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, 2025

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 001-38942

ARCTURUS THERAPEUTICS HOLDINGS INC.
(Exact name of Registrant as specified in its Charter)

Delaware	**32-0595345**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
10285 Science Center Drive San Diego, California	**92121**
(Address of principal executive offices)	(Zip Code)

(858) 900-2660
(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 $0.001 per share	ARCT	The Nasdaq Stock Market LLC

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

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

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the 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, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided 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. **Yes** ☒ **No** ☐

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

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

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

The aggregate market value of the common equity held by non-affiliates of the Registrant, based on the closing price of the common stock on The Nasdaq Stock Market on June 30, 2025 was $323.5 million.

As of February 27, 2026, the registrant had 28,423,069 shares of voting common stock outstanding.

Certain portions of the registrant's definitive Proxy Statement for its 2025 Annual Meeting of Stockholders are incorporated by reference into Items 10, 11, 12, 13 and 14 of Part III of this Annual Report on Form 10-K.

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Special Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K, or this Annual Report, and the documents incorporated by reference herein may contain "forward-looking statements" within the meaning of the federal securities laws made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. 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 Part I, Item 1.A, "Risk Factors" in this Annual Report. Except as required by law, we assume no obligation to update these forward-looking statements, whether as a result of new information, future events or otherwise. These statements, which represent our current expectations or beliefs concerning various future events, may contain words such as "may," "will," "expect," "anticipate," "intend," "plan," "believe," "estimate" or other words indicating future results, though not all forward-looking statements necessarily contain these identifying words. Such statements may include, but are not limited to, statements concerning the following:

- our plans and ability to develop and commercialize our product candidates;
- the initiation, design, cost, timing, progress, enrollment and results of, and our expected ability to undertake certain activities and accomplish certain goals with respect to, our research and development activities, preclinical studies and clinical trials, including those related to our therapeutics pipeline candidates ARCT-810 and ARCT-032;
- the likelihood that clinical data will be sufficient for regulatory approval or completed in time to submit an application for regulatory approval within a particular timeframe;
- interactions with regulatory authorities in the United States and foreign countries, including outcomes of meetings with the FDA regarding a regulatory pathway for ARCT-810 and ARCT-032;
- our compliance, and ability to remain in compliance, with the requirements of our collaboration agreements, including our collaboration with Seqirus Inc. ("CSL Seqirus"), and our ability to prevail in any disputes regarding such collaboration agreements;
- the anticipated benefits and success of our collaboration agreement with CSL Seqirus related to the licensure of our STARR® mRNA technology and LUNAR® lipid-mediated delivery, including our timely receipt of upfront and potential royalty and other payments thereunder;
- the status of development activities of the LUNAR-COV19 and LUNAR-FLU programs, and the other infectious disease programs, under our collaboration with CSL Seqirus;
- the status, success and benefits of our arrangements with private and governmental entities, some of which are subject to termination for convenience by our counterparties;
- our compliance, and ability to remain in compliance, with the stringent requirements of our current and potential government contracts, including our arrangements with the Biomedical Advanced Research and Development Authority, a division of the Office of the Assistant Secretary for Preparedness and Response within the U.S. Department of Health and Human Services and the Department of Defense;
- our plans to conduct and advance any of our research and discovery programs;
- the potential safety, immunogenicity, efficacy or regulatory approval of any of our product candidates;
- the potential effects, efficacy and benefits of our technologies and product candidates on their own and in comparison to technologies, drugs or courses of treatment currently available or that may be developed by competitors;
- the likelihood that preclinical or clinical data will be predictive of future clinical results or efficacy or safety of a product candidate;
- the anticipated timing of enrollment, duration, milestones and announcements of results of clinical trials, and the submission of applications to conduct clinical trials;
- the potential administration regimen or dosage, or ability to administer multiple doses of, any of our product candidates;
- the likelihood of optimizing KOSTAIVE's product presentation and formulation;

- our ability to obtain and maintain regulatory approval of our product candidates, and any related restrictions, limitations, and/or warnings in the label of an approved product candidate;
- our ability, and the ability of our partners, to successfully commercialize, and our expectations regarding future therapeutic and commercial potential with respect to, our product candidates;
- the rate and degree of market acceptance of our product candidates;
- the success of competing therapies that are or may become available;
- the size and growth potential of the markets for our product candidates, and our ability to serve those markets and address unmet medical needs;
- our ability to obtain and maintain intellectual property protection for our product candidates;
- our ability to attract and retain experienced and seasoned scientific and management professionals;
- the performance of our third-party suppliers and manufacturers, including the ability to implement and scale-up manufacturing levels as necessary;
- the receipt of relevant approvals related to the manufacture and distribution of our product candidates;
- our strategic alliance partners' election to pursue development and commercialization of any programs or product candidates that are subject to our collaboration and license agreements with such partners;
- our ability to attract collaborators with relevant development, regulatory and commercialization expertise;
- future activities to be undertaken by our strategic alliance partners, collaborators and other third parties;
- our ability to develop sales and marketing capabilities, whether alone or with potential future collaborators;
- our ability to avoid, settle or be victorious at costly litigation with shareholders, former executives or others, should these situations arise;
- our ability to obtain and deploy funding for our operations and to efficiently use our financial and other resources;
- our ability to continue as a going concern; and
- the accuracy of our estimates regarding future expenses, future revenues, cash flows, capital requirements need for additional financing, and possible sources of revenue.

These and other forward-looking statements are only current predictions and are subject to known and unknown risks, uncertainties, and other factors that may cause our or our industry's actual results, levels of activity, performance or achievements to be materially different from those anticipated by the forward-looking statements. In addition, historic results of scientific research, preclinical and clinical trials do not guarantee that future research or trials will suggest the same conclusions, nor that historic results referred to herein will be interpreted the same in light of additional research, preclinical and clinical trial results. The forward-looking statements contained in this Annual Report are subject to risks and uncertainties, including those discussed in our other filings with the United States Securities and Exchange Commission (the "SEC"). Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Although we currently believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance, or achievements.

References to Arcturus

In this Annual Report on Form 10-K, unless otherwise stated or the context otherwise indicates, references to the “Company,” “Arcturus,” “we,” “our” and “us” mean Arcturus Therapeutics Holdings Inc. and its consolidated subsidiaries from and after the effective time of the Redomiciliation (as defined below in Part I, Item 1. "Business" - "Available Information") and, prior to that time, to our predecessor, Arcturus Therapeutics Ltd.

Trademarks and Tradenames

The Arcturus logo and other trademarks of Arcturus appearing in this Annual Report on Form 10-K are the property of Arcturus. All other trademarks, service marks and trade names in this Annual Report on Form 10-K are the property of their respective owners. Solely for convenience, trademarks and trade names referred to in this report may appear without the ® or ™ symbols.

Market Data, Forecasts, and Other Information

Unless otherwise indicated, information in this Annual Report on Form 10-K concerning economic conditions, our industry, and our markets, including our general expectations and competitive position, market opportunity and market size, is based on a variety of sources, including information from independent industry analysts and publications, as well as our own estimates and research. In addition, certain information included references to third-party publications regarding our business, results of operations, products, and product candidates.

Our estimates are derived from industry and general publications, studies and surveys conducted by third-parties, as well as data from our own internal research. These publications, studies and surveys generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information, and we have not independently verified industry data from such third-party sources. While we believe our internal research is reliable and that our internal estimates are reasonable, such research has not been verified by any independent source and our internal estimates are based on our good faith beliefs as of the respective dates of such estimates. This Annual Report on Form 10-K includes references to and citations of third-party publications. Such publications and related materials are provided for informational purposes only. Neither these publications nor the information contained therein is incorporated by reference into, or deemed to form a part of, this Annual Report on Form 10-K, and we do not adopt or endorse the statements made in such materials.

PART I

Item 1. Business

Overview

We are a messenger RNA medicines company focused on the development of liver and respiratory rare disease therapeutics. We have ongoing Phase 2 clinical studies for our RNA therapeutic candidates to potentially treat ornithine transcarbamylase (OTC) deficiency and cystic fibrosis (CF).

We developed the world's first approved self-amplifying messenger RNA (sa-mRNA) vaccine, KOSTAIVE® ("KOSTAIVE"), which we have partnered with Seqirus, Inc. ("CSL Seqirus"), a part of CSL Limited. KOSTAIVE has achieved approval in Japan, the European Union and the United Kingdom as a vaccine against COVID-19, and sales of KOSTAIVE began in Japan in October 2024.

We have several key platform technologies that we leverage to develop and advance a pipeline of mRNA-based therapeutics for rare genetic disorders with significant unmet medical needs and vaccines for infectious diseases. Current mRNA medicines have two critical components: the messenger RNA ("mRNA") constructs and the lipid nanoparticles ("LNP") which help deliver the mRNA to disease-relevant target tissues. We have extensive expertise in the design and optimization of mRNA constructs, including with respect to a type of mRNA technology known as self-amplifying mRNA (sa-mRNA). Our proprietary self-amplifying mRNA technology platform, or STARR® ("STARR"), has been demonstrated to induce a robust, longer-lasting and broader humoral immune response at lower dose levels than conventional mRNA-based vaccines. Our proprietary LNP delivery system, LUNAR® ("LUNAR"), is intended to address the major hurdle in RNA drug development, namely the effective and safe delivery of RNA to disease-relevant target tissues. LUNAR may enable multiple nucleic acid medicines. We also have significant expertise and valuable know-how in the development and scalability of complex and robust manufacturing processes required to deliver the next generation of nucleic acid medicines.

Our internal pipeline includes RNA therapeutic candidates to potentially treat ornithine transcarbamylase (OTC) deficiency and cystic fibrosis (CF), both rare diseases. In our vaccine program, we have partnered with CSL Seqirus, one of the world's leading influenza vaccine providers, on the development and commercialization of mRNA vaccines for COVID-19, influenza and three other infectious diseases. In CSL Limited's half-year results presented on February 11, 2026, CSL Limited reported an accounting write-down of approximately $430 million attributable to our collaboration agreement with CSL Seqirus, citing declining COVID-19 disease burden and more onerous U.S. regulatory requirements.

In our CF program, we enrolled and completed dosing in the three initially planned cohorts of our Phase 2 multiple ascending dose study of ARCT-032, confirming the safety and tolerability of ARCT-032 dosed daily for four weeks. This study was initiated in December 2024 and was designed to identify a safe and effective dose regimen in those with Class I (null) CFTR mutations and people with CF who do not benefit from CFTR modulators. In the study, six CF adults with Class I CFTR mutations inhaled 10 mg doses of ARCT-032 daily over 28 days. Interim results released in October 2025 demonstrated that the treatment was generally safe and well tolerated. Treatment-related adverse events (AEs) that were identified in the single-dose Phase 1 study were also observed in some participants for the first few doses but ceased with continued dosing. Bronchospasm has not been reported in this study thus far, neither with nor without albuterol pretreatment. One serious adverse event (SAE) occurred in a participant after the end of the dosing period. The safety review committee found no convincing evidence that the SAE is related to ARCT-032 and approved the study to proceed. We intend to initiate a 12-week safety and preliminary efficacy study in up to 20 CF participants in the first half of 2026, after the third cohort completes treatment. ARCT-032 has received Orphan Drug Designation by the U.S. Food and Drug Administration (the "FDA") and Orphan Medicinal Product Designation by the European Medicines Agency (the "EMA") for the treatment of CF, and Rare Pediatric Disease Designation from the FDA.

KOSTAIVE is the brand name approved in Japan and Europe for ARCT-154, which is the version of the sa-mRNA COVID vaccine encoding the ancestral strain of SARS-CoV-2, and also for updated variant-specific versions of this vaccine. We may use KOSTAIVE or the specific internally generated name, such as ARCT-154, ARCT-2301 and ARCT-2303, to identify a version of the vaccine.

In our OTC program, we have continued to conduct a Phase 2 double-blind multiple-dose study of ARCT-810. Five patients with OTC deficiency have now completed dosing, and a sixth patient has initiated dosing. A type C meeting with the FDA to discuss our plans for a proposed future pediatric study under the RDEP (Rare Disease

Evidence Principles) is scheduled for the first half of 2026. ARCT-810 has received Orphan Drug Designation from the FDA and Orphan Medicinal Product Designation from the EMA for treatment of OTC deficiency, as well as Fast Track Designation and Rare Pediatric Disease Designation from the FDA.

Commercial sales of KOSTAIVE began in October 2024 in Japan by Meiji Seika Pharma, Ltd. ("Meiji"), CSL Seqirus' exclusive partner in Japan, marking the first commercial sales of an Arcturus-developed product. In September 2025, Meiji launched a new presentation of KOSTAIVE in Japan. The product is a 2-dose vial lyophilized presentation incorporating the updated XEC variant strain. Approval for offshore manufacturing of the 2-dose vial lyophilized presentation was granted by Japan in August 2025, followed by approval for onshore manufacturing in January 2026. KOSTAIVE was approved by the European Commission (EC) in February 2025 and by the United Kingdom in January 2026, providing further validation of our platform by additional significant regulatory authorities.

In December 2024, we initiated dosing of an sa-mRNA vaccine candidate against pandemic avian influenza (bird flu) in a Phase 1 trial funded by the Biomedical Advanced Research and Development Authority ("BARDA"). The study results were received in the second half of 2025, indicating a favorable tolerability and safety profile and the ability to induce a robust and durable humoral immune response in young and older adults.

We also improved our platform technologies and advanced our early-stage research activities and manufacturing process development and operations. We conducted exploratory platform development activities, including the evaluation of genome editing, and new targeting approaches, where our LUNAR and STARR platforms could be useful for identification and development of additional products for our portfolio.

Nucleic Acid Medicines and an Introduction to Arcturus' Platform Technologies

Nucleic Acid Medicines

Nucleic acid medicines have the potential to treat diseases caused by genetic mutations, including diseases that cannot be treated by conventional drugs, such as small molecules and biologics. Some of these medicines function by providing the means for producing a deficient yet vital protein in vivo. Within a cell, DNA carries the blueprint, in the form of genes, which encode critical proteins necessary for life. Each gene's code is transcribed into a nucleic acid molecule called mRNA, which informs the cell's own machinery how to organize amino acid building blocks to make one or more proteins needed for normal biological function.

Nucleic acid therapeutics represent a significant advancement in targeted medicines and several of these therapeutics are being developed by public and private companies. The general objectives of these therapies include:

- to introduce a gene product (e.g., mRNA or DNA) that encodes for a functional protein to replace an absent or defective protein;
- to restore a functional protein by genomic DNA editing of the corresponding gene or RNA editing resulting in the correction of the mRNA sequence;
- to reduce the amount of a target protein in a patient by binding to and destroying the associated target mRNA (antisense DNA or small interfering RNA ("siRNA")); and
- to express proteins from viruses or unique proteins only found in cancer and not in non-cancerous cells resulting in the induction of protective immunity against specific viral pathogens or immune mediated elimination of cancer cells.

Brief Introduction to our LUNAR and STARR Technology Platforms

LUNAR®

A key challenge for nucleic acid medicines is the safe and effective delivery of the nucleic acid molecule into cells. In addition to enabling uptake of the medicine into cells, the nucleic acid delivery vehicle seeks to protect the nucleic acid from degradation prior to cell entry and to release the nucleic acid payload inside the cell. Arcturus has developed a novel lipid-mediated delivery system called LUNAR. LUNAR is comprised of a mixture of biodegradable synthetic lipids and naturally occurring lipids. Lipids are molecules that contain hydrocarbons and make up the building blocks of the structure and function of living cells. Examples of lipids include fats, oils, waxes and phospholipids. LUNAR is designed to address technical challenges facing the delivery of nucleic acid medicines into cells. We continue to expand our library of proprietary synthetic lipids, known as ATX, to over 300 to date. Our

preclinical studies have shown that formulations can be customized for the indication and target cell type of interest, and we have also demonstrated that our proprietary formulation process is scalable and reproducible. Our LUNAR platform is described in more detail below.

STARR®

Our STARR technology is our proprietary self-amplifying mRNA (or sa-mRNA) technology platform. When combined with a delivery system, such as our lipid-mediated delivery system LUNAR, the STARR technology has the potential to generate a protective immune response or drive therapeutic protein expression to prevent against or treat a variety of diseases. Self-amplifying RNA-based prophylactic vaccines developed with STARR trigger rapid and prolonged antigen expression in host cells, which may provide protective immunity against infectious pathogens. We have shown in clinical trials that combining LUNAR and STARR technologies can reduce dose requirements, deliver a superior immune response, and sustain protein expression compared with conventional RNA-based vaccines, potentially enabling faster production of larger volumes of vaccine doses.

Our Pipeline

Therapeutics

Franchise	Indication	Funding	Preclinical	Phase 1	Phase 2	Phase 3	Commercial
Hepatic	Ornithine Transcarbamylase Deficiency	ARCTURUS Therapeutics	→	→	→		
Respiratory	Cystic Fibrosis	CYSTIC FIBROSIS FOUNDATION	→	→	→		

Vaccines

Candidate	Indication	Partner	Preclinical	Phase 1	Phase 2	Phase 3	Commercial
KOSTAIVE®	COVID-19	CSL	→	→	→	→	→
LUNAR®-FLU (ARCT-2138)	Seasonal Influenza	CSL	→	→			
LUNAR®-PanFLU (ARCT-2304)	Pandemic Influenza	CSL	→	→			

(i) Commercialized in Japan; approved by the European Commission and the United Kingdom

Rare Disease Program

The Orphan Drug Act of 1983 (the "Orphan Drug Act") defines a rare disease as a disease affecting fewer than 200,000 individuals in the United States. According to the National Institutes of Health ("NIH"), there are approximately 10,000 such diseases that, together, affect nearly 30 million people in the United States. The European Union (the "EU") defines a rare disease as having a prevalence of fewer than five in 10,000 people. Collectively, these disorders affect between 6% and 7% of the population in the developed world.

There is a pressing need for new medicines for rare diseases as few of the 10,000 known rare diseases have approved treatments. Biopharmaceutical industry researchers are making great progress in the fight against some rare diseases as innovative science has opened new opportunities. More than 770 medicines have been approved by the FDA since the enactment of the Orphan Drug Act and more than 800 medicines are currently in clinical development. Despite recent progress, there is more work to be done to overcome the scientific, operational, and financial challenges that arise.

We believe our technology should provide an excellent platform to address genetically inherited rare diseases. Specifically, we are focusing on developing medicines to treat people with rare respiratory and liver diseases who currently have limited or no treatment options.

Rare Disease Program - LUNAR-CF (Cystic Fibrosis)

The LUNAR-CF program addresses cystic fibrosis (CF) lung disease, a progressive disorder caused by mutations in the CF transmembrane conductance regulator (CFTR) gene. ARCT-032, our lead development candidate for the treatment of CF, uses our LUNAR platform to deliver a codon-optimized CFTR mRNA into airway epithelial cells. This allows airway cells to produce functional human CFTR protein using native translational machinery and protein trafficking pathways which could result in the treatment of the underlying defect

that causes CF lung disease, regardless of the specific mutation. The Cystic Fibrosis Foundation (the "CFF") has partnered with us to support the development of this therapy. ARCT-032 represents the first LUNAR-based mRNA therapeutic delivered by the inhaled route, offering direct delivery to the affected airways to restore functional CFTR.

There are close to 40,000 children and adults living with CF in the United States (and an estimated 105,000 people have been diagnosed with CF across 94 countries). CF can affect people of every racial and ethnic group. Approximately 800 people are newly diagnosed with CF each year in the United States. CF is caused by more than 2,000 known mutations in the CFTR gene. These mutations have been grouped into several different classes based on the mechanism by which they cause reduction in the production and/or function of the CFTR protein. When CFTR is absent or defective, the airway surfaces become dehydrated and coated with a layer of thick mucus that clogs the airways, causing difficulty breathing and often resulting in chronic infections, exaggerated inflammation, structural airway damage, and other serious complications in the lungs. CF is a multi-system disease that may also affect the pancreas, intestines, liver, sinuses, reproductive tract, and sweat glands. The median predicted survival of CF patients has dramatically improved since the introduction of highly effective CFTR modulators, and is approximately 65 years for those born between 2020-2024 in the United States. However, for those people with CF who are not eligible or otherwise cannot take modulators, the predicted survival remains much lower, and the cause of most of the mortality and morbidity is due to the lung disease.

Current non-curative therapies for CF lung disease are directed towards treating symptoms and preventing the progression of the disease. These treatments include aerosolized mucolytics, antibiotics, and airway clearance techniques that are time-consuming and represent a significant treatment burden for people with CF. Many CF patients ultimately suffer from a critical decline in lung function and require lung transplants.

The FDA has approved several CFTR modulator therapies (Kalydeco®, Orkambi®, Symdeko®, Trikafta®, and Alyftrek®) that assist certain classes of abnormal CFTR protein to reach the cell membrane and/or increase functional ion channel activity. The CFTR modulators, while effective in many patients, are mutation-specific and therefore are not effective in all persons with CF. Other treatments are required to target Class I mutations (no CFTR produced; approximately 10% of CF cases worldwide), and people who are intolerant or have poor response to CFTR modulator therapies. We are initially focusing ARCT-032 on these groups of patients, as they currently have the highest unmet need for CF therapies.

ARCT-032 has received Orphan Drug Designation by the FDA and Orphan Medicinal Product Designation by the EMA. The FDA also granted Rare Pediatric Disease Designation for ARCT-032. The Rare Pediatric Disease Designation is designed to recognize rare pediatric diseases in which the serious or life-threatening manifestations primarily affect patients from birth to 18 years of age. With this designation, if ARCT-032 achieves approval for a pediatric indication in the original rare pediatric disease product application in the United States, Arcturus (or the sponsor of ARCT-032) is eligible to receive a voucher for priority review of a subsequent marketing application for a different product.

In 2023, we successfully completed a safety and tolerability Phase 1 single ascending dose study of ARCT-032 (LUNAR-CF), our mRNA therapeutic candidate for CF. Thirty-two healthy participants (eight subjects in each of four dose cohorts) received a single inhaled dose of ARCT-032. Subsequently, seven CF adults received two administrations of ARCT-032 separated by two days in a Phase 1b study extension.

In the Phase 1/1b clinical study, ARCT-032 was generally safe and well tolerated in both the healthy volunteers and the participants with CF. Of the seven total CF participants in the Phase 1b study, six were being treated with CFTR modulators while one subject had Class I mutations that do not benefit from modulator therapy. No serious or severe adverse events (SAEs) were observed, and the safety profile was similar between healthy volunteers and CF participants. Mild, transient events of elevated temperature or feeling hot accompanied by other nonspecific symptoms were observed at dose levels that are higher than those planned for the Phase 2 study. In the CF subjects, lung function measured over eight days did not demonstrate a discernable pattern or safety concern after two doses of ARCT-032. Preliminary findings from the study were presented at the European CF Society Conference in June 2024 in Glasgow, Scotland, and at the North American CF Conference in September 2024 in Boston, MA.

In December 2024, we initiated dosing in our ARCT-032 Phase 2 multiple ascending dose study designed to identify a safe and effective dose in Class I (null) and other CF participants who do not benefit from CFTR modulators. This study is supported by safety and tolerability data collected in healthy volunteers (N = 32) and the

two-administration Phase 1b study in CF adults. The initial three dose cohorts are fully enrolled, with each participant in the Phase 2 CF study (NCT06747858) receiving daily treatments of ARCT-032 over a period of 28 days.

On October 21, 2025, we announced interim results from the ongoing Phase 2 clinical trial of ARCT-032 for CF. In the second cohort of the study, six Class I CF adults received inhaled 10 mg doses of ARCT-032 daily over 28 days. High-resolution computed tomography (HRCT) lung scans analyzed using FDA 510(k)-cleared AI technology, revealed reductions in mucus burden in four of six Class I CF participants. The treatment was generally safe and well tolerated. Bronchospasm was not reported in these participants, either with or without pretreatment with a bronchodilator. Treatment related AEs that were identified in the single-dose Phase 1 study were also observed in some participants for the first few doses but ceased with continued dosing. One SAE occurred in a participant after the end of the dosing period. The safety review committee found no convincing evidence that the SAE was related to ARCT-032 and approved the study to proceed. The third cohort is ongoing and has enrolled four subjects to determine if there is a different response at 15 mg daily over 28 days and if ARCT-032 continues to be generally safe and well tolerated. A fourth cohort is planned to begin enrollment of up to 20 adults with CF to explore safety, tolerability, and efficacy of ARCT-032 administered for 12 weeks.

In December 2025, we published our preclinical data of the ARCT-032 study. This study demonstrates that LUNAR lipid nanoparticles effectively deliver human *CFTR* mRNA to airway epithelia, restoring chloride channel function and mucociliary clearance in primary human cystic fibrosis cells and a ferret model of the disease.

Rare Disease Program – ARCT-810 (LUNAR-OTC)

The LUNAR-OTC development program addresses ornithine transcarbamylase (OTC) deficiency, a rare, life-threatening, genetic disease caused by mutations in the OTC gene that lead to dysfunctional or deficient OTC.

OTC deficiency is the most common of the urea cycle disorders, a group of inherited metabolic disorders that are associated with reduced ability to eliminate ammonia from the body. There are over 5,000 people with OTC deficiency in the United States, and the prevalence is approximately one in 14,000 to one in 77,000 people worldwide. Ammonia is a toxic waste product produced from the breakdown of protein. OTC is a critical enzyme in the urea cycle, which takes place in liver cells and converts ammonia to harmless urea which is eliminated by the kidneys. In patients with OTC deficiency, ammonia accumulates in the blood and is toxic to the brain and liver. Symptoms of high ammonia levels include vomiting, headaches, coma and death. OTC deficiency can cause developmental problems, seizures and death in newborn babies. As an X-linked disorder, OTC deficiency tends to be more severe in males, though female carriers are often affected. Patients with less severe symptoms may present later in life, as adults. Currently no cure exists for OTC deficiency apart from liver transplant; however, this treatment comes with significant risks and complications such as organ rejection, and transplant recipients must take immunosuppressant drugs for the rest of their lives. Current standard of care for OTC deficiency is a low-protein diet, dietary supplements, and nitrogen scavengers to try to prevent accumulation of ammonia. Life-threatening episodes of high ammonia levels can still occur, requiring treatment with dialysis or hemofiltration. These treatments do not address the underlying cause of disease, and there remains a high unmet need for an effective treatment.

Our LUNAR-OTC development candidate, ARCT-810, uses our LUNAR platform to deliver normal OTC mRNA into liver cells which then produce normal functioning OTC with possible disease-modifying effects. Our LUNAR-OTC approach has the potential to treat the underlying defect that causes the debilitating symptoms of OTC deficiency, rather than mitigating symptoms by sequestering ammonia. We have retained worldwide development and commercialization rights to ARCT-810.

LUNAR-OTC has received Orphan Drug Designation from the FDA and Orphan Medicinal Product Designation from the EMA for treatment of OTC deficiency. ARCT-810 was also granted Fast Track Designation in and Rare Pediatric Disease Designation (RPDD). Fast Track Designation is designated to facilitate development and expedite review of new therapeutics intended to treat serious or life-threatening conditions that demonstrate the potential to address important unmet medical needs. Rare Pediatric Disease Designation is designed to recognize rare pediatric diseases in which the serious or life-threatening manifestations primarily affect patients from birth to 18 years of age. Due to such designation, if ARCT-810 achieves approval for a pediatric indication in the original rare pediatric disease product application in the United States, Arcturus (or the sponsor of ARCT-810) is eligible to receive a voucher for priority review of a subsequent marketing application for a different product.

Preclinical data in OTC-deficient murine models demonstrated that dosing of LUNAR-OTC results in robust OTC protein expression and activity, thereby improving ureagenesis, reducing plasma ammonia, and increasing survival.

A Phase 1 double-blind, placebo-controlled, dose-escalation study of ARCT-810 in healthy volunteers, completed in November 2020, and demonstrated favorable safety, tolerability and PK profiles.

A single ascending dose, placebo-controlled Phase 1b study in 16 stable mild OTC-deficient adults was completed in the United States in September 2023. The trial assessed safety, tolerability, and pharmacokinetics of a single dose of ARCT-810, and exploratory biomarkers of drug activity. ARCT-810 was generally safe and well tolerated at doses ranging from 0.1- 0.5mg/kg and no serious or severe adverse events were observed. Sporadic infusion-related reactions (IRRs) were managed with symptomatic treatment and appeared to be less frequent with slower infusion rates. In plasma, ARCT-810 mRNA could be detected for up to four weeks, while ionizable lipid was no longer measurable after 48 hours, indicating rapid degradation of the lipid nanoparticle that was utilized to deliver ARCT-810 mRNA. Study results were presented at the Society for Inherited Metabolic Disorders meeting in Charlotte, North Carolina in April 2024 and at the annual symposium for the Society for the Study of Inborn Errors of Metabolism in Porto, Portugal in August 2024.

A Phase 2 double-blind study of ARCT-810 in stable OTC-deficient adolescents and adults in the European Union and the United Kingdom completed dosing of eight subjects in August 2024 at the 0.3 mg/kg dose level. The participants in this group were randomized 3:1 to receive six doses of ARCT-810 or placebo administered every 14 days. Study results were presented at the 6th International Symposium on Urea Cycle Disorders, Kyoto, Japan and International Congress of Inborn Errors of Metabolism, Kyoto, Japan in September, 2025.

In the second quarter of 2024, we expanded the Phase 2 clinical program of ARCT-810 to the U.S. with an open-label, multiple-dose study to evaluate pharmacodynamics and safety in adult and adolescent patients requiring clinical management for OTC-deficiency. The first OTC deficient participant receiving 0.5 mg/kg ARCT-810 initiated dosing in December 2024 in the United States. Each participant is expected to receive five intravenous infusions administered over two months.

On June 30, 2025, we announced positive multiple dosing data of ARCT-810 from two Phase 2 studies: (i) a completed placebo-controlled study in Europe that randomized eight participants to ARCT-810 0.3 mg/kg or placebo; and (ii) an open-label multiple ascending dose study in the U.S., with interim data from the initial three completed participants. Both studies evaluate safety and pharmacodynamics in adult and adolescent patients requiring clinical management for OTC-deficiency. We continue to enroll participants in the U.S. study. Each participant in the U.S. study is expected to receive five intravenous infusions administered over two months.

A Linear Mixed-Effects Model (LMM) was applied as an exploratory analysis to the Phase 2 glutamine and ureagenesis data. LMM is suitable for analyses of small, rare disease trial datasets. In the Phase 2 randomized European study, glutamine levels in patients who received multiple doses of ARCT-810 significantly (p-value = 0.016; LMM) decreased during the dosing period. In the Phase 2 open-label U.S. study, interim analysis of the first three participants showed a sustained and significant (p-value = 0.004; LMM) decrease in glutamine from baseline, reaching normal levels after the first three doses. In the combined analysis of both Phase 2 studies, significantly (p-value = 0.0055; LMM) decreased glutamine levels were observed. The ongoing U.S. Phase 2 open-label study uses a modified and improved 15N-ureagenesis assay (Allegri et al., 2025). The assay measures relative ureagenesis function (RUF) against a normal range established from healthy controls. The assay is not impacted by ammonia scavengers, has low intraindividual variability, and can distinguish between symptomatic and asymptomatic OTC deficient patients. In the first three participants in the ongoing Phase 2 open-label study, RUF statistically (p-value = 0.026, LMM) increased at all post treatment evaluations from a baseline of 29.0% (SD; 9.1%) to 43.7% (SD; 21.7%) at 28 days post-fifth dose. These results suggest a progressive increase of functional OTC enzymes in the liver with continued administrations of ARCT-810. Two of the three participants achieved RUF > 50% indicating a clinically meaningful improvement in urea cycle flux.

A type C meeting with the FDA to discuss our plans for a proposed future pediatric study under the RDEP (Rare Disease Evidence Principles) is scheduled for the first half of 2026.

Vaccine Programs

According to the National Foundation for Infectious Diseases, over 50,000 people die each year due to vaccine-preventable diseases and related complications in the United States alone (Centers for Medicare and

Medicaid Services, 2018; Walter et al., 2016). Influenza and pneumonia cases approach this number of deaths each year and more than one million individuals in the United States have died of COVID since the beginning of the COVID-19 pandemic (Centers for Disease Control and Prevention). The Department of Health and Human Services estimated that 330,000 lives were saved in the United States due to COVID-19 vaccination in 2021 alone. Outbreaks of new infectious diseases, and the rise of variants to existing viruses, create demand for new and novel approaches to producing vaccines in a more cost-effective and quicker manner.

The COVID-19 pandemic highlighted the efficacy, safety, and rapidity in which nucleic acid medicines can be used to vaccinate vulnerable populations, and our vaccine program has continued to progress. In 2020, we initiated development of our first self-amplifying mRNA vaccine candidate to protect against COVID-19. In December 2022, we entered into a Collaboration and License Agreement ("CSL Collaboration Agreement") with CSL Seqirus, a part of CSL Limited and one of the world's leading influenza vaccine providers, for the global exclusive rights to research, develop, manufacture and commercialize self-amplifying mRNA vaccines against COVID-19, influenza and up to three other infectious diseases and global non-exclusive rights to pandemic pathogens. The CSL Collaboration Agreement combines CSL Seqirus' established global vaccine commercial and manufacturing infrastructure with Arcturus' manufacturing expertise and innovative STARR self-amplifying mRNA vaccine and LUNAR delivery platform technologies. For a more comprehensive discussion of the CSL Collaboration Agreement, please see Item 1 "Business" – "Revenue and Collaboration Arrangements and Other Material Agreements" – "CSL Seqirus."

In November 2023, ARCT-154 (KOSTAIVE) became the world's first approved self-amplifying RNA vaccine following Japan's approval of ARCT-154 for primary immunization and as a booster dose against COVID-19. In September 2024, Japan's Ministry of Health, Labor and Welfare (MHLW) granted approval and authorization for an updated version of KOSTAIVE, targeted to protect against the JN.1 lineage of Omicron subvariants for adults 18 years of age and older. CSL Seqirus' exclusive partner in Japan, Meiji, began distributing the updated vaccine in Japan in October 2024, marking the world's first commercially available sa-mRNA COVID-19 vaccine for adults 18 and older. The approval was based on manufacturing data demonstrating the quality and consistency of the vaccine product, non-clinical immunogenicity data against JN.1 lineage of Omicron subvariants of KOSTAIVE (JN.1), and clinical evidence supporting the safety and immunogenicity of KOSTAIVE (bivalent, BA.4/5 and ancestral strain).

In our influenza vaccine franchise, a Phase 1 clinical trial of our seasonal influenza candidate was conducted in 2024-2025 under our collaboration with CSL Seqirus, and a BARDA-funded Phase 1 clinical trial of our H5N1 pandemic flu candidate was initiated in December 2024 and is ongoing.

KOSTAIVE® and COVID-19 Vaccine Program

Coronaviruses are a family of viruses that can lead to respiratory illness. Three viruses in this family have emerged in the past twenty years: Severe Acute Respiratory Syndrome (SARS-CoV), Middle East Respiratory Syndrome (MERS-CoV), and Severe Acute Respiratory Syndrome 2 (SARS-CoV-2), the virus responsible for the COVID-19 pandemic. Throughout the pandemic, there have been surges of infections as protective health measures have waxed and waned. Uncontrolled viral spread has led to billions of cases worldwide and the selection of viral variants that are more contagious, pathogenic, or both. Since late 2021, infections have been dominated by subvariants of the Omicron strain, which continue to displace previous circulating strains by evading immunity and spreading more efficiently, resulting in an increased risk of breakthrough infection among the vaccinated. Vaccines that induce robust and durable immunity against current and emerging variants of concern ("VOCs") can help to reduce the infection and disease burden for both the public and the health care systems globally.

Our COVID-19 vaccine candidate, KOSTAIVE, is based on our STARR (self-amplifying mRNA) technology platform and our LUNAR platform. It was designed to elicit immune responses against the SARS-CoV-2 spike protein, the critical component that enables viral entry.

KOSTAIVE is the brand name approved in Japan and Europe for ARCT-154, the version of the sa-mRNA COVID-19 vaccine encoding the ancestral strain of SARS-CoV-2, as well as for updated variant-specific versions of this vaccine. We may use KOSTAIVE or internally generated names, such as ARCT-154, ARCT-2301, and ARCT-2303, to identify vaccines targeting specific SARS-CoV-2 variants.

The licensure of KOSTAIVE in Japan in 2023, followed by the approval of an updated version of KOSTAIVE (JN.1 Omicron subvariant) and initiation of commercial sales in Japan in 2024 are significant milestones in the advancement of our vaccine franchise. The approval of KOSTAIVE by the EMA in January 2025 and by the United

Kingdom (the UK Medicines and Healthcare Products Regulatory Agency (MHRA)) in January 2026 provided further validation of our platform by other major regulatory authorities.

On September 5, 2025, the week prior to the planned Biologics License Application ("BLA") submission related to KOSTAIVE, the U.S. Food and Drug Administration (the "FDA") requested that the submission of the BLA filing be delayed due to the FDA's expectation of providing additional advice. On October 14, 2025, the FDA informed us that, although the FDA had previously agreed that our proposed data package could support a single-dose indication, upon further consideration it found that additional data from a clinical endpoint efficacy study will be needed to align with the current COVID-19 vaccine regulatory framework requirements published in The New England Journal of Medicine in May 2025. On September 26, 2025, Meiji Holdings Co., Ltd. announced that its subsidiary, Meiji, launched a new composition of KOSTAIVE®, a self-amplifying mRNA vaccine against COVID-19. The product targets the SARS-CoV-2 Omicron sub lineage JN.1 variant XEC. In non-clinical studies, it induced neutralizing antibodies not only against Omicron JN.1 and XEC, but also against LP.8.1 and the currently circulating variants XFG and NB.1.8.1. The formulation is lyophilized and supplied as a two-dose vial, with one vial per carton.

In 2025, several important manuscripts related to our studies were published, which are summarized below.

- In April 2025, we published a comprehensive analysis of safety data for KOSTAIVE®, with a 12-month follow-up from the pivotal clinical study in Vietnam (NCT05012943), which had 17,582 participants who received at least one dose of the study vaccine. The study confirmed the favorable reactogenicity profile of the vaccine. Acceptable tolerability of KOSTAIVE (ARCT-154) was also observed in older participants and individuals who are at risk of severe consequences of COVID-19 due to underlying medical conditions. Long-term follow-up has not revealed any safety concerns, with no reports of myocarditis or pericarditis. No serious consequences occurred in several pregnancies reported after vaccination. Long-term data from this large trial suggest that KOSTAIVE is safe and well-tolerated.

- In April 2025, our Japanese partner, Meiji, published an analysis characterizing the distribution and clearance of KOSTAIVE (ARCT-154) encoded spike protein and non-structural proteins nsP1, nsP2, nsP3 and nsP4 in the lymph nodes and injection-site muscle in mice following a single vaccination. The study showed the encoded spike protein reached its highest level approximately three days after vaccination and quickly disappeared from the injection site muscle. The spike protein levels also peaked at an early time point in the lymph nodes, it remained detectable 28 days after the vaccination and disappeared by 44 days after the vaccination. Expression of nsP1, nsP2 and nsP4 was observed in the injected muscle and/or the lymph nodes for up to 15 days post-vaccination. The data indicates that the extended expression of spike proteins in lymph nodes may be responsible for the induction of higher and prolonged levels of neutralizing antibodies. The study also confirmed that the self-replication is limited over time.

- In July 2025, we published the manuscript 'Immunogenicity of ARCT-154, a self-amplifying mRNA COVID-19 vaccine, in different booster settings where we summarized extensive clinical data and concluded that KOSTAIVE (ARCT-154), administered as a homologous or heterologous booster after previous COVID-19 vaccination or natural exposure, provides robust, broad and durable immune responses against SARS-CoV-2 viruses.

- In July 2025, a researcher from Tokyo University, Japan, published the manuscript 'A second-generation, self-amplifying COVID-19 Vaccine: World's first approval and distribution in the Japanese market with vaccine hesitancy. The manuscript positions KOSTAIVE as a second-generation mRNA vaccine, differentiating it based on effective dose, durability, and breadth of immune response, and summarizes experience from the first year of routine use of the vaccine in Japan.

- In August 2025, the manuscript 'Immunogenicity and Safety of Self-Amplifying mRNA COVID-19 Vaccine (ARCT-2303), With or Without Co-Administration of Seasonal Inactivated Influenza Vaccine in Adults: a Phase 3, Randomised, Controlled, Observer-blind, Multicentre Study' was accepted by eClinicalMedicine. The manuscript presents the results of a recent pivotal Phase 3 clinical study and concludes that KOSTAIVE (ARCT-2303; XBB.1.5 strain) induces a robust immune response against the SARS-CoV-2 vaccine variant and can be co-administered with licensed influenza vaccines in adults, without affecting the safety or immunogenicity of either vaccine.

- In December 2025, in collaboration with the McNamara Lab at Harvard, we presented the manuscript 'Sustained Humoral Activation through self-amplifying mRNA Vaccination Enhances Longitudinal Antibody Function in a Phase III Trial. The authors applied a system serology approach to analyze post-vaccination serum samples from participants who received KOSTAIVE (ARCT-154) and a conventional mRNA vaccine (BNT162B2, Comirnaty). The study demonstrated that ARCT-154 elicited a unique antibody response defined by a sustained, activating profile to the vaccine-encoded Spike protein and a broad spectrum of drifted Spikes. Notably, activating FcγRIIIA-binding antibodies showed sustained stimulation in the ARCT-154-treatment arm, which translated into enhanced natural killer (NK) cell activation.

Commercialization of KOSTAIVE in Japan

Meiji has launched in Japan the two-dose vial of KOSTAIVE updated for the JN.1 variant XEC, following receipt of approval, in August 2025, from Japan's Pharmaceuticals and Medical Devices Agency (PMDA). KOSTAIVE first received marketing authorization approval in Japan in 2023 for use as a primary immunization and booster in Japan for adults 18 years and older. The updated versions were approved and commercialized in the 2024-2025 and 2025-2026 seasons.

In January 2025, CSL Seqirus' partner Meiji received approval for a partial amendment to the manufacturing and marketing approval of KOSTAIVE to include manufacturing sites in Japan. With this approval, Meiji and ARCALIS, Inc., Arcturus' manufacturing joint venture in Japan, have been added as manufacturing sites. As a result, KOSTAIVE, with active pharmaceutical ingredients manufactured at such sites, may be shipped for commercial use in Japan.

Approval of KOSTAIVE (ARCT-154) in Europe

In February 2025, the European Commission granted marketing authorization for KOSTAIVE (ARCT-154) for individuals 18 years of age and older. The European Commission approval follows a positive opinion adopted by the Committee for Medicinal Products for Human Use (CHMP) of the EMA on December 12, 2024. The centralized marketing authorization of KOSTAIVE provided by the EC is valid in all 27 European Union (EU) member states and 3 additional European Economic Area (EEA) countries summarized here: Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, The Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain and Sweden.

KOSTAIVE BLA Submission

On September 5, 2025, the week prior to the planned Biologics License Application ("BLA") submission related to KOSTAIVE, the FDA requested that the submission of the BLA filing be delayed due to the FDA's expectation of providing additional advice. On October 14, 2025, the FDA informed us that, although the FDA had previously agreed that our proposed data package could support a single-dose indication, upon further consideration it finds that additional data from a clinical endpoint efficacy study will be needed to align with the current COVID-19 vaccine regulatory framework requirements published in The New England Journal of Medicine in May 2025. The FDA's sudden changes to regulatory requirements for COVID-19 vaccines have indefinitely delayed the U.S. BLA filing for KOSTAIVE.

Approval of KOSTAIVE (ARCT-154) in United Kingdom

In January 2026, the UK Medicines and Healthcare products Regulatory Agency (MHRA) under the International Recognition Procedure (IRP) granted marketing authorization for KOSTAIVE for individuals 18 years and older.

Clinical Studies of KOSTAIVE (COVID-19 vaccine)

In connection with the development of KOSTAIVE, we have conducted seven clinical studies, including four pivotal studies described below.

Pivotal Phase 1/2/3 Efficacy, Safety, and Immunogenicity Study of KOSTAIVE (ARCT-154) in Vietnam (NCT05012943)

This randomized, observer-blinded, placebo-controlled, and active-controlled study enrolled more than 19,000 adult individuals across multiple sites in Vietnam and demonstrated that a 2-dose vaccination series with

ARCT-154 induced protection in the seronegative population against heterologous SARS-CoV-2 variants (mainly Delta) with vaccine efficacy of 56.6% (48.7–63.3) for COVID-19 of any severity and 95.3% (80.5–98.9) for severe COVID-19. The vaccine was immunogenic against the ancestral SARS-CoV-2 strain and induced a cross-neutralizing immune response against new emergent variants. The vaccine was well tolerated, and safety analysis did not identify specific safety concerns. The study results served as the basis for vaccine licensure in Japan, the European Union, and the UK.

The results were broadly published and presented in multiple international forums.

The study was conducted in collaboration with Vinbiocare Biotechnology Joint Stock Company ("Vinbiocare"), a member of the Vingroup Joint Stock Company (Vingroup) group, and was sponsored by Vinbiocare.

Pivotal Phase 3 Non-Inferiority Study of KOSTAIVE (ARCT-154) in Japan (jRCT 2071220080).

This Meiji-sponsored, randomized, multicenter, observer-blind, active-controlled study evaluating the safety and immunogenicity of a booster dose of ARCT-154 and assessing its non-inferiority to COMIRNATY® (Monovalent, Original strain). The study demonstrated immunological non-inferiority of KOSTAIVE versus COMIRNATY for the ancestral SARS-CoV-2 strain and immunological superiority for the epidemiologically dominant Omicron BA.4/5 variant. KOSTAIVE also demonstrated a more durable humoral immune response up to 12 months post-booster dose. Overall, the study results support the favorable benefit/risk profile of the ARCT-154 vaccine when administered as a booster dose in adults who previously received other mRNA COVID-19 vaccines.

The study results were publicly disclosed in April 2024.

Pivotal Phase 3 Study of Bivalent Version of KOSTAIVE (ARCT-2301) in Japan (jRCT2031230340)

This Meiji-sponsored study of a bivalent version of KOSTAIVE (ancestral strain and Omicron BA.4/5) to further support immunogenicity and safety data for the self-amplifying mRNA platform and facilitate the timely release of future seasonal updates of our COVID-19 vaccine against evolving variants of concern. As with the monovalent vaccine, the bivalent sa-mRNA formulation demonstrated superior immunogenicity compared with the conventional bivalent mRNA vaccine COMIRNATY, with a higher immune response persisting up to six months after a booster dose, and broader variant coverage, supporting the robustness of the sa-mRNA vaccine platform for future vaccine strain updates.

The study results were published in March 2025.

Pivotal Phase 3 Co-administration Study of KOSTAIVE (ARCT-2303) and Seasonal Influenza Vaccines (NCT06279871).

This CSL- and Arcturus-funded randomized, observer-blind, placebo-controlled, phase 3 study aimed to generate additional immunogenicity and safety data in multiple ethnicities to support regulatory filings in the U.S. and globally. The study also assessed the co-administration of the ARCT-2303 vaccine with the age-appropriate seasonal influenza vaccines. The study results demonstrated robust immunogenicity of the XBB1.5-containing vaccine and support the concomitant administration of KOSTAIVE with licensed non-adjuvanted and adjuvanted influenza vaccines in both young and older adults. The safety and reactogenicity of co-administered vaccines were comparable to those of standalone administration. No safety concerns were raised based on the study results.

COVID-19 Vaccine Product Format

The product format of KOSTAIVE that began commercialization in Japan in October 2024 is a lyophilized product presentation. The stability and cold chain characteristics of KOSTAIVE in a lyophilized format compares favorably to frozen liquid format, and our ongoing development of proprietary manufacturing technology has led to significant increases in refrigerated and ambient temperature shelf-lives for both lyophilized and liquid drug products.

Seasonal Flu Collaboration Program

LUNAR-FLU (Seasonal Influenza)

Influenza is estimated to cause one billion infections globally every year and hundreds of thousands of deaths, especially in the elderly and individuals with underlying medical conditions. In many regions, influenza is seasonal, with infections peaking during November through April in the Northern Hemisphere and May through September in

the Southern Hemisphere. Year-round surveillance by the World Health Organization ("WHO") in collaboration with various national health agencies informs WHO recommendations on the strains of influenza most likely to spread during the upcoming influenza season. National health agencies (such as the FDA) then make the final decision of which strains should be covered by vaccines licensed in their country.

Our LUNAR-FLU (seasonal) program, partnered with CSL Seqirus, has the objective of producing a safe and effective seasonal influenza vaccine candidate with significant advantages over the traditional egg-based inactivated quadrivalent vaccine. Inaccurate predictions of circulating influenza strains as well as mutations due to adaptation in egg-grown vaccines can substantially reduce efficacy on a year-to-year basis. We believe the ability of mRNA platforms to nimbly adapt to new viral strains should help improve efficacy. In addition, we do not expect mRNA vaccines to face the challenge from mutations common to egg-grown vaccines.

LUNAR-FLU has been designed to leverage our expertise in both our LUNAR lipid delivery platform and STARR self-amplifying mRNA technology. These technologies have been shown to deliver effective protection against COVID-19 and has been optimized to elicit robust immunogenicity with acceptable reactogenicity at a lower dose than conventional mRNA vaccines, with the objective of creating a highly effective influenza vaccine for use in general and high-risk populations. We conducted a Phase 1 study of ARCT-2138, a sa-mRNA seasonal influenza vaccine candidate encoding haemagglutinin (HA) and neuraminidase (NA) of four seasonal influenza strains as recommended by the World Health Organization (WHO). Overall, the study showed the potential of a self-amplifying mRNA vaccine, encoding eight antigens, to induce an immune response in both young and older adults with a dose as low as 2 μg, and was tolerable across a dose range of 2 to 20 μg.

Pandemic Avian Influenza Program (H5N1 Influenza)

Our LUNAR-H5N1 program continues to progress under the award from BARDA that we obtained in 2022 to advance through Phase 1 a vaccine to protect against disease caused by H5N1 highly-pathogenic avian influenza. H5N1 influenza is a significant concern in animal health. To date, H5N1 flu has affected over 10,000 wild birds, nearly a thousand dairy cows, and over 130 million poultry. Elevated H5N1 infections in animals have led to increasing numbers of human infections including two confirmed severe cases in the United States and one death. Most of the confirmed human infections are due to exposure of U.S. dairy and poultry workers to infected dairy cows and poultry. We are working diligently with our partners, BARDA and CSL Seqirus, to clinically validate our low-dose STARR mRNA technology for H5N1 to assist towards pandemic preparedness.

In April 2025, the FDA granted Fast Track Designation for ARCT-2304. This designation recognizes the potential of ARCT-2304 as an innovative approach to address unmet medical needs for the prevention of disease caused by pandemic influenza A virus H5N1, a significant global health risk. Fast Track Designation from the FDA is granted to vaccines intended to prevent serious conditions caused by infectious diseases. The designation is designed to expedite the development and review process, providing several benefits, including enhanced communication with the FDA, eligibility for priority review, and the possibility of a rolling review.

Our Phase 1 study of ARCT-2304, an sa-mRNA pandemic influenza A/H5N1 vaccine candidate, released interim results in September 2025. The study objectives were to evaluate the safety and tolerability of the vaccine and to characterize the immune response across three dose levels in 132 young adults (18-59 years of age) and 80 older adults (60-80 years of age). ARCT-2304 induced a humoral immune response after a single dose (as measured by microneutralization and enzyme-linked lectin anti-neuraminidase assays) in all tested dose levels. Administering a second dose of ARCT-2304 further increases immune responses. The magnitude of the anti-HA response was higher after an 8-week interval than after a 4-week interval in both young and older adults. ARCT-2304 in dose levels 5 and 12 μg (2 doses administered 4 or 8 weeks apart) and 1.5 μg (2 doses administered 8 weeks apart) induces a hemagglutinin-specific immune response similar to or higher than that after the MF59-adjuvanted pandemic vaccine (in both young and older adults). Immunogenicity monitoring up to eight months after the first vaccination confirmed high antibody persistence and substantial durability of vaccine-induced immunity. No safety or tolerability concerns were raised from available data.

Platform Technologies and R&D Programs

We have four key proprietary platform technologies:

- lipid-mediated delivery (LUNAR®)
- mRNA and protein design

- self-amplifying mRNA (STARR®)
- manufacturing and formulation for mRNA medicines

LUNAR (Lipid-Mediated Delivery) Platform

Our LUNAR lipid-mediated delivery technology includes a diverse, growing library of over 300 proprietary lipids that we are rationally designing to be versatile, while maximizing efficacy and improving tolerability of a diverse selection of nucleic acids, refining the LNPs to target specific cell types, and determining the most favorable routes of administration. A key feature of our LUNAR lipids is their biodegradability, decreasing the undesired effects caused by lipid accumulation that are associated with tolerability issues present in other lipid-mediated RNA medicine delivery platforms. Our team continues to advance our LUNAR lipid formulated nucleic acid platform in a scalable and highly reproducible manner, reducing the costs of goods for the therapies in our pipeline.

In addition to our LUNAR lipid-mediated delivery technology, we believe we have created innovative, proprietary advancements in producing mRNA medicines, including improvements that increase purity, scalability, efficiency in production times, and adaptability to different mRNA modification strategies. We strive to use these proprietary innovations to benefit each mRNA medicine in our pipeline.

We continue to invest in and improve our LUNAR lipid-mediated delivery of mRNA with continuous improvements in our mRNA and sa-mRNA platforms in conjunction with improvements in our next generation proprietary lipids to improve targeting, efficacy and safety profiles for both our vaccine and therapeutic protein platforms. This investment has led to key innovations ensuring that our LUNAR formulated drug product candidates have optimal characteristics for therapeutic use, which we believe sets us apart from other nucleic acid therapeutics and lipid-mediated delivery platforms. As such, we consider ourselves a leader in the research and development of mRNA therapeutics for multiple indications.

We continue to conduct exploratory platform development activities, including the evaluation of genome editing, and new targeting approaches, where our LUNAR and STARR platforms could potentially be useful for identification and development of additional products for our portfolio.

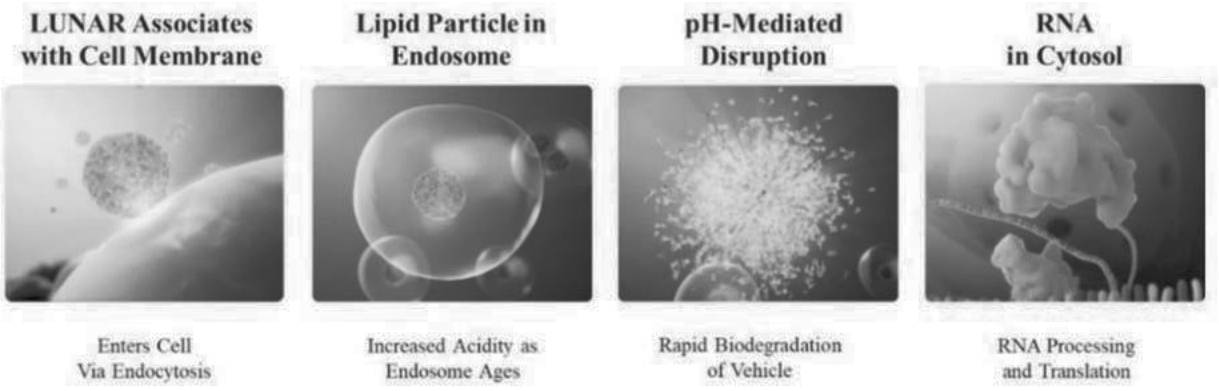
Key Attributes of Our LUNAR Lipid-Mediated Delivery Technology

We have designed our LUNAR lipid-mediated delivery platform to address major challenges with nucleic acid medicine delivery, including transfection efficiency, adverse immune reactions and liver damage.

LUNAR is a multi-component, lipid-mediated drug delivery system that utilizes our proprietary lipids, called ATX lipids. Each of our ATX lipids contains an ionizable head group and a biodegradable lipid backbone. The head group is a key chemical component of the ATX lipid, making it pH-sensitive and providing it distinct advantages as a component of our LUNAR lipid formulation. At acidic pH, ATX lipids are positively charged, facilitating interaction with the negatively charged nucleic acid, thereby enabling LUNAR particle formation. At physiological pH (e.g., pH 7.4), the ATX lipids within the LUNAR formulations are neutrally charged, reducing the toxicity often seen with permanently positively charged lipid-mediated delivery technology. Upon uptake into a cell by endocytosis (a process that forms a cellular structure called an endosome around the LUNAR formulated nucleic acid therapeutic), the head group again becomes positively charged due to the low pH of the endosome, disrupting the endosome and the LUNAR particle, resulting in release of the nucleic acid therapeutic into the cell where it is translated to produce a therapeutic protein.

The disruption of the LUNAR particle also releases the components of the formulation into the cell, where the ATX lipid is degraded by enzymes called esterases in the cell allowing for the lipids to be cleared from the cell. We designed the ATX lipid to be rapidly biodegradable by engineering chemical structural components, called esters, into the ATX backbone that are sensitive to esterases. This degradation prevents ATX lipids from accumulating inside the cell and causing toxicity.

Biodegradable, highly optimized for each cell type



LUNAR-platform development

The development of our LUNAR platform is focused on continuous innovation and advancement in the following areas:

- Design, manufacture and incorporate novel ATX lipids into formulations to enrich our library of proprietary ATX lipids for target cell/tissue specificity, improved tolerability and translatability to larger species;
- Develop, optimize and innovate manufacturing processes for LUNAR formulations to ensure RNA encapsulation across compositions and scales;
- Develop stabilization strategies (e.g. lyophilized presentation) for LUNAR formulations to mitigate the need for frozen storage and to extend shelf-life; and
- Continually optimize and innovate LUNAR screening paradigm to enable rigorous selection of ATX lipids for various therapeutic programs and routes of administration.

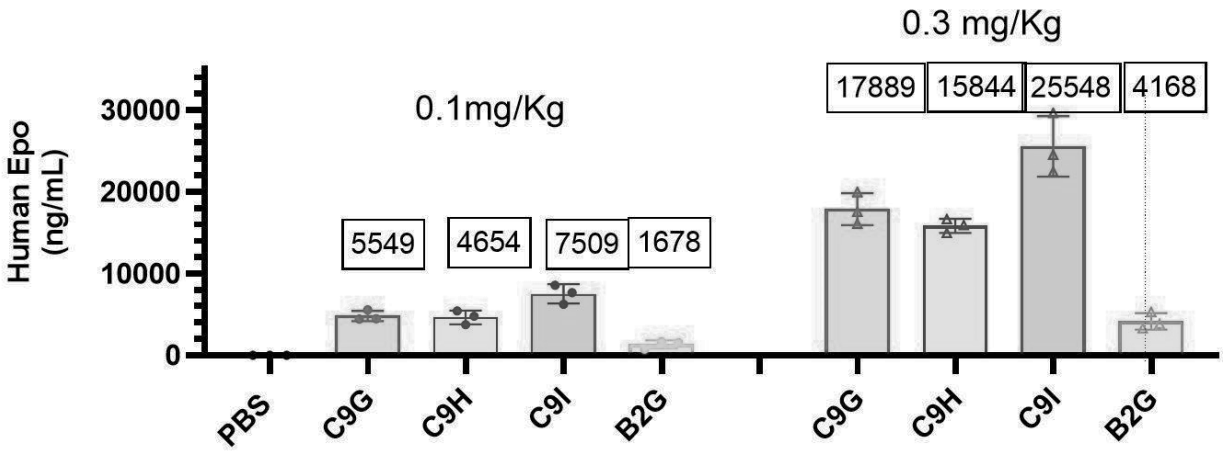
Through the above efforts, our versatile LUNAR platform continues to drive internal and partner programs.

ATX Lipid Design and In Vivo Screening Process

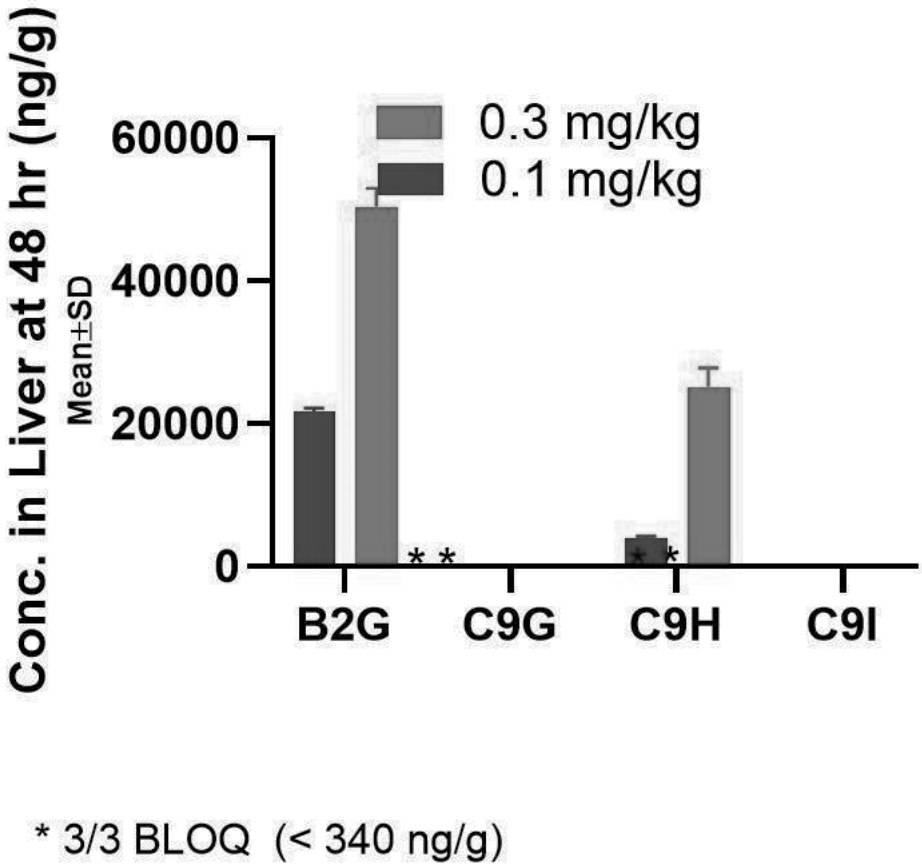
As mentioned above, we have generated a growing library of more than 300 proprietary ATX lipids. ATX lipids are rationally designed to fit different applications and vary depending on the target cell type and route of administration. We perform extensive formulation screening for each nucleic acid therapeutic candidate to determine the optimal ATX lipid to be used and the appropriate excipient composition (LUNAR composition) for the nucleic acid therapeutic candidate, the desired route of administration, and target cell type.

The design of ATX lipids is an iterative process based on in vivo protein expression and tolerability results from previous ATX lipid candidates. To date, we have developed seven generations of ATX lipids. New ATX lipids are chemically synthesized and used to package mRNAs expressing a secreted protein. The ATX lipid formulated RNAs must meet specific chemical and biophysical acceptance criteria before being tested for biological activity. RNA formulations meeting all acceptance criteria are first screened for protein expression in mice. Active candidates are further verified by evaluating protein expression in non-human primates. Active candidates are then tested for tolerability and preliminary tissue clearance rates following administration. Active ATX lipid candidates demonstrating high levels of protein expression and equivalent or improved tissue clearance rates are then assigned to a specific disease target for development of therapeutic applications. The following results are from an in vivo mRNA expression study which identified three new highly active LUNAR lipids with regard to protein expression in non-human primates compared to the positive control.

Expression of Human EPO in Mice 6 hours After IV Administration (Figure 1)



Mouse Liver Clearance of LUNAR Lipids 48 hours After IV Administration (Figure 2)



* 3/3 BLOQ (< 340 ng/g)

Expression of Human EPO in Non-Human Primates 6 Hours After IV Administration (Figure 3)

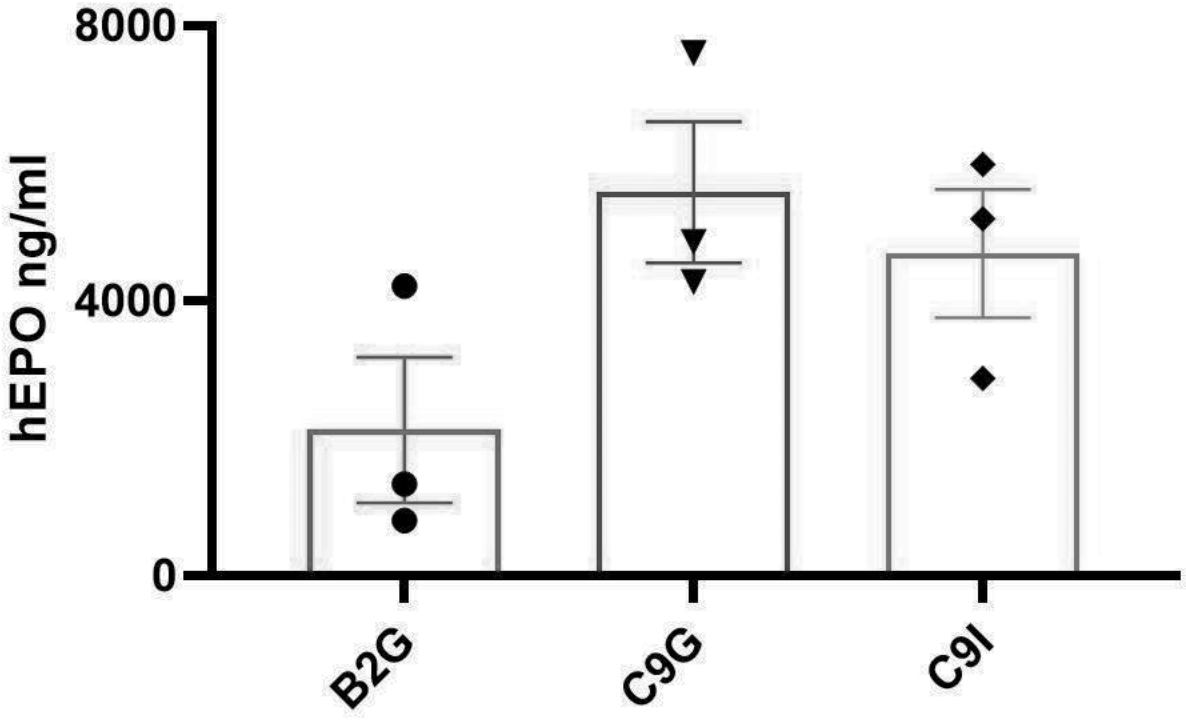


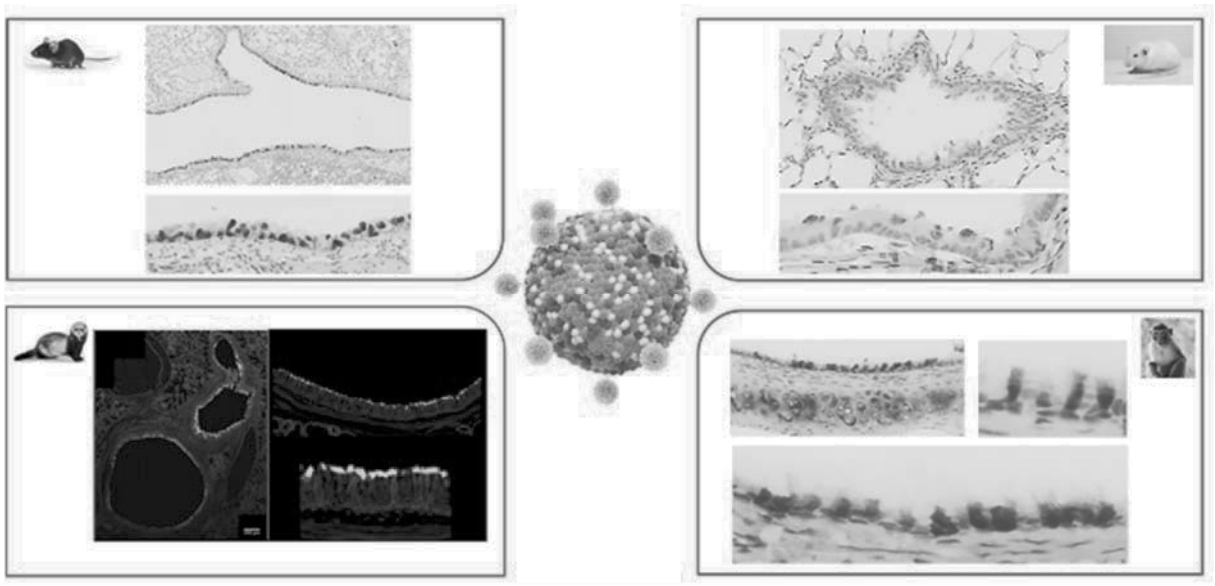
Figure 1: mice were injected intravenously with 4 different ATX lipid formulations containing mRNA expressing human erythropoietin (hEPO). The ATX lipids that were screened were C9G, C9H, C9I and B2G at 0.1 mg/kg and 0.3 mg/kg RNA doses. ATX lipid B2G formulation is a positive control to which expressions from the other formulations are compared. Mice were bled 6 hours after injection and assayed for hEPO, a secreted protein.

Figure 2: shows the clearance of the ATX lipids from the mouse liver 48 hours after administration of 0.1mg/kg and 0.3 mg/kg RNA doses. C9G, C9H and C9I yielded much higher expression levels of hEPO than B2G, the positive control for both doses tested. It also shows that the residual amount of C9G and C9I were below the limit of detection and the residual amount of C9H was at least 10-fold less than the remaining amount of B2G at the 0.1 mg/kg RNA dose and at least two-fold less than the residual amount of B2G at the higher RNA dose.

Figure 3: C9G and C9I formulations were tested for EPO expression in non-human primates at a single dose and assayed for secreted hEPO in the blood six hours after IV administration. Both C9G and C9I yielded significantly higher expression levels than the positive control, B2G further confirming the superior performance of the new LUNAR formulations. Hence, this lipid screen identified three LUNAR lipids that yielded greater RNA expression in mice and two LUNAR lipids in NHPs and were rapidly cleared from the liver within 48 hours after administration. This demonstrated the ability to design and execute LUNAR formulations using our advanced generation lipids with many-fold higher protein expression and ready biodegradability.

Lung Targeting

Aerosol capabilities have been developed for the CF program using our proprietary lipid nanoparticle delivery platform, LUNAR. Characterization and optimization of the aerosolized LUNAR formulations in targeting airway epithelium have been achieved in rodent (mice, rat) and nonrodent models (ferret, NHP) as depicted in the image using a reporter mRNA encapsulated in LUNAR. We expect that the validation attained for the inhaled LUNAR platform in the CF program will serve as a translatable approach to support other respiratory approaches where targeting airway epithelium is needed.



LUNAR delivery to airway epithelium demonstrated in vivo across species (rodents, ferrets, NHPs).

LUNAR Safety and Tolerability (i.v. administration)

As part of the screening method for our proprietary lipids, we conduct an initial lipid tolerability screen in Balb/C and C57Bl/6 mice strains to ascertain the initial maximum tolerated dose in rodent species(s). LUNAR formulations encapsulating hEPO mRNA with different ATX lipids are intravenously administered to these mouse strains at three and five mg/kg doses and monitored for clinical signs. Blood was drawn at six and 48 hours after LUNAR administration and assayed for both liver functions and cytokine elevations. Liver function changes are determined by measuring for any increase in alanine aminotransferase (ALT) and aspartate aminotransferase (AST) enzymes in the blood. A significant increase in these enzymes (i.e., above five times the normal range) indicates a negative effect on liver function. The results show that many of the LUNAR formulations that were tested are tolerable up to three mg/kg in both strains of mice for LUNAR formulations containing DSPC. Moreover, there is an even greater improvement in tolerability of up to five mg/kg when the helper lipid is PCA57. Thus, with these innovations we believe that we have substantially improved both the potency and tolerability of our LUNAR platform.

Our Proprietary mRNA and Protein Design Technology

The mRNA programs in our pipeline benefit from our in-house expertise in protein and mRNA design, which helps us address many of the known challenges that face the viability of mRNA therapeutics today. We have identified several design elements of mRNA compounds that provide improved translation (the process of making protein based on the instructions/codes in the mRNA) of our mRNA therapeutics, including untranslated regions derived from species that have not previously been combined with human mRNA sequences. This platform technology is applicable to many different human mRNA sequences that we are currently investigating in our discovery efforts. We are able to engineer human protein sequences to increase the half-life of the proteins produced by our mRNA therapies and can more efficiently direct specific types of proteins to certain cellular structures of interest. These innovations are broadly applicable to several programs that are part of our mRNA discovery efforts.

In addition to these platform technologies, we have developed a proprietary tool to aid our team in the efficient design and development of new mRNA drug candidates. Our mRNA Design Suite is a cloud-based software suite with a collection of proprietary bioinformatic algorithms aimed at achieving highly improved potency of a drug substance through optimization of mRNA sequences. The algorithms were developed in house through the integration of experimentally validated optimization processes. Through multi-layered in silico quality control pipelines, mRNA Design Suite promptly generates high-quality and error-free sequences accompanied by various statistics. Additionally, mRNA Design Suite seamlessly interacts with our plasmid/mRNA production database to accelerate the process from mRNA design to gene synthesis, cloning, and mRNA production.

Our STARR mRNA Technology

Our distinct and proprietary self-amplifying mRNA (sa-mRNA) platform technology (STARR) incorporates proprietary design algorithms that optimize sa-mRNA to enhance expression of the applicable antigen while minimizing structures that could inhibit expression. The replicase, an RNA-dependent RNA polymerase, is encoded upstream of the antigen of interest and functions to increase the duration of antigen/transgene expression compared to conventional mRNA (Figure 6). When combined with LUNAR delivery, STARR has demonstrated reduced dose requirements and more durable, superior immune responses compared with conventional mRNA vaccines in preclinical studies and clinical trials.

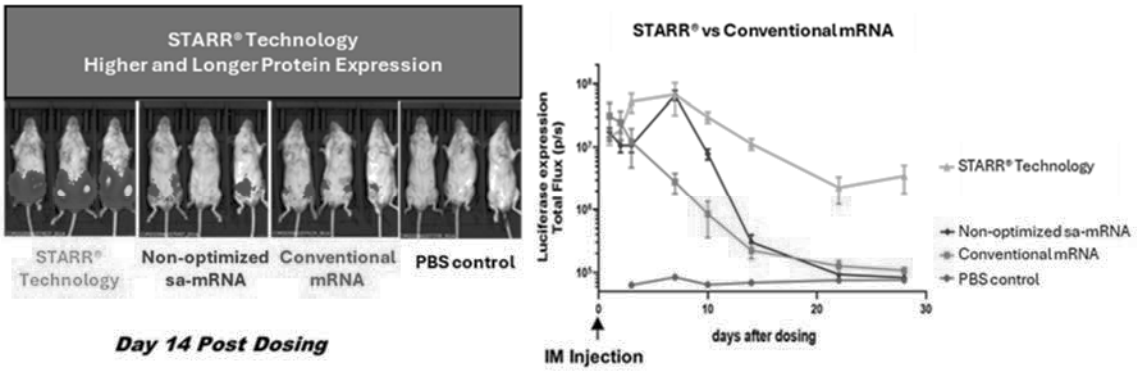


Figure 6: The luciferase expression from an optimized sa-mRNA, STARR Technology (Green), a non-optimized sa-mRNA (Blue) and the conventional RNA (Purple). The STARR Technology was shown to yield at least a 30-fold greater expression level than conventional RNA. The STARR Technology also demonstrated a longer duration of expression compared to the conventional RNA and also the non-optimized self-amplifying RNA.

Our Proprietary Manufacturing Technology

We continue to innovate and improve our capabilities to manufacture nucleic acid medicines with high standards of quality, efficiency, and in compliance with Good Manufacturing Practices and its analogous regulations outside the U.S. Our technologies work to improve every aspect of the drug product manufacturing process from design to filling and packaging. Nucleic acid manufacturing relies on the confluence of complex technologies in the chemical and biological sciences that require extreme precision in their execution. Consequently, the nucleic acid medicines industry has faced many challenges across all steps of the manufacturing process, most notably the ability to scale processes to produce batches of adequate size while continuing to meet product specifications. Notable capabilities include:

- mRNA Drug Substance Manufacturing – We have developed the ability to manufacture mRNA drug substance with high product yield and exceptional product purity. In addition, we have developed reliable and efficient testing methodologies for characterizing mRNA drug substance. We continue to innovate in this area to further improve the cost, yield, purity and stability of mRNA drug substance.
- Drug Product Formulation – The formulation of mRNA drug substance with our LUNAR delivery platform is essential to achieving effective in vivo delivery and translation of the mRNA. We have developed advanced processes and know-how that enable us to manufacture lipid-encapsulated compounds at large volumes to help ensure that lipid-encapsulated compounds that meet key product specifications, including purity, particle size, concentration, stability, and percent encapsulation, in both liquid and lyophilized product formats. The continued advancement of these capabilities is an important focus of our platform development.

In our efforts to improve these and other capabilities, we use qualified scale down models to optimize operating conditions for each manufacturing step for both drug substance and drug product. Optimized conditions identified by these small-scale models are applied to the cGMP manufacturing processes. This manufacturing development process is also utilized for evaluating potential additives that improve drug substance and drug product quality and efficacy, improve manufacturing efficiency and reduce manufacturing costs. Some of the major accomplishments that have been achieved using this manufacturing development process are increased drug

substance yield, reduction in drug substance impurities, increased manufacturing efficiency, and extended refrigerated and ambient temperature shelf life.

Discovery Programs

The versatile nature of our platform technologies may allow for a broad spectrum of nucleic acid medicines. We have conducted, and will continue to conduct, efforts to explore potential new drugs through our discovery and enabling technologies programs, though we are prioritizing our later stage programs.

Discovery Programs – HPV

Arcturus is advancing the development of a post-exposure HPV therapeutic vaccine candidate. Although prophylactic HPV vaccinations have substantially lowered the incidence of cervical cancer in developed countries, cervical cancer is still the fourth leading cause of cancer in women globally with the vast majority (approximately 90%) of cases in countries that have not yet widely adopted prophylactic HPV vaccinations and other cervical cancer prevention strategies, including screening and treatment. Cervical cancer typically develops years after initial HPV exposure due to a failure to clear the virus and the integration of viral oncogenes. A therapeutic vaccine which induces T-cell responses targeting the integrated HPV genes in precancerous cells could help prevent precancer and cancer in those already exposed to HPV. The Gates Foundation awarded Arcturus a grant of $3.9 million in November 2024 to support the development of such a therapeutic HPV vaccine through the clinical candidate nomination stage.

Enabling Technologies

Enabling Technologies – Cancer vaccines

Our LUNAR Cancer vaccine discovery efforts are aimed at developing an immunotherapy against a tumor via activated T-cells. We contemplate that the vaccine would encode an antigen(s) that would be specifically presented by (or associated with) a tumor, such that the vaccination would elicit T cell responses that recognize and attack the tumor. We have applied our learnings from our more-advanced LUNAR-COVID-19 vaccine program to establish both STARR (self-amplifying) and conventional mRNA platforms for immuno-oncology therapy.

In a preclinical study, our proof of concept (POC) vaccine encoding AH1 antigen of gp70 protein which is highly expressed on the surface of mouse colorectal carcinoma cell line CT26 has demonstrated clear effectiveness in a syngeneic mouse model of a colorectal CT26 cell line. With intramuscular administration of the STARR vaccine (two doses of 10 ug), treated with a checkpoint inhibitor (CPI), anti-PD1/PDL1 antibody, led to a substantial reduction of tumor growth in comparison to the CPI treatment by itself (Panel A). Moreover, the same level of efficacy was achieved with a single administration of a 0.2 ug dose of the STARR vaccine.

With various LUNAR formulations, conventional mRNA vaccine expressing the AH1 antigen also demonstrated a robust T cell response (Panel B) and reduction of tumor growth with anti-PD1/PDL1 treatment in the syngeneic mouse model. We believe that these POC results from the two platforms might lead to applicability to various types of cancer with flexibility in dosing regimens.

Our efforts to date have focused on the selection of neoantigens, and other common tumor-specific antigens encoded in the cancer vaccines. Common tumor antigens can be shared among patients, and therefore target broader patient populations, whereas a neoantigen vaccine would be a personalized vaccine specific for an individual patient. Additional advancements of the LUNAR Cancer Vaccine program include the improvement of antigen cassette designs, STARR RNA elements, and immune modulator molecules, all of which can significantly enhance T cell responses.

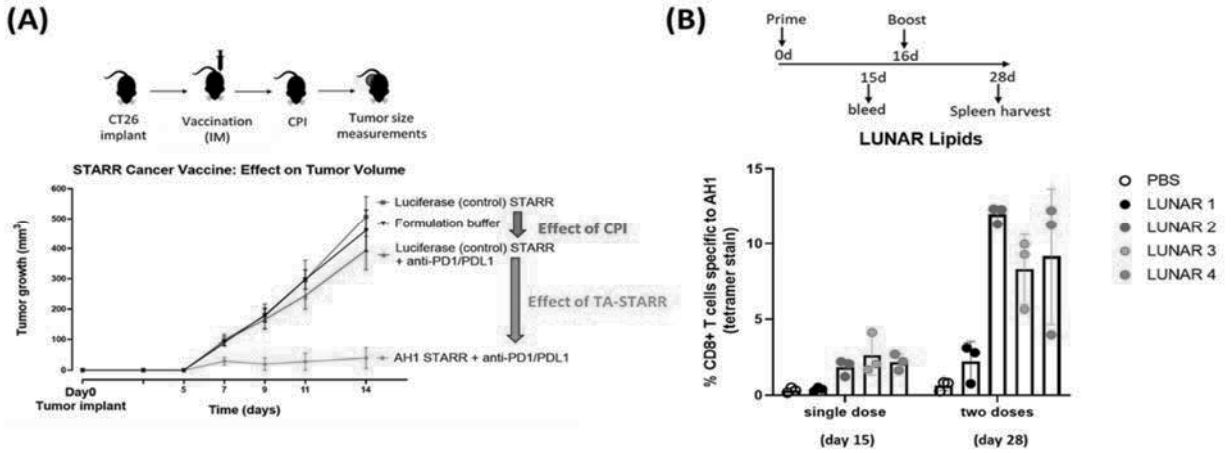


Figure 7: Antitumor activity and T cell response by Arcturus cancer vaccines. A. STARR vaccine expressing a tumor antigen led to a significant reduction of the tumor growth rate of a colorectal cancer cell line, CT26. B. T cell responses elicited by conventional mRNA cancer vaccine by various LUNAR formulations.

Along with these platform improvements, we sought to understand how T cell responses induced by conventional mRNA, which have shown great promise in recent personalized cancer vaccine trials, differ from T cell responses induced by our STARR platform, especially after multiple vaccinations. We compared T cell responses in mice vaccinated with either sa-mRNA (STARR) encoding 13 epitopes known to generate responses in C57BL/6 mice to those in mice vaccinated with a conventional (N1-psuedouridine modified) mRNA encoding those same epitopes. All vaccines were formulated with our LUNAR lipids. Each mouse received a series of five vaccinations with an interval of two weeks between vaccinations (Figure 8A). We found that even after five vaccinations, mice vaccinated with sa-mRNA showed more than twice the CD8+ T cell response compared to mice vaccinated with conventional mRNA vaccine (Figure 8B).

Because sa-mRNA technology allows for extended duration of antigen expression, the possibility of T cell exhaustion after multiple vaccinations was a concern. We assessed the levels of CD8+ T cells expression PD-1 or Lag-3, well characterized exhaustion markers, and found significantly lower levels of exhaustion markers in mice vaccinated with sa-mRNA compared to conventional mRNA (Figure 8C). We hypothesize that the additional innate immune stimulation from the replicase intermediates may be responsible for the reduction in exhaustion makers. CD8+ memory subsets were also analyzed. While we expected to see increases in CD8+ T cell memory subsets overall, we observed that we saw an increase in the important T cell effector (Tem) subsets at the expense of T central memory (Tcm) in sa-mRNA vaccinated mice after 5 vaccinations (Figure 8D). The generation of Tem cells is an important prognostic indicator of vaccine efficacy in cancer vaccination. Lastly, we wanted to verify that T cells induced by multiple vaccinations with sa-mRNA were functional, so we assessed the levels of granzyme B, an important cytotoxic effector molecule, in CD8 T cells before and after stimulation. Prior to stimulation sa-mRNA vaccinated mice had significantly higher granzyme B compared to conventional mRNA vaccinated mice. After peptide stimulation, T cells from sa-mRNA vaccinated mice showed increased degranulation (as indicated by levels of CD107a, a degranulation marker) compared to T cells from conventional mRNA vaccinated mice (Figure 8E). Altogether, our data indicate that our STARR platform not only delivers a higher magnitude of epitope-specific responses compared to conventional mRNA, but that the T cell response induced by the STARR platform is better suited for clinical efficacy even after multiple vaccinations by inducing highly functional and cytotoxic T cells with the relevant memory markers (Tem).

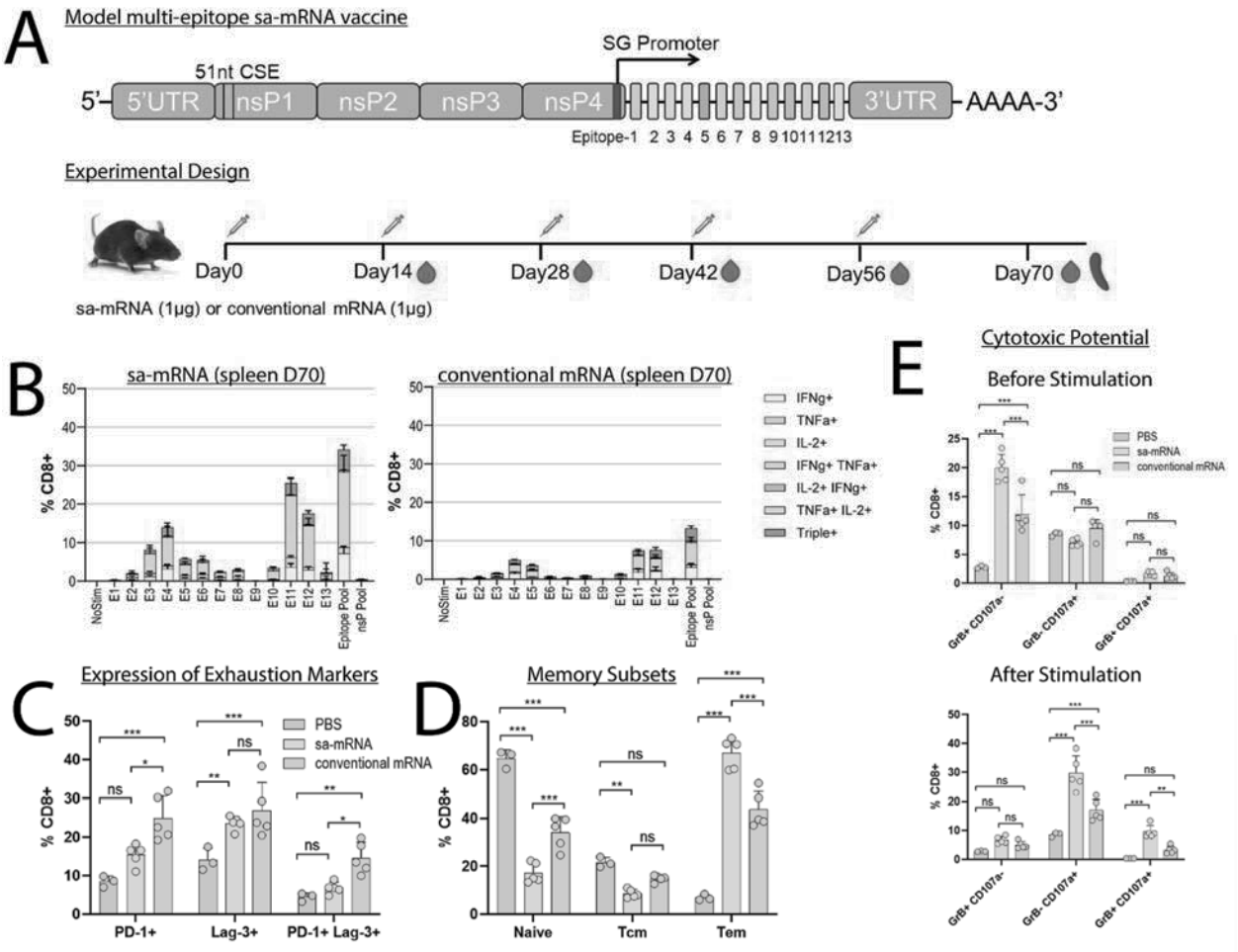


Figure 8: CD8 T cell responses after multiple vaccinations with sa-mRNA (STARR) vaccines and conventional mRNA vaccines formulated with LUNAR lipids. (A) Design of sa-mRNA vaccine encoding 13 H-2b restricted T cell epitopes (top). The conventional mRNA vaccine used the same epitope cassette. C57Bl/6 mice were vaccinated 5 times (two-week interval between vaccinations) and spleens were collected two weeks after the last vaccination (bottom). (B) Epitope specific responses to encoded epitopes were higher in sa-mRNA vaccinated mice compared to conventional mRNA vaccinated mice after 5 vaccinations. (C) The T cell exhaustion markers PD-1 and Lag-3 were assessed and lower levels of PD-1 and PD-1/Lag3 were observed on CD8+ T cells from sa-mRNA vaccinated mice. (D) Naïve (CD62L+CD44-), T central memory (Tcm; CD62L+CD44+), and T effector memory (Tem; CD62L-CD44+) were assessed in all mouse groups. sa-mRNA vaccinated mice showed the highest levels of Tem cells, an important prognostic indicator of vaccine efficacy. (E) CD8+ T cells were also assessed for granzyme B levels and surface levels of the degranulation marker, CD107A, before (top) and after (bottom) simulation with the encoded peptides. Prior to stimulation, sa-mRNA vaccinated mice had the highest levels of granzyme B. When stimulated, these cells lost granzyme B expression through degranulation, as indicated by the higher levels of CD107a, indicating functional degranulation of cytotoxic mediators was higher in sa-mRNA vaccinated mice compared to conventional mRNA vaccinated mice.

Enabling Technologies – Immuno-oncology

Cell-based therapies for hematologic malignancies using chimeric antigen receptor (CAR) T cells have made significant advances in the past decade. The success of CAR-T cells in immuno-oncology has led to a growing number of therapies utilizing other immune cell types engineered to express a variety of immunomodulatory molecules. Yet, despite their promise, extensive challenges still exist with this therapeutic approach. Some of the issues include toxicity, potential for insertional mutagenesis of the CAR construct, T cell malignancies, and an ex vivo manufacturing process that is complex, time consuming and costly. We believe that our LUNAR-I/O approach has the potential to ameliorate some of these issues. For example:

1. RNA-driven CAR expression in lymphocytes or immune cell types would be transient and therefore expected to have a lower side effect profile;
2. There is no integration into the germline DNA allowing for co-delivery of multiple therapeutic molecules without the risk of insertional mutagenesis; and
3. Generation of CAR-expressing cells by a process that is quicker and cheaper, particularly when targeting specific immune cell subtypes in vivo.

Our efforts to date have focused on targeting T lymphocytes in vivo with either CAR-mRNA or CAR-STARR (self-amplifying RNA) constructs in combination with other immunostimulatory molecules.

Supply and Manufacturing

Our supply and manufacturing strategies are focused on supporting the following:

1. multiple pre-clinical and clinical pipeline candidates;
2. late-stage clinical and commercial scale COVID vaccine products; and
3. regional and global product demand.

We have built a global manufacturing footprint with our partners, including Aldevron, Catalent, Recipharm, Polymun and ARCALIS. With such collaborations, we have established an Integrated Global Supply Chain Network with our primary and secondary sourcing contract development & manufacturing organizations (CDMOs) based in the United States, EU and Asia for producing critical raw materials, drug substance, and packaged finished product.

We have manufactured and supplied gram quantities of drug substance, and have scaled-up and validated our finished drug products (COVID Vaccine) through our CDMOs for clinical studies, and commercial readiness. We continue to dedicate, resources to advance our sophisticated manufacturing know-how, including formulation of lipid nanoparticles, which improves manufacturing efficiency and capacity.

We believe we have established sufficient manufacturing capacity through our CDMOs to meet our current internal research, development, and potential commercial needs, as well as our obligations under existing agreements with our partners. Additionally, we continue to evaluate relationships with additional suppliers to increase overall capacity and diversify our supply chain.

Revenue and Collaboration Arrangements and Other Material Agreements

In addition to our internal programs, we have collaborated or partnered with other parties on discovery, development, manufacturing or other efforts based on our proprietary platform technologies. Among other collaboration arrangements,

- we have a collaboration with CSL Seqirus for vaccines against SARS-CoV-2 (COVID-19), influenza and three other infectious diseases;
- we have received funding from the CFF to support our LUNAR-CF development program; and
- we have a contract with BARDA to support the development of a low-dose pandemic influenza candidate based on our proprietary self-amplifying messenger RNA-based vaccine platform.

CSL Seqirus

In November 2022, we entered into the CSL Collaboration Agreement with CSL Seqirus for the global exclusive rights to research, develop, manufacture and commercialize self-amplifying mRNA vaccines. The CSL Collaboration Agreement became effective on December 8, 2022, following clearance under the Hart-Scott-Rodino Antitrust Improvements Act.

Under the CSL Collaboration Agreement, CSL Seqirus receives global exclusive rights to our technology for vaccines against SARS-CoV-2 (COVID-19), influenza and three other infectious diseases. Specifically, the collaboration agreement grants CSL Seqirus a license to our STARR mRNA technology and LUNAR lipid-mediated delivery, as well as mRNA drug substance and drug product manufacturing expertise. CSL has also been granted global non-exclusive rights in the field of pandemic preparedness (i.e., pathogens identified as priority diseases by the WHO), with the right to convert to an exclusive license.

The CSL Collaboration Agreement sets forth how the parties will collaborate to research and develop vaccine candidates. In the COVID-19 field, we undertake activities for certain regulatory filings for our leading self-amplifying mRNA vaccine candidate in COVID-19, ARCT-154, in the United States and Europe and for research and development activities of a next-generation COVID vaccine candidate. CSL Seqirus leads and is responsible for all other research and development in COVID-19, influenza and the other fields.

We received an up-front payment of $200.0 million, with the potential to receive development milestones totaling more than $1.3 billion if all products are registered in the licensed fields. We also are entitled to potentially receive up to $3.0 billion in commercial milestones based on "net sales" of vaccines in the various fields. In addition, we are entitled to receive a 40% share of net profits from COVID-19 vaccine sales and up to low double-digit royalties of annual net sales for vaccines against influenza, pandemic preparedness and three additional infectious diseases. Entitlement to all such payments is subject to the strict conditions, requirements, royalty reduction provisions and other limitations set forth in the CSL Collaboration Agreement.

Either party may terminate the CSL Collaboration Agreement on a field-by-field basis for material breach by the other party, following notice and opportunity to cure. CSL Seqirus may also terminate the collaboration agreement in its entirety or on a field-by-field basis for any reason or no reason whatsoever, with certain limitations. The CSL Collaboration Agreement may also be terminated by CSL Seqirus for safety reasons, clinical data nonviability, commercial nonviability and other specified reasons.

In March 2024, we entered into Amendment Number Two to the CSL Collaboration Agreement to reflect updates to the development program and other adjustments consistent with our prior disclosures regarding the Collaboration and License Agreement ("Amendment Number Two"). Amendment Number Two, among other things, adjusts (i) the development plans for certain product candidates, (ii) various development milestones related to such product candidates, (iii) provisions of the CSL Collaboration Agreement related to specific royalty payments, (iii) provisions of the CSL Collaboration Agreement related to distributors, and (iv) proprietary payment calculations related to the foregoing.

On May 30, 2025, we initiated an arbitration against CSL Seqirus before the International Chamber of Commerce, seeking payment of a milestone under the CSL Collaboration Agreement based on the European Commission's grant of marketing authorization for a presentation of KOSTAIVE® in the European Union.

In CSL Limited's half-year results presented on February 11, 2026, CSL Limited reported an accounting write-down of approximately $430 million attributable to our collaboration agreement with CSL Seqirus, citing declining COVID-19 disease burden and more onerous U.S. regulatory requirements.

Cystic Fibrosis Foundation Agreement

On May 16, 2017, pursuant to a Development Program Letter Agreement (as amended, the "CFF Agreement") with the CFF, CFF agreed to award us funding for a development program to identify lead CFTR mRNA sequences and LUNAR formulations, demonstrate tolerability of LUNAR CFTR mRNA, and demonstrate translatability of aerosolized LUNAR. The award includes a grant of rights to CFF know-how to assist us to research, develop, commercialize, make or otherwise exploit a product. If the award results in a successful commercialized product, we will pay CFF (i) royalties on sales of the product up to a maximum of a single-digit multiple of the total award amount actually paid to us by CFF, and (ii) thereafter, a single-digit percentage of annual net sales. Further, in the event of a license, sale or other transfer of the product or our development program technology (including a change of control transaction), we will pay CFF a percentage of such license, sale or transfer payments actually received by us or our shareholders (subject to a royalty cap). On August 1, 2019, we entered into an amendment to the CFF Agreement. Pursuant to the amendment, (i) CFF will increase the amount it will award to advance LUNAR-CF, (ii) we will provide a certain amount of matching funds for remaining budgeted costs, and (iii) the related disbursement schedule from CFF to us was modified such that (a) a disbursement was made upon execution of the amendment, (b) an agreed upon amount will be disbursed to us within thirty days of the first day of each of January, April, July and October 2020, and (c) the last payment will be disbursed upon us invoicing CFF to meet good manufacturing practices and submitting an IND application. In January 2022, the parties signed an additional amendment for CFF to fund the development of a CF ferret model for application in the development of ARCT-032, our LUNAR-CF candidate.

On September 25, 2023, we entered into an additional amendment (the "Fourth Amendment") to the CFF Agreement, pursuant to which we and CFF agreed to: (a) increase the Amount of Award (as defined in the CFF Agreement and applicable amendment) from CFF to advance LUNAR-CF by up to $9 million (for a total to date of

up to approximately $25 million), and required Arcturus to provide $15 million in matching funds for remaining budgeted costs; (b) modify the existing rates and caps on royalties due to CFF under the CFF Agreement, including the addition of an option for Arcturus to reduce the royalty rate through a one-time payment; (c) modify the calculation of payments from Arcturus to CFF in the event of certain dispositions or licensing of cystic fibrosis or other pulmonary assets or of a change of control of Arcturus; and (d) make corresponding changes to exhibits, definitions and other provisions of the CFF Agreement.

BARDA

In August 2022, we entered into a cost reimbursement contract with the Biomedical Advanced Research and Development Authority ("BARDA") of the U.S. Department of Health and Human Services to support the development of a low-dose pandemic influenza candidate based on our proprietary self-amplifying messenger RNA-based vaccine platform.

The contract is to support our non-clinical and pre-clinical development, early-stage clinical development through Phase 1, and associated drug product manufacturing, regulatory and quality-assurance activities over a period of three years. The contract provides for reimbursement by BARDA of Arcturus' permitted costs incorporated into the contract, up to $63.2 million. The contract does not include the purchase of any pandemic influenza vaccine that eventually may be developed. The contract is terminable by BARDA at any time under specified circumstances, including for convenience.

This contract is part of BARDA's ongoing efforts to bolster pandemic preparedness and response capabilities by investing in innovative medical counter-measures that can help prevent the medical consequences that result from outbreaks caused by pandemic influenza and emerging infectious diseases. In December 2024, we initiated a Phase 1 clinical trial for our H5N1 pandemic flu candidate that is supported by funding from BARDA.

ARCALIS Joint Venture

In April 2021, Arcturus and Axcelead, Inc., a company existing under the laws of Japan ("Axcelead"), formed a joint venture entity, named ARCALIS, Inc. ("ARCALIS"), which operates as a corporation under the laws of Japan. Axcelead is an integrated drug discovery solutions provider to the pharmaceutical industry in Japan, having succeeded to a portion of the drug discovery research department of Takeda Pharmaceutical Company Limited in 2017. The goal of ARCALIS is to be a contract development and manufacturing organization focused on mRNA manufacturing that would provide manufacturing services to us and also to third parties.

ARCALIS has constructed facilities for the manufacture of mRNA drug substance and mRNA-LNP liquid and lyophilized drug product financed largely by grants from the Japanese government.

In January 2025, Meiji Seika Pharma, along with ARCALIS, received Ministry of Health, Labour and Welfare (MHLW) approval for adding commercial manufacturing sites in Japan for KOSTAIVE. Domestically produced products with active pharmaceutical ingredients manufactured at ARCALIS's Minami-soma facilities, and formulated at Meiji Seika Pharmatech, have been shipped for commercial use in Japan for the 2024-25 and 2025-26 seasons.

Legacy Arrangements

During our formative period, we entered into various collaboration, development and license agreements with larger parties in our industry, providing for the designation of targets for collaborative development using our platform technologies. Although, as we have previously reported, parties to these agreements, including Ultragenyx, continue to have exclusive rights to certain of these targets, other than as reported above, there has been no significant development activities under the programs.

Intellectual Property

Our business success depends in part on our ability to obtain and maintain intellectual property protection for our proprietary technologies, inventions and know-how, and on our ability to operate without infringing on the proprietary rights of others. We strive to protect our intellectual property through a combination of patents, trademarks, trade secrets, licensing agreements, invention assignment agreements and confidentiality agreements with employees, advisors, consultants and contractors.

We rely on continuing technological innovation to strengthen our proprietary position in the field of nucleic acid medicines. Therefore, we plan to continue to file patent applications in jurisdictions around the world as we

discover and develop novel nucleic acid technology platforms and novel nucleic acid therapeutic candidates. We cannot guarantee that future applications will be issued.

Our Patent Portfolio

As of January 31, 2026, we own over 500 patents and pending patent applications. The claims of these patents and pending applications include compositions of matter, methods of use, manufacturing processes and drug product formulations. These claims cover the use of our core platform technologies including the use of LUNAR® and lipid components to deliver nucleic acids, specific nucleic acid modalities for treating disease, as well as our proprietary technology regarding the design, manufacture, and purification of nucleic acids for use in therapy. Claims also cover the composition of matter, formulation, and use of our therapeutic candidates to prevent and/or treat target diseases including OTC deficiency, CF, COVID-19 and Influenza. If issued, our patents are expected to expire between 2028 and 2046, without taking into account any possible patent term extensions.

Our patent portfolio is built upon a strategy of robust protection for our LUNAR and STARR® platforms as described below:

- LUNAR – Our patent holdings continue to grow in scope and territory for our LUNAR platform with patents and patent applications directed to composition of matter including chemical structures for our growing library of proprietary lipids, manufacture of lipid nanoparticles (including lyophilization), and use of our LUNAR technology for nucleic acid delivery and drug delivery in more than 50 countries around the world.
- STARR – In 2019, we began to develop our STARR platform which combines our proprietary LUNAR delivery systems with technologies that enable self-transcribing and self-amplifying RNA. As noted above, our robust LUNAR portfolio provides protection for delivery vehicles that can enable specific and effective delivery of STARR-based drug substances. As with our LUNAR portfolio, our patent holdings directed to our STARR platform have a broad geographical footprint. This portfolio is generally directed to specially designed RNA constructs, specific nucleotide and amino acid sequences, and lipid formulations comprising the same. We anticipate that further patents will be filed as we continue to innovate with respect to our STARR platform and that current applications covering these developments in our STARR platform, if granted, will last until 2046, not including any patent term extensions.

Patent Terms

The term of individual patents depends on the countries in which they are obtained. The patent term is 20 years from the earliest effective date of filing a non-provisional patent application in most of the countries in which we file.

Under the Drug Price Competition and Patent Term Restoration Act (also known as the Hatch-Waxman Act), U.S. patent holders can apply for a patent term extension to compensate for the patent term lost during the FDA regulatory review process. Patent extension is only available for patents covering FDA-approved drugs. The extension can be up to five years beyond the original expiration date of the patent and cannot extend a patent term for longer than 14 years from the date of product approval. Only one patent extension is granted per approved drug. Similar provisions may be available in foreign jurisdictions, including Europe. We intend to apply for patent term extensions where possible.

Trade Secrets

We have developed valuable trade secrets to protect our product candidates and proprietary processes, including trade secrets related to the design and optimization of nucleic acids, the design and optimization of lipid compositions for delivery of nucleic acids, manufacturing and formulation processes, and analytical techniques.

Certain Risks to Intellectual Property

Our commercial success also depends in part on our non-infringement of the patents or proprietary rights of third parties. For a more comprehensive discussion of the risks related to our intellectual property, please see Item 1A “Risk Factors” – “Risks Related to Our Intellectual Property.”

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions.

Our success depends in part on our ability to:

- preserve trade secrets;
- prevent third parties from infringing upon our proprietary rights; and
- operate our business without infringing the patents and proprietary rights of third parties, both in the United States and internationally.

We seek to protect our proprietary technology and processes, in part, by confidentiality and invention assignment agreements with our employees, consultants, scientific advisors and other contractors. These agreements may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our employees, consultants, scientific advisors or other contractors use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Product Approval and 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 products such as those we are developing. Any product candidate that we develop must be authorized or approved by the FDA before it may be legally marketed in the United States and by the appropriate foreign regulatory agency before it may be legally marketed in foreign countries.

U.S. Drug Development Process

In the United States, the development, manufacturing, and marketing of human drugs and vaccines are subject to extensive regulation. The FDA regulates drugs under the Federal Food, Drug and Cosmetic Act ("FDCA") and implementing regulations, and biological products, including vaccines, under provisions of the FDCA and the Public Health Service Act ("PHSA"). Drugs and vaccines are also subject to other federal, state and local statutes and regulations. 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. The process required by the FDA before a drug or biological product may be marketed in the United States generally involves the following:

- completion of nonclinical laboratory tests, animal studies and formulation and stability studies according to good laboratory practices ("GLP") or other applicable regulations;
- submission to the FDA of an application for an IND, which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials according to the FDA's regulations commonly referred to as current good clinical practices ("GCPs") to establish the safety and efficacy of the proposed drug for its intended use;
- submission to the FDA of a new drug application ("NDA") or biologics license application ("BLA") for a new drug or biologics;
- satisfactory completion of FDA inspections of the manufacturing facility or facilities where the drug is produced to ensure compliance with the FDA's current good manufacturing practice standards ("cGMP"), to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- potential FDA inspection of the nonclinical and clinical trial sites that generated the data in support of the NDA or BLA; and
- FDA review and approval of the NDA or BLA.

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

Before testing any compounds with potential therapeutic value in humans, the drug candidate enters the preclinical study stage. Preclinical tests, also referred to as nonclinical studies, include discovery and target identification, in vitro testing to assess biological activity, mechanism of action, and potential toxicity, as well as animal studies to assess the potential safety, pharmacokinetics, and pharmacological activity of the drug candidate.

Clinical trials involve the administration of the drug candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's direct control. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety.

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

- Phase 1. The drug is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing may be conducted in patients;
- Phase 2. The drug is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule; and
- 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, a well-controlled Phase 3 clinical trial is required by the FDA for approval of an NDA or BLA.

Post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These clinical trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication.

U.S. review and approval processes

The results of product development, nonclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling and other relevant information are submitted to the FDA as part of an NDA or BLA requesting approval to market the product. The submission of an NDA or BLA is subject to the payment of substantial user fees; a waiver of such fees may be obtained under certain limited circumstances.

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. In addition, the FDA may require post marketing clinical trials, sometimes referred to as Phase 4 clinical trials, which are designed to further assess a product's safety and effectiveness and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized.

Post-approval requirements

Approved products remain subject to ongoing FDA regulation, including requirements relating to manufacturing, labeling, promotion, adverse event reporting and periodic inspections. Failure to comply with applicable requirements may result in enforcement actions, including warning letters, fines, product recalls, suspension or withdrawal of approval, or other penalties.

Regulation in Europe and Other Regions

In addition to U.S. requirements, we must obtain regulatory approvals in foreign jurisdictions prior to conducting clinical trials or marketing products outside the United States. Regulatory requirements vary by country

but generally involve processes comparable to those of the FDA, including review of clinical data, manufacturing information and product labeling.

Competition

Our Business in General

The RNA pipeline across the biopharma industry is expansive, with mostly early-stage assets. Published market reports indicate that there are 1,000+ RNA assets in development with approximately 90% in pre-clinical and Phase 1 studies RNA assets in development are across a broad therapeutic range making for a diffused therapeutic focus across the field.

Competition is intensifying in this space as both biotech and larger pharma companies invest more in RNA technology and RNA pipelines mature in three key areas: RNA platform development (targeted on build of RNA platform components and delivery), platform discovery (unlocking broader therapeutic applicability) and in technology-aided platform accelerators (accelerate RNA design, development, and production - to further leverage advantage of RNA versus traditional technologies). Pharmaceutical and biotechnology companies are heavily pursuing opportunities to build foundational platforms and to expand and accelerate RNA applications. As a result, we face competition at the technology platform and therapeutic indication levels from both large and small biopharmaceutical companies, academic institutions, governmental agencies and public and private research institutions.

Many of our competitors, including those with strategic partners, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Mergers and acquisitions, recently and into the future, may result in resource concentration among a potentially consolidated number of competitors.

Our success will be based in part upon our ability to identify, develop and manage a portfolio of product candidates that are safer and more effective than competing products in the treatment of our targeted patients. The commercial opportunity could be reduced or eliminated if competitors develop and commercialize products that are safer, more effective, are more convenient or are less expensive than any products we may develop in our respective areas. Our collaboration with CSL Seqirus may allow us to compete commercially on the world stage within the COVID and influenza markets.

We are aware of several other companies that are working to develop nucleic acid medicines, including gene therapy, gene editing, mRNA (including sa-mRNA), siRNA, and antisense therapeutics. Many of these companies, such as Genevant Sciences and Acuitas Therapeutics, are also developing nucleic acid delivery platforms which compete with LUNAR technology.

Below we have included what we believe to be the competitive landscape for certain of the medicines that we currently have in development.

Lung Franchise ARCT-032 (LUNAR-CF)

The lead candidate of our lung franchise is ARCT-032, an mRNA therapeutic candidate for cystic fibrosis based on our proprietary drug substance mRNA technology platform and our LUNAR lipid nanoparticle delivery platform has advanced into Phase 2 clinical development.

We are aware of product candidates of the following companies that we consider as competitors or future competitors to ARCT-032: Moderna/Vertex, Recode Therapeutics, Eloxx Pharmaceuticals, 4DMT, Spirovant, SalioGen, Splisense, Krystal Biotech, Sionna and Enterprise Therapeutics.

Liver Franchise ARCT-810 (LUNAR-OTC)

Our liver franchise has advanced into mid-stage clinical development with ARCT-810 in Phase 2 clinical development. Potential competitors include, but are not limited to, Ultragenyx and iECURE which are advancing a gene therapy program for OTC in clinical development. Additional companies working on therapies targeting people with OTC deficiency include, Bloomsbury Genetic Therapies and Moderna, which has a therapeutic candidate in pre-clinical development.

LUNAR-COVID-19 Vaccine (KOSTAIVE®)

Our vaccine franchise is based on our self-amplifying STARR technology platform and our lipid nanoparticle delivery platform called LUNAR. This franchise has advanced into the market with the approval of KOSTAIVE® in Japan and geographic expansion is underway to other markets through our collaboration with CSL Seqirus. We consider the following companies with approved or late-stage clinical development vaccines as some of our competitors or future competitors to our partnered COVID-19 vaccine franchise: Pfizer/BioNTech, Moderna, and Sanofi/Novavax. Dozens of other companies are continuing to develop COVID-19 vaccines. However, the majority of these companies use conventional mRNA (not self-amplifying) and protein-based vaccine technology as the basis for their COVID-19 vaccines.

LUNAR-FLU Vaccine

We have partnered our influenza vaccine franchise with CSL Seqirus. We consider the following companies as some of the competitors or future competitors to our partnered LUNAR-Flu vaccine franchise: Pfizer, Moderna, Novavax, and Sanofi. The flu industry is evaluating a shift to utilizing mRNA-based platforms in addition to other non-egg based technologies and traditional (egg-based) technologies.

Multiple Areas

Of the competitors noted above, the following compete with us across multiple areas of our portfolio and/or aspects of our platform technologies:

- While we are the first and only company with an approved sa-mRNA vaccine in a major market, there are two other manufacturers with approved conventional mRNA-based vaccines, according to information published by the relevant companies:
    - BioNTech, in collaboration with Pfizer, has a marketed COVID-19 conventional mRNA vaccine, COMIRNATY®, available in multiple geographies, and is developing an mRNA flu vaccine and a COVID-19/flu combination vaccine, as well as latent virus and other vaccines of global public health interest in early development.
    - Moderna manufactures two other approved conventional mRNA-based COVID-19 vaccines, Spikevax® and mNEXSPIKE®, which are available in multiple geographies. Moderna's pipeline includes both infectious disease and rare disease assets. From an infectious disease perspective, beyond Spikevax, Moderna is developing respiratory (e.g., seasonal flu, pandemic flu, COVID-19/flu combo, RSV, etc.), enteric (Norovius), bacterial (Lyme), latent (e.g., EBV, HSV, etc.), and other virus vaccine candidates ranging from Phase I to Phase III stages of development. Moderna's rare disease pipeline includes intercellular therapeutics and inhaled therapeutics. Through the Moderna-Vertex collaboration, the mRNA-3692 / VX-522 asset for CF is in Phase I. Moderna's mRNA-3139 asset is in preclinical development for OTC.
- The mRNA portfolio resulting from the GSK-CureVac collaboration focuses on vaccines in the prevention of influenza and COVID-19 viruses. Neither entity nor the collaboration has achieved health authority approval for flu and/or COVID-19 mRNA vaccine products. Both the flu and COVID-19 assets are in Phase 2 clinical development; the COVID-19/flu combo is in Phase 1. The GSK–CureVac collaboration is no longer a joint mRNA vaccine development partnership as it has been transformed into a licensing relationship where GSK owns and advances all the infectious-disease mRNA vaccines originally co-developed with CureVac.
- Subsequently, BioNTech formally acquired CureVac in January 2026 BioNTech acquisition of CureVac consolidated ownership of the companies' ongoing IP litigation.

Human Capital

As of December 31, 2025, we had approximately 111 employees, of which 106 were full-time and 5 were part-time. Additionally, we are supported by contractors and scientific consultants in most areas of the business. None of our employees are represented by a labor union or covered by a collective bargaining agreement. We consider relations with our employees to be good. Our ability to advance our research, development, manufacturing and commercialization activities depends largely on our ability to attract, retain and develop qualified personnel. We compete for talent in specialized and competitive markets and support our employees through professional

development and training programs, and generally offer our employees competitive compensation and benefits, including base salary, annual incentive bonuses, equity-based compensation, healthcare and insurance benefits, retirement savings plans and generous paid time off and holidays.

Senior Leadership

On December 11, 2025, we and Andy Sassine, our former Chief Financial Officer and former member of the Board of Directors, mutually agreed to end his employment relationship in an amicable manner effective December 31, 2025. On December 12, 2025, Joe Roberts, our Controller, was appointed interim principal financial officer and interim principal accounting officer. We have initiated a comprehensive search for a new Chief Financial Officer.

Available Information

The Company was founded in 2013 as Arcturus Therapeutics, Inc., and we have maintained our principal executive offices in San Diego, California since that time. In November 2017, Alcobra Ltd., an Israeli limited company, merged with our company, changed its name to Arcturus Therapeutics Ltd. ("Arcturus Israel"), and commenced trading on Nasdaq under the symbol "ARCT." On June 17, 2019, we redomiciled to the United States (the "Redomiciliation") and changed our name to Arcturus Therapeutics Holdings Inc.

Our Internet address is www.arcturusrx.com. Our Annual Reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and proxy statements, and all amendments thereto, are available free of charge on our Internet website. These reports are posted on our website as soon as reasonably practicable after they are electronically filed with the SEC. The public may read and copy any materials that we file with the SEC electronically through the SEC website (www.sec.gov). The information contained on the SEC's website is not incorporated by reference into this Annual Report on Form 10-K and should not be considered to be part thereof.

Item 1A. Risk Factors

In conducting our business, we face many risks that may interfere with our business objectives. Some of these risks could materially and adversely affect our business, financial condition and results of operations. In particular, we are subject to various risks resulting from inherent unknowns and uncertainties in the drug development and commercialization process, as well as changing economic, political, industry, regulatory, business and financial conditions. The risks and uncertainties described below are not the only ones we face.

You should carefully consider the following factors and other information in this Annual Report before you decide to invest in our common stock. If any of the negative events referred to below occur, our business, financial condition and results of operations could suffer. In any such case, the trading price of our common stock could decline, and you may lose all or part of your investment.

Risk Factor Summary

The following is a summary of certain important factors that may make an investment in our company speculative or risky. You should carefully consider the fuller risk factor disclosure set forth in this Annual Report, in addition to the other information herein, including the section of this report titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes.

- *We have a limited operating history, have incurred significant losses since our inception (with the exception of fiscal year 2022) and anticipate that we will continue to incur significant losses for the foreseeable future.*
- *We have not generated any revenue from product sales, have generated only limited collaboration and grant revenue since inception, and may never be profitable in the long term.*
- *We expect that we will need to raise additional capital in the future, which may not be available on acceptable terms, or at all.*
- *We are dependent upon relationships with our collaboration partners, and the failure of these relationships could negatively affect our business and results of operations.*
- *We are highly dependent upon our relationship with CSL Seqirus to further research, manufacture and commercialize self-amplifying mRNA vaccines against COVID-19, influenza and three other infectious diseases; CSL Seqirus has announced a significant write-down of the licensed collaboration programs.*

- *KOSTAIVE might not have a profitable commercial market.*
- *KOSTAIVE only has marketing approval in Japan and Europe and may never achieve marketing approval in any other countries.*
- *Regulatory authorities may change views and recommendations, which could lead to more challenging regulatory paths to approvals and to more expensive clinical and commercial efforts.*
- *Even with the commercialization of KOSTAIVE in Japan, there might not be meaningful sales in Japan. Despite the approval of KOSTAIVE in Europe, KOSTAIVE has not, and might never, achieve commercialization in Europe.*
- *There is significant competition in the development of a vaccine against COVID-19, some competitors' vaccines are already widely accepted in the market, and many of our competitors have substantially greater financial, scientific and other resources than we have.*
- *If we are unable to generate successful results from preclinical and clinical studies of our product candidates, or experience significant delays in doing so, our business may be materially harmed.*
- *Our platform focuses on nucleic acid technology, and mRNA drug products in particular, which are relatively new and any adverse results from nucleic acid or mRNA technologies in the industry could significantly impact our ability to develop and commercialize marketable products.*
- *Changes to our drug product format could significantly impact our timeline to commercialize our products.*
- *We may not be successful in our efforts to identify or discover potential product candidates.*
- *We may find it difficult to identify and enroll patients in our clinical studies, and the limited number of patients who have the diseases for which certain of our product candidates are being studied could delay or prevent clinical studies of certain of our product candidates.*
- *If any of our product candidates cause undesirable side effects or have other properties impacting safety, further clinical trials may be denied or delayed and regulatory approval could be prevented, delayed or limited.*
- *Even if we obtain regulatory approval for a product candidate, we will still face extensive regulatory requirements and our products may face future development and regulatory difficulties.*
- *If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.*
- *Manufacturing issues may arise that could increase product and regulatory approval costs or delay or hinder commercialization.*
- *The commercial success of our product candidates will depend in part upon the acceptance of our product candidates by the medical community, including physicians, patients and healthcare payors.*
- *If our strategic alliances are unsuccessful or are terminated, we may be unable to commercialize certain product candidates and generate revenues.*
- *CSL Limited's recent financial report included a significant write-down related to our licensed assets; a potential separation of CSL Seqirus could disrupt our collaboration and materially harm our business.*
- *If the contract manufacturers we rely on to produce the supply of our preclinical and clinical product candidates, including materials for the manufacture of our product candidates, do not timely deliver adequate quantities of quality materials, development and commercialization of our product candidates would be hindered.*
- *Any disruption in the supply chain of raw materials for, or in the manufacturing capacity and timing for the manufacture of drug substance or drug product for, our product candidates may cause a delay in*

developing and commercializing these product candidates and limit the revenues that we could generate.

- *If the contract research organizations and clinical trial sites we rely on to conduct, supervise and monitor our clinical trials perform in an unsatisfactory manner, it may harm our business.*
- *If we are unable to obtain or protect intellectual property rights related to our products and product candidates, we may not be able to compete effectively in our markets.*
- *Claims that we infringe the intellectual property rights of others, especially in the crowded and competitive field of mRNA patents, may prevent or delay our development and commercialization efforts.*
- *If we fail to obtain licenses to necessary intellectual property or do not comply with our obligations in license agreements, we could lose important rights.*
- *We may be involved in lawsuits to protect or enforce our patents or to defend against third party intellectual property claims, which could be expensive, time consuming and unsuccessful.*
- *We have filed a lawsuit alleging trade secret misappropriation and breach of contract, and any unfavorable outcome or related proceedings could materially and adversely affect our business, financial condition, results of operations, and reputation.*
- *U.S. Government agencies have special contracting authority that gives them the ability to terminate and/or modify their contracts with us.*
- *Our business is subject to audit by the U.S. Government, and a negative audit could adversely affect our business.*

RISKS RELATED TO OUR FINANCIAL CONDITION AND NEED FOR ADDITIONAL CAPITAL

We have a limited operating history, have incurred significant losses since our inception (with the exception of fiscal year 2022) and anticipate that we will continue to incur significant losses for the foreseeable future.

We are a global messenger RNA medicines company with a limited operating history. Since inception, our operations have been primarily limited to acquiring and licensing intellectual property rights, developing our product platform, undertaking research, partnering assets and running clinical product development programs. We only have one product that, through our partners CSL Seqirus and Meiji, is being commercialized, and it is currently only commercialized in Japan. Consequently, any predictions about our future success or viability, or any evaluation of our business and prospects, is difficult and may not be accurate. In 2025 we recognized a significant portion of our revenue from non-recurring milestone payments and license revenue under our collaboration agreement with CSL Seqirus. We may not receive any future milestone payments from CSL Seqirus. We have not recognized any revenue from product sales since our inception.

As of December 31, 2025, we had an accumulated deficit of $514.6 million.

We have devoted most of our financial resources to research and development, including our preclinical and clinical development activities. To date, we have funded our operations primarily through upfront payments, research funding and milestone payments from strategic alliances and collaborations, and through the sale of equity and convertible securities. We expect to continue to incur substantial and increased expenses, losses and negative cash flows as we expand our development activities and advance our programs. If our product candidates are not successfully developed or commercialized, including because of a lack of capital, or if we do not generate enough revenue following marketing approval, we will not achieve profitability and our business may fail. Even if we or our strategic alliance partners successfully obtain regulatory approval to market a product candidate, our revenues will also depend upon the size of any markets in which our product candidates have received market approval and our ability to achieve sufficient market acceptance and adequate market share for our products.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. The net losses we incur may fluctuate significantly from quarter to quarter. We anticipate that our expenses will increase substantially if and as we:

- continue our research and development of our product candidates, both independently and under our strategic alliance agreements;
- seek to identify additional targets and product candidates;
- acquire or in-license other products and technologies;
- advance product candidates into and through clinical trials;
- seek marketing approvals for any product candidates that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- maintain, expand and protect our intellectual property portfolio;
- hire additional clinical, regulatory, research, executive and administrative personnel; and
- create additional infrastructure to support our operations and our product development and planned future commercialization efforts.

We have not generated any revenue from product sales, have generated only limited collaboration and grant revenue since inception, and may never be profitable in the long term.

Our ability to generate revenue and achieve profitability depends on our ability, alone or with strategic alliance partners, to successfully complete the development of, obtain the necessary regulatory approvals for and commercialize our product candidates. Our ability to generate revenues from product sales depends heavily on our success in:

- the commercialization efforts of our collaboration partner, CSL Seqirus;
- completing our research and development of product candidates;
- initiating and completing clinical trials for product candidates with favorable results;
- seeking, obtaining, and maintaining marketing approvals for product candidates that successfully complete clinical trials;
- establishing and maintaining supply and manufacturing relationships with capable parties;
- launching and commercializing product candidates for which we may obtain marketing approval, with an alliance partner or, if launched independently, successfully establishing a sales force, marketing and distribution infrastructure;
- maintaining, protecting and expanding our intellectual property portfolio; and
- attracting, hiring and retaining qualified personnel.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to predict reliably the timing or amount of increased expenses and when we will be able to achieve and maintain profitability, if ever. In addition, our expenses could increase beyond expectations if we are required by the FDA, or other foreign regulatory agencies to perform studies and trials in addition to those that we currently anticipate.

Even if our internal product candidates are approved for commercial sale, or KOSTAIVE continues to achieve approvals in more countries, we anticipate incurring significant costs associated with commercializing any approved product. Even if we generate revenues from the sale of any approved products, we may not become profitable and may need to obtain additional funding to continue operations.

We expect that we will need to raise additional capital in the future, which may not be available on acceptable terms, or at all.

Developing pharmaceutical products, including conducting studies and clinical trials, is extremely expensive. We expect our research and development expenses to substantially increase in connection with our ongoing activities, particularly as we advance our product candidates towards and through clinical trials. We expect that we

will need to raise additional capital to support our operations and such funding may not be available to us on acceptable terms, or at all. As of December 31, 2025, we had unrestricted cash and cash equivalents of $230.9 million, which we expect should be sufficient to fund currently planned operations for the near future, at least the next 12 months. But if our plans change or we face unexpected circumstances, our capital resources may be depleted more rapidly than we currently anticipate. For example, our clinical trials may encounter technical, regulatory or other difficulties. Any of these events would increase our development costs more than we expect. In order to support our long-term plans, we will need to raise additional capital or otherwise obtain funding through additional strategic alliances if we choose to initiate preclinical or clinical trials for product candidates that are not currently subject to a collaboration. In any event, we will require additional capital to obtain regulatory approval for, and to commercialize, future product candidates. Even if the results of clinical studies of our product candidates are positive, the stock market might not react favorably, which would weaken our ability to raise additional capital.

A portion of our current cash balance is expected to be utilized during fiscal year 2026 to fund (i) advances to our LUNAR-CF program in clinical trials, (ii) the continued Phase 2 trial of ARCT-810, our LUNAR-OTC candidate, (iii) expenses incurred prior to customer payments under the CSL Collaboration Agreement and BARDA agreement and (iv) continued exploratory activities related to our platform and other general administrative activities.

Any additional fundraising efforts may divert our management from our day-to-day activities, which may delay and hinder our ability to develop and commercialize future product candidates. We may be unable to raise sufficient amounts of additional capital when needed and on acceptable terms, which could require us to:

- significantly delay, scale back or discontinue the development or commercialization of any current or future product candidates;
- seek strategic alliances for research and development programs or clinical trials at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available; or
- relinquish or license on unfavorable terms, our rights to technologies or any future or current product candidates that we otherwise would seek to develop or commercialize ourselves.

We are dependent upon relationships with our collaboration partners, and the failure of these relationships could negatively affect our business and results of operations.

We are subject to a number of risks associated with our dependence on our relationships with our collaboration partners, including:

- our collaboration partners may terminate their collaboration agreements with us for reasons specified in the collaboration agreements, including our breach;
- the need for us to identify and secure on commercially reasonable terms the services of third parties to perform key activities, including development and commercialization activities, currently performed by our collaboration partners in the event that a collaboration partner was to terminate its collaboration with us;
- disagreements with our collaboration partners regarding the satisfaction of milestones;
- adverse decisions by a collaboration partner regarding the amount and timing of resource expenditures for the development, commercialization, distribution, and sale of our drug products;
- failure by a collaboration partner to perform its duties under its collaboration agreement with us (e.g., its failure to comply with regulatory requirements);
- failure by a collaboration partner to timely deliver accurate and complete financial information to us or to maintain adequate and effective internal control over its financial reporting may negatively affect our ability to meet our financial reporting obligations as required by the SEC;

- collaboration partners' and their affiliates' development and commercialization of products that compete directly or indirectly with our products or products candidates;

- decisions by a collaboration partner to prioritize other of its current or future products more highly than our drug products or our product candidates;

- possible disagreements with a collaboration partner as to the timing, nature and extent of our development plans or distribution and sales and marketing plans; and

- the financial returns to us, if any, under our collaboration agreements depend in large part on the achievement of milestones and generation of product sales, and if our partners fail to perform or satisfy their obligations under the collaboration agreement, the development and commercialization of our drug products could be delayed, hindered or may not occur and our business and prospects could be materially and adversely affected.

Due to these factors and other possible disagreements with our collaboration partners, we may be delayed or prevented from further developing, manufacturing or commercializing our drug products or our product candidates or we may become involved in litigation or arbitration, which would be time consuming and expensive.

If any collaboration partner were to terminate our collaborative relationship unilaterally, we would need to undertake development, commercialization or distribution or sale activities for our drug products and product candidates solely at our own expense, and/or seek one or more other partners for some or all of these activities worldwide. If we pursued these activities on our own, it would significantly increase our capital and infrastructure requirements, might limit the indications we are able to pursue for our drug products and our product candidates, and could prevent us from effectively developing and commercializing our drug products and our product candidates. If we sought to find one or more other pharmaceutical company partners for some or all of these activities, we may not be successful in such efforts, or they may result in collaborations that have us expending greater funds and efforts than our relationships with our current collaboration partners.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

Under the Tax Cuts and Jobs Act, as modified by the Coronavirus Aid, Relief, and Economic Security Act, or CARES Act, U.S. federal net operating losses ("NOLs") incurred in 2018 and in future years may be carried forward indefinitely, but the deductibility of such federal NOLs is limited. To the extent that we continue to generate taxable losses for United States federal income tax purposes, unused NOLs will carry forward to offset future taxable income (subject to any applicable limitations), if any. Under Sections 382 and 383 of the Internal Revenue Code, as amended, if a corporation undergoes an "ownership change," generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period, the corporation's ability to use its pre-change NOLs and other pre-change tax attributes (such as research tax credits) to offset its post-change income may be significantly limited. We believe we may have triggered an "ownership change" limitation; however, we have not completed a study in accordance with Sections 382 and 383 of the Code to determine whether this ownership change has occurred or what the possible effects of an ownership change would be on our ability to use NOLs. We may also experience ownership changes in the future as a result of subsequent shifts in our share ownership. As a result, if we earn net taxable income, our ability to use our pre-change NOL carryforwards to offset U.S. federal or state taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. Similar provisions of U.S. state tax law may also apply to limit our use of accumulated state tax attributes, including our state NOLs. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, even if we attain profitability, we may be unable to use a material portion of our NOLs and other tax attributes, which could negatively impact our future cash flows.

RISKS RELATED TO THE DEVELOPMENT AND COMMERCIALIZATION OF PRODUCT CANDIDATES

We are highly dependent upon our relationship with CSL Seqirus to further research, manufacture and commercialize self-amplifying mRNA vaccines against COVID-19, influenza and three other infectious diseases; CSL Seqirus has announced a significant write-down of the licensed collaboration programs.

In November 2022, we entered into the CSL Collaboration Agreement with CSL Seqirus, for the research, manufacture and global commercialization of self-amplifying mRNA vaccines against COVID-19, influenza and three other infectious diseases. If such relationship is unsuccessful, if CSL Seqirus terminates its collaboration agreement with us, or if we determine it is in our best interests to terminate the agreement, it could negatively impact our ability to generate net product revenue. Failure by CSL Seqirus to perform its duties under its collaboration agreement with us may negatively affect us. In CSL Limited's half-year results presented on February 11, 2026, CSL Limited reported an accounting write-down of approximately $430 million attributable to our collaboration agreement with CSL Seqirus, citing decline in the COVID-19 market and more onerous U.S. regulatory requirements. Such action and CSL's statements indicate that CSL Seqirus no longer believes that the collaboration assets will generate sufficiently probable, risk-adjusted economic benefits. The development of the licensed assets and even commercialization activity may be significantly impacted. If CSL Seqirus ceases, suspends or materially reduces development and commercialization activities of our technology under the CSL Collaboration, our business and prospects could be materially and adversely affected. Any disagreement with CSL Seqirus regarding the satisfaction of milestones, or of CSL Seqirus' obligations toward development or commercialization of the licensed programs, could result in a dispute that could result in termination of a program, and possibly costly litigation or arbitration which may divert management attention and resources.

A potential separation of CSL Seqirus could disrupt our collaboration and materially harm our business.

Reports that CSL Limited intends to separate or spin off its vaccine business, including its subsidiary CSL Seqirus, could disrupt or adversely affect our collaboration with CSL Seqirus and materially harm our business. We cannot predict the timing, terms, structure, or ultimate consummation of any potential separation, and even the announcement or pendency of such a transaction may create uncertainty and execution risk that could adversely affect CSL Seqirus's performance under our agreements and, as a result, our programs, timelines and costs. For example, a separation could lead to shifting strategic priorities, changes in management focus, or reduced access to corporate resources, capital, manufacturing networks or commercial infrastructure previously available to CSL Seqirus as part of the CSL group. In addition, any stand-alone entity may have a different risk profile, capital structure, credit quality, or appetite for development and commercial investment, which could impair its ability or willingness to satisfy funding, diligence, supply, or commercialization obligations or to continue programs that were prioritized prior to the separation.

KOSTAIVE might not have a profitable commercial market.

If the prevalence of COVID-19 and public concern about the virus continues to decline, the potential market opportunity will shrink for KOSTAIVE under our collaboration with CSL Seqirus. Further, as additional COVID-19 vaccines are approved and production of existing COVID-19 vaccines improves, there may be downward pressure on prices. Therefore, even if we and CSL Seqirus can get through the extremely costly, long and risky process of developing and obtaining regulatory approval to market a vaccine globally, it may not be commercially successful. This failure could be due to reduced demand for COVID-19 vaccines, increased regulatory hurdles, lower prices, distribution problems, competitors' products or many other reasons. Our manufacturing process for KOSTAIVE includes a step for lyophilization to enhance the stability of the vaccine product. The additional step of lyophilization adds time and costs to the overall production output, which could adversely impact the production volumes and profitability of our COVID-19 vaccines if approval to market a vaccine is achieved. Any changes to our manufacturing processes or our product format could take a long time, be expensive and be unsuccessful. It is also still unclear if the vaccines will enable adequate long-term protection, as (i) many vaccinated individuals have become ill due to "breakthrough infections" and have transmitted the virus to many others, (ii) there are millions of individuals who refuse to be vaccinated or who cannot be vaccinated due to pre-existing conditions, (iii) it is unclear how long the vaccine protection will last, and (iv) genetic mutations or variants of the virus already have had, and are expected to continue to have, an adverse impact on the efficacy of available vaccines. If we cannot, with and through our partner, develop and commercialize a vaccine that adequately addresses some of these shortcomings of vaccines currently on the market, we cannot expect to have commercial success.

KOSTAIVE only has marketing approval in Japan and Europe and may never achieve marketing approval in any other countries.

Although we have marketing approval for KOSTAIVE in Japan and Europe, we do not have approval for KOSTAIVE in any other countries and may never achieve marketing approval in any other countries. Our continued development efforts for KOSTAIVE, and the ongoing efforts to retain approval of updated versions, is dependent on the efforts of our partner, CSL Seqirus. KOSTAIVE could face increased research and development costs, including

for clinical trials, non-clinical studies and CMC, when updating COVID-19 vaccines containing new variants of concern based on WHO and FDA recommendations. If key regulatory authorities, such as the FDA, determine that our data is inadequate or unacceptable, or make the path to regulatory approval more difficult, we may not be able to achieve regulatory approval and any additional study may prove too costly for us to conduct without a strategic partner. The U.S. is the largest market for vaccines, and if we do not receive approvals to market KOSTAIVE in the U.S., the overall commercial market for KOSTAIVE could be substantially lower than the overall market of our competitors.

Even with the commercialization of KOSTAIVE in Japan, there might not be meaningful sales in Japan. Despite the approval of KOSTAIVE in Europe, KOSTAIVE has not, and might never, achieve commercialization in Europe.

We are relying on our partner, CSL Seqirus, and CSL Seqirus' partner, Meiji Seika Pharma (Meiji), to conduct further development and commercialization of KOSTAIVE in Japan. Even if KOSTAIVE continues to be commercialized in Japan, there might not be meaningful sales, due to competition, pricing, product profile, vaccine uptake by the public or other factors. To date, demand for KOSTAIVE in Japan has been weak, and future sales may decrease and our partners may decide to cease commercialization. Although KOSTAIVE has received approval in Europe, KOSTAIVE has not, and might never, achieve commercialization in Europe, due to a numbers of factors, such as the competitiveness of different product presentations and formats and the wide market penetration of existing COVID-19 vaccine makers.

There is significant competition in the COVID-19 vaccine market, some competitors' vaccines are already widely accepted in the market, and many of our competitors have substantially greater financial, scientific and other resources than we have.

Pfizer, Moderna and Novavax have received full approvals or emergency use authorization from the FDA and many other health regulatory authorities throughout the world, and other biopharmaceutical companies have received approvals or authorizations from many health regulatory authorities other than the FDA, for their COVID-19 vaccines and have already commercialized them on a large scale and have vaccinated billions of people around the world.

Even with the partnering of our COVID-19 program and initial commercialization in Japan, we are already at a significant competitive disadvantage to those companies with vaccines on the market, as well as many other competitors pursuing vaccine candidates. Many other competitors have significantly greater product candidate development, manufacturing and marketing resources than we do. Larger pharmaceutical and biotechnology companies have extensive experience in clinical testing and obtaining regulatory approval for their products, and may have the resources to heavily invest to accelerate discovery and development of their vaccine candidates. Our business could be further materially and adversely affected by our competitors' commercialization of their vaccines before our vaccine candidate is approved in various countries. If the COVID-19 vaccines of our competitors are shown to be safer, more effective against multiple variants, have fewer or less severe side effects, have broader market acceptance, are more convenient or are less expensive than any vaccine candidate than KOSTAIVE, then KOSTAIVE may not achieve any commercial success even where approved. Furthermore, if any competitors are successful in producing a more efficacious vaccine or other treatment for COVID-19, or if any competitors are able to manufacture and distribute any such vaccines or treatments with greater efficiency, there may be a diversion of potential governmental and other funding away from us and toward such other parties.

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

The biotechnology and pharmaceutical industries are intensely competitive. We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, biotechnology companies and universities and other research institutions. Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing, regulatory and manufacturing organizations. Additional mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis, drug products that are more effective, safer or less costly than any product candidate that we may develop. Our existing competitors and new market entrants may respond more quickly to or integrate new or

emerging technologies such as artificial intelligence and machine learning, undertake more extensive marketing campaigns, have greater access to clinical information to support ongoing product position in the market, have greater financial, marketing and other resources or be more successful in attracting potential customers, employees and strategic partners. There can be no assurance that any products now in development, or that we may seek to develop in the future, will achieve technological feasibility, obtain regulatory approval or gain market acceptance. If we are unable to develop and launch new products, our ability to maintain or expand our market position in the markets in which we participate may be negatively impacted. Our competitors may achieve patent protection, regulatory approval, or product commercialization that would limit our ability to compete with them. These and other competitive pressures could have a material adverse effect on our business.

If we are unable to generate successful results from preclinical and clinical studies of our product candidates, or experience significant delays in doing so, our business may be materially harmed.

Other than the approval of KOSTAIVE in Japan and Europe, we have no products approved for commercial marketing and all of our product candidates are in preclinical or clinical development. Before obtaining regulatory approval for the commercial distribution of our product candidates, we or an existing or future collaborator must conduct extensive preclinical studies and clinical trials to demonstrate the safety and efficacy of our product candidates.

The success of our product candidates will depend on several factors, including the following:

- successfully designing preclinical studies which may be predictive of clinical outcomes;
- successful enrollment in clinical trials and completion of preclinical and clinical studies with favorable results;
- receipt of marketing approvals from applicable regulatory authorities;
- obtaining and maintaining patent and trade secret protection for future product candidates;
- establishing and maintaining manufacturing relationships with third parties or establishing our own manufacturing capability; and
- successfully commercializing our products, if approved, including successfully establishing a sales force, marketing and distribution infrastructure, whether alone or in collaboration with others.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully complete the development or commercialization of our product candidates, which would materially harm our business.

Our platform focuses on nucleic acid technology, and mRNA drug products in particular, which are relatively new and any adverse results from nucleic acid or mRNA technologies in the industry could significantly impact our ability to develop and commercialize marketable products.

We have concentrated our therapeutic product research and development efforts on nucleic acid technology, and mRNA in particular, and our future success depends on the successful development and acceptance of this technology for drug products. The development and commercialization of drug products based on nucleic acid technologies, including mRNA, are relatively new. The scientific evidence to support the feasibility of developing product candidates based on these discoveries is both preliminary and limited. If nucleic acid or mRNA approaches to drug products encounter setbacks based on the safety, efficacy, distribution, costs or other factors, it will significantly hurt our prospects and the value of our common stock.

Our focus on nucleic acid technology for developing drugs as opposed to more proven technologies for drug development increases the risks associated with our business. If we are not successful in developing any product candidates using nucleic acid technology, we may be required to change the scope and direction of our product development activities. In that case, we may not be able to identify and successfully implement an alternative product development strategy.

Changes to our drug product presentation could significantly impact our timeline to commercialize our products.

Each of our products, including KOSTAIVE, has a certain drug product presentation. We evaluate and implement the product presentation attributes based on our considerations of regulatory and commercial potential, along with scientific feasibility. There can be no assurance that the product presentation or characteristics of any of

our products will be sufficient to achieve regulatory approval or commercialization per planned timelines. For example, the stability of our products and the vial presentations could impact the commercial attractiveness of a product, and different markets may favor different characteristics. Any changes to drug product formats will likely add additional cost and may delay approvals.

We may not be successful in our efforts to identify or discover potential product candidates.

The success of our business depends primarily upon our ability to identify, develop and commercialize messenger RNA medicines. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for a number of reasons, including:

- our research methodology or that of our strategic alliance partners may be unsuccessful in identifying potential product candidates;
- potential product candidates may be shown to have harmful side effects or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval; or
- our strategic alliance partners may change their development profiles for potential product candidates or abandon a therapeutic area.

If any of these events occur, we may be forced to abandon our development efforts for a program or programs, which would have a material adverse effect on our business and could potentially cause us to cease operations. Research programs to identify new product candidates require substantial technical, financial and human resources. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful.

If clinical trials of our product candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

Before obtaining marketing approval from regulatory authorities for the sale of product candidates, we or our strategic alliance partners must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidates in humans. Clinical trials are expensive, difficult to design and implement, can take many years to complete and are uncertain as to the outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical studies and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval for their products. Furthermore, even if prior animal studies have demonstrated the potential safety and efficacy of our product candidates, there can be no guarantee that such results will be reproducible in preclinical studies and clinical trials involving human subjects.

Events which may result in a delay or unsuccessful completion of clinical development include:

- delays in reaching an agreement with the FDA or other regulatory authorities on final trial design;
- delays in submitting or acceptance of, an application for authorization to administer an investigational new drug product to humans through the submission or acceptance of an IND application to the FDA, or foreign regulatory authority;
- imposition of a clinical hold of our clinical trial operations or trial sites by the FDA or other regulatory authorities;
- delays in reaching agreement on acceptable terms with prospective contract research organizations (“CROs”) and clinical trial sites;
- our inability to adhere to clinical trial requirements directly or with third parties such as CROs;
- clinical trial site or CRO non-compliance with GCPs, GLPs, or other regulatory requirements;
- inability or failure of clinical trial sites to adhere to the clinical trial protocol;

- delays in obtaining required IRB approval at each clinical trial site, or an IRB suspending or terminating a trial;
- delays in recruiting suitable patients to participate in a trial;
- delays in the testing, validation, manufacturing and delivery of the product candidates to the clinical sites;
- delays in having patients complete participation in a trial or return for post-treatment follow-up;
- delays caused by patients dropping out of a trial due to protocol procedures or requirements, product side effects or disease progression;
- clinical sites dropping out of a trial to the detriment of enrollment;
- time required to add new clinical sites; or
- delays by our contract manufacturers to produce and deliver sufficient supply of clinical trial materials.

If we or our strategic alliance partners are required to conduct additional clinical trials or other testing of any product candidates beyond those that are currently contemplated, are unable to successfully complete clinical trials of any such product candidates or other testing, or if the results of these trials or tests are not positive, are only modestly positive or if there are safety concerns, we or our strategic alliance partners may:

- be delayed in obtaining marketing approval for our future product candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as originally intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to additional post-marketing testing requirements; or
- have the product removed from the market after obtaining marketing approval.

Our product development costs will also increase if we experience delays in testing or marketing approvals. We face risks that clinical trials may not begin as planned, may need to be restructured or may not be completed on schedule, or at all. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or could allow our competitors to bring products to market before we do, which would impair our ability to successfully commercialize our product candidates. Any inability to timely and successfully complete preclinical and clinical development, whether independently or with our strategic alliance partners, could result in additional costs to us or impair our ability to generate revenues from product sales, regulatory and commercialization milestones and royalties.

We may find it difficult to identify and enroll patients in our clinical studies, and the limited number of patients who have the diseases for which certain of our product candidates are being studied could delay or prevent clinical studies of certain of our product candidates.

Identifying and qualifying patients to participate in clinical studies of our product candidates is critical to our success. The timing of our clinical studies depends in part on the speed at which we can recruit patients to participate in testing our product candidates, and we may experience delays in our clinical studies if we encounter difficulties in enrollment.

In addition, certain conditions for which we plan to evaluate our current product candidates are rare genetic diseases, and have limited patient pools from which to draw for clinical studies. For example, we estimate that approximately 8,000 patients in the developed world suffer from late-onset OTC deficiency, for which LUNAR-OTC is being studied. In addition to the rarity of these diseases, the eligibility criteria of our clinical studies will further limit the pool of available study participants as we will require patients to have specific characteristics that we can measure or to assure their disease is either severe enough or not too advanced to include them in a study. The process of finding and diagnosing patients may prove costly, especially since the rare diseases we are studying are commonly underdiagnosed. We also may not be able to identify, recruit, and enroll a sufficient number of appropriate patients to complete our clinical studies because of demographic criteria for prospective patients, the

perceived risks and benefits of the product candidate under study, the proximity and availability of clinical study sites for prospective patients, and the patient referral practices of physicians. The availability and efficacy of competing therapies and clinical studies can also adversely impact enrollment.

If we are unable to promptly enroll an adequate number of patients in our studies for the foregoing or other reasons, the timeline for conducting studies and obtaining regulatory approval of potential products will be delayed, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenue from any of these product candidates could be delayed or prevented. Furthermore, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical studies may also ultimately lead to the denial of regulatory approval of our product candidates. Delays in achieving approval to conduct and in completing our clinical studies will increase our costs, slow down our product candidate development and approval process, and jeopardize our ability to commence product sales and generate revenue. Any of these occurrences may harm our business, financial condition, and prospects significantly.

If any of our product candidates cause undesirable side effects or have other properties impacting safety, approvals to proceed with further clinical trials may be denied or delayed and regulatory approval could be prevented, delayed or limited.

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials, or to deny or delay approvals to proceed with further clinical trials, and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other regulatory authorities. It is likely that there will be side effects associated with use of our product candidates. If results of our trials reveal a high and unacceptable severity and prevalence of side effects, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of, or deny approval of, our product candidates for any or all targeted indications. Such side effects could also affect patient recruitment, the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may materially and adversely affect our reputation and financial condition.

Further, clinical trials by their nature test product candidates in only samples of the potential patient populations. With a limited number of patients and limited duration of exposure in such trials, rare and severe side effects of our product candidates may not be uncovered until a significantly larger number of patients are exposed to the product candidate.

If any of our product candidates receives marketing approval, and causes serious, unexpected, or undesired side effects, a number of potentially significant negative consequences could result after we begin commercialization, including:

- regulatory authorities may withdraw, suspend, or limit their approval of the product or impose restrictions on its distribution in the form of a modified risk evaluation and mitigation strategy;
- regulatory authorities may require the addition of labeling statements, such as warnings or contraindications;
- we may be required to change the way the product is administered or conduct additional clinical trials or post-marketing surveillance;
- we could be sued and held liable for harm caused to patients; or
- our reputation may suffer.

Any of these events could prevent us or our partners from achieving or maintaining market acceptance of the affected product and could substantially increase the costs of commercializing our future products and impair our ability to generate revenues from the commercialization of these products either by us or by our strategic alliance partners.

Even if we complete the necessary preclinical studies and clinical trials, we are required to obtain regulatory approval to commercialize a product candidate and we cannot, therefore, predict the timing of any revenue from a future product.

The extent and timing of any product revenue is highly unpredictable because regulatory authorities may not complete their review processes in a timely manner, or we may not be able to obtain regulatory approval for many reasons including:

- regulatory authorities disagreeing with the design or implementation of our clinical trials;
- such authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- such authorities may not accept clinical data from trials which are conducted at clinical facilities or in countries where the standard of care is potentially different from that of the United States, such as our phase 1/2/3 clinical trial of ARCT-154 conducted in Vietnam;
- unfavorable or unclear results from our clinical trials or results that may not meet the level of statistical significance required by the FDA or foreign regulatory agencies for approval;
- serious and unexpected drug-related side effects experienced by participants in our clinical trials or by individuals using drugs similar to our product candidates;
- the population studied in the clinical trial may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- such authorities may not agree that the data collected from clinical trials of our product candidates are acceptable or sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere, and such authorities may impose requirements for additional preclinical studies or clinical trials;
- such authorities may disagree regarding the formulation, labeling and/or the specifications of our product candidates;
- such authorities may find deficiencies in the manufacturing processes or facilities of manufacturers with which we contract for clinical and commercial supplies; or
- regulations or interpretations of such authorities may significantly change in a manner rendering our or any of our potential future collaborators' clinical data insufficient for approval.

Additional delays may result if an FDA advisory committee recommends restrictions on approval or recommends non-approval. In addition, we or our strategic alliance partners may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory agency policy during the period of product development, clinical trials and the review process.

Our rare disease candidates, even if approved, might not have a profitable commercial market.

Rare diseases, by definition, have a relatively small population of patients, thereby limiting the potential market size and increasing pressure on the pricing of drug products in order to have a profitable market opportunity. Further, our rare disease therapeutic candidates require dosing of drug substance in far greater quantities than in our vaccine candidates, which significantly increases the costs of manufacture. Such factors, along with political and societal pressure to minimize pricing, could impact the ability of our products to have sustainable and profitable commercial markets. Therefore, even if we can get through the extremely costly, long and risky process of developing and obtaining regulatory approval to market a drug candidate, it may not be commercially successful.

Current regulatory authorities in the United States may change or institute policies that increase challenges for clinical development, regulatory approval and commercialization of our vaccine and other programs

Leadership and policy priorities at the HHS and the FDA have changed and may continue to evolve, which could result in modifications to regulatory requirements, approval standards or development pathways applicable to vaccines and therapeutic products. Although certain regulatory initiatives may be intended to streamline development, recent FDA guidance has adversely affected the timing and expected costs of our programs. On September 5, 2025, the week prior to our planned submission of a Biologics License Application for KOSTAIVE, the FDA requested that we delay our submission and in October 2025 informed us that, although the FDA had previously agreed that our proposed data package could support a single-dose indication, upon further consideration it found that additional data from a clinical endpoint efficacy will be needed based on a revised COVID-19 vaccine regulatory framework. In addition, changes in governmental policies, funding priorities, or staffing levels, including reductions in force or work stoppages affecting federal agencies, could delay regulatory review processes or

otherwise negatively impact the development, approval or commercialization of our product candidates. Any such developments could materially adversely affect our business, financial condition and results of operations.

Even if we obtain regulatory approval for a product candidate, we will still face extensive regulatory requirements and our products may face future development and regulatory difficulties.

Even if we obtain regulatory approval in the United States, the FDA may still impose significant restrictions on the indicated uses or marketing of our product candidates, or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance. The FDA may also require a risk evaluation and mitigation strategy as a condition of approval of our product candidates, which could include requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Additionally, the manufacturing processes, packaging, distribution, adverse event reporting, labeling, advertising, promotion, and recordkeeping for the product will be subject to extensive and ongoing FDA regulatory requirements, in addition to other potentially applicable federal and state laws. These requirements include monitoring and reporting of adverse events and other post-marketing information and reports, registration, as well as continued compliance with current good manufacturing practice, or cGMP, regulations. The holder of an approved NDA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. If we or a regulatory agency discovers previously unknown problems with a product such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions relative to that product or the manufacturing facility, including requiring recall or withdrawal of the product from the market or suspension of manufacturing.

If we or our strategic partners fail to comply with applicable regulatory requirements following approval of any of our product candidates, a regulatory agency may:

- issue a warning letter asserting that we are in violation of the law;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve a pending NDA or supplements to an NDA submitted by us;
- seize product or require a product recall; or
- refuse to allow us to enter into supply contracts, including government contracts.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize our future products, if approved, and generate revenues.

We may use our financial and human resources to pursue a particular research program or product candidate and fail to capitalize on programs or product candidates that may be more profitable or for which there is a greater likelihood of success.

As a result of our limited financial and human resources, we will have to make strategic decisions as to which targets and product candidates to pursue and may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through strategic alliance, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate, or we may allocate internal resources to a product candidate in a therapeutic area in which it would have been more advantageous to enter into a partnering arrangement.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our

operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed applicable insurance coverage we may have as well as our financial resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials or other work-related injuries, this insurance may not provide adequate coverage against potential liabilities. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Manufacturing issues may arise that could increase product and regulatory approval costs or delay or hinder commercialization.

As we scale-up manufacturing of product candidates and conduct required stability testing, product, packaging, equipment and process-related issues may require refinement or resolution in order to proceed with any clinical trials and obtain regulatory approval for commercial marketing. We may identify significant impurities, which could result in increased scrutiny by the regulatory agencies, delays in clinical programs and regulatory approval, increases in our operating expenses, or failure to obtain or maintain approval for product candidates or any approved products. The robustness of our manufacturing supply chain to support commercial distribution has not been meaningfully tested. Furthermore, we are required by our contract manufacturers to make financial commitments in advance of the receipt of clinical data or feedback from regulatory authorities, which could result in significant financial obligations.

The commercial success of our product candidates will depend in part upon the acceptance of our product candidates by the medical community, including physicians, patients and healthcare payors.

The degree of market acceptance of any product candidates will depend on a number of factors, including:

- demonstration of clinical safety and efficacy compared to other products;
- the relative convenience, ease of administration and acceptance by physicians, patients and healthcare payors;
- the prevalence and severity of any adverse events;
- limitations or warnings contained in the FDA-approved label for such products;
- availability of alternative treatments;
- pricing and cost-effectiveness;
- the commercial packaging and product presentation preferences;
- the effectiveness of our, or any of our collaborators', sales and marketing strategies;
- our ability to obtain hospital or payor formulary approval;
- our ability to obtain and maintain sufficient coverage from healthcare payors and adequate reimbursement; and
- the willingness of patients to pay out-of-pocket in the absence or inadequacy of coverage by healthcare payors.

Unless other formulations are developed in the future, we expect our compounds to be formulated in an injectable or inhalable form. Injectable medications may be disfavored by patients or their physicians in the event drugs which are easy to administer, such as oral medications, are available. If any of our products is approved, but does not achieve an adequate level of acceptance by physicians, patients and healthcare payors, we may not generate sufficient revenues from such product and we may not become or remain profitable. Such increased competition

may decrease any future potential revenue for future product candidates due to increasing pressure for lower pricing and higher discounts in the commercialization of our product.

If we are unable to establish cost-effective sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may be unable to generate any revenues from product sales.

In order to market any products that may be approved, we must build our sales, marketing, managerial and other non-technical capabilities or make arrangements with outside parties to perform these services. With respect to certain of our current programs as well as future programs, we may rely completely on a strategic alliance partner for sales and marketing. In addition, we intend to enter into strategic alliances with other parties to commercialize other product candidates, if approved, including in markets outside of the United States or for other large markets that are beyond our resources. Although we might establish a sales organization if we are able to obtain approval to market any product candidates for niche markets in the United States, we will also consider the option to enter into strategic alliances for future product candidates in the United States if commercialization requirements exceed our available resources. This will reduce the potential profit generated from the sales of these products.

Our current and any future strategic alliance partners may not dedicate sufficient resources to the commercialization of our product candidates, if approved, or may otherwise fail in their commercialization due to factors beyond our control. If we are unable to establish effective alliances to enable the sale of our product candidates, if approved, to healthcare professionals and in geographical regions, including the United States, that will not be covered by our own marketing and sales force, or if our potential future strategic alliance partners do not successfully commercialize the product candidates that may be approved, our ability to generate revenues from product sales will be adversely affected.

If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate sufficient product revenue and may not become profitable. We will be competing with many companies that currently have extensive and well-funded marketing and sales operations. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

KOSTAIVE has received marketing approval in Japan and Europe, and might in the future receive approvals in other countries outside of the United States. A variety of risks associated with international operations could materially adversely affect our business.

KOSTAIVE has received marketing approval in Japan and Europe and may expand into other countries outside of the United States for such product and for future potential products. As a result, we are and expect that we will be subject to additional risks related to entering into international business relationships, including:

- different regulatory requirements for drug approvals in foreign countries;
- differing payor reimbursement regimes, governmental payors or patient self-pay systems and price controls;
- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- 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; and

- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

Tariffs could adversely affect our business and financial results.

We purchase components of our product candidates, including raw materials, from U.S. domestic sources, as well as various global sources including but not limited to those located in the People's Republic of China ("PRC"), Japan, Austria, Germany, and the United Kingdom. The current U.S. presidential administration has proposed the implementation of a number of tariffs, including tariffs on products and materials from PRC, which could increase our production costs. If tariffs make purchases of materials from certain jurisdictions untenable, we may also need to obtain materials from other sources, when possible, which could also increase our costs and delay our planned clinical trials and manufacture of our products and product candidates. Any of these factors may adversely affect our financial condition or results of operations.

If coverage and adequate reimbursement is not available for any of our future products, it would be difficult for us to sell that product profitably.

Market acceptance and sales of any product candidates that we develop will depend on coverage and reimbursement policies and may be affected by future healthcare reform measures. Government authorities and third-party payors, such as private health insurers, government payors and health maintenance organizations, decide which drugs they will pay for and establish reimbursement levels. We cannot be sure that coverage and adequate reimbursement will be available for any future product candidates. In the United States, the Centers for Medicare & Medicaid Services ("CMS"), an agency within the U.S. Department of Health and Human Services, decides whether and to what extent a new drug will be covered and reimbursed under Medicare. Private payors tend to follow the coverage reimbursement policies established by CMS to a substantial degree. It is difficult to predict what CMS will decide with respect to reimbursement for novel product candidates. Inadequate reimbursement amounts could substantially reduce the demand for, or the price of, our future products. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. If reimbursement is not available, or is available only at limited levels, we may not be able to successfully commercialize product candidates that we develop and that may be approved. Thus, even if we succeed in bringing a product to market, it may not be considered medically necessary or cost-effective, and the amount reimbursed for any products may be insufficient to allow us to sell our products on a competitive basis.

RISKS RELATED TO OUR RELIANCE ON OUTSIDE PARTIES

If our strategic alliances are unsuccessful or are terminated, we may be unable to commercialize certain product candidates and generate revenues.

We depend on alliance partners for financial and scientific resources for the clinical development, manufacture and commercialization of certain of our product candidates. Under these alliances we are likely to have limited influence and control over their approaches to development and commercialization. If strategic alliance partners do not perform in the manner that we expect or fail to fulfill their responsibilities in a timely manner, or at all, the clinical development, regulatory approval and commercialization efforts related to product candidates we have licensed to such strategic alliance partners could be delayed or terminated. These alliances will likely provide us with limited control over the course of development of a product candidate, especially once a candidate has reached the stage of clinical development. Our ability to ultimately recognize revenue from our strategic relationships will depend upon the ability and willingness of our alliance partners to successfully meet their respective responsibilities under our agreements with them.

Our ability to recognize revenues from strategic alliances may be impaired by several factors, including:

- an alliance partner may shift its priorities and resources away from our programs due to a change in its business strategies whether or not permitted under agreement with them, or a merger, acquisition, sale or downsizing of its company or business unit;
- an alliance partner may cease development in therapeutic areas which are the subject of our strategic alliances;
- an alliance partner may change the success criteria for a particular program or potential product candidate thereby delaying or ceasing development of such program or candidate;

- a significant delay in initiation of certain development activities by an alliance partner will also delay payment to us of milestones tied to such activities, thereby impacting our ability to fund our own activities;
- an alliance partner with commercialization obligations may not commit sufficient financial or human resources to the marketing, distribution or sale of a product;
- an alliance partner with manufacturing responsibilities may encounter regulatory, resource or quality issues and be unable to meet demand requirements;
- an alliance partner may exercise its rights under the agreement to terminate a strategic alliance;
- a dispute may arise between us and an alliance partner concerning the research, development or commercialization of a program or product candidate resulting in a delay in payments of milestones or royalties, or the termination of a program, and possibly resulting in costly litigation or arbitration which may divert management attention and resources; and
- an alliance partner may use our proprietary information or intellectual property in such a way as to invite litigation from a third party or fail to maintain or prosecute intellectual property rights such that our rights in such property are jeopardized.

If any of our alliance partners do not elect to pursue the development and commercialization of our development candidates or if they terminate the strategic alliance, then, depending on the event:

- development of product candidates subject to our alliances may be terminated or significantly delayed;
- our cash expenditures could increase significantly if it is necessary for us to hire additional employees and allocate limited resources to the development and commercialization of product candidates that were previously funded, or expected to be funded, by our alliance partners;
- we could bear the risks and costs related to the further development and commercialization of product candidates that were previously the subject of our strategic alliance, including the reimbursement of third parties; and
- in order to fund further development and commercialization, we may need to seek out and establish alternative strategic alliances with other parties; this may not be possible, or we may not be able to do so on terms which are acceptable to us, in which case it may be necessary for us to limit the size or scope of one or more of our programs, increase our expenditures, or seek additional funding by other means.

Any of these events would have a material adverse effect on our results of operations and financial condition.

A potential separation of CSL Seqirus could disrupt our collaboration and materially harm our business.

Reports that CSL Limited intends to separate or spin off its vaccine business, including its subsidiary CSL Seqirus, could disrupt or adversely affect our collaboration and materially harm our business. We are party to a strategic collaboration with CSL Seqirus for the development and commercialization of mRNA vaccines for COVID-19, influenza and certain other infectious diseases. We cannot predict the timing, terms, structure, or ultimate consummation of any potential separation, and even the announcement or pendency of such a transaction may create uncertainty and execution risk that could adversely affect CSL Seqirus's performance under our agreements and, as a result, our programs, timelines and costs. For example, a separation could lead to shifting strategic priorities, changes in management focus, or reduced access to corporate resources, capital, manufacturing networks or commercial infrastructure previously available to CSL Seqirus as part of the CSL group. In addition, any stand-alone entity may have a different risk profile, capital structure, credit quality, or appetite for development and commercial investment, which could impair its ability or willingness to satisfy funding, diligence, supply, or commercialization obligations or to continue programs that were prioritized prior to the separation.

If the outside contractors we rely on to conduct some aspects of our compound formulation, research and studies do not perform satisfactorily and meet deadlines, development of our product candidates could be delayed or precluded.

We do not independently conduct all aspects of our drug discovery activities, compound formulation research or preclinical and clinical studies of product candidates. We currently rely and expect to continue to rely on outside

contractors to conduct some aspects of our preclinical and clinical studies and formulation development, but we remain responsible for ensuring that each of our IND-enabling studies and clinical trials are conducted in accordance with the study plan and protocols for the trial.

If these outside parties terminate their engagements with us or do not successfully carry out their contractual duties, meet expected deadlines or conduct our studies in accordance with regulatory requirements or our stated study plans and protocols, we will not be able to complete, or may be delayed in completing, the necessary preclinical studies to enable us or our strategic alliance partners to select viable product candidates for IND submissions and will not be able to, or may be delayed in our efforts to, successfully develop and commercialize such product candidates.

If the contract manufacturers we rely on to produce the supply of our preclinical and clinical product candidates, including materials for the manufacture of our product candidates do not timely deliver adequate quantities of quality materials, development and commercialization of our product candidates would be hindered.

We rely on outside contractors to produce the supply of our preclinical and clinical product candidates, and we intend to rely on outside contractors to produce future clinical supplies of product candidates and commercial supplies of any approved product candidates. Reliance on outside suppliers and manufacturers entails risks, some of which we would not be subject to if we manufactured the product candidates ourselves, including:

- the inability to meet any product specifications and quality requirements consistently;
- a delay or inability to procure or expand sufficient manufacturing capacity;
- manufacturing and product quality issues related to scale-up of manufacturing;
- costs and validation of new equipment and facilities required for scale-up;
- a failure to comply with cGMP and similar foreign standards;
- the inability to negotiate manufacturing or supply agreements with outside parties on commercially reasonable terms;
- termination or nonrenewal of manufacturing agreements with outside parties in a manner or at a time that is costly or damaging to us;
- the reliance on a limited number of sources, and in some cases, single sources for raw materials, such that if we are unable to secure a sufficient supply of these product components, we will be unable to manufacture and sell future product candidates in a timely fashion, in sufficient quantities or under acceptable terms;
- the lack of qualified backup suppliers for any raw materials that are currently purchased from a single source supplier;
- operations of our contract manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier;
- carrier disruptions or increased costs that are beyond our control; and
- the failure to deliver products under specified storage conditions and in a timely manner.

Any of these events could lead to clinical study delays or failure to obtain regulatory approval, or impact our ability to successfully commercialize future products, if approved. Some of these events could be the basis for detrimental FDA action, including injunction, product recall or seizure, or total or partial suspension of production.

Any disruption in the supply chain of raw materials for, or in the manufacturing capacity and timing for the manufacture of drug substance or drug product for, our product candidates may cause a delay in developing and commercializing these product candidates and limit the revenues that we could generate.

We have established manufacturing relationships with a limited number of suppliers to supply raw materials used to create our product candidates and with a limited number of contract manufacturers to manufacture drug substance and drug product. The availability of continued supply and manufacturing capacity from our current vendors, and the availability of additional suppliers and manufacturers, is limited. We have and may continue to experience some supplier shortages and delivery delays. If our vendors fail to supply materials or to manufacture

substances or products in the required quantities on a timely basis and at commercially reasonable prices, and we are unable to secure one or more replacement vendors in a timely manner at a substantially equivalent cost, our clinical trials may be delayed, and our commercialization prospects could be materially diminished.

Prior to marketing approval for any of our product candidates, a manufacturer and its processes are required to be qualified by the FDA. If supply from the approved manufacturer is interrupted, there could be a significant disruption in our sales of any product. An alternative vendor would need to be qualified through an NDA supplement which could result in further delay. The FDA or other regulatory agencies outside of the United States may also require additional studies if a new supplier is relied upon for commercial production. Switching vendors may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

In addition, if our alliance partners elect to control manufacturing for certain programs, we may lose control over the manufacturing activities for the product candidate, which would reduce our level of manufacturing process development and would make the success of such programs dependent on our partners' ability to manufacture timely and properly.

If the contract research organizations and clinical trial sites we rely on to conduct, supervise and monitor our clinical trials perform in an unsatisfactory manner, it may harm our business.

We and our strategic alliance partners rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials. We and our strategic alliance partners have limited control or influence over their actual performance, but remain responsible for ensuring that clinical trials are conducted in accordance with the applicable protocol, legal, regulatory and scientific standards.

If we or our CROs fail to comply with applicable good clinical practices, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or applicable non-U.S. regulatory agency may require us to perform additional clinical trials before approving any marketing applications. In addition, our future clinical trials will require a sufficiently large number of test subjects to adequately evaluate the safety and effectiveness of a potential drug product. Accordingly, if our CROs fail to comply with these regulations or fail to recruit a sufficient number of patients, we may be required to repeat such clinical trials, which would delay the regulatory approval process and increase our costs.

Our CROs are not our employees, and we are not able to control whether or not they devote sufficient time and resources to our clinical and nonclinical programs. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities, which could possibly harm our competitive position. If our future CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements, or for any other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize our product candidates. As a result, the commercial prospects for such products and any product candidates that we develop would be harmed, our costs could increase, and our ability to generate revenues could be delayed.

We rely on other outside parties to store and distribute drug products for clinical trials. Any performance failure or delays by our distributors could delay clinical development, marketing approval or commercialization of our product candidates, resulting in additional losses and depriving us of potential product revenue.

RISKS RELATED TO OUR INTELLECTUAL PROPERTY

If we are unable to obtain or protect intellectual property rights related to our products and product candidates, we may not be able to compete effectively in our markets.

Our success depends in part on our ability to obtain and maintain patents and other forms of intellectual property rights, including in-licenses of intellectual property rights of others, for our product candidates, methods used to develop and manufacture our product candidates and methods for treating patients using our product candidates, as well as our ability to preserve our trade secrets, to prevent third parties from infringing upon our proprietary rights and to operate without infringing upon the proprietary rights of others. The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be highly uncertain. The patent applications that we own or in-license may fail to result in patents with claims that cover our products or methods in the United States or in other countries.

Our patents could be prevented from issuing or be invalidated after issuance for many reasons, including:

- relevant prior art relating to our patents and patent applications; or
- third party challenges to their validity, enforceability or scope, which may result in patents being narrowed or invalidated.

If the patent applications we hold or have in-licensed with respect to our programs or product candidates fail to issue or are invalidated or if their breadth or strength of protection is threatened, it could dissuade companies from collaborating with us to develop product candidates, and threaten our ability to commercialize, future products.

If we do not prevail in any challenge to our intellectual property rights, we could be required to cease using the related technology or to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license at all, or on commercially reasonable terms. Our defense of a patent or patent application in such a proceeding may not be successful and, even if successful, may result in substantial costs and distract our management and other employees. Even if our patents are issued and are not challenged or invalidated, our patents and patent applications may not adequately protect our intellectual property or products, or prevent others from designing around our claims. In addition, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords is limited. Once the patent life has expired for a product, we may be open to competition from generic medications. Further, if we encounter delays in regulatory approvals, the period during which we could market a product candidate under patent protection could be reduced.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect certain proprietary know-how, including processes for which patents are difficult to enforce, elements of our drug discovery and development processes and elements of our proprietary manufacturing processes. Although each of our employees agrees to assign their inventions to us through an employee inventions agreement, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology are required to enter into confidentiality agreements, such agreements may not be effective in preventing our trade secrets and other confidential proprietary information from being disclosed or accessed by competitors. In addition, competitors and others may independently discover our trade secrets and proprietary information or independently develop substantially equivalent information and techniques, and regulatory agencies may require additional disclosures of proprietary know-how.

Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent material disclosure of the non-patented intellectual property related to our technologies to third parties, and there is no guarantee that we will have any such enforceable trade secret protection, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business.

Claims that we infringe the intellectual property rights of others, especially in the crowded and competitive field of mRNA and delivery technology patents, may prevent or delay our development and commercialization efforts.

As the biotechnology and pharmaceutical industries expand and more patents are issued and as our activities expand and mature, the risk increases that our product candidates and activities may be subject to claims of infringement of the patent rights of others. This risk is significantly heightened because of the many patents and other intellectual property rights related to messenger RNA and its delivery.

Prior to and since the outbreak of the COVID-19 pandemic, many companies have devoted substantial effort to developing vaccines and therapeutics that use mRNA technology and have developed their own intellectual property rights, applied for patents, and licensed rights to patents held by other companies or research institutions. Some of these patents may have broad claims that cover our current or expected activities.

We are aware of patent challenging and enforcement activities in connection with technologies used in mRNA-based COVID-19 vaccines. The outcomes of such activities and the advancement of our programs could give rise to third party claims of infringement against us and our partners.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our and our partners' ability to further develop and commercialize products based on our platform. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of

employee and financial resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay significant royalties, or try to redesign our infringing products, which may be impossible or require substantial time and monetary expenditure, further delaying and commercialization and substantially reducing potential market revenue. In order to continue development, manufacture or sale of a product, we may need to obtain a license from the owner of intellectual property, which may not be available on commercially reasonable terms or at all.

If we fail to obtain licenses to necessary intellectual property or do not comply with our obligations in license agreements, we could lose important rights.

We may need to obtain licenses from owners of intellectual property to advance our research or allow commercialization of our product candidates, and we have done so from time to time. If we fail to obtain any of these licenses at a reasonable cost and on reasonable terms, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensees, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our patents or the patents of our licensees. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or of our licensees is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.

Our defense in a lawsuit may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensees, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during the course of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock.

We have filed a lawsuit alleging trade secret misappropriation and breach of contract, and any unfavorable outcome or related proceedings could materially and adversely affect our business, financial condition, results of operations, and reputation.

On September 23, 2025, we filed a lawsuit in the United States District Court for the Southern District of California against AbbVie Inc., Capstan Therapeutics, Inc., and other defendants asserting claims for trade secret misappropriation and breach of contract. The defendants filed a motion to discuss the complaint in December 2025, and we filed an opposition to that motion in January 2026. The Court has not set a case schedule. Litigation is inherently uncertain, time-consuming, and costly. We may not prevail on our claims, and the defendants may assert counterclaims against us, including challenges to our intellectual property or allegations of our own misconduct, any of which could result in adverse rulings, monetary judgments, fee or cost awards, or other relief that may be material. Even if we are successful in whole or in part, the litigation could result in substantial expense, divert management's attention and operational resources, disrupt relationships with partners, collaborators, or customers, and require the disclosure of sensitive information in discovery that could diminish the value of our trade secrets or other confidential information. The court could deny our requested relief, limit the scope of our asserted rights, or otherwise issue rulings that adversely affect our ability to protect, use, or commercialize our intellectual property and technology. In addition, associated proceedings, including motions practice, discovery disputes, and potential appeals, could be protracted and unpredictable, particularly given that the court has not yet established a case schedule. Any of these outcomes could negatively impact our competitive position, delay or impede our research, development, manufacturing, or commercialization activities, and result in increased legal and compliance costs. As a result, this litigation and any related proceedings could materially and adversely affect our business, financial condition, cash flows, and results of operations.

If we are subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties, we could incur substantial expenses.

We employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. We may also be subject to claims that former employers or other parties have an ownership interest in our patents. Litigation may be necessary to defend against these claims. We may not be successful in defending these claims, and if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees.

Certain of our patents are, and our future owned and in-licensed patents may be, discovered through government funded programs and thus may subject to federal regulations such as "march-in" rights, certain reporting requirements and a preference for U.S.-based companies, and the exercise of such "march-in" rights by the U.S. government could harm our business, financial conditions, results of operations and prospects.

Certain of our patents have been, and our future owned and in-licensed patents may be, discovered through government funded programs. As a result, the U.S. government may have certain rights to intellectual property embodied in our current or future products pursuant to the Bayh-Dole Act of 1980 (the "Bayh-Dole Act"), and implementing regulations, which are amended from time to time. On December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. These U.S. government rights in certain inventions developed under a government-funded program include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right to require us or our licensors to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations, which are also referred to as "march-in rights." The U.S. government also has the right to take title to these inventions if we, or the applicable licensor, fail to disclose the invention to the government and fail to file an application to register the intellectual property within specified time limits. If the U.S. government decides to exercise these rights, it is not required to engage us as its contractor in connection with doing so. To the extent any of our current or future intellectual property is generated through the use of U.S. government funding, the provisions of the Bayh-Dole Act may similarly apply. Any exercise by the government of any of the foregoing rights could harm our business, financial condition, results of operations and prospects.

RISKS RELATED TO OUR BUSINESS OPERATIONS AND INDUSTRY

We may need to expand our organization and may experience difficulties in managing this growth, which could disrupt our operations.

As of December 31, 2025, we had approximately 111 employees. In the future we may expand our employee base to increase our managerial, scientific, operational, commercial, financial and other resources and we may hire more consultants and contractors. Future growth would impose significant additional responsibilities on our management, including the need to identify, recruit, maintain, motivate and integrate additional employees, consultants and contractors. Also, our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure or give rise to operational mistakes, loss of business opportunities, loss of employees or reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. Moreover, if our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow revenues could be reduced, and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize product candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth.

If we cannot continue to attract, retain and motivate key executives and qualified scientists and other personnel, we will not be able to effectively operate our business.

We are highly dependent on principal members of our executive team, and any reduction or loss of their services may adversely impact the achievement of our objectives. While we have entered into employment

agreements with each of our executive officers, any of them could leave our employment at any time, as all of our employees are "at will" employees. Recruiting and retaining other qualified employees for our business, including scientific and technical personnel, will also be critical to our success. We have in the past experienced a high number of resignations, which could recur. Competition for skilled personnel is intense and the turnover rate can be high, as we have recently seen. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical companies for individuals with similar skill sets. In addition, failure to succeed in preclinical studies and clinical trials may make it more challenging to recruit and retain qualified personnel. The inability to recruit any executive or key employee or the loss of the services of any executive or key employee might impede the progress of our research, development and commercialization objectives.

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of employee fraud or other misconduct. Employee misconduct could have significant negative impacts on our business. Misconduct by employees could include intentional or nonintentional failures to comply with the regulations of the FDA and other regulators, to provide accurate information to the FDA and other regulators, to comply with healthcare fraud and abuse laws and regulations in the United States and abroad, to report financial information or data accurately or to disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices.

Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. Although we have adopted a code of conduct and procedures, we may not always be effective in identifying and deterring employee misconduct, controlling unknown or unmanaged risks or losses, or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations.

If we do not fully comply with applicable healthcare fraud and abuse laws, false claims laws and health information privacy and security laws, we could face criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our operations may be directly, or indirectly through our customers, further subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act (the "FCA"). These laws may impact, among other things, our proposed sales, marketing and education programs. In addition, we may be subject to patient privacy regulation by the federal government and by the U.S. states and foreign jurisdictions in which we conduct our business. The healthcare laws and regulations that may affect our ability to operate include:

- The federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, either the referral of an individual, or the purchase or recommendation of an item or service for which payment may be made under a federal healthcare program, such as the Medicare and Medicaid programs. Remuneration has been interpreted broadly to include anything of value. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and those activities may be subject to scrutiny or penalty if they do not qualify for an exemption or safe harbor. A conviction for violation of the Anti-Kickback Statute requires mandatory exclusion from participation in federal healthcare programs. This statute has been applied to arrangements between pharmaceutical manufacturers and those in a position to purchase products or refer others, including prescribers, patients, purchasers and formulary managers. In addition, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (the "ACA"), amended the Social Security Act to provide that the United States 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 civil FCA penalties for which are described below.
- Federal civil and criminal false claims laws and civil monetary penalty laws, including the FCA, which imposes criminal or civil penalties, including through civil whistleblower or qui tam actions, against

individuals or entities for, among other things, knowingly presenting, or causing to be presented, claims for payment to the federal government, including Medicare or Medicaid, that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. FCA liability is potentially significant in the healthcare industry because the statute provides for treble damages and mandatory penalties.

- The civil monetary penalties statute, which imposes penalties against any person or entity who, among other things, is determined to have presented or caused to be presented a claim to a federal healthcare program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.
- The federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which imposes civil and criminal penalties for, among other things, 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 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), knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a healthcare offense and knowingly and willfully falsifying, concealing or covering up 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.
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH"), and its implementing regulations, which imposes certain requirements on certain types of individuals and entities, such as healthcare providers, health plans and healthcare clearing houses, known as "covered entities," as well as their "business associates," independent contractors or agents of covered entities that receive or obtain individually identifiable health information in connection with providing a service on behalf of a covered entity, relating to the privacy, security and transmission of individually identifiable health information.
- The federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to CMS, information related to payments or other transfers of value made to physicians, and further requires applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by physicians and their immediate family members. The support for Patients and Communities Act expanded the scope of reporting, such that beginning January 1, 2021 companies must also report payments and transfers of value provided to other types of healthcare professionals. Failure to submit timely, accurately and completely the required information for all covered payments, transfers of value and ownership or investment interests may result in civil monetary penalties.
- Many state and foreign law equivalents of each of the above federal laws, such as: anti-kickback and false claims laws which may apply to items or services reimbursed by any third party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; state and local laws that require the registration of pharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

In addition, the EU has established its own data security and privacy legal framework, including but not limited to Directive 95/46/EC (the "Data Protection Directive"). The European General Data Protection Regulation ("GDPR") took effect on May 25, 2018, which contains new provisions specifically directed at the processing of health information, higher sanctions and extra-territoriality measures intended to bring non-EU companies under the regulation. We anticipate that over time we may expand our business operations to include additional operations in the EU, including potentially conducting preclinical and clinical trials. With such expansion, we would be subject to

increased governmental regulation in the EU countries in which we might operate, including regulation due to the GDPR.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations or laws that apply to us, we may be subject to substantial penalties, including, without limitation, civil, criminal and administrative penalties, damages, fines, possible exclusion from Medicare, Medicaid and other government healthcare programs, additional reporting requirements and/or oversight, particularly if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance, disgorgement, imprisonment, contractual damages, reputational harm, diminished profits and future earnings, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Recent and future healthcare legislation may further impact our business operations.

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policymakers and payors 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 or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. For example, in March 2010, the ACA was enacted, which made a number of substantial changes in the way healthcare is financed by both governmental and private insurers. The ACA included a number of provisions that may reduce the profitability of drug products, including revising the rebate methodology for covered outpatient drugs under the Medicaid Drug Rebate Program, extending Medicaid rebates to individuals enrolled in Medicaid managed care plans, and requiring drug manufacturers to pay an annual fee based on their market share of prior year total sales of branded programs to certain federal health care programs.

We face potential product liability, and, if successful claims are brought against us, we may incur substantial liability and costs.

The use of our product candidates in clinical trials and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our product candidates or products. For example, unanticipated adverse effects could result from the use of our future products or product candidates which may result in a potential product liability claim. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation;
- withdrawal of clinical trial participants;
- costs due to related litigation;
- distraction of management’s attention from our primary business;
- substantial monetary awards to patients or other claimants;
- the inability to commercialize our product candidates; and
- decreased demand for our products approved for commercial sale.

We have a limited amount of product liability insurance relating to the use of our therapeutics in clinical trials. However, such insurance coverage may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and in the future we may not be able to obtain or maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If and when we obtain marketing approval for product candidates, we intend to expand our insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated adverse effects. A successful product liability claim or series of claims brought against us could cause our share price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business.

Cyber security risks and the failure to maintain the confidentiality, integrity, and availability of our computer hardware, software, and Internet applications and related tools and functions could result in damage to our reputation and/or subject us to costs, fines or lawsuits.

Our business requires manipulating, analyzing and storing large amounts of data. In addition, we rely on a global enterprise software system to operate and manage our business. We also maintain personally identifiable information about our employees and participants in our clinical trials. Our business therefore depends on the continuous, effective, reliable, and secure operation of our computer hardware, software, networks, Internet servers, and related infrastructure. To the extent that our hardware or software malfunctions or access to our data by internal research personnel is interrupted, our business could suffer. The integrity and protection of our employee and company data is critical to our business and our employees and participants in our clinical trials have a high expectation that we will adequately protect their personal information. The regulatory environment governing information, security and privacy laws is increasingly demanding and continues to evolve. Maintaining compliance with applicable security and privacy regulations may increase our operating costs. Although our computer and communications hardware is protected through physical and software safeguards, it is still vulnerable to fire, storm, flood, power loss, earthquakes, telecommunications failures, physical or software break-ins, software viruses, and similar events. These events could lead to the unauthorized access, disclosure and use of non-public information. The techniques used by cyber criminals are sophisticated, change frequently, may originate from less regulated and more remote areas of the world, may not be recognized until launched and can originate from a wide variety of sources, including insider threats and outside groups such as external service providers, organized crime affiliates, terrorist organizations or hostile foreign governments or agencies, or generated using artificial intelligence. As a result, we may not be able to address these techniques proactively or implement adequate preventative measures. If our computer systems are compromised, we could be subject to fines, damages, litigation and enforcement actions, and we could lose trade secrets, the occurrence of which could harm our business. In addition, any sustained disruption in internet access provided by other companies could harm our business.

Our use of artificial intelligence technologies may expose us to operational, cybersecurity, legal and reputational risks.

We permit the use of certain artificial intelligence ("AI") tools, including large language models and AI agents hosted in data centers located in the United States. We have adopted certain enterprise AI platforms, which our employees may access following internal review and approval processes. We also utilize data exfiltration detection technologies designed to monitor AI usage and alert our security team to potential unauthorized or unsanctioned use. AI systems may generate inaccurate, incomplete or misleading outputs, which could result in operational errors, flawed decision-making or the dissemination of incorrect information. In addition, employees may inadvertently input confidential, proprietary or sensitive information into AI tools, which could result in unauthorized disclosure, cybersecurity incidents, regulatory scrutiny, litigation or reputational harm. Our reliance on third-party AI providers also subjects us to risks relating to service disruptions, security vulnerabilities, or changes in provider policies or pricing. The legal and regulatory framework governing AI is rapidly evolving, and new laws or regulations could restrict our use of AI technologies or increase compliance costs. If we fail to effectively manage risks associated with AI use, our business, financial condition and results of operations could be adversely affected.

Business interruptions could delay us in the process of developing our future products.

Our headquarters is located in San Diego, California. We are vulnerable to natural disasters such as earthquakes, mudslides, floods and wildfires, as well as other events that could disrupt our operations. We do not carry insurance for earthquakes or other natural disasters, and we may not carry sufficient business interruption insurance to compensate us for losses that may occur. Any losses or damages we incur could have a material adverse effect on our business operations.

U.S. Government agencies have special contracting authority that gives them the ability to terminate and/or modify their contracts with us.

On August 31, 2022, we entered into a cost reimbursement contract with BARDA to support the development of a low-dose pandemic influenza candidate based on our proprietary self-amplifying messenger RNA-based vaccine platform.

The contract with BARDA, as with most U.S. Government contracts, is subject to audit, and contains termination provisions allowing the government to terminate all or part of the contract at its sole discretion, which will subject us to additional risks. These risks include the ability of the U.S. Government unilaterally to:

- preclude us, either temporarily or for a set period of time, from receiving new contracts or extending our existing or future contracts based on violations or suspected violations of laws or regulations;
- terminate our contract, either for the convenience of the government (at the government's sole discretion, for example, if funds become unavailable or the government no longer wants the work) or for default (for failing to perform in accordance with the contract schedule and terms);
- revise the scope and value of our contract and/or revise the timing for work to be performed;
- audit and object to our contract-related costs and fees, including allocated indirect costs;
- control and potentially prohibit the export of our products, if and when developed;
- claim rights to intellectual property, including products, that may be developed under the contract; and
- add or remove the terms and conditions in our contract.

Termination-for-convenience provisions generally enable us to recover only our costs incurred or committed, settlement expenses, and profit on the work completed prior to termination. A contractor's rights under a termination for convenience are limited to an adjustment of profit and, with the contracting officer's concurrence, a reduction in the estimated cost. Under the general termination for convenience procedures, a partial termination is treated as a full termination when (i) the terminated portion is clearly severable from the balance of the contract or (ii) when contract performance is virtually complete or performance of the continued portion of the contract is only on subsidiary items or is otherwise not substantial. Termination-for-default provisions do not permit these recoveries and could make us liable for excess costs incurred by the U.S. Government in procuring undelivered items from another source.

In addition, the new 2025 U.S. presidential administration has implemented or threatened reductions in force and work stoppages across several U.S. federal agencies. Any such reductions or stoppages at BARDA or other federal agencies could negatively impact our contractual relationships with these entities, which could negatively impact our business and results of operations.

Our business is subject to audit by the U.S. Government, and a negative audit could adversely affect our business.

Several U.S. Government agencies, such as the Defense Contract Audit Agency (the "DCAA"), routinely audit and investigate government contractors. These agencies review, among other things, a contractor's performance under its contracts, incurred costs, cost structure and compliance with applicable laws, regulations and standards.

The DCAA also reviews the adequacy of, and a contractor's compliance with, its internal control systems and policies, including the contractor's purchasing, property, estimating, compensation and management information systems. Any costs found to be improperly allocated to a specific contract will not be reimbursed, while such costs already reimbursed must be refunded. If an audit uncovers improper or illegal activities, we may be subject to civil and criminal penalties and administrative sanctions, including:

- termination of contracts;
- forfeiture of profits;
- suspension of payments;
- fines; and
- suspension or prohibition from conducting business with the U.S. Government.

In addition, we could suffer serious reputational harm if allegations of impropriety were made against us.

A prolonged U.S. federal government shutdown could materially and adversely affect our business, operations, and legal proceedings.

On October 1, 2025, the federal government of the United States began a shutdown at 12:01 a.m. EDT as a result of congressional failure to pass appropriations legislation for the 2026 fiscal year, which began that day, and lasted for 43 days. Subsequent partial federal government shutdowns occurred in January and February of 2026. A continued and prolonged shutdown could materially and adversely affect our business, operations, financial condition, and legal matters. A federal government shutdown may result in the furlough of federal employees, reduced availability of government services, and suspension or delay of activities by key agencies that regulate, fund, or interact with our business, including the SEC, the FDA, the HHS, and the U.S. Patent and Trademark Office. During such periods, review and approval of our filings, applications, and submissions could be delayed, and we may be unable to access or rely upon certain government data or systems. In addition, the Administrative Office of the U.S. Courts and federal judiciary operations rely on appropriated funds and fee-based reserves that may be exhausted in the event of an extended shutdown. If federal court funding lapses or is limited to "essential" functions only, civil litigation, bankruptcy proceedings, and regulatory enforcement actions involving us or our affiliates could be postponed or suspended. Any such delay could impede our ability to resolve disputes, enforce contractual rights, or obtain timely judicial relief, which may have a material adverse effect on our financial position or prospects. Such conditions could negatively impact our access to financing, timing of capital-raising transactions, and the liquidity or trading volume of our securities. Accordingly, the current federal government shutdown, or uncertainty regarding the continuity of government operations could have a material adverse effect on our business, results of operations, and stock price.

RISKS RELATED TO OUR COMMON STOCK

We do not intend to pay dividends on our common stock so any returns to investors will be limited to the value of our shares.

We have never declared or paid any cash dividends on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future.

The market price of our common stock has been, and is expected to continue to be, highly volatile and investors may not be able to resell shares at or above the price at which they purchased the shares.

The trading price of our common stock has been and is likely to continue to be volatile. For example, during the year ended December 31, 2025, our Common Stock closed at a high price of $23.16 on October 21, 2025 and closed at a low price of $5.90 on November 20, 2025. Our share price could be subject to wide fluctuations in response to a variety of factors, including but not limited to the following factors:

- adverse results or delays in preclinical studies or clinical trials;
- inability to obtain additional funding;
- any delay in filing an application for authorization to commence a clinical trial of, or for authorization or approval to market, any of our product candidates and any adverse development or perceived adverse development with respect to the FDA's review of that IND or BLA;
- failure to maintain our existing strategic alliances or enter into new alliances;
- failure of our strategic alliance partners to elect to develop and commercialize product candidates under our alliance agreements or the termination of any programs under our alliance agreements;
- failure by us or our licensors and strategic alliance partners to prosecute, maintain or enforce our intellectual property rights;
- failure to successfully and timely develop and commercialize our product candidates;
- failure to successfully and timely develop and validate manufacturing processes and product presentations;
- changes in laws or regulations applicable to our preclinical and clinical development activities, product candidates or future products;
- inability to obtain adequate product supply for our product candidates or the inability to do so at acceptable prices;
- adverse regulatory decisions;
- introduction of new products, services or technologies by our competitors;
- failure to meet or exceed financial projections we may provide to the public;
- failure to meet or exceed the estimates and projections of the investment community;
- disappointing commercial sales, or profit share or royalty revenue amounts;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us, our strategic alliance partners or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- additions or departures of key scientific or management personnel;
- significant lawsuits, including patent or licensing matters;
- changes in the market valuations of similar companies;
- sales of our common stock by us or our shareholders in the future; and
- trading volume of our common stock.

In addition, companies trading in the stock market in general, and Nasdaq in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies, particularly companies in our industry. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance.

The requirements of being a publicly traded company may strain our resources and divert management's attention.

As a publicly traded company, we have incurred, and will continue to incur, significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act of 2002 (the

"Sarbanes-Oxley Act"), as well as rules subsequently implemented by the SEC and Nasdaq have imposed various requirements on public companies. In July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act (the "Dodd-Frank Act") was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as "say on pay" and proxy access. Shareholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain our current levels of such coverage.

Failure to comply with these requirements could subject us to enforcement actions by the SEC, divert management's attention, damage our reputation, and adversely affect our business, results of operations, or financial condition. In particular, if our independent registered public accounting firm is not able to render the required unqualified attestation, it could result in a loss of investor confidence in the accuracy, reliability, and completeness of our financial reports.

If we are subject to securities class action litigation, we would incur substantial costs and diversion of management's attention.

We may be at risk of securities class action litigation. This risk is especially relevant for us due to our dependence on positive clinical trial outcomes and regulatory approvals of each of our product candidates. In the past, medicines, biotechnology and pharmaceutical companies have experienced significant stock price volatility, particularly when associated with binary events such as clinical trials results and product approvals. If we face such litigation, it could result in substantial costs, divert management's attention and resources, and have a very material adverse effect on our business, operating results and prospects.

Sales of a substantial number of shares of our common stock in the public market by our existing shareholders could cause our share price to fall.

If our existing shareholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline significantly. As of December 31, 2025, 2,048,139 shares of our common stock may be sold pursuant to Rule 144 under the Securities Act of 1933, as amended (the "Securities Act"). Those shareholders are eligible to sell those shares in the public market without restriction, except for shareholders who are deemed our "affiliates" under Rule 144 under the Securities Act. In addition, common stock that is either subject to outstanding options or reserved for future issuance under our employee benefit plans, may become eligible for sale in the public market to the extent permitted by vesting schedules and Rule 144 under the Securities Act. If common stock is sold, or if it is perceived that it will be sold, in the public market, that could cause the trading price to decline.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our shareholders and could cause our share price to fall.

We expect that significant additional capital will be needed in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities (including but not limited to securities issued in connection with the Sales Agreement, as defined below), our shareholders may experience substantial dilution.

Pursuant to our 2019 Omnibus Equity Incentive Plan, as amended, our management is authorized to grant options and other equity-based awards to our employees, directors and consultants. We may issue and sell additional shares of common stock, convertible securities or other equity securities in one or more capital-raising or other transactions at prices and in a manner we determine from time to time, any of which may result in material dilution to investors and/or our existing shareholders. New investors could also be issued securities with rights superior to those of our existing shareholders.

On December 23, 2022, we entered into a Controlled Equity Offering℠ Sales Agreement (as amended, the "Sales Agreement") with Cantor Fitzgerald & Co. ("Cantor") and Wells Fargo Securities, LLC ("Wells Fargo"), relating to shares of our common stock. On August 7, 2023, we entered into Amendment No. 1 to the Sales

Agreement with Cantor, Wells Fargo and William Blair & Company ("William Blair"). In accordance with the terms of the Sales Agreement, we may offer and sell shares of our common stock having an aggregate offering price of up to $200,000,000 from time to time through Cantor, Wells Fargo, or William Blair, each acting as our sales agent. As of the date hereof, we have sold an aggregate of 1,179,201 shares of our common stock under the Sales Agreement for aggregate gross proceeds of approximately $12 million, leaving an aggregate of approximately $188 million of shares of our common stock remaining for future sale under the Sales Agreement.

We may be unable to comply with the applicable continued listing requirements of Nasdaq.

Our common stock is currently listed on Nasdaq. In order to maintain this listing, we must satisfy minimum financial and other continued listing requirements and standards, including a minimum closing bid price requirement for our common stock of $1.00 per share. There can be no assurance that we will be able to comply with the applicable listing standards. For example, if we were to fail to meet the minimum bid price requirement for 30 consecutive business days, we could become subject to delisting. Although Nasdaq may provide us with a compliance period in which to regain compliance with the minimum bid price requirement, we may not be able to regain compliance within the period provided by Nasdaq. In order to regain compliance with such requirement, the closing bid price of our common stock would need to meet or exceed $1.00 per share for at least 10 consecutive business days during the compliance period. If we were not able to regain compliance within the allotted compliance period for this requirement or any other applicable listing standard, including any extensions that may be granted by Nasdaq, our common stock would be subject to delisting. In the event that our common stock is delisted from Nasdaq, liquidity will be reduced, and the trading price of our common stock can be expected to decline immediately. If our common stock is not eligible for quotation or listing on another market or exchange, trading of our common stock could be conducted only in the over-the-counter market or on an electronic bulletin board established for unlisted securities such as the Pink Sheets or the OTC Bulletin Board. In such event, it could become more difficult to dispose of, or obtain accurate price quotations for our common stock and there would likely also be a reduction in our coverage by securities analysts and the news media, which could cause the price of our common stock to decline further.

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

Risk management and strategy

We recognize the critical importance of developing, implementing, and maintaining robust cybersecurity measures to safeguard our information systems and protect the confidentiality, integrity, and availability of our data.

Managing Material Risks & Integrated Overall Risk Management

We have implemented tools and strategies to promote a company-wide culture of cybersecurity risk management. This ensures that cybersecurity considerations are an integral part of our decision-making process. Our IT Department works closely with our leadership and key operating personnel to evaluate and address cybersecurity risks in alignment with our business objectives and operational needs.

Our information security function led by the Director, IT Security and Infrastructure, help to identify, assess and manage the Company's cybersecurity threats and risks. This group works to identify and assess risks from cybersecurity threats by monitoring and evaluating our threat environment and the Company's risk profile using various methods in certain contexts including for example, manual tools, subscribing to reports and services that identify cybersecurity threats, analyzing reports of threat actors, conducting scans of certain environments, evaluating certain threats reported to us, conducting threat and vulnerability assessments, using external intelligence feeds, and using third parties to conduct tabletop incident response exercises among other tests.

Depending on the environment, we implement and maintain various technical, physical, and organizational measures, processes, standards and policies designed to manage and mitigate material risks from cybersecurity threats to our information systems and data. These policies, processes and standards are based on recognized frameworks established by the National Institute of Standards and Technology and include, for example: incident detection and response, disaster recovery/business continuity policies, encryption of certain data, network security controls and data segmentation for certain systems, access controls, physical security, system change control, asset management and tracking, systems monitoring, annual mandated employee training, penetration testing,

cybersecurity insurance, and dedicated cybersecurity staff. Technical safeguards are evaluated and upgraded over time to address risks identified through vulnerability assessments and cybersecurity threat analysis.

Our employees and contractors receive regular cybersecurity awareness training, including topics relating to social engineering and email fraud, to communicate our evolving information security policies, procedures, and standards. Employee training includes periodic phishing exercises to provide our employees with a heightened level of awareness to cybersecurity threats, and to equip them with relevant information to prevent cybersecurity incidents.

Engage Third-parties on Risk Management

Due to the complexity and evolving nature of cybersecurity threats, we engage with a range of external experts, including but not limited to cybersecurity assessors, consultants, and auditors to evaluate and test our risk management systems. These partnerships enable us to leverage specialized knowledge and insights, to help ensure our cybersecurity strategies and processes remain at the forefront of industry best practices. Our collaborations with these third-parties includes regular audits, threat assessments, 24-hour monitoring, and consultation on security enhancements.

Oversee Third-party Risk

Because we are aware of the risks associated with third-party service providers, we conduct thorough security assessments of certain high-risk third-party providers as deemed necessary, before engagement to ensure compliance with industry cybersecurity standards and frameworks. This includes assessments performed by our Director, IT Security and Infrastructure, who oversees the Company's cybersecurity function.

Risks from Cybersecurity Threats

We have not encountered cybersecurity challenges that have materially affected or are reasonably likely to materially affect our operations or financial standing. In the event of a future cybersecurity incident, we have procedures in place to identify whether an incident or associated cybersecurity risks have materially affected or are reasonably likely to materially affect us, help to ensure that any required disclosures are made when required under applicable law or regulation. However, the safeguards might not provide adequate to prevent a material adverse impact from a cybersecurity attack.

Governance

Our policies and procedures provide for the prompt escalation and communication of significant cybersecurity incidents so that Company management can make decisions regarding the handling, disclosure, and reporting of such incidents in a timely and effective manner. We have also implemented standard operating procedures to define the channels by which cybersecurity threats are communicated to the Company's Board of Directors (the "Board"). This ensures that the Board has oversight and effective governance in managing risks associated with cybersecurity threats.

Board of Directors Oversight

The Audit Committee of the Board (the "Audit Committee") is central to the Board's oversight of cybersecurity risks and bears the primary responsibility for this domain. The Audit Committee is composed of board members with diverse expertise including, risk management, and finance, equipping them to oversee cybersecurity risks effectively. The Audit Committee receives briefings on cybersecurity risks from the Director, IT Security and Infrastructure or the Chief Legal Officer as described below in "Management's Role Managing Risk."

Management's Role Managing Risk

The Director, IT Security and Infrastructure and Chief Legal Officer ("CLO") play a pivotal role in informing the Audit Committee on cybersecurity risks. They provide briefings to the Audit Committee on a regular basis, and at least annually, and more frequently as circumstances warrant (including in connection with incidents, significant changes in the threat landscape, or significant program initiatives). The current Director, IT Security and Infrastructure, who is responsible for assessment and management of cybersecurity risks, has over 20 years of experience in information and technology security, including senior roles at several companies in the pharmaceutical industry, and possesses the requisite education, skills, experience, and industry certifications expected of an individual assigned to these duties. These briefings encompass a broad range of topics, including:

- Current cybersecurity landscape and emerging threats;
- Status of ongoing cybersecurity initiatives and strategies;
- Incident reports and learnings from any cybersecurity events; and
- Compliance with regulatory requirements and industry standards.

Risk Management Personnel

Primary responsibility for assessing, monitoring and managing our cybersecurity risks rests with Director, IT Security and Infrastructure. Our IT Leadership team oversees our governance programs, tests our compliance with standards, remediates known risks, stays informed of significant developments in the cybersecurity domain, and leads our employee training program.

Monitor Cybersecurity Incidents

The Director, IT Security and Infrastructure is continually informed about the latest developments in cybersecurity, including potential threats and innovative risk management techniques. This ongoing knowledge acquisition is crucial for the effective prevention, detection, mitigation, and remediation of cybersecurity incidents. In cooperation with other cybersecurity and IT staff, the Director of IT Security and Infrastructure implements and oversees processes for the regular monitoring of our information systems. This includes the deployment of advanced security measures and regular system audits to identify potential vulnerabilities. In the event of a cybersecurity incident, the security team is equipped with a well-defined incident response plan. This plan includes immediate actions to mitigate the impact and long-term strategies for remediation and prevention of future incidents.

Reporting to Board of Directors

The Director of IT Security and Infrastructure, in their respective capacity, inform the Chief Legal Officer (CLO) and other members of senior leadership as needed, of cybersecurity risks and incidents. Furthermore, significant cybersecurity matters, and strategic risk management decisions are required to be escalated to the Board, ensuring that they have comprehensive oversight and can provide guidance on critical cybersecurity issues.

See Item 1A “Risk Factors” – “Risks Related to Business Operations and Industry.”

Item 2. Properties

We have two properties located in San Diego, California. Our principal place of business is located at 10285 Science Center Drive, San Diego, California. The property consists of approximately 43,234 square feet and is leased through September 2032.

Our other property is located at 10628 Science Center Drive, Suite 250, San Diego, California and consists of approximately 24,700 square feet of office space and laboratory space, which was vacated in December 2025 and is leased through March 2027.

We believe that our property is suitable for the conduct of our business.

Item 3. Legal Proceedings

From time to time, we may be involved in various legal proceedings and subject to claims that arise in the ordinary course of business, and the results of litigation and claims are inherently unpredictable and uncertain. Other than as set forth below, we are not currently a party to any material legal proceedings.

On September 23, 2025, we filed a lawsuit against AbbVie Inc., Capstan Therapeutics, Inc. and other defendants in the United States District Court for the Southern District of California, asserting claims for trade secret misappropriation and breach of contract. The defendants filed a motion to discuss the complaint in December 2025, and we filed an opposition to that motion in January 2026. The Court has not set a case schedule.

On May 30, 2025, we initiated an arbitration against CSL Seqirus before the International Chamber of Commerce, seeking payment of a milestone under the CSL Collaboration Agreement based on the European Commission’s grant of marketing authorization for a presentation of KOSTAIVE® in the European Union. On July 25, 2025, CSL Seqirus submitted an Answer in the arbitration contending that it does not have a current obligation to pay the milestone. The arbitration is ongoing with a hearing scheduled to occur in the third quarter of 2026.

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

Market for our Common Stock

Our common stock is listed on the Nasdaq under the symbol "ARCT".

Holders of Common Stock

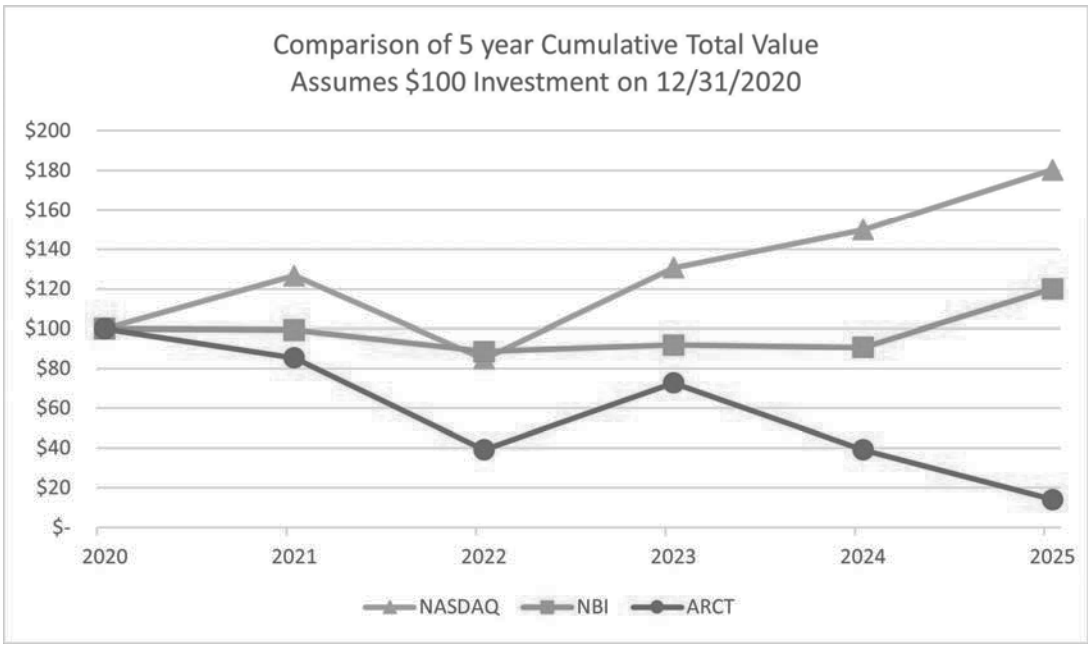
As of February 27, 2026, there were eight registered holders of record of our common stock. Because many of our outstanding shares are held in accounts with brokers and other institutions, the number of beneficial owners is significantly greater than the number of record holders. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

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 the Board and will depend upon, among other factors, our results of operations, financial condition, capital requirements, contractual restrictions, business prospects and other factors the Board may deem relevant.

Stock Performance Graph

The following graph compares the Company's cumulative stockholder return since December 31, 2020 with the Nasdaq Composite Index, and the Nasdaq Biotechnology Index. The graph is based on the assumption that $100 had been invested in Company common stock.



Securities Authorized for Issuance under Equity Compensation Plans

Information about our equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report.

Recent Sales of Unregistered Securities

None.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Item 6. Reserved

Not applicable.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion and analysis together with the consolidated financial statements and related notes included elsewhere herein.

This report includes forward-looking statements which, although based on assumptions that we consider reasonable, are subject to risks and uncertainties which could cause actual events or conditions to differ materially from those currently anticipated and expressed or implied by such forward-looking statements.

Discussions of 2023 items and year-to-year comparisons between 2024 and 2023 that are not included in this Form 10-K can be found within Management's Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report on Form 10-K for the year ended December 31, 2024.

Overview

We are a messenger RNA medicines company focused on the development of liver and respiratory rare disease therapeutics. We have ongoing Phase 2 clinical studies for our RNA therapeutic candidates to potentially treat ornithine transcarbamylase (OTC) deficiency and cystic fibrosis (CF).

We developed the world's first approved self-amplifying messenger RNA (sa-mRNA) vaccine, KOSTAIVE® ("KOSTAIVE"), which we have partnered with Seqirus, Inc. ("CSL Seqirus"), a part of CSL Limited. KOSTAIVE has achieved approval in Japan, the European Union and the United Kingdom as a vaccine against COVID-19, and sales of KOSTAIVE began in Japan in October 2024.

We have several key platform technologies that we leverage to develop and advance a pipeline of mRNA-based therapeutics for rare genetic disorders with significant unmet medical needs and vaccines for infectious diseases. Current mRNA medicines have two critical components: the messenger RNA ("mRNA") constructs and the lipid nanoparticles ("LNP") which help deliver the mRNA to disease-relevant target tissues. We have extensive expertise in the design and optimization of mRNA constructs, including with respect to a type of mRNA technology known as self-amplifying mRNA (sa-mRNA). Our proprietary self-amplifying mRNA technology platform, or STARR® ("STARR"), has been demonstrated to induce a robust, longer-lasting and broader humoral immune response at lower dose levels than conventional mRNA-based vaccines. Our proprietary LNP delivery system, LUNAR® ("LUNAR"), is intended to address the major hurdle in RNA drug development, namely the effective and safe delivery of RNA to disease-relevant target tissues. LUNAR may enable multiple nucleic acid medicines. We also have significant expertise and valuable know-how in the development and scalability of complex and robust manufacturing processes required to deliver the next generation of nucleic acid medicines.

Our internal pipeline includes RNA therapeutic candidates to potentially treat ornithine transcarbamylase (OTC) deficiency and cystic fibrosis (CF), both rare diseases. In our vaccine program, we have partnered with CSL Seqirus, one of the world's leading influenza vaccine providers, on the development and commercialization of mRNA vaccines for COVID-19, influenza and three other infectious diseases. In CSL Limited's half-year results presented on February 11, 2026, CSL Limited reported an accounting write-down of approximately $430 million attributable to our collaboration agreement with CSL Seqirus, citing declining COVID-19 disease burden and more onerous U.S. regulatory requirements.

In our CF program, we enrolled and completed dosing in the three initially planned cohorts of our Phase 2 multiple ascending dose study of ARCT-032, confirming the safety and tolerability of ARCT-032 dosed daily for four weeks. This study was initiated in December 2024 and was designed to identify a safe and effective dose regimen in those with Class I (null) CFTR mutations and people with CF who do not benefit from CFTR modulators. In the study, six CF adults with Class I CFTR mutations inhaled 10 mg doses of ARCT-032 daily over 28 days. Interim results released in October 2025 demonstrated that the treatment was generally safe and well tolerated. Treatment-related adverse events (AEs) that were identified in the single-dose Phase 1 study were also observed in some participants for the first few doses but ceased with continued dosing. Bronchospasm has not been reported in this study thus far, neither with nor without albuterol pretreatment. One serious adverse event (SAE) occurred in a participant after the end of the dosing period. The safety review committee found no convincing evidence that the SAE is related to ARCT-032 and approved the study to proceed. We intend to initiate a 12-week safety and preliminary efficacy study in up to 20 CF participants in the first half of 2026, after the third cohort completes treatment. ARCT-032 has received Orphan Drug Designation by the U.S. Food and Drug Administration (the "FDA") and Orphan Medicinal Product Designation by the European Medicines Agency (the "EMA") for the treatment of CF, and Rare Pediatric Disease Designation from the FDA.

KOSTAIVE is the brand name approved in Japan and Europe for ARCT-154, which is the version of the sa-mRNA COVID vaccine encoding the ancestral strain of SARS-CoV-2, and also for updated variant-specific versions of this vaccine. We may use KOSTAIVE or the specific internally generated name, such as ARCT-154, ARCT-2301 and ARCT-2303, to identify a version of the vaccine.

In our OTC program, we have continued to conduct a Phase 2 double-blind multiple-dose study of ARCT-810. Five patients with OTC deficiency have now completed dosing, and a sixth patient has initiated dosing. A type C meeting with the FDA to discuss our plans for a proposed future pediatric study under the RDEP (Rare Disease Evidence Principles) is scheduled for the first half of 2026. ARCT-810 has received Orphan Drug Designation from the FDA and Orphan Medicinal Product Designation from the EMA for treatment of OTC deficiency, as well as Fast Track Designation and Rare Pediatric Disease Designation from the FDA.

Commercial sales of KOSTAIVE began in October 2024 in Japan by Meiji Seika Pharma, Ltd. ("Meiji"), CSL Seqirus' exclusive partner in Japan, marking the first commercial sales of an Arcturus-developed product. In September 2025, Meiji launched a new presentation of KOSTAIVE in Japan. The product is a 2-dose vial lyophilized presentation incorporating the updated XEC variant strain. Approval for offshore manufacturing of the 2-dose vial lyophilized presentation was granted by Japan in August 2025, followed by approval for onshore manufacturing in January 2026. KOSTAIVE was approved by the European Commission (EC) in February 2025 and by the United Kingdom in January 2026, providing further validation of our platform by additional significant regulatory authorities.

In December 2024, we initiated dosing of an sa-mRNA vaccine candidate against pandemic avian influenza (bird flu) in a Phase 1 trial funded by the Biomedical Advanced Research and Development Authority ("BARDA"). The study results were received in the second half of 2025, indicating a favorable tolerability and safety profile and the ability to induce a robust and durable humoral immune response in young and older adults.

We also improved our platform technologies and advanced our early-stage research activities and manufacturing process development and operations. We conducted exploratory platform development activities, including the evaluation of genome editing, and new targeting approaches, where our LUNAR and STARR platforms could be useful for identification and development of additional products for our portfolio.

Our activities since inception have consisted principally of performing research and development activities, clinical research activities, general and administrative activities and raising capital to fund those efforts. Our activities are subject to significant risks and uncertainties, including failing to secure additional funding before we achieve sustainable revenues and profit from operations. As of December 31, 2025, we had an accumulated deficit of $514.6 million.

Liquidity and Capital Resources

From the Company's inception through the year ended December 31, 2025, the Company has funded its operations principally with the proceeds from revenues earned through collaboration agreements and government contracts, the sale of capital stock and long-term debt. During fiscal year 2025, we received milestone payments totaling $39.1 million from CSL Seqirus. At December 31, 2025, the Company's balance of cash and cash equivalents, including restricted cash, was $232.8 million.

CSL Seqirus, Inc. Collaboration and License Agreement

In November 2022, we entered into the CSL Collaboration Agreement with CSL Seqirus for the global exclusive rights to research, develop, manufacture and commercialize self-amplifying mRNA vaccines. The CSL Collaboration Agreement became effective on December 8, 2022, following clearance under the Hart-Scott-Rodino Antitrust Improvements Act.

Under the CSL Collaboration Agreement, CSL Seqirus receives global exclusive rights to our technology for vaccines against SARS-CoV-2 (COVID-19), influenza and three other infectious diseases. Specifically, the collaboration agreement grants CSL Seqirus a license to our STARR mRNA technology and LUNAR lipid-mediated delivery, as well as mRNA drug substance and drug product manufacturing expertise. CSL has also been granted global non-exclusive rights in the field of pandemic preparedness (i.e., pathogens identified as priority diseases by the WHO), with the right to convert to an exclusive license.

The CSL Collaboration Agreement sets forth how the parties will collaborate to research and develop vaccine candidates. In the COVID-19 field, we undertake activities for certain regulatory filings for our leading self-

amplifying mRNA vaccine candidate in COVID-19, ARCT-154, in the United States and Europe and for research and development activities of a next-generation COVID vaccine candidate. CSL Seqirus leads and is responsible for all other research and development in COVID-19, influenza and the other fields.

We received an up-front payment of $200.0 million, with the potential to receive development milestones totaling more than $1.3 billion if all products are registered in the licensed fields. We also are entitled to potentially receive up to $3.0 billion in commercial milestones based on "net sales" of vaccines in the various fields. In addition, we are entitled to receive a 40% share of net profits from COVID-19 vaccine sales and up to low double-digit royalties of annual net sales for vaccines against influenza, pandemic preparedness and three additional infectious diseases. Entitlement to all such payments is subject to the strict conditions, requirements, royalty reduction provisions and other limitations set forth in the CSL Collaboration Agreement.

Either party may terminate the CSL Collaboration Agreement on a field-by-field basis for material breach by the other party, following notice and opportunity to cure. CSL Seqirus may also terminate the collaboration agreement in its entirety or on a field-by-field basis for any reason or no reason whatsoever, with certain limitations. The CSL Collaboration Agreement may also be terminated by CSL Seqirus for safety reasons, clinical data nonviability, commercial nonviability and other specified reasons.

In March 2024, we entered into Amendment Number Two to the CSL Collaboration Agreement to reflect updates to the development program and other adjustments consistent with our prior disclosures regarding the Collaboration and License Agreement ("Amendment Number Two"). Amendment Number Two, among other things, adjusts (i) the development plans for certain product candidates, (ii) various development milestones related to such product candidates, (iii) provisions of the CSL Collaboration Agreement related to specific royalty payments, (iii) provisions of the CSL Collaboration Agreement related to distributors, and (iv) proprietary payment calculations related to the foregoing.

On May 30, 2025, we initiated an arbitration against CSL Seqirus before the International Chamber of Commerce, seeking payment of a milestone under the CSL Collaboration Agreement based on the European Commission's grant of marketing authorization for a presentation of KOSTAIVE®in the European Union.

In CSL Limited's half-year results presented on February 11, 2026, CSL Limited reported an accounting write-down of approximately $430 million attributable to our collaboration agreement with CSL Seqirus, citing declining COVID-19 disease burden and more onerous U.S. regulatory requirements.

Wells Fargo Credit Agreement

On April 21, 2023, the Company's wholly-owned subsidiary, Arcturus Therapeutics, Inc. entered into a credit agreement with Wells Fargo Bank, National Association ("Wells Fargo") whereby Wells Fargo agreed to make a $50.0 million revolving credit line available to the Company (as amended, the "Wells Fargo Loan") with each Wells Fargo Loan evidenced by a revolving line of credit note (each, a "Note"). On June 26, 2024, the parties entered into Amendment No. 1 to the Wells Fargo Loan, whereby the term was extended by one year to April 2026.

Borrowings under the agreement bore interest at a rate of 1.00% above either the Daily Simple SOFR or Term SOFR (as such terms are defined in the Wells Fargo Loan), with "SOFR" being the rate per annum equal to the secured overnight financing rate as administered by the Federal Reserve Bank of New York. If an Event of Default (as defined in the credit agreement) had occurred, then all Wells Fargo Loans would bear interest at a rate equal to 2.00% above the interest rate applicable immediately prior to the occurrence of the Event of Default.

The original term of the agreement was two years, with an option for one-year renewals subject to Wells Fargo approval and the Company furnishing to Wells Fargo a non-refundable commitment fee equal to 0.25% of the Wells Fargo Loan amount for each such renewal. There was no penalty for terminating the agreement and no penalty for terminating the facility prior to the maturity date of the Wells Fargo Loan. As collateral, the Company had agreed to pledge $55.0 million in cash to be held at the Company's securities accounts with Wells Fargo Securities, LLC, an affiliate of Wells Fargo, pursuant to a security agreement.

In December 2025, the Company terminated the credit agreement and related security agreement, and the $55.0 million of cash previously pledged as collateral was released and is no longer classified as restricted cash.

Grant from the Biomedical Advanced Research and Development Authority

On August 31, 2022, we entered into a cost reimbursement contract (the "BARDA Contract") with the Biomedical Advanced Research and Development Authority ("BARDA"), a division of the Office of the Assistant Secretary for Preparedness and Response ("ASPR") within the U.S. Department of Health and Human Services ("HHS") to support the development of a low-dose pandemic influenza candidate based on our proprietary self-amplifying messenger RNA-based vaccine platform. The BARDA Contract is to support our non-clinical and pre-clinical development, early-stage clinical development through Phase 1, and associated drug product manufacturing, regulatory and quality-assurance activities over a period of three years. It provides for reimbursement by BARDA of our permitted costs up to $63.2 million. As of December 31, 2025, the remaining available funding net of revenue earned was $26.7 million.

General Financial Resources

A portion of our current cash balance is expected to be utilized during fiscal year 2026 to fund (i) advances to our LUNAR-CF program in clinical trials, (ii) the continued Phase 2 trial of ARCT-810, our LUNAR-OTC candidate, (iii) expenses incurred prior to customer payments under the CSL Collaboration Agreement and BARDA agreement and (iv) continued exploratory activities related to our platform and other general administrative activities.

Our future capital requirements are difficult to forecast and will depend on many factors that are out of our control. If we are unable to maintain sufficient financial resources, our business, financial condition and results of operations will be materially and adversely affected. There can be no assurance that we will be able to obtain additional needed financing on acceptable terms or at all. Additionally, equity or debt financings may have a dilutive effect on the holdings of our existing shareholders.

We expect to continue to incur additional losses in the long term, and we will need to raise additional debt or equity financing or enter into additional partnerships to fund development. Our ability to transition to profitability is dependent on regulatory approvals and subsequent sales of KOSTAIVE, and identifying and developing other successful mRNA drug and vaccine candidates. If we are not able to achieve planned milestones or incur costs in excess of our forecasts, we will need to reduce discretionary spending, discontinue the development of some or all of our programs, which will delay part of our development programs, all of which will have a material adverse effect on our ability to achieve our intended business objectives.

Funding Requirements

We anticipate that we will continue to generate losses for the foreseeable future, and we expect the losses to increase as we continue the development of, and seek regulatory approvals for, our product candidates, and begin commercialization of our products. As a result, we will require additional capital to fund our operations in order to support our long-term plans. We believe that our current cash position will be sufficient to meet our anticipated cash requirements through at least the next twelve months, assuming, among other things, no significant unforeseen expenses and continued funding from partners at anticipated levels. We intend to seek additional capital through equity and/or debt financings, collaborative or other funding arrangements with partners or through other sources of financing when and as needed. Should we seek additional financing from outside sources, we may not be able to raise such financing on terms acceptable to us or at all. If we are unable to raise additional capital when required or on acceptable terms, we may be required to scale back or discontinue the advancement of product candidates, reduce headcount, liquidate our assets, file for bankruptcy, reorganize, merge with another entity, or cease operations.

Our future funding requirements are difficult to forecast and will depend on many factors, including but not limited to the following:

- the development of our cystic fibrosis and OTC deficiency therapeutic candidates;
- the achievement of milestones under our strategic alliance agreements;
- maintaining and/or expanding our manufacturing network and capabilities;
- the terms and timing of any other strategic alliance, licensing and other arrangements that we may establish, including those with CSL Seqirus and CSL Seqirus' arrangement with Meiji, and any related payments thereunder;
- the initiation, progress, timing and completion of preclinical studies and clinical trials for our product candidates;

- the number and characteristics of product candidates that we pursue;
- the outcome, timing and cost of regulatory approvals;
- delays that may be caused by changing regulatory requirements;
- the cost and timing of hiring new employees to support our continued growth;
- the costs involved in filing and prosecuting patent applications and enforcing and defending patent claims;
- the costs and timing of procuring clinical and commercial supplies of our product candidates;
- the costs and timing of establishing sales, marketing and distribution capabilities;
- the costs associated with legal proceedings;
- the costs associated with potential litigation related to collaboration agreements; and
- the extent to which we acquire or invest in businesses, products or technologies.

The following table shows a summary of our cash flows for the years ended December 31, 2025 and 2024:

	Year Ended December 31,	
(in thousands)	**2025**	**2024**
Cash provided by (used in):		
Operating activities	$ (74,271)	$ (59,747)
Investing activities	(230)	(648)
Financing activities	13,382	5,418
Net decrease in cash and restricted cash	$ (61,119)	$ (54,977)

Operating Activities

Net cash used in operating activities was $74.3 million for the year ended December 31, 2025, compared to $59.7 million for the year ended December 31, 2024. The $14.5 million increase was primarily due to a $29.7 million increase in accounts receivable and a $21.2 million decrease in accrued liabilities, reflecting the timing of billings, collections, and payments, as well as a $12.6 million decrease in share-based compensation due to reduced headcount and a lower stock price. These changes were partially offset by a $31.3 million smaller decrease in deferred revenue compared to the prior year, a $15.2 million reduction in net loss, a $7.5 million increase in cash provided by prepaid expenses and other assets, and the net impact of other working capital and non-cash items, which together reduced the overall increase in cash used in operating activities.

Investing Activities

Net cash used in investing activities of $0.2 million in 2025 and $0.6 million in 2024 reflected the acquisition of property and equipment.

Financing Activities

Net cash provided by financing activities was $13.4 million for the year ended December 31, 2025, compared to $5.4 million in 2024. The primary driver of the increase was an $11.7 million increase in proceeds from the issuance of common stock under our Sales Agreement for at-the-market equity offerings, partially offset by a $3.6 million decrease in proceeds from the exercise of stock options.

Results of Operations

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the consolidated financial statements included in this Annual Report. Our historical results of operations and the year-to-year comparisons of our results of operations that follow are not necessarily indicative of future results.

Revenues

We enter into arrangements with pharmaceutical and biotechnology partners and government agencies that may contain upfront payments, license fees for research and development arrangements, research and development funding, milestone payments, option exercise and exclusivity fees and royalties on future sales. The following table summarizes our total revenues for the periods indicated:

	Years Ended December 31,		Change 2025 vs 2024	
(in thousands)	2025	2024	Change	%
Collaboration revenue	$ 67,221	$ 138,389	$ (71,168)	-51%
Grant revenue	14,810	13,921	889	6%
Total	$ 82,031	$ 152,310	$ (70,279)	-46%

Revenue decreased by $70.3 million during the year ended December 31, 2025 as compared to the year ended December 31, 2024. The decrease during 2025 primarily relates to a $72.2 million decrease in revenue related to the CSL collaboration agreement, primarily due to a $33.1 million decrease in milestone achievements during 2025 as compared to 2024, and a $15.8 million decrease in revenue related to CSL commercial supply agreements, along with decreased revenue recognition from amortization during 2025 as a result of reduced development activities. The decrease was partially offset by an increase in grant revenue of $0.9 million related to the reimbursable research and development expenses for the agreements with BARDA and the Gates Foundation.

Operating Expenses

Our operating expenses consist of research and development and general and administrative expenses.

	Years Ended December 31,		Change 2025 vs 2024	
(in thousands)	2025	2024	Change	%
Operating expenses:				
Research and development, net	$ 112,212	$ 195,156	$ (82,944)	-43%
General and administrative	46,079	52,823	(6,744)	-13%
Total	$ 158,291	$ 247,979	$ (89,688)	-36%

The following table presents our total research and development expenses by category:

Research and Development Expenses, net

	Year Ended December 31,		Change 2025 vs 2024	
(in thousands)	2025	2024	Change	%
LUNAR-COVID	$ 16,115	$ 70,464	$ (54,349)	-77%
LUNAR-OTC	5,748	9,509	(3,761)	-40%
BARDA	8,366	7,807	559	7%
LUNAR-CF, net	17,489	17,227	262	2%
Early-stage programs	594	16,096	(15,502)	-96%
Discovery technologies	8,016	6,278	1,738	28%
Payroll and benefits	43,987	57,474	(13,487)	-23%
Facilities and equipment	11,897	10,301	1,596	15%
Total research and development expenses, net	$ 112,212	$ 195,156	$ (82,944)	-43%

Our research and development expenses consist primarily of external manufacturing costs, in-vivo research studies and clinical trials performed by contract research organizations, clinical and regulatory consultants, personnel related expenses, facility related expenses and laboratory supplies related to conducting research and development activities.

Research and development expenses were $112.2 million for the year ended December 31, 2025, compared with $195.2 million for the year ended December 31, 2024. The decrease was primarily driven by lower manufacturing and clinical costs related to the LUNAR-COVID program, reflecting the program's transition from a development program to the commercial phase. Additional decreases were attributable to lower manufacturing costs for the LUNAR-CF and LUNAR-FLU programs, as well as lower clinical costs associated with the LUNAR-OTC

program. These reductions were partially offset by higher clinical costs for Phase 2 of the LUNAR-CF program. Payroll and benefits expenses also decreased, primarily due to lower stock-based compensation expense and a reduction in headcount.

Early-stage programs represent programs that are in the pre-clinical or Phase 1 clinical stage and may be partnered or unpartnered, and primarily includes the LUNAR-FLU program which is partnered with CSL Seqirus. Discovery technologies represent our efforts to expand our product pipeline and are primarily related to pre-partnered studies and new capabilities assessment. A few of our programs are part of our collaborative relationships. The related expenses may be partially offset with funds that have been reimbursed or awarded to the Company and consist of external manufacturing costs, lab supplies, equipment, and consulting and professional fees. Expenses for both early-stage programs and discovery technologies are expected to decrease as we shift our focus to later-stage programs.

Payroll and benefits primarily consists of employee salaries and benefits, share-based compensation and consultant costs. We expect that payroll and benefits costs will not increase over the next twelve months

Facilities and equipment expenses include rent, common area maintenance ("CAM") costs, depreciation, shipping costs and various other costs related to the operation of our two office and laboratory locations. These costs increased primarily due to a lease-related impairment recognized in the fourth quarter after the Company vacated an office location with no further operational use.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related benefits for our executive, administrative and accounting functions and professional service fees for legal and accounting services as well as other general and administrative expenses.

General and administrative expenses were $46.1 million and $52.8 million for the years ended December 31, 2025 and 2024, respectively. The decrease was primarily due to reduced share-based compensation expense as well as reduced payroll and benefits associated with reductions in headcount.

Finance income (expense), net

	Years Ended December 31,		Change 2025 vs 2024	
(in thousands)	2025	2024	Change	%
Interest income	$ 10,104	$ 15,195	$ (5,091)	-34%
Interest expense	(9)	—	(9)	100%
Total	$ 10,095	$ 15,195	$ (5,100)	-34%

Interest income is generated on cash and cash equivalents. The decrease in interest income from 2024 to 2025 was the result of lower interest rates during the year ended 2025 and a decrease in cash and cash equivalents.

Critical Accounting Policies and Estimates

Our significant accounting policies are summarized in *"Note 2 Summary of Significant Accounting Policies,"* included in our consolidated financial statements included elsewhere in this annual report on Form 10-K.

The preparation of our consolidated financial statements in conformity with "GAAP" requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of expenses during the reporting period. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, assumptions related to revenue recognition, accrual of research and development expenses, determination of incremental borrowing rates, and the valuations of stock options. We based our estimates on historical experience, known trends and other market-specific or other relevant factors that we believe to be reasonable under the circumstances. On an ongoing basis, management evaluates these estimates when there are changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. Actual results could differ from those estimates.

Revenue Recognition

We recognize revenue when control of the products and services is transferred to our customers in an amount that reflects the consideration we expect to receive from our customers in exchange for those products and services. This process involves identifying the contract with a customer, determining the performance obligations in the contract, determining the contract price, allocating the contract price to the distinct performance obligations in the contract, and recognizing revenue when the performance obligations have been satisfied.

Our collaboration agreements typically contain promised goods and services, including technology licenses or options to obtain technology licenses, research and development and regulatory services. Upon entering into a collaboration agreement, we are required to make the following judgments:

Identifying the performance obligations and measuring progress

Our assessment of what constitutes a separate performance obligation requires us to apply judgment. Specifically, we are required to identify which goods and services we are required to provide under the contract are distinct, if any. For performance obligations that are satisfied over time, we typically use the percentage-of-completion method which requires us to estimate the total forecasted costs required to complete the performance obligation. Adjustments to these estimates could materially impact the timing and amount of recognized revenue. If actual costs exceed initial estimates, revenue recognized to date may need to be adjusted downward, negatively impacting current period results. Conversely, favorable cost variances could accelerate revenue recognition.

Determining the transaction price, including any variable consideration

To determine the transaction price, we review the amount of consideration we are eligible to earn under the agreement. We apply a constraint to any payments we may receive in the future to avoid significant reversals since the payments are typically not probable because they are contingent upon certain future events.

We are required to reassess the total transaction price at each reporting period to determine if we should include additional payments that have become probable in the transaction price.

Allocating the transaction price to each of our performance obligations

When we allocate the transaction price to more than one performance obligation, we make estimates of the relative stand-alone selling price of each performance obligation because we do not typically sell our goods or services on a stand-alone basis. The estimate of the relative stand-alone selling price requires us in some cases to make significant judgments. In cases where we deliver a license at the start of an agreement, we use valuation methodologies, such as costs to recreate plus margin, to value the license. Additionally, when we estimate the selling price for research and development and regulatory services, we make estimates, including: the number of internal hours we will spend on the services, the cost of work we and third parties will perform and the cost of clinical trial material we will use.

The revenue we recognize each period is comprised of several types of revenue, including license fees, amortization from upfront payments, milestone payments, research and development and other services. Each of these types of revenue require us to make various judgments and estimates.

Amortization from Upfront Payments

For certain agreements, we recognize revenue from the amortization of upfront payments as we perform research and development, technology transfer and consulting services. We use an input method to estimate the amount of revenue to recognize each period. This method requires us to make estimates of the total costs we expect to incur in order to complete our promised research and development services or the total length of time it will take us to complete our promised research and development services. If we change our estimates, we may have to adjust our revenue.

Milestone Payments

When recognizing revenue related to milestone payments, we typically judge and estimate whether the milestone payment is probable (discussed in detail above under "Determining the transaction price, including any variable consideration").

License Fees

In some cases, we deliver a license upon execution of an agreement. If we determine that our partner has full use of the license and we do not have any additional material performance obligations related to the license after delivery, then we consider the license to be a separate performance obligation. We generally recognize as license revenue the total amount of the transaction price we determine to be allocated to the performance obligation based upon the relative stand-alone selling price of a license when we deliver the license to our partner. We discuss the estimates we make related to the relative stand-alone selling price of a license in detail above under "Allocating the transaction price to our performance obligations."

Research and Development Expenses, Including Clinical Trial Accruals/Expenses

Research and development costs consist of salaries and benefits, including share-based compensation, laboratory supplies and facility costs, as well as fees paid to other entities that conduct certain research and development activities on our behalf, such as clinical research organizations, or CROs, and contract manufacturing organizations, or CMOs. Research and development costs are expensed as incurred.

Clinical trial expenses are a significant component of research and development expenses, and we outsource a significant portion of these clinical trial activities to third parties. Third-party clinical trial expenses include investigator fees, site and patient costs, CRO costs, and costs for central laboratory testing and data management. The accrual for site and patient costs includes inputs such as estimates of patient enrollment, patient cycles incurred, clinical site activations, and other pass-through costs. These inputs are required to be estimated due to a lag in receiving the actual clinical information from third parties. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected on the balance sheets as prepaid assets or accrued expenses. These third-party agreements are generally cancelable, and related costs are recorded as research and development expenses as incurred. Non-refundable advance clinical payments for goods or services that will be used or rendered for future research and development activities are recorded as a prepaid asset and recognized as expense as the related goods are delivered or the related services are performed. When evaluating the adequacy of the accrued expenses, we analyze progress of the studies, including the phase or completion of events, invoices received and contracted costs. We make estimates of our accrued balances as of each balance sheet date based on facts and circumstances known to our internal personnel at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary. Judgments and estimates may be made in determining the accrued balances at the end of any reporting period. Actual results could differ from the estimates made. Our historical clinical trial accrual estimates have not been materially different from our actual costs.

Leases

We cannot readily determine the interest rate implicit in the lease, therefore, we use our incremental borrowing rate to measure lease liabilities. The incremental borrowing rate is the rate of interest that we would have to pay to borrow over a similar term, and with a similar security, the funds necessary to obtain an asset of a similar value to the right-of-use, or ROU, asset in a similar economic environment. The incremental borrowing rate therefore reflects what we 'would have to pay', which requires estimation when no observable rates are available or when they need to be adjusted to reflect the terms and conditions of the lease. We estimate the incremental borrowing rate using observable inputs (such as market interest rates) when available and are required to make certain entity and asset-specific estimates. The incremental borrowing rate used in the calculation of the present

value of lease payments in calculating lease liabilities and the corresponding ROU requires the use of significant judgment by management.

Share-Based Compensation

We recognize compensation expense related to stock options granted to employees and nonemployees based on the estimated grant date fair value and recognize forfeitures as they occur. We estimate the grant date fair value, and the resulting share-based compensation expense, using the Black-Scholes option-pricing model for service-based and performance-based awards. The grant date fair value of the share-based awards is recognized on a straight-line basis over the requisite service period, which is typically the vesting period of the respective awards. The Black-Scholes option-pricing model requires the use of highly subjective assumptions to determine the fair value of share-based awards. Such assumptions involve inherent uncertainties and the application of significant judgment. As a result, if factors or expected outcomes change and we use significantly different assumptions or estimates, our share-based compensation could be materially different.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Our primary exposure to market risk is interest income and expense sensitivity, which is affected by changes in the general level of United States interest rates. Due to the nature of our investments, we believe that we are not subject to any material market risk exposure. We do not hold a material balance in foreign currencies or engage in derivative financial instruments that could materially impact our financial position.

Item 8. Financial Statements and Supplementary Data

The consolidated financial statements and related financial statement schedules required to be filed are listed in the Index to Consolidated Financial Statements and are incorporated herein and in Item 15 of Part IV of this Annual Report on Form 10-K.

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

Our disclosure controls and procedures (as defined in Rules 13a-15(e) or 15d-15(e)) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”) are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC’s rules and forms and to ensure that information required to be disclosed is accumulated and communicated to management, including our principal executive and financial officers, to allow timely decisions regarding disclosure. Our Chief Executive Officer and Principal Financial Officer, with assistance from other members of management, have reviewed the effectiveness of our disclosure controls and procedures, and, based on their evaluation, have concluded that the disclosure controls and procedures were effective as of December 31, 2025.

Management’s Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining an adequate system of internal control over financial reporting and for the assessment of the effectiveness of internal control over financial reporting as defined in Rule 13a-15(f) under the Exchange Act. Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with “U.S. GAAP” and includes those policies and procedures that: (1) pertain to the maintenance of records that accurately and fairly reflect our transactions and the dispositions of our assets; (2) provide reasonable assurance that our transactions are recorded as necessary to permit preparation of financial statements in accordance with “GAAP” and that our receipts and expenditures are being made only in accordance with appropriate authorizations; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our financial statements.

Management assessed our internal control over financial reporting as of December 31, 2025 based on the criteria established in Internal Control-Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Management's assessment included evaluation of such elements as the

design and operating effectiveness of key financial reporting controls, process documentation, accounting policies, and our overall control environment. This assessment is supported by testing and monitoring performed both by our Internal Audit function and our Finance function.

Based on our assessment, management concluded that our internal control over financial reporting was effective as of December 31, 2025.

Management reviewed the results of its assessment with our Audit Committee. The effectiveness of our internal control over financial reporting as of December 31, 2025 has been audited by Deloitte & Touche LLP, an independent registered public accounting firm, and their opinion is stated in their report, which is included in Part II, Item 8 of the Annual Report on Form 10-K.

Remediation of Previously Reported Material Weakness

As previously reported in Part II, Item 9A. "Controls and Procedures" of our Annual Reports on Form 10-K for the fiscal year ended December 31, 2024, we identified a material weakness related to information technology general controls ("ITGCs") that support the financial reporting process. Specifically, the remediated material weakness related to ineffective controls over (i) user access to ensure appropriate segregation of duties and adequate restriction of user and privileged access to financial applications, programs and data, to the appropriate personnel; (ii) program change management for financial applications to ensure that information technology ("IT") program and data changes affecting financial IT applications and underlying accounting records are identified, tested, authorized and implemented appropriately; and (iii) IT operations controls to ensure that critical interface jobs are monitored.

We have completed execution of our remediation plan for this material weakness and, as of December 31, 2025, successfully remediated this material weakness by implementing the following measures:

- updated and enhanced the IT policies and relevant internal controls to consider and address ITGCs including access security and change management;
- limited elevated access profiles in financially relevant IT systems and software to appropriate personnel;
- developed and enhanced access administration controls over provisioning, deprovisioning, and authentication;
- developed and enhanced user access reviews for financially relevant IT systems;
- designed and refined controls over change management and IT operations controls to monitor critical interface jobs;
- hired an internal audit manager with an appropriate level of knowledge and experience;
- engaged an accounting advisory firm to assist with the documentation, evaluation, remediation, and testing of our internal control over financial reporting; and
- provided training to control owners and relevant personnel to improve documentation that supports effective control activities, including evidence over the completeness and accuracy of information used in controls.

Changes in Internal Control over Financing Reporting

Other than the remediation efforts completed and described above, there were no changes in our internal control over financial reporting during the fiscal quarter ended December 31, 2025 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Disclosure Controls and Procedures, and Internal Controls Over Financial Reporting

Our management, including our principal executive officer and principal financial officer, does not expect that our disclosure controls and procedures or 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 objectives of the control system are 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.

Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, 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. The design of any system of controls is also 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. Due to inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Arcturus Therapeutics Holdings Inc.

Opinion on Internal Control Over Financial Reporting

We have audited the internal control over financial reporting of Arcturus Therapeutics Holdings, Inc. and subsidiaries (the "Company") as of December 31, 2025, based on criteria established in Internal Control — Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2025, based on criteria established in Internal Control — Integrated Framework (2013) issued by COSO.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated financial statements as of and for the year ended December 31, 2025, of the Company and our report dated March 3, 2026, expressed an unqualified opinion on those financial statements.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become

inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Deloitte & Touche LLP

San Diego, California

March 3, 2026

Item 9B. Other Information

Rule 10b5-1 Trading Plans

For the three months ended December 31, 2025, none of our directors or officers adopted or terminated a "Rule 10b5-1 trading arrangement" (as defined in Item 408 of Regulation S-K of the Exchange Act) intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not Applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Information required by this item will be contained in our Definitive Proxy Statement for our 2026 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2025. Such information is incorporated herein by reference.

Item 11. Executive Compensation

Information required by this item will be contained in our Definitive Proxy Statement for our 2026 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2025. Such information is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

Information required by this item will be contained in our Definitive Proxy Statement for our 2026 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2025. Such information is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence

Information required by this item will be contained in our Definitive Proxy Statement for our 2026 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2025. Such information is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services

Information required by this item will be contained in our Definitive Proxy Statement for our 2026 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2025. Such information is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules

(a)

(1) The information required by this item is included in Item 8 of Part II of this Annual Report.;

(2) Financial statement schedules not listed above have been omitted because information required to be set forth therein is not applicable, not required, or the information required by such schedules is shown in the consolidated financial statements or the notes thereto.

(3) See the exhibit index preceding the signature pages to this Annual Report, which is incorporated by reference herein.

(b) See the exhibit index preceding the signature pages to this Annual Report, which is incorporated by reference herein.

(c) Not applicable.

Item 16. Form 10-K Summary

None.

Exhibit Index

Exhibit Number	Description
1.1	Controlled Equity Offering℠ Sales Agreement, dated as of December 23, 2022 by and between Cantor Fitzgerald & Co, Wells Fargo Securities, LLC and Arcturus Therapeutics Holdings Inc. Incorporated by reference to Exhibit 1.2 to Registration Statement on Form S-3 filed on December 23, 2022 (File No. 333269003).
1.2	Amendment No. 1 to Controlled Equity Offering℠ Sales Agreement by and between Cantor Fitzgerald & Co, Wells Fargo Securities, LLC, William Blair & Company, L.L.C., and Arcturus Therapeutics Holdings Inc. Incorporated by reference to Exhibit 1.1 to Form 8-K filed on August 7, 2023.
3.1	Certificate of Incorporation. Incorporated by reference to Annex B to the proxy statement/prospectus which forms part of the Registration Statement on Form S-4 filed on March 18, 2019 (File No. 333-230353).
3.2	Certificate of Amendment, dated November 25, 2020. Incorporated by reference to Exhibit 3.1 to Form 8-K filed on November 25, 2020 (File No. 001-38942).
3.3	Bylaws of Arcturus Therapeutics Holdings Inc. Incorporated by reference to Exhibit 3.2 to the Company's Registration Statement on Form S-3, filed with the SEC on May 8, 2020 (File No. 333-238139).
4.1*	Description of Registrant's Securities.
10.1†	Form of Indemnification Agreement. Incorporated by reference to Exhibit 10.1 to the Company's Annual Report on Form 10-K for the year ended December 31, 2019 filed on March 16, 2020 (File No. 001-38942).
10.2†	Amended and Restated 2019 Omnibus Equity Incentive Plan. Incorporated by reference Exhibit 4.3 to the Registration Statement on Form S-8 filed on August 5, 2020 (File No. 001-38942).
10.3†	Arcturus Therapeutics Ltd. Amended and Restated Compensation Policy for Company Office Holders. Incorporated by reference to Exhibit 99.2 to the Company's Report of Foreign Private Issuer on Form 6-K filed on July 27, 2018 (File No. 001-35932).
10.4**	Research and Exclusive License Agreement, by and between Arcturus Therapeutics, Inc. and Synthetic Genomics, Inc., effective October 24, 2017. Incorporated by reference to Exhibit 4.8 to Form 20-F filed on May 14, 2018 (File No. 001-35932).
10.5**	Letter Agreement, by and between Arcturus Therapeutics, Inc. and the Cystic Fibrosis Foundation, dated May 16, 2017. Incorporated by reference to Exhibit 4.11 to Form 20-F filed on May 14, 2018 (File No. 001-35932).
10.6**	Amendment No. 2 to Letter Agreement, by and between Arcturus Therapeutics, Inc. and the Cystic Fibrosis Foundation, dated August 1, 2019. Incorporated by reference to Exhibit 10.16 to Form 10-Q filed on August 14, 2019.
10.7	Lease Agreement, by and between Arcturus Therapeutics, Inc. and ARE-SD Region No. 44, LLC, dated October 4, 2017. Incorporated by reference to Exhibit 4.6 to Form 20-F filed on May 14, 2018 (File No. 001-35932).

Exhibit Number	Description
10.8	First Amendment to Lease Agreement, by and between Arcturus Therapeutics Holdings Inc. and ARE-SD Region No. 44, LLC dated February 1, 2020. Incorporated by reference to Exhibit 10.23 to the Company's Annual Report on Form 10-K for the year ended December 31, 2019 filed on March 16, 2020 (File No. 001-38942).
10.9**	Acceptance Letter, dated March 4, 2020, by and between Arcturus Therapeutics Holdings Inc. and the Economic Development Board of Singapore. Incorporated by reference to Exhibit 10.24 to the Company's Annual Report on Form 10-K for the year ended December 31, 2019 filed on March 16, 2020 (File No. 001-38942).
10.10**	Manufacturing Support Agreement, dated November 7, 2020, by and between Arcturus Therapeutics Holdings Inc. and the Economic Development Board of Singapore. Incorporated by reference to Exhibit 10.33 to Quarterly Report on Form 10-Q filed on November 9, 2020 (File No. 001-38942).
10.11†	2020 Employee Stock Purchase Plan. Incorporated by reference to Exhibit 4.3 to Form S-8 filed on August 5, 2020 (File No. 001-38942).
10.12	Second Amendment to Lease, by and between Arcturus Therapeutics, Inc. and ARE-SD Region No. 44, LLC, dated November 13, 2020. Incorporated by reference to Exhibit 10.29 to the Company's Annual Report on Form 10-K for the year ended December 31, 2020 filed on March 1, 2020 (File No. 001-38942).
10.13	Third Amendment to Lease, by and between Arcturus Therapeutics, Inc. and ARE-SD Region No. 44, LLC, dated February 25, 2021. Incorporated by reference to Exhibit 10.30 to the Company's Annual Report on Form 10-K for the year ended December 31, 2020 filed on March 1, 2021 (File No. 001-38942).
10.14†	Arcturus Therapeutics Holdings Inc. Severance Policy for Executives. Incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed on April 26, 2021 (File No. 001-38942).
10.15†	Employment Agreement, dated as of June 13, 2019, between the Company and Joseph Payne. Incorporated by reference to Exhibit 10.1 to Form 8-K12B filed on June 14, 2019 (File No. 001-38942)
10.16†	Employment Agreement, dated as of June 13, 2019, between the Company and Andy Sassine. Incorporated by reference to Exhibit 10.2 to Form 8-K12B filed on June 14, 2019 (File No. 001-38942)
10.17†	Employment Agreement, dated as of June 13, 2019, between the Company and Dr. Padmanabh Chivukula. Incorporated by reference to Exhibit 10.3 to Form 8-K12B filed on June 14, 2019 (File No. 001-38942)
10.18†	2021 Inducement Equity Incentive Plan. Incorporated by reference to Exhibit 4.1 to Form S-8 filed on October 20, 2021 (File No. 333-260391).
10.19	Lease, by and between Arcturus Therapeutics, Inc. and TPSC IX, LLC, dated September 29, 2021. Incorporated by reference to Exhibit 10.35 to Form 10-Q filed on November 9, 2021 (File No. 001-38942).
10.20	Technology License and Technical Support Agreement, signed July 29, 2021 and effective July 30, 2021, by and between Arcturus Therapeutics, Inc. and Vinbiotech Research and Manufacture Joint Stock Company. Incorporated by reference to Exhibit 10.32 to Quarterly Report on Form 10-Q filed on August 10, 2021 (File No. 001-38942).

Exhibit Number	Description
10.21	Framework Drug Substance Supply Agreement, signed July 29, 2021 and effective July 30, 2021, by and between Arcturus Therapeutics, Inc. and Vinbiotech Research and Manufacture Joint Stock Company. Incorporated by reference to Exhibit 10.33 to Quarterly Report on Form 10-Q filed on August 10, 2021 (File No. 001-38942).
10.22†	Amended and Restated 2019 Omnibus Equity Incentive Plan, as amended. Incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed on June 14, 2024 (File No. 001-38942).
10.23**	Study Support Agreement effective October 31, 2022 by and between Arcturus Therapeutics, Inc. and Vinbiocare Biotechnology Joint Stock Company. Incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed on November 4, 2022 (File No. 001-38942).
10.24**	Cost Reimbursement Contract dated August 31, 2022, by and between Arcturus Therapeutics Holdings Inc. and Biomedical Advanced Research and Development Authority of the U.S. Department of Health and Human Services. Incorporated by reference to Exhibit 10.36 to Quarterly Report on Form 10-Q filed on November 9, 2022 (File No. 001-38942).
10.25**	Collaboration and License Agreement, dated November 1, 2022, by and between Arcturus Therapeutics Holdings Inc. and CSL Limited. Incorporated by reference to Exhibit 10.38 to Quarterly Report on Form 10-Q filed on November 9, 2022 (File No. 001-38942).
10.26**	Manufacturing Support Agreement Termination Letter, dated March 23, 2023, by and between Arcturus Therapeutics, Inc. and the Economic Development of Singapore. Incorporated by reference to Exhibit 10.41 to Annual Report on Form 10-K filed on March 29, 2023 (File No. 001-38942).
10.27**	Credit Agreement dated April 21, 2023, by and between Arcturus Therapeutics, Inc. and Wells Fargo Bank, National Association. Incorporated by reference to Exhibit 10.28 to Quarterly Report on Form 10-Q filed on May 9, 2023 (File No. 001-38942).
10.28**	Security Agreement dated April 21, 2023, by and between Arcturus Therapeutics, Inc. and Wells Fargo Bank, National Association. Incorporated by reference to Exhibit 10.29 to Quarterly Report on Form 10-Q filed on May 9, 2023 (File No. 001-38942).
10.29**	Revolving Line of Credit Note dated April 21, 2023, by and between Arcturus Therapeutics, Inc. and Wells Fargo Bank, National Association. Incorporated by reference to Exhibit 10.30 to Quarterly Report on Form 10-Q filed on May 9, 2023 (File No. 001-38942).
10.30**	Amendment Number One to Collaboration and License Agreement, dated August 3, 2023, by and between Arcturus Therapeutics, Inc. and Seqirus Inc. Incorporated by reference to Exhibit 10.31 to Quarterly Report on Form 10-Q filed on November 14, 2023 (File No. 001-38942).
10.31**	Amendment No. 4 to Letter Agreement, dated September 25, 2023, by and between Arcturus Therapeutics, Inc. and the Cystic Fibrosis Foundation. Incorporated by reference to Exhibit 10.32 to Quarterly Report on Form 10-Q filed on November 14, 2023 (File No. 001-38942)
10.32**	First Amendment to Credit Agreement and First Amendment to Revolving Line of Credit, dated June 26, 2024, by and between Arcturus Therapeutics, Inc. and Wells Fargo Bank, National Association. Incorporated by reference to Exhibit 10.35 to Quarterly Report on Form 10-Q filed on August 5, 2024 (File No. 001-38942).

Exhibit Number	Description
10.33	Fifth Amendment to Lease, by and between Arcturus Therapeutics, Inc. and ARE-SD Region No. 44, LLC, dated July 12, 2024. Incorporated by reference to Exhibit 10.36 to Quarterly Report on Form 10-Q filed on November 7, 2024 (File No. 001-38942).
10.34	Separation Agreement and General Release between Arcturus Therapeutics Holdings Inc. and Andy Sassine dated 11, 2025. Incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed on December 15, 2025 (File No. 001-38942).
10.35	Employment Agreement between Arcturus Therapeutics Holdings Inc. and Joe Roberts dated July 3, 2018. Incorporated by reference to Exhibit 10.2 to Current Report on Form 8-K filed on December 15, 2025 (File No. 001-38942).
19.1*	Arcturus Therapeutics Holdings, Inc. Insider Trading Policy
21.1*	List of subsidiaries of Arcturus Therapeutics Holdings, Inc.
23.1*	Consent of Independent Registered Public Accounting Firm
23.2*	Consent of Independent Registered Public Accounting Firm
24.1*	Power of Attorney (included on the signature page of this Annual Report).
31.1*	Certification by Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) under the Securities Exchange Act of 1934, as amended.
31.2*	Certification by Principal Financial and Accounting Officer pursuant to Rule 13a-14(a) or 15d-14(a) under the Securities Exchange Act of 1934, as amended.
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Principal Financial and Accounting Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
97.1*	Arcturus Therapeutics Holdings, Inc. Clawback Policy
101*	The following financial statements and footnotes from the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2025 formatted in Inline Extensible Business Reporting Language (Inline XBRL): 101.INS Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document 101.SCH Inline XBRL Taxonomy Extension Schema
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

** Certain confidential portions of this exhibit have been redacted from the publicly filed document because such portions are (i) not material and (ii) would be competitively harmful if publicly disclosed.

† Management compensatory plan, contract or arrangement.

SIGNATURES

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

ARCTURUS THERAPEUTICS HOLDINGS INC.

Date: March 3, 2026

By: /s/ Joseph E. Payne
Name: Joseph E. Payne
Title: President, Chief Executive Officer and Director

The undersigned officers and directors of Arcturus Therapeutics Holdings Inc., hereby severally constitute and appoint Joseph E. Payne and Dr. Padmanabh Chivukula, and each of them individually, with full power of substitution and resubstitution, as their true and lawful attorneys and agents, to do any and all acts and things in their name and behalf in their capacities as directors and officers and to execute any and all instruments for them and in their names in the capacities indicated below, which said attorneys and agents, may deem necessary or advisable to enable said corporation to comply with the Securities Exchange Act of 1934, as amended, and any rules, regulations and requirements of the Securities and Exchange Commission, in connection with this Annual Report on Form 10-K, including specifically but without limitation, power and authority to sign for them or any of them in their names in the capacities indicated below, any and all amendments hereto, and they do hereby ratify and confirm all that said attorneys and agents, or either of them, may lawfully do or cause to be done by virtue hereof.

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

Name	Title	Date
/s/ Joseph E. Payne **Joseph E. Payne**	President, Chief Executive Officer and Director *(principal executive officer)*	March 3, 2026
/s/ Dr. Moncef Slaoui **Dr. Moncef Slaoui**	Chairman of the Board	March 3, 2026
/s/ Joseph Roberts **Joseph Roberts**	Corporate Controller *(principal financial and accounting officer)*	March 3, 2026
/s/ Dr. Magda Marquet **Dr. Magda Marquet**	Director	March 3, 2026
/s/ James Barlow **James Barlow**	Director	March 3, 2026
/s/ Edward Holmes **Edward Holmes**	Director	March 3, 2026
/s/ Dr. Peter Farrell **Dr. Peter Farrell**	Director	March 3, 2026
/s/ Dr. John Markels **Dr. John Markels**	Director	March 3, 2026
/s/ Jing Marantz **Jing Marantz**	Director	March 3, 2026

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the shareholders and the Board of Directors of Arcturus Therapeutics Holdings, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Arcturus Therapeutics Holdings, Inc. and subsidiaries (the "Company") as of December 31, 2025, and 2024, the related consolidated statements of operations, comprehensive loss, stockholder's equity, and cash flows, for each of the two years in the period ended December 31, 2025 and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025 and 2024, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2025, in conformity with accounting principles generally accepted in the United States of America.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2025, based on criteria established in Internal Control — Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 3, 2026, expressed an unqualified opinion on the Company's internal control over financial reporting.

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 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. 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 critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Collaboration Revenue — Refer to Note 2 and Note 3 to the financial statements

Critical Audit Matter Description

The Company has entered into a license and collaborative research and development arrangement with Seqirus, Inc. There are five distinct performance obligations under this arrangement. The Company recognizes revenue over time for all performance obligations except for the vaccine license. The vaccine license is recognized at the point in time it is transferred. The accounting for revenue recognized over time measures the progress using an input method which is based on costs incurred toward the satisfaction of the performance obligation. As of December 31, 2025, Collaboration revenue was $67.2 million, of which $66 million relates to the agreement with Seqirus, Inc.

Given the judgments necessary to estimate total costs to be incurred to satisfy the performance obligations, as well as the high volume of expense data used in the revenue calculation, auditing such estimates required extensive audit effort and a high degree of auditor judgment when performing audit procedures and evaluating the results of those procedures.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to the recognition of revenue for the Seqirus, Inc. arrangement included the following, among others:

- We tested the operating effectiveness of controls over collaboration revenue, including those related to the determination of the timing and amount of revenue recognized.
- We evaluated the total costs incurred related to each performance obligation by inspecting, on a sample basis, underlying source documents to determine costs were recorded to the correct performance obligation.
- We evaluated the assumptions used in the estimates of total costs and the estimated measure of progress for recognizing revenue by:
    - Analyzing period-over-period changes in the total cost assumption, identifying any significant fluctuations.
    - Inspecting third-party evidence of the agreed-upon total costs to be incurred and comparing that to the total cost to be incurred used by the Company in the calculation.

/s/ Deloitte & Touche LLP

San Diego, California

March 3, 2026

We have served as the Company's auditor since 2024.

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Arcturus Therapeutics Holdings Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated statements of operations and comprehensive loss, changes in stockholders' equity and cash flows of Arcturus Therapeutics Holdings Inc. and its subsidiaries (the Company) for the year ended December 31, 2023, 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 results of the Company's operations and its cash flows for the year ended December 31, 2023, in conformity with U.S. generally accepted accounting principles.

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 audit. We are a public accounting firm registered with the 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 audit 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. Our audit 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 audit 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 audit provides a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We served as the Company's auditor from 2018 to 2024.

San Diego, California

March 14, 2024

except for Note 12, as to which the date is

March 6, 2025

ARCTURUS THERAPEUTICS HOLDINGS INC. AND ITS SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

(in thousands, except per share data)	As of December 31, 2025	2024
Assets		
Current assets:		
Cash and cash equivalents	$ 230,909	$ 237,028
Restricted cash	—	55,000
Accounts receivable	5,564	3,974
Prepaid expenses and other current assets	4,973	9,977
Total current assets	241,446	305,979
Property and equipment, net	6,736	9,531
Operating lease right-of-use asset	21,081	26,674
Non-current restricted cash	1,885	1,885
Total assets	$ 271,148	$ 344,069
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 4,235	$ 7,194
Accrued liabilities	23,898	38,781
Deferred revenue	8,246	19,514
Total current liabilities	36,379	65,489
Deferred revenue, net of current portion	—	12,604
Operating lease liability, net of current portion	20,784	24,998
Total liabilities	57,163	103,091
Stockholders' equity:		
Common stock: $0.001 par value; 60,000 shares authorized; issued and outstanding shares were 28,414 at December 31, 2025 and 27,000 at December 31, 2024	28	27
Additional paid-in capital	728,547	689,758
Accumulated deficit	(514,590)	(448,807)
Total stockholders' equity	213,985	240,978
Total liabilities and stockholders' equity	$ 271,148	$ 344,069

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

ARCTURUS THERAPEUTICS HOLDINGS INC. AND ITS SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(in thousands, except per share data)	Year Ended December 31, 2025	2024	2023
Revenue:			
Collaboration revenue	$ 67,221	$ 138,389	$ 157,748
Grant revenue	14,810	13,921	9,051
Total revenue	82,031	152,310	166,799
Operating expenses:			
Research and development, net	112,212	195,156	192,133
General and administrative	46,079	52,823	52,871
Total operating expenses	158,291	247,979	245,004
Loss from operations	(76,260)	(95,669)	(78,205)
Gain (loss) from foreign currency	382	(471)	(229)
Finance income, net	10,095	15,195	16,591
Gain on debt extinguishment	—	—	33,953
Net loss before income taxes	(65,783)	(80,945)	(27,890)
(Benefit) provision for income taxes	—	(4)	1,835
Net loss	(65,783)	(80,941)	(29,725)
Net loss per share, basic and diluted	$ (2.40)	$ (3.00)	$ (1.12)
Weighted-average shares outstanding, basic and diluted	27,386	27,000	26,628
Comprehensive loss	$ (65,783)	$ (80,941)	$ (29,725)

ARCTURUS THERAPEUTICS HOLDINGS INC. AND ITS SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

(in thousands)	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2022	**26,555**	**$ 27**	**$ 608,426**	**$ (338,141)**	**$ 270,312**
Share-based compensation	—	—	34,649	—	34,649
Issuance of common stock upon exercise of stock options	238	—	2,668	—	2,668
Issuance of common stock under equity plans	35	—	609	—	609
Net loss	—	—	—	(29,725)	(29,725)
Balance at December 31, 2023	**26,828**	**$ 27**	**$ 646,352**	**$ (367,866)**	**$ 278,513**
Share-based compensation	—	—	37,988	—	37,988
Issuance of common stock upon exercise of stock options	228	—	4,736	—	4,736
Issuance of common stock under equity plans	40	—	682	—	682
Net loss	—	—	—	(80,941)	(80,941)
Balance at December 31, 2024	**27,096**	**$ 27**	**$ 689,758**	**$ (448,807)**	**$ 240,978**
Share-based compensation	—	—	25,408	—	25,408
Issuance of common stock upon exercise of stock options	104	—	1,109	—	1,109
Issuance of common stock under equity plans	35	—	585	—	585
Proceeds from issuance of common stock, net of issuance costs	1,179	1	11,687	—	11,688
Net loss	—	—	—	(65,783)	(65,783)
Balance at December 31, 2025	**28,414**	**$ 28**	**$ 728,547**	**$ (514,590)**	**$ 213,985**

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

ARCTURUS THERAPEUTICS HOLDINGS INC. AND ITS SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)	Year Ended December 31, 2025	2024	2023
Operating activities			
Net loss	$ (65,783)	$ (80,941)	$ (29,725)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	3,025	3,544	2,957
Share-based compensation expense	25,408	37,988	34,649
Gain on debt extinguishment	—	—	(33,953)
Foreign currency transaction loss	382	471	90
Other non-cash expenses	—	—	502
Impairment of right-of-use assets	1,897	—	—
Changes in assets and liabilities:			
Accounts receivable	(1,590)	28,090	(29,300)
Prepaid expenses and other current assets	5,004	(2,456)	1,165
Right-of-use assets	3,696	4,562	4,045
Accounts payable	(2,959)	1,915	(2,238)
Accrued liabilities	(15,265)	5,932	(588)
Deferred revenue	(23,872)	(55,207)	38,606
Lease liabilities	(4,214)	(3,645)	(4,309)
Net cash used in operating activities	(74,271)	(59,747)	(18,099)
Investing activities			
Acquisition of property and equipment	(230)	(648)	(2,901)
Net cash used in investing activities	(230)	(648)	(2,901)
Financing activities			
Proceeds from debt	15,000	—	20,000
Proceeds from exercise of stock options	1,109	4,736	2,668
Proceeds from issuance of common stock under equity plans	585	682	609
Proceeds from issuance of common stock, net of issuance costs	11,688	—	—
Payments on debt obligations	(15,000)	—	(47,364)
Net cash provided by (used in) financing activities	13,382	5,418	(24,087)
Net decrease in cash, cash equivalents and restricted cash	(61,119)	(54,977)	(45,087)
Cash, cash equivalents and restricted cash, beginning of year	293,913	348,890	393,977
Cash, cash equivalents and restricted cash, end of year	$ 232,794	$ 293,913	$ 348,890

	Year Ended December 31, 2025	2024	2023
Supplemental disclosure of cash flow information			
Cash paid for interest	$ —	$ —	$ 2,127
Cash paid for income taxes	$ —	$ 1,407	$ —
Non-cash investing activities			
Right-of-use assets acquired through operating leases	$ —	$ 2,736	$ —
Non-cash asset disposal	$ 2,345	$ 473	$ —
Purchase of property and equipment in accounts payable and accrued expenses	$ —	$ —	$ 68

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

ARCTURUS THERAPEUTICS HOLDINGS INC. AND ITS SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1. Organization

Description of Business

Arcturus Therapeutics Holdings Inc. (the “Company” or "Arcturus") is a messenger RNA medicines company focused on the development of liver and respiratory rare disease therapeutics. Arcturus became a clinical stage company in 2020 when it announced that its Investigational New Drug (“IND”) application for ornithine transcarbamylase (“OTC”) deficiency and its Clinical Trial Application (“CTA”) for candidate LUNAR-COV19 were approved by applicable health authorities. In 2023, our COVID-19 vaccine, ARCT-154 (also referred to as KOSTAIVE®), received marketing authorization approval in Japan for adults 18 years and older, and in September 2024 KOSTAIVE became the world’s first approved and commercially available self-amplifying RNA (sa-mRNA) vaccine.

Note 2. Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

The accompanying consolidated financial statements include the accounts of Arcturus Therapeutics Holdings Inc. and its subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation. These consolidated financial statements are prepared in conformity with accounting principles generally accepted in the United States (“U.S. GAAP”), which requires management to make estimates and assumptions regarding the valuation of certain debt and equity instruments, the equity method investment, share-based compensation, accruals for liabilities, income taxes, revenue and deferred revenue, leases, expense accruals, and other matters that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Although these estimates are based on management’s knowledge of current events and actions the Company may undertake in the future, actual results could materially differ from those estimates.

Segment Information

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker in making decisions regarding resource allocation and assessing performance. The Company and its chief operating decision-maker view the Company’s operations and manage its business in one operating segment, which includes all activities related to the discovery, development and commercialization of messenger RNA medicines.

Cash and Cash Equivalents

Cash equivalents are short-term highly liquid investments that are readily convertible to cash with original maturities of three months or less at the date of purchase.

Restricted cash

Restricted cash includes cash required to be set aside as security for lease payments and to maintain a letter of credit for the benefit of the landlord for the Company’s offices. At December 31, 2025 and 2024, the Company had restricted cash of $1.9 million in conjunction with property leases in San Diego, California, and such restriction is expected to be removed at the end of the lease term.

Fair Value Measurements

Fair value is defined as the exit price, or the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants as of the measurement date. A hierarchy has been established for inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the most observable inputs be used when available.

Observable inputs are inputs that market participants would use in valuing the asset or liability developed based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the factors market participants would use in valuing the asset or liability developed based upon the best information available under the circumstances. The hierarchy consists of three levels. Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities. Level 2 inputs include 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 inputs (other than quoted prices) that are observable for the asset or liability, either directly or indirectly. Level 3 inputs are unobservable inputs for the asset or liability. Categorization within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement.

Accounts Receivable

Accounts receivable are recorded at the net invoice value and are non-interest bearing. The Company considers receivables past due based on the contractual payment terms. The Company reserves for specific receivables if collectability is no longer reasonably assured. Estimates for allowances for doubtful accounts are determined based on existing contractual obligations, historical payment patterns, and individual customer circumstances. The Company reevaluates such reserves on a regular basis and adjusts its reserves as needed. Once a receivable is deemed to be uncollectible, such balance is charged against the reserve. No reserves have been recorded as of December 31, 2025 or 2024.

Concentration of Credit Risk and Significant Customers

The Company is exposed to concentrations of credit risk primarily related to cash, cash equivalents, and accounts receivable.

Cash and Cash Equivalents

The Company mitigates credit risk exposure by maintaining cash and cash equivalents only with high-credit-quality financial institutions and investing in instruments with short maturities. The Company continuously monitors counterparty risk to minimize potential financial exposure.

Accounts Receivable Concentration

As of December 31, 2025 and 2024, the Company had significant concentrations of credit risk related to accounts receivable from a limited number of customers. The following customers accounted for 10% or more of total accounts receivable in each respective period:

As of December 31, 2025:

- BARDA – 64% of total accounts receivable
- CSL – 19% of total accounts receivable

As of December 31, 2024:

- BARDA – 60% of total accounts receivable
- CSL – 20% of total accounts receivable

The Company monitors its credit exposure through regular assessments of counterparty risk and maintains ongoing collection efforts to mitigate potential credit losses.

Revenue Concentration

The Company generates a substantial portion of its revenue from a limited number of key customers. The following customers accounted for 10% or more of total revenue for each period:

For the year ended December 31, 2025:

- CSL – 80% of total revenue
- BARDA – 16% of total revenue

For the year ended December 31, 2024:

- CSL – 91% of total revenue

For the year ended December 31, 2023:

- CSL – 92% of total revenue

Given this concentration, the Company's financial performance and cash flows may be materially impacted if there are changes in demand, contract renewals, or the financial condition of these key customers. The Company continues to evaluate opportunities to expand its customer base and mitigate concentration risk over time.

Joint Ventures, Equity Method Investments and Variable Interest Entities

Investments for which the Company exercises significant influence, but does not have control are accounted for under the equity method. Equity method investment activity is related to the Company's joint venture in ARCALIS, Inc. with Axcelead, Inc. The Company's share of the investees' results is presented as either income or loss from equity method investees in the accompanying consolidated statements of operations and comprehensive loss. As of December 31, 2025, the carrying value of the equity-method investment in ARCALIS remained at zero.

Property and Equipment, net

Property and equipment are stated at cost, net of accumulated depreciation and amortization. The cost of property and equipment is depreciated or amortized using the straight-line method over the respective useful lives of the assets, ranging from three to five years. Leasehold improvements are amortized using the straight-line method over the shorter of the estimated useful life of the asset or the lease term. Long-lived assets, including property and equipment are reviewed for impairment whenever events or circumstances indicate that the carrying amount of these assets may not be recoverable. The determinants used for this evaluation include management's estimate of an asset's ability to generate positive income from operations and positive cash flow in future periods, as well as the strategic significance of the assets to the Company's business objectives. The Company did not recognize any impairment losses for the years ended December 31, 2025, 2024 or 2023.

Comprehensive Loss

Comprehensive loss is defined as the change in stockholders' equity during a period from transactions and other events and circumstances from non-owner sources. There was no other comprehensive loss or income tax effect related to unrealized losses in the years ended December 31, 2025, 2024 or 2023.

Revenue Recognition

At contract inception, the Company analyzes its collaboration arrangements to assess whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities and therefore within the scope of ASC Topic 808, Collaborative Arrangements (ASC 808). For collaboration arrangements within the scope of ASC 808 that contain multiple elements, the Company first determines which elements of the collaboration reflect a vendor-customer relationship and are therefore within the scope of ASC 606.

The Company determines revenue recognition for arrangements within the scope of Topic 606 by performing the following five steps: (i) identify the contract; (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 a performance obligation.

The terms of the Company's revenue agreements include license fees, upfront payments, milestone payments, reimbursement for research and development activities, option exercise fees, consulting and related technology transfer fees and royalties on sales of commercialized products. The event-based milestone payments represent variable consideration, and the Company uses the most likely amount method to estimate this variable consideration because the Company will either receive the milestone payment or will not, which makes the potential milestone payment a binary event. The most likely amount method requires the Company to determine the likelihood of earning the milestone payment. Given the high degree of uncertainty around achievement of these milestones, the Company determines the milestone amounts to be fully constrained and does not recognize revenue until the uncertainty associated with these payments is resolved. The Company will recognize revenue from sales-based royalty payments when or as the sales occur. The Company will re-evaluate the transaction price in each reporting period as uncertain events are resolved and other changes in circumstances occur.

A performance obligation is a promise in a contract to transfer a distinct good or service to the collaborative partner and is the unit of account in Topic 606. A contract's transaction price is allocated to each distinct performance obligation based on relative standalone selling price and recognized as revenue when, or as, the performance obligation is satisfied.

For performance obligations that are recognized over time, the Company measures the progress using an input method. The input methods used are based on the effort expended or costs incurred toward the satisfaction of the performance obligation. The Company estimates the amount of effort expended, including the time estimated it will take to complete the activities, or costs incurred in a given period, relative to the estimated total effort or costs to satisfy the performance obligation. This approach requires the Company to make numerous estimates and use significant judgment. If estimates or judgments change over the course of the collaboration, a cumulative catch up of revenue is recognized in the period such changes are identified.

See *"Note 3, Revenue"* for specific details surrounding the Company's arrangements.

Grant revenue

Grant revenue consists of funding under cost reimbursement programs primarily from federal and non-profit foundation sources for qualified research and development activities performed by the Company. Such amounts are invoiced and recorded as revenue as grant-funded activities are performed, with any advance funding recorded as deferred revenue until the activities are performed.

Leases

The Company determines if an arrangement is a lease at inception. Lease right-of-use assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. For operating leases with an initial term greater than 12 months, the Company recognizes operating lease right-of-use assets and operating lease liabilities based on the present value of lease payments over the lease term at the commencement date. Operating lease right-of-use assets are comprised of the lease liability plus any lease payments made and excludes lease incentives. Lease terms include options to renew or terminate the lease when the Company is reasonably certain that the renewal option will be exercised or when it is reasonably certain that the termination option will not be exercised. For the Company's operating leases, if the interest rate used to determine the present value of future lease payments is not readily determinable, the Company estimates its incremental borrowing rate as the discount rate for the lease. The Company's incremental borrowing rate is estimated to approximate the interest rate on a collateralized basis with similar terms and payments, and in similar economic environments. Lease expense for lease payments is recognized on a straight-line basis over the lease term. The Company has elected the practical expedient to not separate lease and non-lease components.

See *"Note 11, Commitments and Contingencies"* for specific details surrounding the Company's leases.

Research and Development Costs, net

All research and development costs are expensed as incurred. Research and development costs consist primarily of salaries, employee benefits, costs associated with preclinical studies and clinical trials (including amounts paid to clinical research organizations and other professional services), pre-launch inventory, in-process research and development expenses and license agreement expenses. Payments made prior to the receipt of goods or services to be used in research and development are capitalized until the goods are received or the services are performed. The Company recognizes grants that fall within the scope of ASC 808 as contra research and

development expense in the consolidated statement of operations on a systematic basis over the periods in which the entity recognizes as expenses the related costs for which the grants are intended to compensate.

The Company records accruals for estimated research and development costs, comprising payments for work performed by third party contractors, laboratories, participating clinical trial sites, and others. Some of these contractors bill monthly based on actual services performed, while others bill periodically based upon achieving certain contractual milestones. For the latter, the Company accrues the expenses as goods or services are used or rendered.

Clinical trial activities performed by third parties are accrued and expensed based upon estimates of the proportion of work completed over the life of the individual clinical trial and patient enrollment rates in accordance with agreements established with Clinical Research Organizations ("CROs") and clinical trial sites. Estimates are determined by reviewing contracts, vendor agreements and purchase orders, and through discussions with internal clinical personnel and external service providers as to the progress or stage of completion of trials or services and the agreed-upon fee to be paid for such services.

General and Administrative Costs

General and administrative expenses consist primarily of personnel-related costs, including share-based compensation, for executives, finance, legal, human resources, business development, and other administrative and operational functions, professional fees, accounting and legal services, information technology and facility-related costs, and expenses associated with obtaining and maintaining intellectual property ("IP"). These costs relate to the operation of the business, unrelated to the research and development function, or any individual program.

Pre-Launch Inventory

Prior to obtaining initial regulatory approval for an investigational product candidate, the Company expenses costs relating to production of inventory as research and development expense in its consolidated statements of operations and comprehensive loss, in the period incurred. When the Company believes regulatory approval and subsequent commercialization of an investigational product candidate is probable, and the Company also expects future economic benefit from the sales of the investigational product candidate to be realized, it will then capitalize the costs of production as inventory.

Share-Based Compensation

The Company records share-based compensation for equity awards granted to employees, consultants, officers and directors within general and administrative and research and development expenses on the statements of operations and comprehensive loss. Share-based compensation is recognized over the requisite service period of the individual awards using the straight-line attribution method, which generally equals the vesting period. Employees and officers' stock options have a ten-year life and generally vest 25% on the first anniversary of the grant and in 1/36th equal installments on each monthly anniversary thereafter, such that options are fully vested on the four-year anniversary of the date of grant. The exercisability and vesting periods of equity awards granted to consultants and directors vary.

The fair value of stock options is estimated using a Black-Scholes valuation model on the date of grant. This method requires certain assumptions be used as inputs, such as the fair value of the underlying common stock, expected term of the option before exercise, expected volatility of the Company's common stock, expected dividend yield, and a risk-free interest rate. The Company has limited historical stock option activity and therefore estimates the expected term of stock options granted using the simplified method, which represents the average of the contractual term of the stock option and its weighted-average vesting period. Through the third quarter of 2024, the Company estimated expected volatility using the historical volatility of a peer group of publicly traded companies. Beginning in the fourth quarter of 2024 and continuing into fiscal year 2025, the Company used its own historical volatility to estimate expected volatility, as it had accumulated sufficient trading history and stock price data to support the use of Company-specific volatility. The Company has not declared or paid any dividends and does not currently expect to do so in the foreseeable future. The risk-free interest rates used are based on the implied yield currently available in United States Treasury securities at maturity with a term equivalent to the expected term of the stock options. The effect of forfeited or cancelled awards is recorded when the forfeiture or cancellation occurs.

Statement of Cash Flows

The following table provides a reconciliation of cash and cash equivalents and restricted cash reported within the consolidated balance sheets to the total of such amounts shown in the consolidated statement of cash flows:

	As of December 31,		
(in thousands)	**2025**	**2024**	**2023**
Cash and cash equivalents	$ 230,909	$ 237,028	$ 292,005
Restricted cash - current	—	55,000	55,000
Non-current Restricted cash	1,885	1,885	1,885
Total cash, cash equivalents and restricted cash shown in the statement of cash flows	$ 232,794	$ 293,913	$ 348,890

Income Tax Expense

Income taxes are accounted for using an asset and liability approach that requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the financial reporting basis and the tax basis of the Company's assets and liabilities at the applicable tax rates, along with net operating loss and tax credit carryovers. The Company records a valuation allowance against its deferred tax assets to reduce the net carrying value to an amount that it believes is more likely than not to be realized. Management has considered estimated taxable income and ongoing prudent and feasible tax planning strategies in assessing the amount of the valuation allowance. Based upon the weight of available evidence, which includes the Company's historical operating performance and limited potential to utilize tax attribute carryforwards, the Company has determined that total deferred tax assets should be fully offset by a valuation allowance. When the Company establishes or reduces the valuation allowance against its deferred tax assets, its provision for income taxes will increase or decrease, respectively, in the period such determination is made.

The Company is required to file federal and state income tax returns in the United States and various other state jurisdictions. The Company also files income tax returns in the foreign countries in which it operates. The preparation of these income tax returns requires the Company to interpret the applicable tax laws and regulations in effect in such jurisdictions, which could affect the amount of tax paid by the Company.

Additionally, the Company follows an accounting standard addressing the accounting for uncertainty in income taxes that prescribes rules for recognition, measurement, and classification in the consolidated financial statements of tax positions taken or expected to be taken in a tax return.

Net Loss per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of shares of common stock outstanding for the period, without consideration for common stock equivalents. Diluted net loss per share is calculated by dividing the net loss by the weighted-average number of shares of common stock and dilutive common stock equivalents outstanding for the period determined using the treasury-stock method. Dilutive shares of common stock for the years ended December 31, 2025, 2024 and 2023 were comprised of stock options and restricted stock units.

No dividends were declared or paid during the reporting periods.

Recently Adopted Accounting Pronouncements

In November 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures, which requires public entities to disclose information about their reportable segments' significant expenses and other segment items on an interim and annual basis. Public entities with a single reportable segment are required to apply the disclosure requirements in ASU 2023-07, as well as all existing segment disclosures and reconciliation requirements in ASC 280 on an interim and annual basis. The Company adopted ASU 2023-07 for annual reporting periods beginning January 1, 2024 and interim reporting periods beginning January 1, 2025. The adoption of ASU 2023-07 had no significant impact on our financial statement disclosures. See "*Note 12, Segment Information*" for further information.

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740) - Improvements to Income Tax Disclosures. The new standard requires a company to expand its existing income tax disclosures, specifically related to the rate reconciliation and income taxes paid. The Company adopted ASU 2023-09 prospectively beginning in fiscal year 2025. See "*Note 10, Income Taxes*" for further information.

Recently Issued Accounting Standards Not Yet Adopted

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies and adopted by the Company as of the specified effective date. The Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on the consolidated financial statements and disclosures.

In November 2024, the FASB issued ASU 2024-03, Income Statement–Reporting Comprehensive Income–Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses, which requires public entities to disclose specified information about certain costs and expenses on an interim and annual basis. ASU 2024-03 is effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027, with early adoption permitted. The Company is currently evaluating the impact that adoption of ASU 2024-03 will have on the financial statement disclosures.

NOTE 3. Revenue

The Company has entered into license agreements and collaborative research and development arrangements with pharmaceutical and biotechnology companies, as well as consulting, related technology transfer, product revenue and government grant agreements. Under these arrangements, the Company is entitled to receive license fees, consulting fees, product fees, technological transfer fees, upfront payments, milestone payments if and when certain research and development milestones, technology transfer milestones or success-based milestones are achieved, royalties on approved product sales and reimbursement for research and development activities. The Company's costs of performing these services are included within research and development expenses. The Company's milestone payments are typically defined by achievement of certain preclinical, clinical, and commercial success criteria. Preclinical milestones may include in vivo proof of concept in disease animal models, lead candidate identification, and completion of IND-enabling toxicology studies. Clinical milestones may, for example, include successful enrollment of the first patient in or completion of Phase 1, 2 and 3 clinical trials, and commercial milestones are often tiered based on net or aggregate sale amounts. The Company cannot guarantee the achievement of these milestones due to risks associated with preclinical and clinical activities required for development of nucleic acid medicine-based therapeutics and vaccines.

The following table presents changes in the balances of receivables and contract liabilities related to revenue generating agreements during the year ended December 31, 2025:

(in thousands)	December 31, 2024	Additions	Deductions	December 31, 2025
Contract Assets:				
Accounts receivable	$ 3,974	$ 57,200	$ (55,610)	$ 5,564
Contract Liabilities:				
Deferred revenue	$ 32,118	$ 57,823	$ (81,695)	$ 8,246

During the year ended December 31, 2025, the Company recognized $26.4 million in revenue from the deferred revenue balance as of December 31, 2024.

The following table summarizes the Company's revenue for the periods indicated. Approximately $67.1 million, $138.4 million and $154.9 million of total revenue represents revenue derived from foreign countries for the years ended December 31, 2025, 2024 and 2023, respectively.

	For the Year Ended December 31,		
(in thousands)	2025	2024	2023
Collaboration revenue:			
CSL Seqirus	$ 65,982	$ 138,389	$ 154,264
Ultragenyx	—	—	1,837
Other	1,239	—	1,647
Total collaboration revenue	$ 67,221	$ 138,389	$ 157,748
Grant revenue:			
BARDA	$ 13,236	$ 13,921	$ 9,051
Gates Foundation	$ 1,574	$ —	$ —
Total grant revenue	$ 14,810	$ 13,921	$ 9,051

Accounts receivable is comprised of the following as of December 31, 2025 and 2024:

	December 31,	
(in thousands)	2025	2024
Billed accounts receivable	$ 1,957	$ 1,472
Unbilled accounts receivable	3,607	2,502
Total accounts receivable	$ 5,564	$ 3,974

Billed accounts receivable represent amounts invoiced under the Company's collaboration and reimbursement arrangements that remain outstanding. Unbilled accounts receivable represent reimbursable costs incurred or revenue recognized for which invoices have not yet been issued as of the balance sheet date in accordance with contractual billing terms. Substantially all unbilled accounts receivable are expected to be billed and collected within 12 months.

The following paragraphs provide information regarding the nature and purpose of the Company's most significant revenue arrangements.

CSL Seqirus

On November 1, 2022, the Company entered into a Collaboration and License Agreement (as amended, the "CSL Collaboration Agreement") with Seqirus, Inc., a part of CSL Limited ("CSL Seqirus"), for the global exclusive rights to research, develop, manufacture, and commercialize vaccines. Under the terms of the CSL Collaboration Agreement, the Company provides CSL Seqirus with an exclusive global license to its mRNA technology (including STARR®) and LUNAR® lipid-mediated delivery, along with mRNA drug substance and drug product manufacturing processes. CSL Seqirus will lead the development and commercialization of vaccines under the collaboration. The collaboration plans to advance vaccines against SARS-CoV-2 (COVID-19), influenza, pandemic preparedness as well as three other infectious diseases. In September 2024, our COVID-19 vaccine

KOSTAIVE® became the world's first approved and commercially available self-amplifying RNA (sa-mRNA) vaccine.

The Company received a $200.0 million upfront payment and is eligible to receive over $1.3 billion in development milestones if all products are registered in the licensed fields and is entitled to potentially receive up to $3.0 billion in commercial milestones based on "net sales" of vaccines in the various fields. In addition, the Company is eligible to receive a 40% net profit share for COVID-19 vaccine products and up to low double-digit royalties for vaccines for pandemic preparedness and against seasonal influenza as well as three other infectious disease pathogens.

In evaluating the CSL Collaboration Agreement in accordance with ASC 606, the Company concluded that CSL Seqirus is a customer. The Company identified all promised goods/services within the CSL Collaboration Agreement, and when combining certain promised goods/services, the Company concluded that there are five distinct performance obligations. The nature of the performance obligations consists of the delivery of the vaccine license, research and development services for COVID-19 and non-COVID-19 vaccines and regulatory activities for COVID-19 vaccines. For each performance obligation, the Company estimated the standalone selling price based on 1) in the case of the license, the fair value using costs to recreate plus margin method and 2) in the case of research and development services and regulatory activities, cost plus margin for estimated full-time equivalent ("FTE") costs, direct costs including laboratory supplies, contractors, and other out-of-pocket expenses for research and development services and regulatory activities.

As of December 31, 2025, the transaction price primarily consisted of upfront consideration received and milestones achieved. Additional variable consideration was not included in the transaction price at December 31, 2025 because the Company could not conclude that it is probable that including the variable consideration will not result in a significant revenue reversal.

The Company allocated the transaction price to the performance obligations in proportion to their standalone selling price. The vaccine license was recognized at the point in time it was transferred in 2022. The research and development and regulatory activities performance obligations are recognized over a period of time based on the percentage of services rendered using the input method, meaning actual costs incurred divided by total costs budgeted to satisfy the performance obligation. Any consideration related to sales-based royalties will be recognized when the amounts are probable of non-reversal, provided that the reported sales are reliably measurable and the Company has no remaining promised goods/services, as they are constrained and therefore have also been excluded from the transaction price. The revenue recognized during 2025 relates to the license delivered, milestones achieved and research and development and manufacturing services performed through December 31, 2025.

Total deferred revenue as of December 31, 2025 and 2024 for the CSL Collaboration Agreement was $6.2 million and $30.7 million, respectively.

During 2023, the Company entered into an amendment to the CSL Collaboration Agreement, pursuant to which the Company agreed to sponsor and conduct a Phase 1 clinical study in the influenza field. As part of the amendment, the Company received $17.5 million from CSL Seqirus. The amendment also provides for up to $1.5 million in additional payments which are achievable upon meeting certain clinical milestones relating to the Phase 1 clinical study in the influenza field. The Company previously concluded that the expansion of research and development support services under the CSL Collaboration Agreement represented an option that was not a material right. Therefore, the Company concluded the promise to sponsor and conduct the Phase 1 clinical study is a separate contract and the sole performance obligation under the new arrangement. During the period ended December 31, 2025, the Company recognized $3.2 million related to the performance obligation, which was fully satisfied during the period.

In March 2024, the Company entered into an amendment to the CSL Collaboration Agreement, pursuant to which the parties agreed to, among other things, adjust (i) the development plans for certain product candidates, (ii) various development milestones related to such product candidates, and (iii) provisions of the CSL Collaboration related to distributors, and (iv) proprietary payment calculations related to the foregoing.

BARDA Grant

In August 2022, the Company entered into a cost reimbursement contract (the "BARDA Contract") with the Biomedical Advanced Research and Development Authority ("BARDA"), a division of the Office of the Assistant Secretary for Preparedness and Response (ASPR) within the U.S. Department of Health and Human

Services (HHS) for an award of up to $63.2 million for the development of a pandemic influenza vaccine using the Company's STARR® self-amplifying mRNA vaccine platform technology. The Company earns grant revenue for performing tasks under the agreement.

The Company determined that the BARDA Contract is not in the scope of ASC 808 or ASC 606. Applying International Accounting Standards No. 20 ("IAS 20"), Accounting for Government Grants and Disclosure of Government Assistance, by analogy, the Company recognizes grant revenue from the reimbursement of direct out-of-pocket expenses, overhead allocations and fringe benefits for research costs associated with the grant. The costs associated with these reimbursements are reflected as a component of research and development expense in the Company’s condensed consolidated statements of operations and comprehensive loss.

The Company recognized $13.2 million and $13.9 million of grant revenue during the years ended December 31, 2025 and 2024, respectively, which is included in revenue on the Company's consolidated statements of operations. As of December 31, 2025, the remaining available funding net of revenue earned was $26.7 million.

Gates Foundation

During the year ended December 31, 2025, the Company recognized $1.6 million of grant revenue related to cost reimbursement under two grants awarded by the Gates Foundation.

The grants support development of (i) a therapeutic HPV vaccine candidate and (ii) durability assessments of self-amplifying mRNA COVID-19 vaccine platforms. Grant funding is conditional upon achievement of defined milestones and submission of periodic progress and financial reports. Revenue is recognized as qualifying costs, including employee FTE labor and related expenses, are incurred in accordance with the terms of each agreement.

Unspent or uncommitted amounts remain deferred until the associated performance obligations are satisfied. As of December 31, 2025, deferred grant revenue related to these agreements totaled $2.1 million.

NOTE 4. Fair Value Measurements

The Company establishes the fair value of its assets and liabilities using the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The Company established a fair value hierarchy based on the inputs used to measure fair value.

The three levels of the fair value hierarchy are as follows:

Level 1: Quoted prices in active markets for identical assets or liabilities.

Level 2: Inputs, other than the quoted prices in active markets, that are observable either directly or indirectly.

Level 3: Unobservable inputs in which little or no market data exists and are therefore determined using estimates and assumptions developed by the Company, which reflect those that a market participant would use.

The Company's assets measured at fair value on a recurring basis consisted of money market funds. As of December 31, 2025, the Company's had money market funds with a fair value of $229.1 million, which were classified within Level 1 of the fair value hierarchy. The fair value of these financial instruments was measured based on quoted prices.

NOTE 5. Accrued Liabilities Detail

Accrued liabilities consisted of the following:

	December 31,	
(in thousands)	2025	2024
Accrued compensation	$ 6,948	$ 13,305
Cystic Fibrosis Foundation liability	6,394	7,443
Current portion of operating lease liability	4,214	3,552
Accrued facilities costs	1,400	—
Clinical trial accruals	399	2,828
Vinbiocare contractual liabilities	—	2,421
Legal accrual	771	130
Other accrued research and development expenses	3,772	9,102
Total	$ 23,898	$ 38,781

NOTE 6. Property and Equipment, Net

Property and equipment, net consisted of the following:

	December 31,	
(in thousands)	2025	2024
Research equipment	$ 14,942	$ 16,864
Computers and software	1,069	1,131
Office equipment and furniture	604	703
Leasehold improvements	2,612	2,644
Total	$ 19,227	$ 21,342
Less accumulated depreciation and amortization	(12,491)	(11,811)
Property and equipment, net	$ 6,736	$ 9,531

Depreciation and amortization expense was $3.0 million, $3.5 million and $3.0 million for the years ended December 31, 2025, 2024 and 2023, respectively. Construction in progress is primarily comprised of research equipment not yet placed in service.

NOTE 7. Debt

Wells Fargo Credit Agreement

The Company's wholly-owned subsidiary, Arcturus Therapeutics, Inc. ("Arcturus Therapeutics") entered into a credit agreement with Wells Fargo Bank on April 21, 2023, and amended on June 26, 2024, whereby Wells Fargo will make a $50.0 million revolving credit line available to the Company (the "Loan") and each draw on the Loan evidenced by a revolving line of credit note (the "Note"). On June 26, 2024, the parties entered into Amendment No. 1 to the Wells Fargo Loan, whereby the term was extended by one year to April 2026.

Borrowings under the agreement will bear interest at a rate of 1.00% above either the Daily Simple SOFR or Term SOFR (as such terms are defined in the Note), with "SOFR" being the rate per annum equal to the secured overnight financing rate as administered by the Federal Reserve Bank of New York. If an Event of Default (as defined in the agreement) occurs, then all Loans shall bear interest at a rate equal to 2.00% above the interest rate applicable immediately prior to the occurrence of the Event of Default.

The term of the agreement was originally two years, with an option for one-year renewals subject to Wells Fargo approval and Arcturus Therapeutics furnishing to Wells Fargo a non-refundable commitment fee equal to 0.25% of the Loan amount for each such renewal. There is no penalty for terminating the facility prior to the maturity date of the Note. As collateral, the Company has agreed to pledge $55.0 million in cash to be held in the Company's securities accounts with Wells Fargo Securities, LLC, an affiliate of Wells Fargo, pursuant to a security agreement.

In December 2025, the Company terminated the credit agreement and related security agreement. No amounts were outstanding under the Loan at the time of termination. As a result, $55.0 million of cash previously pledged as collateral was released and is no longer classified as restricted cash as of December 31, 2025.

NOTE 8. Stockholders' Equity

Net Loss Per Share

Potentially dilutive securities that were not included in the calculation of diluted net loss per share for the year ended December 31, 2025 and 2024 as they were anti-dilutive totaled 0.6 million and 1.4 million, respectively. Potentially dilutive securities that were not included in the calculation of diluted earnings per share for the year ended December 31, 2023 as they were anti-dilutive totaled 0.8 million.

Sales Agreement

On December 23, 2022, the Company entered into a Controlled Equity Offering℠ Sales Agreement, which was amended on August 7, 2023 (as amended, the "Sales Agreement") with Cantor Fitzgerald & Co. ("Cantor"),Wells Fargo Securities, LLC ("Wells Fargo Securities"), and William Blair & Company, L.L.C. ("William Blair") relating to shares of the Company's common stock. In accordance with the terms of the Sales Agreement, the Company may offer and sell shares of its common stock having an aggregate offering price of up to $200 million from time to time through Cantor, Wells Fargo Securities, or William Blair, each acting as the Company's sales agent.

During the three months ended December 31, 2025, the Company sold 1,179,201 shares of its common stock pursuant to the Sales Agreement at a weighted-average price of $10.38 per share, resulting in gross proceeds of approximately $12.2 million. After deducting offering costs of $0.5 million, the Company received net proceeds of approximately $11.7 million from these sales. In December 2025, the Company filed, and subsequently had declared effective, a replacement shelf registration statement on Form S-3, which replaced the prior registration statement and continues to support the Sales Agreement.

NOTE 9. Share-Based Compensation

In June 2024 at the Company's 2024 Annual Meeting of Stockholders (the "2024 Annual Meeting"), the stockholders of the Company approved an amendment to the Company's 2019 Omnibus Equity Incentive Plan (as amended, the "2019 Plan") which, among other things, increased the aggregate number of shares authorized for use in making awards to eligible persons under the 2019 Plan by 2,000,000 shares, for a total of up to 10,750,000 shares available for issuance. As of December 31, 2025, a total of 903,396 shares remain available for future issuance under the 2019 Plan, subject to the terms of the 2019 Plan.

In October 2021, the Company adopted the 2021 Inducement Equity Incentive Plan which covers the award of up to 1,000,000 shares of common stock (the "2021 Plan") effective as of October 15, 2021. Approval of the Company's stockholders is not required as a condition to the effectiveness of the 2021 Plan for so long as the plan is in compliance with applicable Nasdaq inducement plan rules. In April 2022, the compensation committee of the Company's board of directors approved a proposal to reduce the total number of shares available for future issuance under the 2021 Plan to 130,000. Pursuant to the terms of the plan, shares underlying awards that are forfeited, cancelled, or terminated without issuance are returned to the share reserve. As of December 31, 2025, a total of 162,164 shares remain available for future issuance under the 2021 Plan, subject to the terms of the 2021 Plan.

Share Options

The following table presents the weighted-average assumptions used in the Black-Scholes valuation model by the Company in calculating the fair value of stock options granted:

	For the Year Ended December 31,		
	2025	2024	2023
Expected life (in years)	6.01	5.88	6.04
Expected volatility	104.7%	91.4%	76.1%
Expected dividend yield	—%	—%	—%
Risk-free interest rate	4.23%	4.24%	3.91%
Grant date weighted average fair value	$ 11.81	$ 22.62	$ 18.87

The following table summarizes the Company's stock option activity for the year ended December 31, 2025:

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding – December 31, 2024	8,078,752	$ 32.38	7.2	$ 9,247
Granted	2,029,190	$ 11.37		
Exercised	(103,440)	$ 10.72		
Forfeited/cancelled	(1,135,895)	$ 33.90		
Outstanding – December 31, 2025	8,868,607	$ 29.20	6.26	$ 13,333
Exercisable – December 31, 2025	6,046,218	$ 33.12	5.45	$ 8,652

At December 31, 2025, the total unrecognized compensation cost of $30.1 million will be recognized over the weighted-average remaining service period of approximately 2.5 years. The fair value of the options vested during the years ended December 31, 2025 , 2024 and 2023 was $29.3 million, $40.5 million and $35.3 million, respectively. The total intrinsic value of options exercised during the years ended December 31, 2025, 2024 and 2023 was $0.5 million, $3.3 million and $4.3 million, respectively.

Restricted Stock Units

In August 2023, the Company granted 18,786 restricted stock units ("RSUs") to its board of directors, when the market value of the Company's common stock was $34.92 per share. These RSUs fully vested at the Company's 2024 annual stockholders' meeting. However, the release of the units remains subject to specific conditions and will occur only in the event of a board separation or a change in control.

The following table summarizes the Company's RSU activity for the year ended December 31, 2025:

	Number of Shares	Weighted-Average Grant Date Fair Value
Outstanding – December 31, 2024	18,786	$ 34.92
Awarded	-	
Released	-	
Forfeited	-	
Outstanding – December 31, 2025	18,786	$ 34.92

Share-based compensation expenses included in the Company's statements of operations and comprehensive income loss for the years ended December 31, 2025, 2024 and 2023 were:

	For the Year Ended December 31,		
(in thousands)	2025	2024	2023
Research and development	$ 13,248	$ 18,456	$ 14,950
General and administrative	12,160	19,532	19,699
Total	$ 25,408	$ 37,988	$ 34,649

NOTE 10. Income Taxes

A reconciliation of (loss) income before income taxes for domestic and foreign locations is as follows:

	For the Year Ended December 31,		
(In thousands)	2025	2024	2023
United States	$ (65,783)	$ (80,945)	$ (27,890)
Foreign	—	—	—
Total (loss) income before income taxes	$ (65,783)	$ (80,945)	$ (27,890)

A reconciliation of income tax (benefit) expense for the years ended December 31, 2025, 2024 and 2023 is as follows:

	For the Year Ended December 31,		
	2025	2024	2023
Current:			
Federal	$ —	$ (11)	$ 1,246
State	—	7	589
Foreign	—	—	—
Total current income tax (benefit) expense	$ —	$ (4)	$ 1,835
Deferred:			
Federal	$ —	$ —	$ —
State	—	—	—
Foreign	—	—	—
Total deferred income tax expense	—	—	—
Total income tax (benefit) expense	$ —	$ (4)	$ 1,835

The table below provides the updated requirements of ASU No. 2023-09, Improvements to Income Tax Disclosures ("ASU 2023-09") for 2025. The effective income tax rate for the years ended December 31, 2025 differs from the statutory federal income tax rate as follows (in thousands, except percentages):

	For the Year Ended December 31, 2025	
	$	%
U.S. federal statutory rate	$ (13,814)	21.0%
State and local income taxes, net of federal income tax effect [1]	(69)	0.1%
Effects of cross-border tax laws - Global intangible low-tax income	4,501	(6.8%)
Tax credits - research and development credits	(1,587)	2.4%
Changes in valuation allowance	6,189	(9.4%)
Nontaxable or nondeductible items:		
Stock-based compensation	2,946	(4.5%)
Limitations on the deductibility of officer compensation	1,533	(2.3%)
Other	137	(0.2%)
Changes in unrecognized tax benefits	143	(0.4%)
Other	21	0.1%
Provision for income taxes	$ —	0.0%

(1) State tax expense in the State of California comprises the majority (greater than 50 percent) of the tax effect in this category.

As previously disclosed for the years ended December 31, 2024 and 2023, prior to the adoption of ASU 2023-09, the Company's effective income tax rate differed from the statutory federal income tax rate as follows:

	For the Year Ended December 31,	
	2024	2023
Federal statutory income tax rate	21.0%	21.0%
State income taxes, net of federal benefit	1.9%	1.9%
Share-based compensation	(1.9%)	(2.5%)
Officers compensation	(3.4%)	(7.4%)
Research and development credits	24.0%	20.0%
Uncertain tax positions	(3.7%)	(2.4%)
Change in tax rate	(1.4%)	0.2%
Change in valuation allowance	(36.1%)	(36.5%)
Other	(0.2%)	(0.3%)
Permanent differences	(0.2%)	(0.7%)
Provision for income taxes	0.0%	(6.7%)

A summary of income taxes paid, net of (refunds) received, for the year ended December 31, 2025 is as follows:

(In thousands)	December 31, 2025
Federal income taxes paid, net of (refunds) received	$ —
State income taxes paid, net of (refunds) received	—
Foreign income taxes paid, net of (refunds) received	—
Total income taxes paid, net of (refunds) received	$ —

The significant components of deferred income taxes are as follows:

(in thousands)	December 31, 2025	2024
Deferred tax assets:		
Net operating loss	$ 38,566	$ 25,413
Tax credits	30,219	27,472
Accrued liabilities	689	2,966
Deferred revenue	2,808	5,515
Basis difference in equity investments	2,053	2,127
Capitalized R&D	53,549	60,104
Right-of-use lease liability	5,578	6,601
Share-based compensation	15,232	14,872
Total gross deferred tax assets	148,694	145,070
Deferred tax liabilities:		
Depreciation and amortization	(462)	(858)
Right-of-use asset	(4,704)	(6,168)
Total gross deferred tax liabilities	(5,166)	(7,026)
Valuation allowance	(143,528)	(138,044)
Net deferred tax asset	$ —	$ —

In assessing the realization of the deferred tax assets, the Company considers whether it is more likely than not that some portion of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which temporary differences representing net future deductible amounts become deductible. Due to lack of available sources of taxable income, the Company recorded a full valuation allowance against its net deferred tax assets as sufficient uncertainty exists regarding the future realization of these assets. As of December 31, 2025 and 2024, the Company recorded a valuation allowance of $143.5 million and $138.0 million, respectively. The valuation allowance changed by $5.5 million and $29.2 million for the years ended December 31, 2025 and 2024, respectively.

Pursuant to Internal Revenue Code (IRC) Sections 382 and 383, annual use of the Company's federal and state net operating loss, research and development credit carryforwards, and other tax attributes may be limited in the event a cumulative change in ownership of more than 50% occurs within a three-year period. The Company has experienced changes in prior years and there is a risk that additional ownership changes may occur in the future. If a change in ownership occurs, the NOL carryforwards and other tax attributes could be limited or restricted. At December 31, 2025, the Company has federal and state net operating losses, or NOL, carryforwards of approximately $115.5 million and $203.1 million, respectively. The federal net operating loss carryforward includes losses generated in 2018 and after, which can be carried forward indefinitely. The state net operating loss carryforward includes $0.7 million of losses that can be carried forward indefinitely. The remaining state net operating losses begin to expire in 2039.

At December 31, 2025, the Company has federal and state research and development credit carryforwards of approximately $18.1 million and $12.5 million, respectively. If not utilized, the federal credit carryforwards begin to expire in 2037. $1.0 million of the state credit begins to expire in 2037 and the remainder carries forward indefinitely. Additionally, the Company has an Orphan Drug Credit of $8.9 million as of December 31, 2025, which will begin to expire in 2042 unless previously utilized.

The company accounts for income taxes in accordance with ASC 740-10, *Accounting for Uncertainty in Income Taxes*. The impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more likely than not to be sustained upon audit by the relevant taxing authority. An uncertain tax position will not be recognized if it has less than 50% likelihood of being sustained.

A reconciliation of unrecognized tax benefits is as follows (in thousands):

	December 31,	
(in thousands)	**2025**	**2024**
Beginning balance of unrecognized tax benefits	$ 6,780	$ 3,587
(Decrease) Increase for prior period tax positions	(763)	1,243
Increase for current period tax positions	925	1,950
Ending balance of unrecognized tax benefits	$ 6,942	$ 6,780

Amounts in the summary rollforward would not impact our effective tax rate if recognized as the Company maintains a full valuation on its net deferred tax assets. The Company is subject to taxation and files income tax returns in the United States, various U.S. states and foreign jurisdictions. The Company's tax years from 2014 to date are subject to examination by the U.S., and state taxing authorities due to the carryforward of unutilized net operating losses and research and development credits. The general statute of limitations in the foreign jurisdictions where the Company files tax returns is 4 to 5 years. The Company's policy is to recognize interest expense and penalties related to income tax matters as income tax expense. There was no tax related interest or penalties recognized for the years ended December 31, 2025 and 2024 and 2023.

Deferred income taxes are not required for undistributed earnings of the Company's foreign subsidiary as they can be distributed tax free and without withholding taxes.

On July 4, 2025, the One Big Beautiful Bill Act (the "Act") was signed into law. The Act reinstates and makes permanent 100% first-year bonus depreciation under Section 168(k) for qualified property acquired and placed in service after January 19, 2025. Additionally, the Act permanently allows immediate expensing of domestic research and experimentation expenditures under Section 174 for tax years beginning after December 31, 2024. The Company has reflected the effects of the Act in its income tax provision in accordance with ASC 740.

NOTE 11. Commitments and Contingencies

Cystic Fibrosis Foundation Therapeutics Funding agreement

On September 25, 2023, the Company amended its Development Program Letter Agreement, dated May 16, 2017 and as amended July 13, 2018 and August 1, 2019, with the Cystic Fibrosis Foundation ("CFF"). Pursuant to the amendment, (i) CFF increased the amount it will award to advance LUNAR-CF to $24.6 million from approximately $15.6 million, and (ii) the Company agreed to incur at least $15.0 million toward activities under the research plan. During the fourth quarter of 2023, the Company received the full payment from CFF related to the amendment. For the years ended December 31, 2025, 2024 and 2023, the Company recognized contra expense of $1.0 million, $0.2 million and $1.4 million, respectively. As of December 31, 2025, $6.4 million remained in accrued liabilities.

Leases

In October 2017, the Company entered into a non-cancellable operating lease agreement for office space adjacent to its previously occupied headquarters. The commencement of the lease began in March 2018 and the lease extends for approximately 84 months from the commencement date with a remaining lease term through March 2025. Monthly rental payments are due under the lease and there are escalating rent payments during the term of the lease. The Company is also responsible for its proportional share of operating expenses of the building and common areas. In conjunction with the new lease, the Company received free rent for four months and received a tenant improvement allowance of $0.1 million. The Company entered into an irrevocable standby letter of credit with the landlord for a security deposit of $0.1 million upon executing the lease which is included (along with additional funds required to secure the letter of credit) in the balance of non-current restricted cash. In March 2024, the Company negotiated with the lessor to extend the lease through March 2027.

In December 2025, the Company vacated this office space with no intention of operating out of the location in the future. The Company remains obligated to make the remaining lease payments through March 2027, and therefore recorded an impairment loss in the amount of $1.9 million during the three months ended December 31, 2025, as there was no future economic benefit from the lease.

In February 2020, the Company entered into a second non-cancellable operating lease agreement for office space near its current headquarters. The lease extended for 13 months from the commencement date and included a right to extend the lease for one twelve-month period. In February 2021, the Company opted to extend the lease through March 2025 to coincide with the lease term of the Company's headquarters. In January 2024, the Company vacated this office space with no intention of operating out of the location in the future. The Company was still engaged in the lease for the property and obligated to make the remaining lease payments through March 2025, and therefore recorded an impairment loss in the amount of $1.3 million during the three months ended March 31, 2024, as there was no future economic benefit from the lease. In July 2024, the Company terminated the existing lease agreement, in accordance with its terms, thereby ending their contractual obligation to pay for the premises.

In September 2021, the Company entered into a third non-cancellable lease agreement for office, research and development, engineering and laboratory space near its current headquarters, and such lease term commenced during the second quarter of 2022. The initial term of this lease extends ten years and eight months from the date of possession, and the Company has the right to extend the term of the lease for an additional five-year period. When the lease term was determined for the operating lease right-of-use assets and lease liabilities, the extension option for the lease was not included. The lease has a monthly base rent ranging from $0.3 million to $0.4 million which escalates over the lease term. The Company received a free rent period of four months and also pays for various operating costs, including utilities and real property taxes. The Company entered into an irrevocable standby letter of credit with the landlord for a security deposit of $2.0 million upon executing the lease which is included (along with additional funds required to secure the letter of credit) in the balance of non-current restricted cash.

Operating lease right-of-use asset and liability on the consolidated balance sheets represent the present value of remaining lease payments over the remaining lease terms. The Company does not allocate lease payments to non-lease components; therefore, payments for common-area-maintenance and administrative services are not included in the operating lease right-of-use asset and liability. The Company uses its incremental borrowing rate to calculate the present value of the lease payments, as the implicit rate in the lease is not readily determinable.

As of December 31, 2025, the remaining payments of the operating lease liability were as follows:

(in thousands)	Remaining Lease Payments
2026	$ 5,274
2027	4,132
2028	3,822
2029	3,937
2030	4,055
Thereafter	7,758
Total remaining lease payments	28,978
Less: imputed interest	(3,980)
Total operating lease liabilities	$ 24,998
Weighted-average remaining lease term (in years)	6.4
Weighted-average discount rate	4.6%

Operating lease costs consist of the fixed lease payments included in operating lease liability and are recorded on a straight-line basis over the lease terms. Operating lease costs were $5.0 million, $4.5 million and $5.6 million for the years ended December 31, 2025, 2024 and 2023, respectively.

NOTE 12. Segment Information

The Company operates in one business segment, which includes all activities related to the discovery, development and commercialization of messenger RNA medicines. The determination of a single business segment is consistent with the consolidated financial information regularly provided to the Company's chief operating decision maker ("CODM"). The Company's CODM is its Chief Executive Officer, who reviews and evaluates consolidated net loss for purposes of assessing performance, making operating decisions, allocating resources, and planning and forecasting for future periods. The CODM does not evaluate the operating segment using asset or liability information.

The following table presents information about reported segment revenues, segment loss, and significant segment expenses:

	For the Year Ended December 31,		
(in thousands)	2025	2024	2023
Revenues	$ 82,031	$ 152,310	$ 166,799
Less:			
Research and development:			
LUNAR-COVID	16,115	70,464	81,262
LUNAR-OTC	5,748	9,509	9,315
BARDA	8,366	7,807	5,465
LUNAR-CF, net	17,489	17,227	14,666
Early-stage programs	594	16,096	12,460
Discovery technologies	8,016	6,278	6,405
Payroll and benefits	43,987	57,474	50,924
Facilities and equipment	11,897	10,301	11,636
Total research and development	112,212	195,156	192,133
General and administrative	46,079	52,823	52,871
Other [(1)]	(10,477)	(14,728)	(48,480)
Net loss	$ (65,783)	$ (80,941)	$ (29,725)

(1) Primarily includes interest income and expense, foreign currency gains and losses, and income taxes. The year ended December 31, 2023 includes a $34.0 million gain on debt extinguishment related to forgiveness of the Singapore Loan.

NOTE 13. Related Party Transactions

See "*Note 2, Joint Ventures, Equity Method Investments and Variable Interest Entities*" for specific details surrounding the Company's agreement with Axcelead to form the joint venture entity, ARCALIS, Inc.

NOTE 14. Subsequent Events

None.