-employee director, as defined in Rule 16b-3 promulgated under the Exchange Act, an outside director, as defined pursuant to Section 162(m) of the Code, and satisfies the NYSE American exchange listing independence requirements.

The functions of this committee include, among other things:

- reviewing, modifying and approving (or, if it deems appropriate, making recommendations to the full board of directors regarding) our overall compensation strategy and policies;
- reviewing and approving (or, if it deems appropriate, making recommendations to the full board of directors regarding) the compensation and other terms of employment of our executive officers, including the terms of any employment agreements, severance arrangements, change-of-control protections and any other compensatory arrangements for our executive officers;
- reviewing and approving (or, if it deems appropriate, making recommendations to the full board of directors regarding) performance goals and objectives relevant to the compensation of our executive officers and assessing their performance against these goals and objectives;
- reviewing and approving (or, if it deems appropriate, making recommendations to the full board of directors regarding) the equity incentive plans, compensation plans and similar programs advisable for us, as well as modifying, amending or terminating existing plans and programs;
- evaluating (including, if it deems appropriate, with the input of some or all of the other members of the board of directors) risks associated with our compensation policies and practices and assessing whether risks arising from our compensation policies and practices for our employees are reasonably likely to have a material adverse effect on us;
- reviewing and making recommendations to the full board of directors regarding the type and amount of compensation to be paid or awarded to our non-employee board members;
- administering our equity incentive plans;
- establishing policies with respect to equity compensation arrangements;

- establishing policies with respect to votes by our stockholders to approve executive compensation as required by Section 14A of the Exchange Act and determining our recommendations regarding the frequency of advisory votes on executive compensation, to the extent required by law;
- reviewing and assessing the independence of compensation consultants, legal counsel and other advisors as required by Section 10C of the Exchange Act;
- reviewing the competitiveness of our executive compensation programs and evaluating the effectiveness of our compensation policy and strategy in achieving expected benefits to us;
- reviewing the adequacy of its charter on a periodic basis;
- reviewing with management and approving our compensation-related disclosures and related tables in our periodic reports or proxy statements to be filed with the SEC;
- preparing the report that the SEC requires in our annual proxy statement, if required by then-applicable SEC rules; and
- reviewing and assessing on an annual basis its own performance.

### *Nominating and Corporate Governance Committee*

Our Nominating and Corporate Governance Committee consists of Dr. Bastiani (Chair) and Dr. Kostas. Our board of directors has determined that each of the members of this committee satisfies the NYSE American exchange listing independence requirements. The Nominating and Corporate Governance Committee of the board of directors is responsible for, among other things:

- identifying, reviewing and evaluating candidates to serve on our board of directors consistent with criteria approved by our board of directors;
- assessing the performance of management and the board of directors, including board committees, seeking input from senior management, the full board of directors and others, which assessment shall include, among other things, an evaluation of the board's contribution as a whole and overall board composition and makeup, including the reelection of current board members;
- evaluating, nominating and recommending individuals for membership on our board of directors;
- evaluating nominations by stockholders of candidates for election to our board of directors;
- considering and assessing the independence of members of our board of directors;
- developing a set of corporate governance policies and principles, periodically reviewing and assessing these policies and principles and their application and recommending to our board of directors any changes to such policies and principles;
- reviewing the adequacy of its charter on an annual basis; and
- reviewing and assessing on an annual basis its own performance.

## **Limitation of Liability and Indemnification**

Sections 23B.08.510 and 23B.08.570 of the Washington Business Corporation Act authorize Washington corporations to indemnify directors and officers under certain circumstances against expenses (including legal expenses) and liabilities incurred in legal proceedings in which they are involved by reason of being a director or officer, as applicable. Section 23B.08.560 of the Washington Business Corporation Act authorizes a corporation, if authorized by its articles of incorporation or by a provision in the corporation's bylaws approved by its stockholders, to indemnify or agree to indemnify a director made a party to a proceeding, or obligate itself to advance or reimburse expenses incurred in a proceeding, without regard to the limitations imposed by Sections 23B.08.510 through 23B.08.550; provided that no such indemnity shall indemnify any director from or on account of (a) acts or omissions of the director finally adjudged to be intentional misconduct or a knowing violation of law, (b) conduct of the director finally adjudged to be in violation of Section 23B.08.310 of the Washington Business Corporation Act (which section relates to unlawful distributions) or (c) any transaction with respect to which it was finally adjudged that such director personally received a benefit in money, property or services to which the director was not legally entitled.

Article 11 of our current articles of incorporation, provides that, to the fullest extent that the Washington Business Corporation Act permits the limitation or elimination of the liability of a director, a director shall not be liable to us or our stockholders for monetary damages for conduct as a director. Section 10 of our amended and restated bylaws requires us to indemnify every present or former director or officer against expenses, liabilities and losses incurred in connection with serving as a director or officer, as applicable, and to advance expenses of such director or officer incurred in defending any proceeding covered by the indemnity.

We maintain a policy of directors' and officers' liability insurance that insures the directors and officers against the cost of defense, settlement or payment of a judgment under certain circumstances. We have also entered into indemnification agreements with our executive officers and directors that provide for the indemnification of directors and executive officers to the fullest extent permitted by the Washington Business Corporation Act against expenses reasonably incurred by such persons in any threatened, pending or completed action, suit, investigation or proceeding in connection with their service as (i) a director or officer or (ii) a director, officer, employee or agent of another corporation or of a partnership, joint venture, trust or other enterprise, including service with respect to employee benefit plans, at our request. In addition, the indemnification agreements we are obligated to advance expenses pursuant to the indemnification agreements under certain circumstances and the agreements also provide for procedural protections, including a determination by a reviewing party as to whether the indemnitee is permitted to be indemnified under applicable law. In addition, we have agreed that we will be the indemnitor of first resort should the indemnitee have rights to indemnification provided by other persons.

The limitation of liability and indemnification provisions in our articles of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against directors for breach of their fiduciary duties. They may also reduce the likelihood of derivative litigation against directors and officers, even though an action, if successful, might benefit us and our stockholders. A stockholder's investment may be harmed to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions.

We believe that these provisions in our articles of incorporation and amended and restated bylaws and our indemnification agreements are necessary to attract and retain qualified persons as directors and officers.

At present, there is no pending litigation or proceeding involving any of our directors or executive officers as to which indemnification is required or permitted, and we are not aware of any threatened litigation or proceeding that may result in a claim for indemnification.

## **DELINQUENT SECTION 16(A) REPORTS**

Section 16(a) of the Exchange Act requires our directors, executive officers and any persons beneficially holding more than 10% of our common stock to report their initial ownership of our common stock and any subsequent changes in that ownership to the SEC. Our executive officers, directors and greater than 10% stockholders are required by SEC regulation to furnish us with copies of all Section 16(a) forms they file.

Specific due dates for these reports have been established and we are required to identify those persons who failed to timely file these reports. To our knowledge, based solely on a review of the copies of such reports furnished to us and written representations from our directors and officers that no other reports were required, during the fiscal year ended December 31, 2020, all of our directors, officers and greater than 10% stockholders complied with the Section 16(a) filing requirements.

We have adopted a code of ethics for directors, officers (including our principal executive officer, principal financial officer, principal accounting officer and controller) and employees, known as the Code of Business Conduct and Ethics. The Code of Business Conduct and Ethics is available on our website at <http://www.Armatabio.com> under the Corporate Governance section of our Investor Relations page. We will promptly disclose on our website (i) the nature of any amendment to the policy that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions and (ii) the nature of any waiver, including an implicit waiver, from a provision of the policy that is granted to one of these specified individuals that is required to be disclosed pursuant to SEC rules and regulations, the name of such person who is granted the waiver and the date of the waiver.

## Item 11. EXECUTIVE COMPENSATION

Set forth below is certain information regarding the historical compensation of our named executive officers during the year ended December 31, 2020 and 2019 including the historical compensation of certain C3J executive officers who are now executive officers following the completion of the Merger. For additional information about our current officers and directors, see the section titled “Management.”

### Executive Compensation

The named executive officers as of December 31, 2020 were:

- Todd R. Patrick, Chief Executive Officer;
- Brian Varnum, Ph.D., President and Chief Development Officer;
- Steve Martin, Chief Financial Officer

### Summary Compensation Table

The following table provides information regarding the compensation paid during the last two fiscal years to the named executive officers.

<u>Name and Principal Position</u>	<u>Year</u>	<u>Salary (\$)</u>	<u>Bonus (\$)</u>	<u>Option Awards (\$) (1)</u>	<u>Non-Equity Incentive Plan Compensation (\$)</u>	<u>All Other Compensation (\$)</u>	<u>Total (\$)</u>
Todd Patrick	2020	515,500	—	53,504	257,750	—	826,754
Chief Executive Officer	2019	412,000	—	714,556	144,200	—	1,270,756
Brian Varnum, Ph. D.	2020	398,750	—	53,504	159,500	—	611,754
President and Chief Development Officer	2019	320,000	—	714,556	89,600	—	1,124,156
Steve Martin	2020	350,000	—	53,504	140,000	—	543,504
Senior VP and Chief Financial Officer	2019	320,000	—	357,278	89,600	—	766,878

(1) In accordance with SEC rules, this column represents the aggregate grant date fair value of the option awards granted during 2019 and 2020 computed in accordance with Financial Accounting Standards Board Accounting Standards



Codification Topic 718 for stock-based compensation transactions. Assumptions used in the calculation of these amounts are included in Note 14 to the consolidated financial statements included in this Annual Report. These amounts do not reflect the actual economic value that will be realized by the named executive officer upon the vesting of the stock options, the exercise of the stock options, or the sale of the common stock underlying such stock options.

## Base Salary

The base salaries of the named executive officers in 2020, as applicable, were generally determined and approved by the board of directors, based on the recommendation of the Compensation Committee.

- Mr. Patrick's annual base salary for the period January 1, 2019 through March 31, 2020 was \$412,000. Effective April 1, 2020, Mr. Patrick's annual base salary was \$550,000.
- Dr. Varnum's annual base salary for the period January 1, 2019 through March 31, 2020 was \$320,000. Effective April 1, 2020, Mr. Varnum's annual base salary was \$425,000.
- Mr. Martin's annual base salary for the period January 1, 2019 through March 31, 2020 was \$320,000. Effective April 1, 2020, Mr. Martin's annual base salary was \$360,000.

## Annual Bonus

In addition to base salaries, the named executive officers are eligible to receive annual performance-based cash bonuses, which are designed to provide appropriate incentives to our executives to achieve defined annual corporate goals and to reward our executives for individual achievement towards these goals. The performance-based bonus generally is based on the extent to which we achieved the specified corporate goals that our board of directors or Compensation Committee established. After the end of the year, the board of directors and/or Compensation Committee review our performance against the established corporate goals and approve the extent to which we achieved such goals.

Under the terms of his offer letter agreement described below, Mr. Patrick was eligible to receive an annual performance-based bonus for 2019 and 2020 equal to, at target, between 50% and 100% of his annual salary based on our achievement of certain performance goals. Each of Dr. Varnum and Mr. Martin was eligible to receive an annual performance-based bonus for 2019 and 2020 equal to, at target, 40% of his annual salary based on our achievement of certain performance goals.

The annual performance-based bonus opportunities are based entirely on the extent to which we achieved corporate goals relating to capital raising, partner and grant funding and progress with clinical development and manufacturing for the period commencing on the closing of the Merger through December 31, 2019, and for the fiscal year ending December 31, 2020. The corporate goals were established so that target attainment is not assured. Instead, our executives are required to demonstrate significant effort, dedication, and achievement to attain payment for performance at target or above.

In December 2019, the Compensation Committee reviewed interim performance results against these corporate goals and decided that it needed more time to properly evaluate performance results. In March 2020, the Compensation Committee conducted another evaluation of our performance relative to the corporate goals and made a recommendation, that the board approved, to authorize payout for the 2019 performance-based bonuses at the 70% achievement level. As a result, the named executive officers received the following performance-based bonuses for 2019: Mr. Patrick — \$144,200; Dr. Varnum — \$89,600 and Mr. Martin — \$89,600. These amounts are listed in the "Non-Equity Incentive Plan Compensation" column of the Summary Compensation Table.

In December 2020, the Compensation Committee reviewed performance results against the corporate goals and made a recommendation, that the board approved, to authorize payout for the 2020 performance-based bonuses at the 100% achievement level. As a result, the named executive officers received the following performance-based bonuses

for 2020: Mr. Patrick - \$257,750; Dr. Varnum - \$159,500; Mr. Martin - \$140,000. These amounts are listed in the “Non-Equity Incentive Plan Compensation” column of the Summary Compensation Table.

### **Equity-Based Awards**

Our equity-based incentive awards were designed to align our interests with those of our employees and consultants, including the named executive officers. Our board of directors or our Compensation Committee approve equity grants. Vesting of equity awards was generally tied to continuous service and serves as an additional retention measure. Our executives may have been awarded an initial new hire grant upon commencement of service and may have received additional grants, as the board of directors or Compensation Committee determined appropriate, in order to incentivize and/or reward such executives.

We traditionally granted stock options to the named executive officers under our equity incentive plans, the terms of which are described below under “Equity Incentive Plans.” Following the completion of the Merger in May of 2019, the board of directors’ granted stock options to the named executive officers and certain employees of the Company. Please see “Outstanding Equity Awards at Fiscal Year End” below.

### **Agreements with our Named Executive Officers**

Below are descriptions of our employment agreements with the named executive officers governing the terms of their service with us. For a discussion of the severance pay and other benefits that may be provided in connection with a termination of service and/or a change in control under the arrangements with the named executive officers, please see “Payments and Benefits upon Termination or Change in Control” below.

Todd R. Patrick, our Chief Executive Officer, is subject to an Employment Agreement, dated October 1, 2018, between Mr. Patrick and the Company as amended on January 3, 2019 (the “Patrick Employment Agreement”). The Patrick Employment Agreement provides for an initial term of three years. Mr. Patrick will be paid an annual base salary as may be established from time to time by the board of directors, and an annual cash bonus, in accordance with a milestone-based structure established by the board of directors, enabling him to earn between 50% and 100% of the amount of his base salary as a bonus. He will also be eligible for all fringe benefit plans available to other full-time employees. If Mr. Patrick is terminated without Cause or resigns for Good Reason (in each case as defined in the Patrick Employment Agreement), then he will be entitled to a severance payment equal to his base salary plus 50% of his bonus (the bonus to be paid whether earned or unearned) for the then-remaining term of the Patrick Employment Agreement, or through September 30, 2021, such payment to be lengthened to a minimum of one year or twelve (12) months of base salary and bonus, if his termination occurs during any month during the 2021 calendar year. Effective December 31, 2020, Mr. Patrick’s annual base salary is \$550,000.

Dr. Varnum, our President and Chief Development Officer, is subject to an employment agreement dated January 18, 2012 between Dr. Varnum and the Company. Dr. Varnum’s employment under the agreement is at will and is terminable by us or Dr. Varnum at any time. Under the terms of the agreement, Dr. Varnum currently receives an annual base salary of \$425,000 through December 31, 2020, and an annual target performance bonus of 40% of his annual salary based on our achievement of certain performance objectives. Dr. Varnum is also entitled to certain severance benefits as described below under the section entitled “Payments and Benefits upon Termination or Change in Control.”

Mr. Martin, our Chief Financial Officer, is subject to an employment agreement dated January 18, 2016, as amended on April 1, 2017. Mr. Martin’s employment under the agreement is at will and is terminable by us or Mr. Martin at any time. Under the terms of the agreement, Mr. Martin currently receives an annual base salary of \$360,000 through December 31, 2020, and an annual target performance bonus of 40% of his annual salary based on our achievement of certain performance objectives. Mr. Martin retained his position as Chief Financial Officer following the Merger, and the terms of his offer letter agreement remain as described herein. Mr. Martin is also entitled to certain severance benefits as described below under the section entitled “Payments and Benefits upon Termination or Change in Control.”

## **Payments and Benefits upon Termination or Change in Control**

Mr. Patrick. Under the terms of the Patrick Employment Agreement, if Mr. Patrick is terminated without Cause or resigns for Good Reason (in each case as defined in the Patrick Employment Agreement), then he will be entitled to a severance payment equal to his base salary plus 50% of his bonus (the bonus to be paid whether earned or unearned) for the then-remaining term of the Patrick Employment Agreement, or through September 30, 2021, such payment to be lengthened to a minimum of one year or twelve (12) months of base salary and bonus, if his termination occurs during any month during the 2021 calendar year.

Dr. Varnum. Under the terms of the offer letter agreement with Dr. Varnum, Dr. Varnum is entitled to receive six months of continued base salary if his employment with us was terminated without cause or if he resigned for good reason provided that he provided us with an effective release of claims.

Mr. Martin. Under the terms of the offer letter agreements with Mr. Martin, Mr. Martin is entitled to receive 12 months of continued base salary if his employment with us was terminated without cause or if he resigned for good reason, and additionally, if such termination or resignation occurred in connection with a change in control, full acceleration of his equity awards, provided that in either case he provided us with an effective release of claims.

All of the named executive officers held stock options under our equity incentive plans that were granted subject to the general terms of our equity incentive plans and form of stock option agreements. A description of the termination and change in control provisions in such equity incentive plans and stock options granted thereunder is provided below under “Equity Incentive Plans,” and the specific vesting terms of each of the named executive officer’s stock options are described below under “Outstanding Equity Awards at Fiscal Year End.”

All of the named executive officers held stock options under our equity incentive plans that were granted subject to the general terms of our equity incentive plans and form of stock option agreements. The specific vesting terms of each of the named executive officer’s stock options are described below under “— Outstanding Equity Awards at Fiscal Year End.” If within 1 month prior to, or within 12 months after, a change in control, the named executive officer is terminated due to an involuntary termination (not including death or disability) without cause or due to a voluntary termination with good reason, then any unvested stock options held by that officer will vest in full.

## Outstanding Equity Awards at Fiscal Year End

The following table sets forth certain information regarding all outstanding equity awards held by the named executive officers as of December 31, 2020. All figures have been adjusted to reflect the impact of the Merger and related assumption of C3J equity awards and the reverse split.

Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price (\$)	Option Expiration Date
Mr. Patrick	56,056 (1)	—	38.12	4/24/2024
	74,681 (2)	224,043 (2)	3.15	5/21/2029
	—	23,000 (5)	3.15	12/7/2030
	<u>130,737</u>	<u>247,043</u>		
Dr. Varnum	20,718 (3)	—	27.37	3/12/2022
	986 (1)	—	33.05	6/25/2022
	15,193 (1)	—	38.12	4/21/2024
	4,932 (1)	—	38.12	12/8/2024
	74,681 (2)	224,043 (2)	3.15	5/21/2029
	—	23,000 (5)	3.15	12/7/2030
	<u>116,510</u>	<u>247,043</u>		
Mr. Martin	713 (1)	—	399.00	1/17/2026
	1,152 (4)	—	60.20	3/31/2021
	8,072 (1)	1,856 (1)	12.74	9/6/2027
	37,341 (2)	112,021 (2)	3.15	5/21/2029
	—	23,000 (5)	3.15	12/7/2030
	<u>47,278</u>	<u>136,877</u>		

- (1) Twenty-five percent of the shares vest one year after the grant date, with the balance vesting in equal monthly installments thereafter over the next three years, subject to continued service and the potential vesting acceleration described in the option agreement.
- (2) Twenty-five percent of the shares vest on each anniversary of the grant date, subject to continued service and the potential vesting acceleration described in the option agreement.
- (3) Twenty percent of the shares vest one year after grant date, with the balance vesting in equal monthly installments thereafter over the next four years, subject to continued service.
- (4) One hundred percent of the shares vested upon grant date of April 1, 2017.
- (5) Fifty percent of the shares vest each anniversary of the grant date, subject to continued service and the potential vesting acceleration described in the option agreement.

## Equity Incentive Plans

### 2016 Equity Incentive Plan

The 2016 Plan was approved by our board of directors in April 2016 and subsequently approved by the stockholders in June 2016, and was most recently amended and restated effective as of May 8, 2019, to reflect our name change and the reverse split, as well as to increase the share reserve by 987,355 shares, for a total share reserve of 1,213,917 on a post-reverse split basis. We continue to grant awards under the 2016 Plan. The plan provides for the issuance of incentive 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 our board of directors to employees, including officers, non-employee directors and consultants who provide services to us or to a subsidiary of ours.

### Employee Stock Purchase Plan

Additional long-term equity incentives are provided through the ESPP, which became effective in connection with our 2016 Annual Meeting of Shareholders in May 2016 and which we continue to use pursuant to the terms described herein. The ESPP is intended to qualify as an “employee stock purchase plan” within the meaning of Section 423 of the Internal Revenue Code. Our board of directors has delegated its authority to administer the ESPP to our Compensation Committee. Under the ESPP, all of our regular employees (including the named executive officers) may participate and may contribute, normally through payroll deductions, up to 15% of their earnings for the purchase of our common stock. The ESPP is implemented through a series of offerings of purchase rights to eligible employees. Under the ESPP, we may specify offerings with a duration of not more than 27 months and may specify shorter purchase periods within each offering. Each offering will have one or more purchase dates on which our common stock will be purchased for employees participating in the offering. Unless otherwise determined by our Compensation Committee, shares are purchased for accounts of employees participating in the ESPP at a price per share equal to the lower of (a) 85% of the fair market value of our common stock on the first date of an offering or (b) 85% of the fair market value of our common stock on the date of purchase.

### Non-Employee Director Compensation

The following table and related footnotes show the compensation paid during the year ended December 31, 2020 to our non-employee directors, other than Mr. Patrick, whose 2020 compensation is set forth under “Summary Compensation Table” above.

Name	Fees Earned or Paid in Cash (\$)	Option Awards (\$) (1)	All Other Compensation (\$)	Total (\$)
Richard Bastiani	74,750	53,504	—	128,254
Odysseas Kostas	38,572	137,257	—	175,830
Robin C. Kramer	3,677	69,787	—	73,465
Joseph Patti	54,282	53,504	—	107,785
Todd Peterson	46,339	53,504	—	99,843
Sarah J. Schlesinger	40,185	137,257	—	177,443
Richard Bear (2)	4,713	—	—	4,713
Jeremy Curnock Cook (3)	49,911	—	—	49,911
H. Stewart Parker (3)	59,231	—	—	59,231
Michael S. Perry, Ph.D. (2)	6,598	—	—	6,598

(1) In accordance with SEC rules, this column represents the aggregate grant date fair value of the option awards granted during 2020 computed in accordance with Financial Accounting Standards Board Accounting Standards Codification Topic 718 for stock-based compensation transactions. Assumptions used in the calculation of these amounts are included in Note 14 to the consolidated financial statements included in this Annual Report. The aggregate number of

option awards outstanding (including exercisable and unexercisable stock options) as of December 31, 2020, for each non-employee director was as follows:

Board of Directors:	Stock Options Outstanding	Stock Options Exercisable
Richard Bastiani	51,192	14,501
Odysseas Kostas	50,383	—
Robin C. Kramer	30,000	—
Joseph Patti	50,383	13,692
Todd Peterson	50,383	13,692
Sarah J. Schlesinger	50,383	—
Richard Bear (2)	—	—
Jeremy Curnock Cook (3)	14,800	14,800
H. Stewart Parker (3)	14,501	14,501
Michael S. Perry, Ph.D. (2)	—	—

(2) Resigned as a director on February 12, 2020.

(3) Resigned as a director on December 8, 2020.

In September 2015, the board of directors approved a revised compensation structure for non-employee directors and following the Merger the new members of our board of directors elected to retain the current cash compensation schedule. In 2020, the chairman of our board of directors received an annual cash retainer of \$60,000 and each other non-employee director received an annual cash retainer of \$40,000. For the Audit Committee, the committee chair received an additional annual cash retainer of \$15,000 and each member received an additional annual cash retainer of \$6,000. For the Compensation Committee, the committee chair received an additional annual cash retainer of \$10,000 and each member received an additional annual cash retainer of \$5,000. For the Nominating and Corporate Governance Committee, the committee chair received an additional annual cash retainer of \$5,000 and each member received an additional annual cash retainer of \$3,000.

#### ***Treatment of C3J Stock Options and Restricted Stock Awards in the Merger***

At the effective time of the Merger, each option to purchase shares of C3J common stock issued by C3J (a “C3J Stock Option”) under C3J’s Amended and Restated 2006 Stock Option Plan and 2016 Stock Plan (together, the “C3J Stock Plans”) that was outstanding and unexercised immediately prior to the effective time of the Merger, whether or not vested, was converted into an option to purchase shares of our common stock, and we assumed the C3J Stock Plans and each outstanding C3J Stock Option in accordance with its terms. Accordingly, following the Merger: (i) each C3J Stock Option assumed by us is exercisable solely for shares of our common stock; (ii) the number of shares of our common stock subject to each C3J Stock Option assumed by us was determined by multiplying (A) the number of shares of C3J common stock that were subject to such C3J Stock Option, as in effect immediately prior to the effective time of the Merger, by (B) the Exchange Ratio, and rounding the resulting number down to the nearest whole number of shares of our common stock; (iii) the per share exercise price for our common stock issuable upon exercise of each C3J Stock Option assumed by us was determined by dividing (A) the per share exercise price of the C3J common stock subject to such C3J Stock Option, as in effect immediately prior to the effective time of the Merger, by (B) the Exchange Ratio and rounding the resulting exercise price up to the nearest whole cent; and (iv) any restriction on the exercise of any C3J Stock Option assumed by us continued in full force and effect and the term, exercisability, vesting schedule and other provisions of such C3J Stock Option otherwise remained unchanged, except that: (A) we may amend the terms of the C3J Stock Options and the C3J Stock Plans to reflect our substitution of the C3J Stock Options with options to purchase Armata common stock; and (B) our board of directors succeeded to the authority and responsibility of C3J’s board of directors with respect to each C3J Stock Option assumed by us.

At the effective time of the Merger, each restricted stock award with respect to C3J common stock (a “C3J RSA”) that was outstanding immediately prior to the effective time of the Merger was assumed by us and converted into

restricted stock awards with respect to our common stock, and we assumed the applicable restricted stock agreements and each such C3J RSA in accordance with its terms. All rights with respect to C3J common stock under the C3J RSAs assumed by us were converted into rights with respect to our common stock. Accordingly, following the Merger: (i) each C3J RSA assumed by us relates to shares of our common stock; (ii) the number of shares of our common stock subject to each C3J RSA assumed by us was determined by multiplying (A) the number of shares of C3J common stock that were subject to such C3J RSA, as in effect immediately prior to the effective time of the Merger, by (B) the Exchange Ratio and rounding the resulting number down to the nearest whole number of shares of our common stock; and (iii) any restriction on any C3J RSA assumed by us continued in full force and effect and the vesting schedule and other provisions of such C3J RSA otherwise remained unchanged, subject to certain exceptions.

## **Employee Benefit Matters**

Under the terms of the Agreement and Plan of Merger and Reorganization, dated January 3, 2019, as amended on March 25, 2019, by and among AmpliPhi, a wholly owned subsidiary of AmpliPhi and C3J (the “Merger Agreement”), for purposes of vesting, eligibility to participate, and level of benefits under the employee benefit plans, programs, contracts or arrangements of us or any of our subsidiaries (including, following the effective time of the Merger, C3J and its subsidiary), each employee who continued to be employed by us, C3J or any of our or its respective subsidiaries immediately following the Merger was credited with his or her years of service with us, C3J or any of our or its respective subsidiaries and their respective predecessors.

## **Limitation of Liability and Indemnification**

Sections 23B.08.510 and 23B.08.570 of the Washington Business Corporation Act authorize Washington corporations to indemnify directors and officers under certain circumstances against expenses (including legal expenses) and liabilities incurred in legal proceedings in which they are involved by reason of being a director or officer, as applicable. Section 23B.08.560 of the Washington Business Corporation Act authorizes a corporation, if authorized by its articles of incorporation or by a provision in the corporation’s bylaws approved by its stockholders, to indemnify or agree to indemnify a director made a party to a proceeding, or obligate itself to advance or reimburse expenses incurred in a proceeding, without regard to the limitations imposed by Sections 23B.08.510 through 23B.08.550; provided that no such indemnity shall indemnify any director from or on account of (a) acts or omissions of the director finally adjudged to be intentional misconduct or a knowing violation of law, (b) conduct of the director finally adjudged to be in violation of Section 23B.08.310 of the Washington Business Corporation Act (which relates to unlawful distributions) or (c) any transaction with respect to which it was finally adjudged that such director personally received a benefit in money, property or services to which the director was not legally entitled.

Article 11 of our articles of incorporation provides that, to the fullest extent that the Washington Business Corporation Act permits the limitation or elimination of the liability of a director, a director shall not be liable to us or our stockholders for monetary damages for conduct as a director. Section 10 of our bylaws requires us to indemnify every present or former director or officer against expenses, liabilities and losses incurred in connection with serving as a director or officer, as applicable, and to advance expenses of such director or officer incurred in defending any proceeding covered by the indemnity; provided, however, that any indemnity is in accordance with Washington law and does not include indemnification of intentional misconduct, knowing violation of law, or other violations of Washington law, including receipt of benefits in which a director or officer is not entitled.

We maintain a policy of directors’ and officers’ liability insurance that insures the directors and officers against the cost of defense, settlement or payment of a judgment under certain circumstances. We have also entered into indemnification agreements with our executive officers and directors that provide for the indemnification of directors and executive officers to the fullest extent permitted by the Washington Business Corporation Act against expenses reasonably incurred by such persons in any threatened, pending or completed action, suit, investigation or proceeding in connection with their service as (i) a director or officer of us or (ii) a director, officer, employee or agent of another corporation or of a partnership, joint venture, trust or other enterprise, including service with respect to employee benefit plans, at our request. In addition, we are obligated to advance expenses pursuant to the indemnification agreements under certain circumstances, and the agreements also provide for procedural protections, including a determination by a reviewing party as to whether the indemnitee is permitted to be indemnified under applicable law.

The limitation of liability and indemnification provisions in our articles of incorporation and bylaws may discourage stockholders from bringing a lawsuit against directors for breach of their fiduciary duties. They may also reduce the likelihood of derivative litigation against directors and officers, even though an action, if successful, might benefit us and our stockholders. A stockholder's investment may be harmed to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions.

We believe that these provisions in our articles of incorporation and bylaws and our indemnification agreements are necessary to attract and retain qualified persons as directors and officers.

At present, there is no pending litigation or proceeding involving any of our directors or executive officers as to which indemnification is required or permitted, and we are not aware of any threatened litigation or proceeding that may result in a claim for indemnification

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

The following table sets forth information regarding beneficial ownership of our capital stock by:

- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our common stock;
- each of our directors;
- each of our named executive officers; and
- all of our current executive officers and directors as a group.

The percentage ownership information in the table below is based on 20,622,065 shares of common stock outstanding as of March 1, 2021.

Information with respect to beneficial ownership provided in the table below is based upon information supplied by officers, directors and principal stockholders and Schedules 13D and 13G and Form 4 filed with the SEC. We have determined beneficial ownership in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities. In addition, the rules include shares of common stock issuable pursuant to the exercise of stock options or warrants that are either immediately exercisable or exercisable on or before April 29, 2021, which is 60 days after February 28, 2021. These shares are deemed to be outstanding and beneficially owned by the person holding those options or warrants for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person. Unless otherwise indicated, the persons or entities identified in this table have sole voting and investment power with respect to all shares shown as beneficially owned by them, subject to applicable community property laws.



Except as otherwise noted below, the address for each person or entity listed in the table is c/o Armata Pharmaceuticals Inc., 4503 Glencoe Avenue, Marina del Rey, California 90292.

Beneficial Owner	Beneficial Ownership	
	Number of Shares	Percent of Total
<b>Greater than 5% Stockholders</b>		
Innoviva, Inc.	21,157,424 (1)	67.8 %
Delta Dental of Wisconsin	2,107,675 (2)	10.2 %
Delta Dental Plan of Michigan, Inc.	1,265,802 (3)	6.1 %
<b>Directors and Named Executive Officers</b>		
Richard J. Bastiani, Ph.D. (Director)	28,390 (4)	* %
Odysseas D. Kostas, M.D. (Director)	21,171,116 (5)	63.7 %
Robin C. Kramer (Director)	—	* %
Joseph M. Patti, Ph.D. (Director)	13,692 (6)	* %
Todd C. Peterson, Ph.D. (Director)	13,692 (7)	* %
Sarah J. Schlesinger, M.D. (Director)	21,171,116 (8)	63.7 %
Todd R. Patrick (Chief Executive Officer and Director)	334,823 (9)	1.8 %
Brian Varnum, Ph. D. (President and Chief Development Officer)	148,564 (10)	* %
Steve R. Martin (Chief Financial Officer)	46,978 (11)	* %
Duane Morris (Vice President of Operations)	52,213 (12)	* %
<b>All current executive officers and directors as a group (10 persons) (13)</b>	<b>21,823,160</b>	<b>69.1 %</b>

\* Represents beneficial ownership of less than 1%.

- (1) The shares listed were reported on a Schedule 13D/A filed with the SEC on January 26, 2021, with respect to shares of common stock held by Innoviva, Inc. and Innoviva Strategic Opportunities, LLC. Innoviva, Inc. holds 8,710,800 shares of common stock and warrants to acquire an additional 8,710,800 shares of common stock. Innoviva Strategic Opportunities, LLC holds 1,867,912 shares of common stock and warrants to acquire an additional 1,867,912 shares of common stock. The principal business address of the reporting persons is c/o Innoviva, Inc., 1350 Old Bayshore Highway, Suite 400, Burlingame, CA 94010. In 2020, Innoviva designated Odysseas Kostas, M.D. and Sarah Schlesinger, M.D., two of the members of the board of directors of Innoviva, to serve on the Board. As such, solely for purposes of Section 16 of the Exchange Act of 1934, as amended, Innoviva, Inc. and Innoviva Strategic Opportunities, LLC may be deemed to be directors by deputization. For purposes of the exemption under Rule 16b-3 promulgated under the Exchange Act, the Board approved the acquisition of any direct or indirect pecuniary interest in any shares of common stock, including any shares of common stock issuable upon the exercise of the aforementioned warrants.
- (2) The shares listed were reported on a Schedule 13D filed with the SEC on May 21, 2019, with respect to shares of Common Stock held by Delta Dental of Wisconsin and Wyssta Investments Inc. Delta Dental of Wisconsin beneficially owns 1,628,994 shares of Common Stock, and Wyssta Investments Inc. beneficially owns 478,681 shares of Common Stock. Wyssta Investments Inc. is a wholly-owned subsidiary of Delta Dental of Wisconsin and, as such, Delta Dental of Wisconsin has the sole power to vote or dispose of the shares owned by Wyssta Investments Inc. As such, Delta Dental of Wisconsin holds sole voting and dispositive power of 2,107,675 shares. The principal business address of the reporting persons is c/o Delta Dental of Wisconsin, 2801 Hoover Road, Stevens Point, Wisconsin 54481.
- (3) The shares listed were reported on a Schedule 13G filed with the SEC on May 17, 2019, with respect to shares of Common Stock held by Delta Dental Plan of Michigan, Inc. and Renaissance Holding Company. Delta Dental Plan of Michigan, Inc. owns, directly or indirectly, approximately 68% of the outstanding Common Stock of Renaissance Holding Company. Delta Dental Plan of Michigan, Inc. and Renaissance Holding Company hold shared voting and dispositive power of 1,265,802 shares. The principal business address of the reporting persons is 4100 Okemos Road, Okemos, Michigan 48864.

- (4) Consists of (a) 13,889 shares of Common Stock and (b) 14,501 shares of Common Stock that Mr. Bastiani has the right to acquire from us within 60 days of March 1, 2021, pursuant to the exercise of stock options.
- (5) Consists of (a) 13,692 shares of Common Stock that Dr. Kostas has the right to acquire from us within 60 days of March 1, 2021 pursuant to the exercise of stock options, (b) 8,710,800 shares of common stock and warrants exercisable for 8,710,800 shares of common stock held by Innoviva, Inc., and (c) 1,867,912 shares of common stock and warrants exercisable for 1,867,912 shares of common stock held by Innoviva Strategic Opportunities, LLC. Innoviva, Inc and Innoviva Strategic Opportunities, LLC are entities with which Dr. Kostas is affiliated due to his position as a director of Innoviva, Inc. Dr. Kostas may be deemed to have shared voting and dispositive power over the shares beneficially owned by Innoviva, Inc. and Innoviva Strategic Opportunities, LLC, but disclaims such beneficial ownership except to the extent of their pecuniary interest therein, if any.
- (6) Consists of 13,692 shares of Common Stock that Dr. Patti has the right to acquire from us within 60 days of March 1, 2021, pursuant to the exercise of stock options.
- (7) Consists of 13,692 shares of Common Stock that Dr. Peterson has the right to acquire from us within 60 days of March 1, 2021, pursuant to the exercise of stock options.
- (8) Consists of (a) 13,692 shares of Common Stock that Dr. Schlesinger has the right to acquire from us within 60 days of March 1, 2021 pursuant to the exercise of stock options, (b) 8,710,800 shares of common stock and warrants exercisable for 8,710,800 shares of common stock held by Innoviva, Inc., and (c) 1,867,912 shares of common stock and warrants exercisable for 1,867,912 shares of common stock held by Innoviva Strategic Opportunities, LLC. Innoviva, Inc and Innoviva Strategic Opportunities, LLC are entities with which Dr. Schlesinger is affiliated due to her position as a director of Innoviva, Inc. Dr. Schlesinger may be deemed to have shared voting and dispositive power over the shares beneficially owned by Innoviva, Inc. and Innoviva Strategic Opportunities, LLC, but disclaims such beneficial ownership except to the extent of their pecuniary interest therein, if any.
- (9) Consists of (a) 49,058 shares of Common Stock, (b) 155,028 restricted shares of Common Stock, and (c) 130,737 shares of Common Stock that Mr. Patrick has the right to acquire from us within 60 days of March 1, 2021 pursuant to the exercise of stock options.
- (10) Consists of (a) 203 shares of Common Stock, (b) 31,851 restricted shares of Common Stock and (c) 116,510 shares of Common Stock that Dr. Varnum has the right to acquire from us within 60 days of March 1, 2021, pursuant to the exercise of stock options.
- (11) Consists of (a) 26 shares of Common Stock and (b) 46,952 shares of Common Stock that Mr. Martin has the right to acquire from us within 60 days of March 1, 2021, pursuant to the exercise of stock options.
- (12) Consists of (a) 5,612 shares of Common Stock, (b) 20,532 restricted shares of Common Stock and (c) 26,069 shares of Common Stock that Mr. Morris has the right to acquire from us within 60 days of March 1, 2021, pursuant to the exercise of stock options.
- (13) Represents beneficial ownership of our common stock held by our current directors and executive officers as a group as of March 1, 2021, including any options and warrants exercisable within 60 days of March 1, 2021.

### **Equity Compensation Plan Information**

In March 2009, our board of directors and stockholders adopted our 2009 Stock Incentive Plan, or the 2009 Plan. There are no shares of common stock remaining for future awards under the 2009 Plan.

In October 2012, our board of directors approved and adopted our 2012 Stock Incentive Plan, or the 2012 Plan. There are no shares of common stock remaining for future awards under the 2012 Plan.

In December 2013, our board of directors adopted the 2013 Stock Incentive Plan, or the 2013 Plan. Our stockholders approved the 2013 Plan in February 2014 and an amendment to the plan in August 2015. The 2013 Plan replaced the 2012 Plan. There are no shares of common stock remaining for future awards under the 2013 Plan.

In April 2016, our board of directors adopted our 2016 Equity Incentive Plan, or the 2016 Plan. In connection with the Merger, the name of the 2016 Plan was changed to the Armata Pharmaceuticals, Inc. 2016 Equity Incentive Plan. In connection with the Merger, the Company assumed the C3J Jian, Inc. Amended 2006 Stock Option Plan (the “Assumed 2006 Plan”) and the C3J Therapeutics, Inc. 2016 Stock Plan (the “Assumed 2016 Plan”). These plans provided for stock option and restricted stock awards (“RSAs”) to C3J employees in years prior to the Merger with AmpliPhi. Pursuant to the Merger Agreement, all of the outstanding C3J stock options and restricted stock awards granted under the Assumed 2006 Plan and the Assumed 2016 Plan were converted into and became stock options and restricted stock awards in the Company.

In June 2019, the Company added 987,354 shares of common stock to the shares authorized for issuance under the 2016 Plan pursuant to an amendment to such plan approved by the Company’s shareholders at a special meeting held on May 8, 2019. In addition, 115,336 shares of common stock were automatically added to the shares authorized for issuance under the 2016 Plan on January 1, 2019 pursuant to an “evergreen” provision contained in the 2016 Plan.

The following table provides information as of December 31, 2020 with respect to our equity compensation plans:

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	1,668,926	\$ 6.30	138,814
Equity compensation plans not approved by security holders	—	—	—
Total	1,668,926	\$ 7.61	138,814

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

#### **Related-Person Transactions Policy and Procedures**

We have adopted a written related-person transactions policy that sets forth our policies and procedures regarding the identification, review, consideration and oversight of “related-person transactions.” For purposes of our policy only, a “related-person transaction” is a transaction, arrangement or relationship (or any series of similar transactions, arrangements or relationships) in which we and any “related person” are participants involving an amount that exceeds \$120,000 (or such lower threshold as may be applicable to us from time to time pursuant to the rules and regulations of the SEC or the NYSE American exchange).

Transactions involving compensation for services provided to us by an employee, consultant or director are not considered related-person transactions under this policy. A related person is any person who is, or at any time since the beginning of our last fiscal year, was, an executive officer, director or director nominee, any holder of more than 5% of our common stock, any of the foregoing’s immediate family members and any entity owned or controlled by any such persons.

Under the policy, where a transaction has been identified as a related-person transaction, management must present information regarding the proposed related-person transaction to our Audit Committee (or, where review

by our Audit Committee would be inappropriate, to another independent body of our board of directors) for approval. The presentation must include a description of, among other things, the material facts, the direct and indirect interests of the related persons, the benefits of the transaction to us and whether any alternative sources for comparable services or products are available. To identify related-person transactions in advance, we rely on information supplied by our executive officers, directors, director nominees and certain significant stockholders. In considering related-person transactions, our Audit Committee or other independent body of our board of directors takes into account the relevant available facts and circumstances including, but not limited to:

- the risks, costs and benefits to us;
- the impact on a director's independence in the event the related person is a director, immediate family member of a director or an entity with which a director is affiliated;
- the terms of the transaction;
- the terms available to or from, as the case may be, unrelated third parties.

In the event a director has an interest in the proposed transaction, the director must recuse himself or herself from the deliberation and approval.

### **Certain Related-Person Transactions**

Described below are any transactions occurring since January 1, 2016, and any currently proposed transactions, to which C3J or Armata was a party and in which:

- The amounts involved exceeded or will exceed the lesser of (i) \$120,000 and (ii) 1% of the average of the respective company's total assets at year-end for the last two completed fiscal years; and
- A director, director nominee, executive officer, holder of more than 5% of the outstanding capital stock of the respective company, or any member of such person's immediate family had or will have a direct or indirect material interest.

### ***Financing Transaction***

#### ***February 2019 Private Placement***

On February 5, 2019, we entered into a share purchase agreement with certain investors, pursuant to which we agreed to sell, and the Investors agreed to buy, in a private placement, shares of common stock (the "2019 Financing Shares") immediately following the Effective Time of the Merger, having an aggregate purchase price of \$10.0 million (the "2019 Financing"). An aggregate of 1,991,269 shares of Armata common stock were issued to the Investors in the 2019 Financing at a price of approximately \$5.02192 per share. The 2019 Financing Shares were issued in reliance on the exemption from registration provided by Section 4(a)(2) of the Securities Act, and such shares bear appropriate restrictive legends. In addition, the 2019 Financing Shares were subject to the provisions of the lock-up agreements entered into by certain officers, directors and stockholders of us and C3J concurrently with the execution of the Merger Agreement, pursuant to which they accepted certain restrictions on transfers of their shares of our common stock for the 180-day period following the effective time of the Merger.

Immediately following the closing of the Merger and the 2019 Financing, the former C3J security holders (including the Investors) owned approximately 76% of the aggregate number of shares of our common stock (of which approximately 20% was comprised of the 2019 Financing Shares) and our security holders as of immediately prior to the Merger owned approximately 24% of the aggregate number of shares of our common stock.

In connection with the 2019 Financing, we entered into a registration rights agreement with the Investors, dated May 9, 2019, pursuant to which we agreed, subject to certain exceptions, to cause the 2019 Financing Shares to be registered for resale under the Securities Act.

#### *February 2020 Private Placement*

On January 27, 2020, we entered into the Securities Purchase Agreement with Innoviva, pursuant to which the Company agreed to issue and sell to Innoviva, in a private placement, up to 8,710,800 newly issued shares of our common stock (the “Private Placement Shares”) and warrants (the “Common Warrants”) to purchase up to 8,710,800 shares of common stock, with an exercise price per share of \$2.87 (the “Private Placement”). Each share of common stock was sold together with one Common Warrant, and the per-unit purchase price is \$2.87.

First Closing: The Private Placement occurred in two tranches. The first closing (the “First Closing”) occurred on February 12, 2020, at which time Innoviva purchased 993,139 Private Placement Shares and 993,139 Common Warrants, which was the maximum number of Private Placement Shares and Common Warrants issuable to Innoviva in compliance with any and all applicable laws and without the requirement for the prior receipt of the stockholders’ approval under the listing requirements of the NYSE American, in exchange for an aggregate gross cash payment of approximately \$2.8 million. The First Closing was subject to the satisfaction of certain previously disclosed closing conditions (including obtaining voting agreements (the “*Voting Agreements*”) from stockholders of the Company representing at least 50.1% of the outstanding shares of common stock).

Second Closing: At the closing of the second tranche (the “Second Closing”), Innoviva purchased 7,717,661 Private Placement Shares and 7,717,661 Common Warrants for an aggregate purchase price of approximately \$22.2 million.

Registration Rights Agreement and Investor Rights Agreement: As part of the First Closing of the Private Placement, the Company entered into a registration rights agreement (the “Registration Rights Agreement”) and an investor rights agreement (the “Investor Rights Agreement”) with Innoviva. Pursuant to the Registration Rights Agreement, on April 1, 2020, the Company filed a registration statement on Form S-3 covering the resale of the securities issued and sold pursuant to the Securities Purchase Agreement with the Commission, which was declared effective on April 8, 2020. The Investor Rights Agreement provides that for so long as Innoviva and its affiliates hold at least 12.5% of the outstanding shares of our common stock on a fully-diluted basis, Innoviva has the right to designate two (2) directors to our board of directors and for so long as Innoviva and its affiliates hold at least 8% but less than 12.5% of the outstanding shares of Common Stock on a fully-diluted basis, Innoviva has the right to designate one (1) director to our board of directors, subject to certain qualifications and conditions in the Investor Rights Agreement. The Investor Rights Agreement also provides for participation rights for Innoviva to participate in our future offerings of equity securities.

#### *2021 Private Placement*

On January 26, 2021, we entered into the Securities Purchase Agreement with Innoviva Strategic Opportunities LLC, a wholly-owned subsidiary of Innoviva, (collectively, “Innoviva”), pursuant to which we agreed to issue and sell to Innoviva, in the 2021 Private Placement, 6,153,847 newly issued shares of our common stock (“Shares”) and warrants to purchase 6,153,847 shares of common stock (“Common Warrants”), with an exercise price per share of \$3.25. Each share of common stock was sold together with one common warrant granting the warrant holder the right to purchase an additional share of common stock at \$3.25 per share. The 2021 Private Placement occurred in two tranches.

First Closing: The First Closing occurred on January 26, 2021. Innoviva purchased 1,867,912 Shares and Common Warrants to purchase 1,867,912 shares of common stock for an aggregate purchase price of approximately \$6.1 million.

Second Closing: The Second Closing occurred on March 17, 2021. Innoviva purchased 4,285,935 Shares and Common Warrants to purchase 4,285,935 shares of common stock for an aggregate purchase price of approximately \$13.9 million.

#### Registration Rights Agreement and Investor Rights Agreement:

As part of the First Closing of the 2021 Private Placement, we entered into a registration rights agreement (the “Registration Rights Agreement”) and an amended and restated investor rights agreement (the “Amended and Restated Investor Rights Agreement”) with Innoviva.

Pursuant to the Registration Rights Agreement, we must file a registration statement on Form S-1 or Form S-3 (the “Shelf Registration Statement”) covering the resale of the securities issued and sold pursuant to the Securities Purchase Agreement with the Commission on a continuous basis pursuant to Rule 415 promulgated under the Securities Act of 1933, as amended (the “*Securities Act*”), or if Rule 415 is not available for offers and sales of such securities, by such other means of distribution of such securities as Innoviva may reasonably specify. We must use its commercially reasonable efforts to cause the Shelf Registration Statement to be declared effective under the Securities Act as promptly as possible after the filing thereof, but in any event (i) no later than the fifteenth (15th) day following the filing of the Shelf Registration Statement in the event of no “review” by the Commission, (ii) no later than the sixtieth (60th) day following the filing of the Shelf Registration Statement in the event of “limited review” by the Commission, or (iii) in the event of a “review” by the Commission, the one hundred and twentieth (120th) day following the filing of the Shelf Registration Statement, subject to certain exceptions..

The Amended and Restated Investor Rights Agreement provides that for so long as Innoviva and its affiliates hold at least 12.5% of the outstanding shares of common stock of Armata on a fully-diluted basis, Innoviva shall have the right to designate two (2) directors to our board of directors and for so long as Innoviva and its affiliates hold at least 8%, but less than 12.5%, of the outstanding shares of common stock of the Company on a fully-diluted basis, Innoviva shall have the right to designate one (1) director, subject to certain conditions and qualifications set forth in the A&R IRA. The A&R IRA also provides Innoviva with certain subscription rights in the event of any new issuances.

#### ***Change in Control and Severance Benefits Arrangements***

We have entered into certain change in control and severance benefits arrangements with our officers, as more fully described in the section above entitled “Executive Compensation.”

#### ***Director and Executive Officer Compensation***

The compensation of our directors and named executive officers, including employment agreements and other compensatory arrangements with executive officers and stock option grants to executive officers and directors, is more fully described in the section above entitled “Executive Compensation.”

#### ***Indemnification Agreements***

We have entered, and intend to continue to enter, into separate indemnification agreements with each of our directors and executive officers, as described in the section above entitled “Executive Compensation — Limitation of Liability and Indemnification.” In addition, the Merger Agreement provided that, for a period of six years following the effective time of the Merger, we will indemnify and hold harmless each person who is, has been, or who became prior to the effective time of the Merger, a director, officer, fiduciary or agent of us and our subsidiaries or C3J, respectively, against all claims, losses, liabilities, damages, judgments, fines and reasonable fees, costs and expenses, including attorneys’ fees and disbursements, incurred in connection with any claim, action, suit, proceeding or investigation,

whether civil, criminal, administrative or investigative, arising out of or pertaining to the fact that such person is or was a director, officer, fiduciary or agent of C3J or us or any of its or our respective subsidiaries, whether asserted or claimed prior to, at or after the effective time, in each case, to the fullest extent permitted under applicable law. Each such person will be entitled to advancement of expenses incurred in the defense of any such claim, action, suit, proceeding or investigation from us.

The Merger Agreement also provided that the provisions relating to the indemnification, advancement of expenses and exculpation of our present and former directors and officers set forth in our articles of incorporation and bylaws will not be amended, repealed or otherwise modified for a period of six years from the effective time of the Merger in any manner that would adversely affect the rights of individuals who, at the effective time of the Merger, were our officers or directors. The Merger Agreement required that, after the closing of the Merger, our articles of incorporation and bylaws were to contain provisions at least as favorable as the provisions relating to the indemnification, advancement of expenses and exculpation of present and former directors and officers set forth in our articles of incorporation and bylaws prior to the Merger.

Prior to the effective time of the Merger, we secured and prepaid, at C3J's expense, a six year "tail policy" on our then-existing directors' and officers' liability insurance policy.

#### **Item 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES**

The following table represents aggregate fees incurred for Ernst & Young LLP services by Armata Pharmaceuticals, Inc. for the year ended December 31, 2020, as well as the following during the year ended December 31, 2019:

- Armata Pharmaceuticals, Inc. includes fees incurred by the combined company from May 9, 2019, the date of Merger, to December 31, 2019.
- AmpliPhi Biosciences Corporation includes fees incurred from January 1, 2019 to May 9, 2019, the date of the Merger.
- C3J Therapeutics, Inc. includes fees incurred from January 1, 2019 to May 9, 2019, the date of the Merger.

	<b>Fiscal Year Ended December 31, 2020</b>	<b>Fiscal Year Ended December 31, 2019</b>
<b>Armata Pharmaceuticals, Inc.</b>		
Audit Fees	\$ 362,000	\$ 277,000
Audit Related Fees	105,000	94,000
Tax Fees	—	—
All Other Fees	—	—
<b>Total</b>	<b>\$ 467,000</b>	<b>\$ 371,000</b>
<b>AmpliPhi Biosciences Corporation</b>		
Audit Fees	\$ —	\$ 143,000
Audit Related Fees	—	102,000
Tax Fees	—	—
All Other Fees	—	—
<b>Total</b>	<b>\$ —</b>	<b>\$ 245,000</b>
<b>C3J Therapeutics, Inc.</b>		
Audit Fees	\$ —	\$ 26,000
Audit Related Fees	—	—
Tax Fees	—	—
All Other Fees	—	—
<b>Total</b>	<b>\$ —</b>	<b>\$ 26,000</b>
<b>Grand total</b>	<b>\$ 467,000</b>	<b>\$ 642,000</b>

Representatives of Ernst & Young LLP attended all of the meetings of the Audit Committee occurring during the years ended December 31, 2020 and 2019.

The Audit Committee approves in advance the engagement and fees of the independent registered public accounting firm for all audit services and non-audit services, based upon independence, qualifications and, if applicable, performance. The Audit Committee may form and delegate to subcommittees of one or more members of the Audit Committee the authority to grant pre-approvals for audit and permitted non-audit services, up to specific amounts. All audit services provided by Ernst & Young LLP for the periods presented were pre-approved by the Audit Committee.



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