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

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2024

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 For The Transition Period From To**

Commission File Number 001-38942

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.)
10628 Science Center Drive, Suite 250 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, 2024 was $602.7 million.

As of March 4, 2025, the registrant had 27,119,823 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 compliance, and ability to remain in compliance, with the requirements of our collaboration agreements, including our collaboration with Seqirus Inc. ("CSL Seqirus");
- 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 continued development activities of the LUNAR-COV19 and LUNAR-FLU 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 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 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 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;
- the likelihood or timing of any regulatory approval, and the likelihood that the marketing approval of ARCT-154 in Japan will be predictive of any future marketing approvals in other countries or for other versions of our LUNAR-COV19 or other product candidates or of any commercial sales;
- 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 plans to develop and commercialize our product candidates;
- 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;
- interactions with regulatory authorities in the United States and foreign countries;
- 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.

PART I

Item 1. Business

Overview

We are a messenger RNA medicines company focused on the development of infectious disease vaccines and opportunities within liver and respiratory rare diseases. We developed the world's first approved self-amplifying messenger RNA (sa-mRNA) vaccine, KOSTAIVE® ("KOSTAIVE"). KOSTAIVE achieved approval in Japan in 2023 as a vaccine against COVID-19. Sales of KOSTAIVE began in Japan in October 2024, marking our transition to a commercial stage company.

We have several key platform technologies that we leverage to develop and advance a pipeline of mRNA-based vaccines and therapeutics for infectious diseases and for rare genetic disorders with significant unmet medical needs. 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 believe we are among the world leaders in both areas. 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 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 therapeutics to disease-relevant target tissues. LUNAR may enable multiple nucleic acid medicines. The approval of KOSTAIVE in Japan was a significant milestone which validates our LUNAR and STARR platforms, as well as sa-mRNA more generally as a meaningful modality. Finally, we 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 Seqirus, Inc. ("CSL Seqirus"), a part of CSL Limited and one of the world's leading influenza vaccine providers, on the development and commercialization of mRNA vaccines for COVID-19, influenza and certain other infectious diseases.

We made significant progress in 2024. Commercial sales of KOSTAIVE began in October 2024 in Japan by Meiji Seika Pharma ("Meiji"), CSL Seqirus' exclusive partner in Japan, marking the first commercial sales of an Arcturus-developed product. In February 2025, we received approval of KOSTAIVE from the European Commission (EC), which provided further validation of our platform by another significant regulatory authority.

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.

We initiated dosing in a Phase 1 clinical trial of a novel seasonal influenza sa-mRNA vaccine candidate under our collaboration with CSL Seqirus in January 2024. 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").

In our OTC program, we completed dosing of eight subjects in August 2024 in a Phase 2 double-blind multiple-dose study of ARCT-810. In the second quarter of 2024, we expanded the Phase 2 clinical program of ARCT-810 with an open-label, multiple-dose study which initiated dosing in December 2024. ARCT-810 has received Orphan Drug Designation from the FDA and Orphan Medicinal Product Designation from the European Medicines Agency (the "EMA") for treatment of OTC deficiency, as well as Fast Track Designation and Rare Pediatric Disease Designation from the FDA.

In our CF program, we initiated dosing in December 2024 in a Phase 2 multiple ascending dose study of ARCT-032 designed to identify a safe and effective dose in people with Class I (null) CFTR mutations and other CF patients who do not benefit from CFTR modulators. In July 2024, we completed dosing and follow-up visits for seven participants in a safety and tolerability Phase 1b clinical study in New Zealand of ARCT-032 in adults with CF. ARCT-032 has received Orphan Drug Designation by the FDA and Orphan Medicinal Product Designation by the EMA for the treatment of CF, and Rare Pediatric Disease Designation from the FDA.

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 potentially be useful for identification and development of additional products for our portfolio. Also, with our sourcing partners, we manufactured cGMP (current good manufacturing practices) batches yielding significant quantities of clinical trial materials for global studies of our candidates, and with our collaborator, CSL Seqirus, we have established commercial production processes for the COVID-19 vaccine program.

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, from which all proteins necessary for life are encoded. 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 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

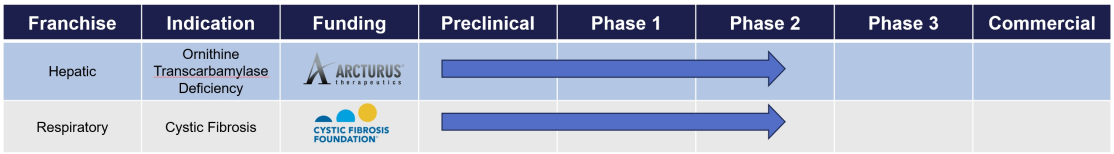
A key challenge for nucleic acid medicines is the safe and effective delivery of the nucleic acid molecule into cells. In addition to enabling uptake of the medicine into cells, the nucleic acids delivery vehicle seeks to protect the nucleic acid from degradation prior to cell entry and to release the 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, termed ATX, with 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

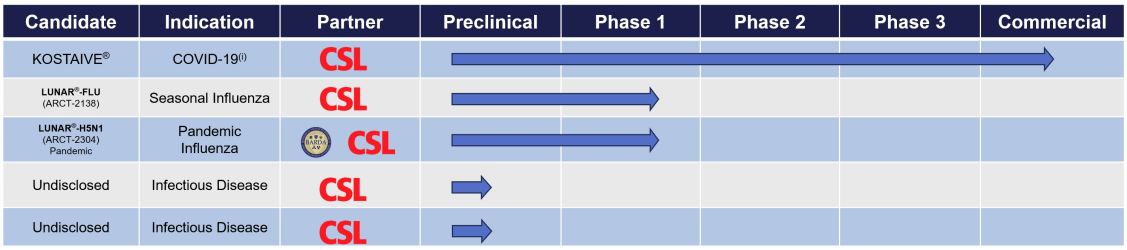
Our STARR technology is our proprietary self-amplifying mRNA (or sa-mRNA) technology platform. When combined with a delivery system, such as our lipid-mediated delivery system LUNAR, the STARR technology has the potential to generate a protective immune response or drive therapeutic protein expression to prevent against or treat a variety of diseases. Self-amplifying RNA-based prophylactic vaccines developed with STARR trigger rapid and prolonged antigen expression within host cells which may provide protective immunity against infectious pathogens. We have clinically shown that the combination of LUNAR and STARR technology can result in lower dose requirements with superior immune response and sustained protein expression compared to conventional RNA-based vaccines, which may enable production of greater volumes of vaccine doses more quickly.

Our Pipeline

Therapeutics



Vaccines



(i) Commercialized in Japan

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. 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 has 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 the 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 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 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 initiated in January 2024 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.

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 promote immune responses to the spike protein of the SARS-CoV-2 virus, the critical part of the virus that allows infection to occur.

KOSTAIVE is the brand name approved in Japan and Europe for ARCT-154, which is the version of the sa-mRNA COVID-19 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 the vaccine.

The approval 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, all as further described below, are significant milestones in the advancement of our vaccines franchise. The recent approval of KOSTAIVE (ARCT-154 version) by the EMA in January 2025 provides further validation of our platform by another significant regulatory authority, in addition to expanding the potential commercialization of KOSTAIVE.

During 2024, several important publications were released relating to our studies, which are summarized below.

- In May 2024, Nature Communications published results from the 19,000 subject study performed in Vietnam, with results demonstrating that two 5µg doses of ARCT-154 were well-tolerated, immunogenic and provided significant protection against multiple strains of COVID-19. This publication relates to the study described below – "*Pivotal Phase 1/2/3 Study in Vietnam"*.
- In November 2024, npj Vaccines, a Nature Portfolio journal, published the results of Phase 3c of the pivotal Phase 1/2/3 study in Vietnam, demonstrating higher immune response and protective efficacy of ARCT-154 compared to an approved adenovirus-vector COVID-19 vaccine (DOI: 10.1038/s41541-024-01017-5).
- In October 2024, Lancet Infectious Diseases published the follow-up article '12-month persistence of immune responses to self-amplifying mRNA COVID-19 vaccines: ARCT-154 versus BNT162b2 vaccine' (https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(24)00615-7/fulltext), which confirmed a better neutralizing immune response against a panel of SARS-CoV-2 strains in pre-immunized Japanese adults boosted with ARCT-154 compared with the conventional mRNA vaccine, BNT162b2, which persisted up to 12 months post-vaccination, including in those age 50 years and older. This publication relates to the study described below – "*Phase 3 Study of Bivalent Version of KOSTAIVE (COVID-19 Vaccine) Candidate in Japan*".

Approval of KOSTAIVE in Japan

KOSTAIVE (ARCT-154 version) received marketing authorization approval in November 2023 from the Japanese Ministry of Health, Labour and Welfare for use as a primary immunization and booster in Japan for adults 18 years and older. The approval was based on positive clinical data from several ARCT-154 studies, including a 19,000-participant efficacy, safety and immunogenicity study performed in Vietnam, as well as a Phase 3 booster study in Japan.

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. 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, and clinical evidence supporting the safety and immunogenicity of KOSTAIVE (bivalent, BA.4/5 and ancestral strain).

In January 2025, CSL Seqirus' partner Meiji announced that it 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.

Clinical Studies of KOSTAIVE (COVID-19 vaccine)

In connection with the development of KOSTAIVE, we have conducted or are conducting the studies described below.

Pivotal Phase 1/2/3 Study in Vietnam

During 2021, we entered into a collaboration with Vinbiocare Biotechnology Joint Stock Company ("Vinbiocare"), a member company of the Vingroup Joint Stock Company (Vingroup) group of companies. As part of a collaboration with Vinbiocare, ARCT-154, our next-generation, self-amplifying mRNA-based vaccine for COVID-19, was advanced into a Phase 1/2/3 study in Vietnam, funded and sponsored by Vinbiocare (the "Vinbiocare Study"). The trial was randomized, observer-blinded, placebo and active-controlled, and intended to assess the safety, immunogenicity, and efficacy of ARCT-154. The Phase 3 arm of the Phase 1/2/3 study was initiated in September 2021. The study enrolled over 19,000 adult subjects in Vietnam, including individuals with medical conditions, putting them at higher risk of severe complications of COVID-19. The Phase 3b placebo-controlled efficacy portion of the study enrolled over 16,000 participants. The study 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 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 were used as a basis for vaccine licensure in Japan and the European Union.

In August 2023, we submitted the primary manuscript with efficacy, immunogenicity and safety results of the pivotal Phase 1/2/3 clinical study of ARCT-154 in Vietnam (https://www.nature.com/articles/s41467-024-47905-1). Later, we published the results of Phase 3c part of the study, comparing the immunogenicity and efficacy of ARCT-154 and licensed adenoviral vector vaccine ChAdOx-1S, demonstrating higher immunogenicity and relative vaccine efficacy (19.8% (95% CI: 4.0–33.0)) of ARCT-154 compared to ChAdOx-1S (https://pmc.ncbi.nlm.nih.gov/articles/PMC11585660/).

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

Meiji sponsored a randomized, multicenter, Phase 3, observer-blind, active-controlled comparative study to evaluate the safety and immunogenicity of a booster dose of ARCT-154 and to evaluate the non-inferiority of ARCT-154 over COMIRNATY® (Monovalent, Original strain). The study completed enrollment in February 2023 with 828 participants, with half in the ARCT-154 group and half in a comparator group.

The study met all primary and secondary immunogenicity endpoints, including a secondary pre-defined superiority assessment over COMIRNATY (Omicron BA.4/5 strain). Overall, the safety and immunogenicity results of the study support the favorable benefit/risk profile of the ARCT-154 vaccine when administered as a booster dose in adult individuals who previously received other mRNA COVID-19 vaccines.

In October 2024, Lancet Infectious Diseases published the follow-up article '12-month persistence of immune responses to self-amplifying mRNA COVID-19 vaccines: ARCT-154 versus BNT162b2 vaccine', which confirmed a better neutralizing immune response against a panel of SARS-CoV-2 strains in pre-immunized Japanese adults boosted with ARCT-154 compared with the conventional mRNA vaccine, BNT162b2, which persisted up to 12 months post-vaccination, including in those age 50 years and older.

Phase 3 Study of Bivalent Version of KOSTAIVE (COVID-19 Vaccine) Candidate in Japan

In September 2023, Meiji initiated a Phase 3 clinical study with ARCT-2301, a bivalent version of KOSTAIVE (ancestral strain and Omicron BA.4/5) to further support immunogenicity and safety data for our self-amplifying mRNA platform, which may facilitate the timely release of future seasonal updates of our COVID-19 vaccine against evolving variants of concern. The study enrolled 930 healthy adults and individuals with comorbidities, who previously received three to five doses of mRNA COVID-19 vaccines, including the last booster at least three months prior to recruitment, and compared the investigational vaccine (ARCT-2301) and COMIRNATY (ancestral strain and BA.4/5) to evaluate safety and immunogenicity between observer-blind groups. The bivalent vaccine met the primary study endpoint (non-inferiority).

Both the geometric mean titer (GMT) ratio and seroresponse rate (SRR) difference of neutralizing antibodies against SARS-CoV-2 (Omicron BA.4/5 and Wuhan strains) met pre-specified non-inferiority and superiority criteria versus COMIRNATY. There were no causally-associated severe or serious adverse events with ARCT-2301.

As with the monovalent vaccine, the bivalent sa-mRNA formulation demonstrated superior immunogenicity over the conventional bivalent mRNA vaccine COMIRNATY, a higher immune response persisting up to six months after a booster dose, and improved breadth, supporting the robustness of the sa-mRNA vaccine platform for future vaccine strain updates. The study results were presented at OPTIONS XII for the Control of Influenza conference in Brisbane, Australia, in September 2024.

Phase 3 Co-administration Study of KOSTAIVE (Monovalent XBB1.5) and Seasonal Influenza Vaccines

In March 2024, Arcturus and CSL Seqirus initiated a Phase 3 pivotal study with the ARCT-2303 candidate vaccine containing the XBB1.5 Omicron variant. The study aimed to generate additional immunogenicity and safety data in multiple ethnicities to support regulatory filings in the U.S. and globally. In addition, the study assessed the co-administration of the ARCT-2303 vaccine with the age-appropriate seasonal influenza vaccines. Overall, 1,499 adults, including older adults, were recruited in the study in Australia, Costa Rica, Honduras and the Philippines.

The study results showed that all four primary study objectives and key secondary study objectives were met. ARCT-2303 demonstrated a superior immune response compared to ARCT-154 as measured by neutralizing antibodies against Omicron XBB.1.5 in terms of GMT ratio and SRR difference. Co-administration of ARCT-2303 and quadrivalent influenza vaccine (QIV; Flucelvax, CSL) in adults 18-64 years old showed a noninferior immune response compared to standalone QIV. Co-administration of ARCT-2303 and QIV also showed a noninferior immune response compared to standalone ARCT-2303. Co-administration of ARCT-2303 and adjuvanted QIV (Fluad, CSL) in adults 65 years of age and above showed similar results for co-administered and separately administered groups. The safety and reactogenicity of co-administered vaccines were comparable with 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. In conjunction with our collaborator, CSL Seqirus, we are working to optimize KOSTAIVE's formulation to better meet the needs of healthcare professionals and their patients.

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 U.S. Food and Drug Administration ("FDA")) then make the final decision of which strains should be covered by vaccines licensed in their country.

Our LUNAR-FLU (seasonal) program, now exclusively licensed to 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 take advantage of our expertise in both LUNAR lipid delivery systems and our STARR self-amplifying mRNA technology. This platform has 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. Working with CSL Seqirus, we generated a comprehensive non-clinical data package to support the initiation of the Phase 1 clinical trial with a novel influenza sa-mRNA vaccine candidate. A Phase 1 dose-finding safety and immunogenicity study was initiated in January 2024 in Australia and is ongoing.

Pandemic Avian Influenza Program (H5N1 Influenza)

Our LUNAR-H5N1 program, which is part of the CSL Collaboration Agreement, 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.

The Phase 1 study of ARCT-2304, a self-amplifying mRNA (sa-mRNA) vaccine candidate, also known as LUNAR-H5N1, initiated dosing in December 2024. The randomized placebo-controlled Phase 1 trial (NCT06602531) is being conducted at multiple sites in the U.S. and designed to enroll approximately 200 healthy adults (120 participants 18-59 years old; 80 participants 60-80 years old). The primary objective of this initial clinical trial is to evaluate safety and immune responses of three different dose levels and two different vaccination schedules of ARCT-2304 vaccine. Immune responses are measured by hemagglutination inhibition (HAI), virus microneutralization (MN) and neuraminidase enzyme-linked lectin assays (ELLA). The clinical study is fully funded by Biomedical Advanced Research and Development Authority (BARDA). For a more comprehensive discussion of the funding award, please see Item 1 "Business" – "Revenue and Collaboration Arrangements and Other Material Agreements" – "BARDA."

Preclinical Ferret Studies of ARCT-2304 (LUNAR-H5N1)

Several ferret challenge studies have been conducted to establish the efficacy of ARCT-2304, our clinical candidate for the LUNAR-pandFLU program. ARCT-2304 vaccinated ferrets were challenged with the same influenza strain, H5N1 A/Indonesia/5/2005, encoded by the vaccine and protected all ferrets from lethal challenge. Robust HAI and NI titers were observed after two doses of the vaccine and nasal titers in the days following challenge were lower than in either the unvaccinated ferrets (PBS) or ferrets vaccinated with an adjuvanted recombinant trimeric hemagglutinin (rHA). Further, fewer signs of lung damage were observed in ARCT-2304 ferrets compared to either unvaccinated or rHA vaccinated ferrets.

In a separate experiment, ARCT-2304 vaccinated ferrets were challenged with an antigenically drifted strain from a different clade of H5N1, A/Vietnam/1203/2004. ARCT-2304 vaccinated ferrets were compared to unvaccinated ferrets and to ferrets receiving an adjuvanted trimeric rHA vaccine encoding either the same strain as encoded by ARCT-2304 (A/Indonesia) or the challenge strain (A/Vietnam). ARCT-2304 vaccinated ferrets were protected from death from this antigenically drifted strain. While HAI and NI titers were lower against A/Vietnam than against A/Indonesia, ARCT-2304 vaccinated ferrets had the lowest nasal wash titers of any group and showed no signs of lung damage in contrast to unvaccinated ferrets and ferrets vaccinated with adjuvanted trimeric rHA protein.

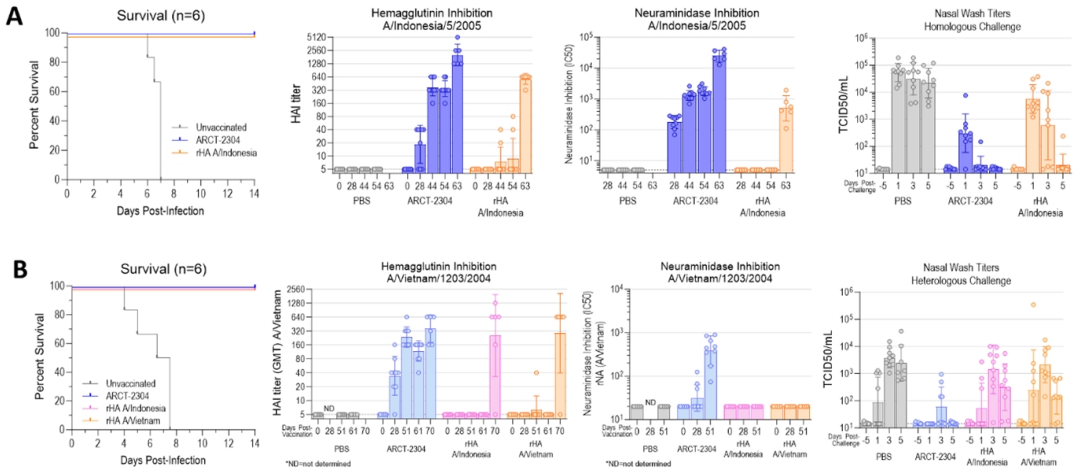


Figure 1: A) Ferrets were vaccinated twice (day 0 & 28) with either ARCT-2304 (5µg) or an adjuvated (Addavax) recombinant trimeric HA protein (15µg) and challenged 3 weeks (day 49 post-vaccination) after the last vaccination with a lethal dose of the homologous H5N1 A/Indonesia/5/2005 strain. All vaccinated ferrets survived infection while all unvaccinated (PBS) ferrets succumbed to the infection by day 7 post-infection. ARCT-2304 ferrets had the highest HAI and NI titers among vaccinated groups both prior to and after challenge. In addition, nasal wash titers were lowest in the ARCT-2138 vaccinated ferrets. B) Ferrets were vaccinated twice (day 0 & 28) with either ARCT-2304 (5µg) or an adjuvated (Addavax) recombinant trimeric HA protein (15µg) encoding the same strain at ARCT-2304 (A/Indonesia) or the challenge strain (A/Vietnam) and challenged 4 weeks (day 56 post-vaccination) after the last vaccination with a lethal dose of H5N1 A/Vietnam/1203/2004 strain. While lower HAI and NI titers were observed against the heterologous A/Vietnam strain, all vaccines elicited protection from lethal infection. Similar to the heterologous challenge, however, the lowest nasal wash titers were observed in the ARCT-2304 vaccinated group.

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 – 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 nitrogenscavengers 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 have 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 study 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 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. Patient follow-up is completed, and data management and analysis are ongoing.

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.

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 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), and 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 one of 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 born between 2018-2022 in the United States is approximately 56 years, 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 disease severity and to prevent 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®, and Trikafta®) 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.

In 2023, we initiated and 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. A subsequent protocol amendment to transition to a safety and tolerability Phase 1b clinical study of ARCT-032 in adults with CF received regulatory approval in August 2023 and completed dosing and follow-up visits for seven CF participants in August 2024, with each CF participant having received two administrations of ARCT-032 separated by two days.

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. Each participant in the Phase 2 CF study (NCT06747858) is expected to receive daily treatments of ARCT-032 over a period of 28 days.

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.

An extensive portfolio of nonclinical studies supported the advancement of ARCT-032 to the clinic. Our comprehensive data set showcasing the potential for ARCT-032 as a disease-modifying treatment has been presented at the major CF conferences in North America and Europe. For example, we presented data at the North American Cystic Fibrosis Conference in November 2023 that demonstrated that a single dose of ARCT-032, administered in the airways of CF ferrets by microsprayer, effectively doubled the mucociliary transport rate in vivo.

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.

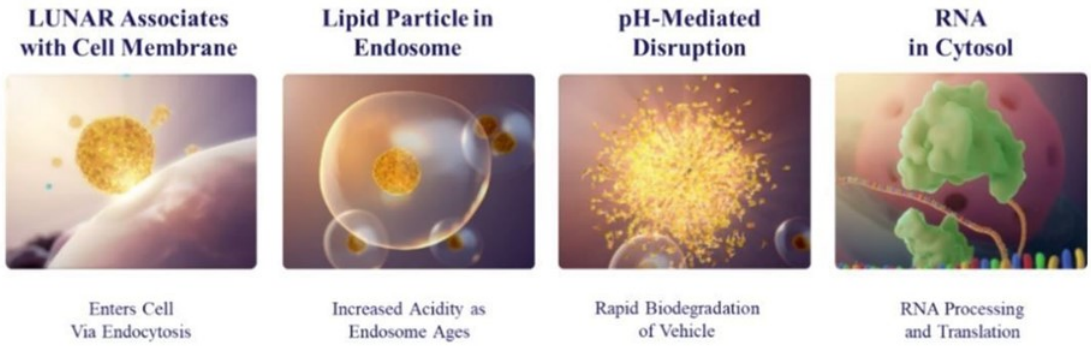
Key Attributes of Our LUNAR Lipid-Mediated Delivery Technology

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 contain 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, disrupting the endosome and the LUNAR particle, resulting in release of the nucleic acid therapeutic into the cell where is it 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 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 cellular enzymes, called 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.

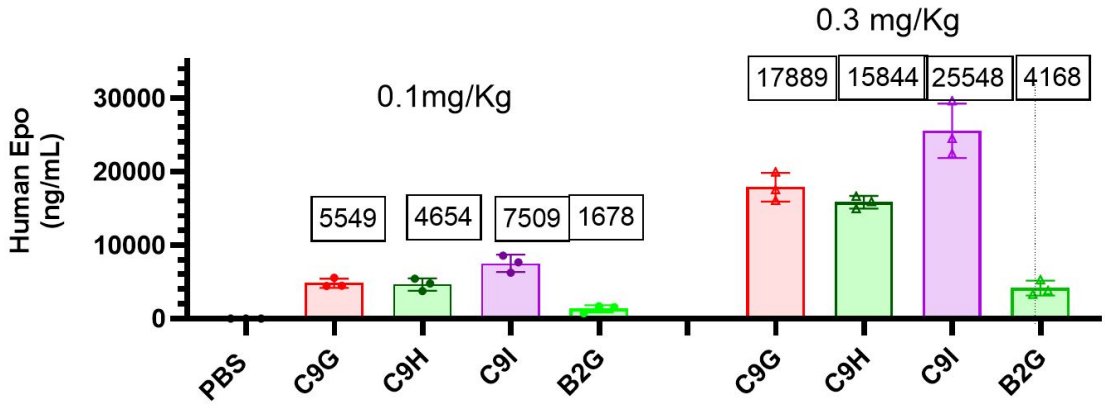
Through the above efforts, our versatile LUNAR platform continues to drive internal and partner programs.

ATX Lipid Design and In Vivo Screening Process

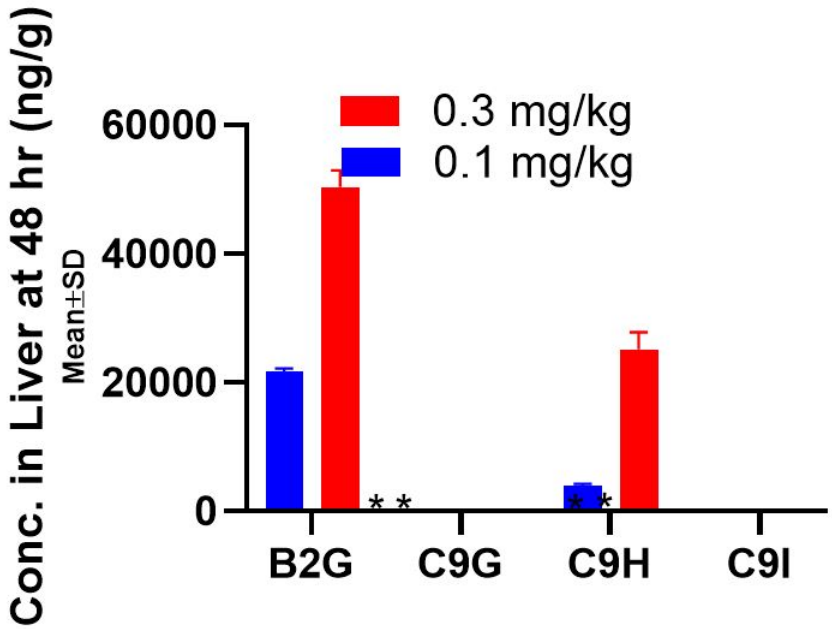
As mentioned above, we have generated a growing library of more than 300 proprietary ATX lipids. ATX lipids are rationally designed to fit their respective applications and vary depending on the target cell type and route of administration. We perform extensive formulation screening for each nucleic 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. 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 then tested for tolerability and preliminary tissue clearance rates following administration. Active candidates are further verified by evaluating protein expression in non-human primates. 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 2)



Mouse Liver Clearance of LUNAR Lipids 48 hours After IV Administration (Figure 3)



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

Expression of Human EPO in Non-Human Primates 6 Hours After IV Administration (Figure 4)

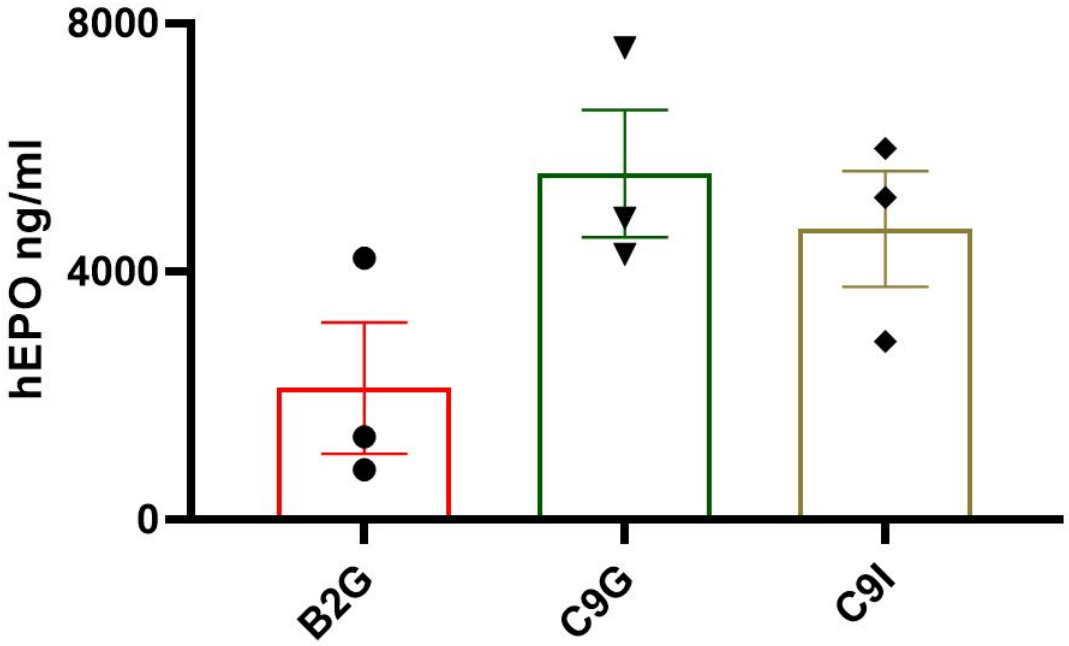


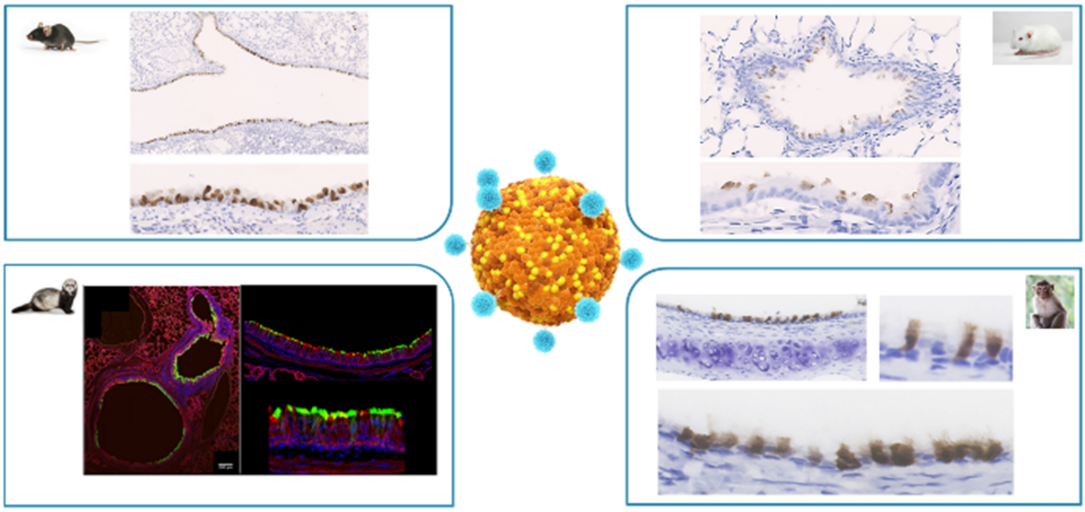
Figure 2: mice were injected intravenously with 4 different LUNAR lipid formulations containing mRNA expressing human erythropoietin (EPO). The LUNAR lipids that were screened were C9G, C9H, C9I and B2G at 0.1 mg/kg and 0.3 mg/kg RNA doses. LUNAR lipid B2G formulation is a positive control to which expressions from the other formulations are compared. Mice were bled 6 hours after injection and assayed for EPO, a secreted protein.

Figure 3: shows the clearance of the LUNAR 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 EPO 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 4: 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

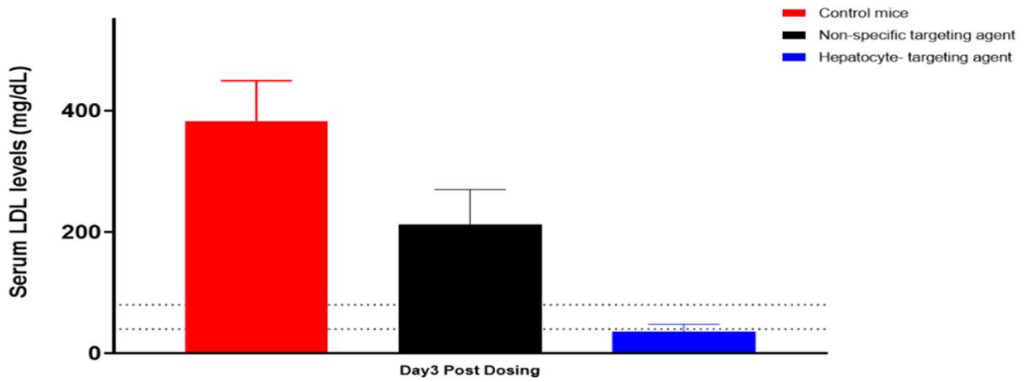
Aerosol capabilities have been developed for the CF program using our proprietary lipid nanoparticle delivery platform, LUNAR. Characterization and optimization of the aerosolized LUNAR formulations in targeting airway epithelium have been achieved in rodent (mice, rat) and nonrodent models (ferret, 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 airways epithelium demonstrated in vivo across species (rodents, ferrets, NHPs)

Alternate Liver Targeting

As proof of concept for augmenting LUNAR liver-targeting capabilities, we have developed data on LUNAR formulations containing a propriety hepatocyte targeting agent. Traditional lipid nanoparticle-mediated delivery to hepatocytes occurs via uptake by the low-density lipoprotein receptor (LDLR). LUNAR's advanced generation lipids have excellent liver targeting capabilities on their own. But diseases mediated by LDLR deficiency such as familiar hypercholesterolemia require alternate liver targeting and LUNAR delivery approaches. Therefore, we evaluated this targeting agent in an LDLR-deficient mouse model and found that only the LUNAR formulations with this targeting agent were able to deliver mRNA to the hepatocytes compared to LUNAR formulations that did not contain the targeting agent. Based on this promising data, we are expanding these platform development efforts.



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 (STARR) includes proprietary algorithms that inform the design and optimization of sa-mRNA to enhance expression of the applicable antigen while minimizing structures that might 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 expression compared to conventional (conventional) mRNA. The enhanced expression leads to higher immunogenicity at lower doses than conventional mRNA vaccines in preclinical studies (Figure 6 below).

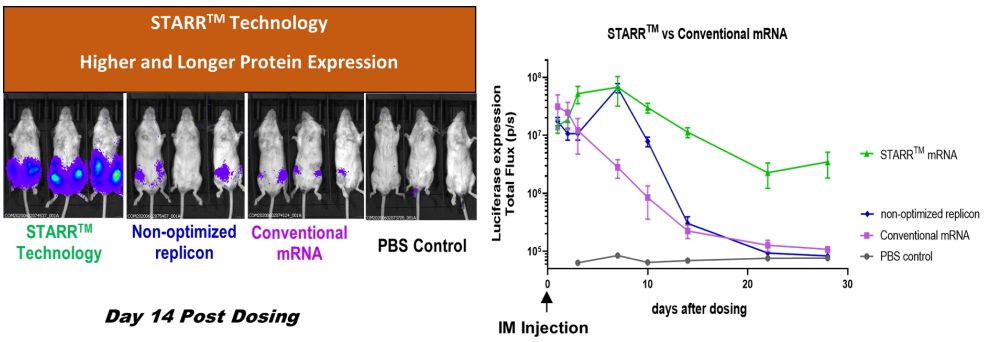


Figure 2: The luciferase expression from an optimized sa-mRNA, STARR Technology (Green), a non-optimized sa-mRNA (Blue) and the conventional RNA (Purple). The STARR Technology was shown to yield at least a 30-fold greater expression level than conventional RNA. The STARR Technology also demonstrated a longer duration of expression compared to the conventional RNA and also the non-optimized self-amplifying RNA.

Vaccine candidates with STARR technology have been demonstrated to induce a longer-lasting and broader humoral immune response at lower dose levels than conventional mRNA-based vaccines.

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 – Vaccine Programs (Lyme Disease and Gonorrhea)

Based on the clinical and regulatory validation of LUNAR and STARR technologies provided by the approval of KOSTAIVE, a self-amplifying messenger RNA (sa-mRNA) vaccine for COVID-19, we initiated vaccine discovery programs for Lyme disease and gonorrhea. The discovery programs rely on the evidence of superior immunogenicity, durability, and breadth of immune response compared to conventional mRNA vaccines, as observed in the COVID-19 program.

Lyme disease is a bacterial infection and is the most common vector-borne disease in the United States. Infection can spread to joints, the heart and the nervous system. Gonorrhea is a sexually transmitted disease (STD) that can infect the mucous membranes of the reproductive tract. It is the second most commonly reported bacterial sexually transmitted infection in the United States. We selected these diseases based on high unmet medical needs, good understanding of the path forward in vaccine target selection, and demonstration of proof of concept, as well as platform advantages that may be translated in a favorable vaccine product.

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 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.

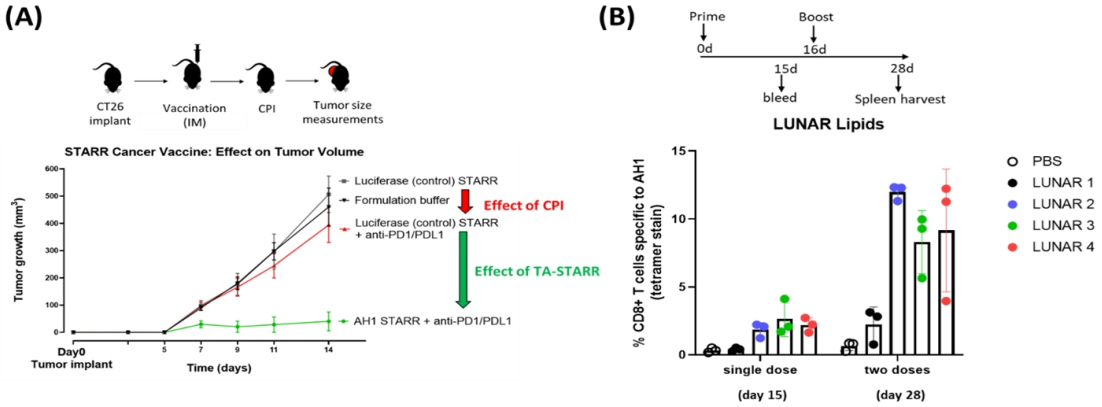


Figure 11: Antitumor activity and T cell response by Arcturus cancer vaccines. A. STARR vaccine expressing a tumor antigen led to a significant reduction of the tumor growth rate of a colorectal cancer cell line, CT26. B. T responses elicited by conventional mRNA cancer vaccine by various LUNAR formulations.

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.

The goal of the LUNAR-I/O program is to leverage the inherent advantages of both RNA and LUNAR technology to maximize clinical effectiveness of CAR-expressing cells. Initial experiments demonstrated that our proprietary LUNAR lipid nanoparticles can transfect > 90% of both primary human CD8+ and CD4+ T lymphocytes in vitro. 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. In furtherance of optimizing commercial efforts, we continue, with our collaborator CSL Seqirus, to evaluate and advance manufacturing process and capabilities and technology transfers, including the pursuit of different product presentations.

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 Collaboration and License Agreement between CSL and the Company 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.

The CSL Collaboration Agreement allows us to fulfill our obligations under the award from the Biomedical Advanced Research and Development Authority (BARDA) relating to rapid pandemic influenza response, announced by Arcturus in August 2022.

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

On August 14, 2023, we announced that ARCALIS Inc. (ARCALIS), our manufacturing joint venture in Japan to support the production of mRNA vaccines and therapeutics, had been awarded up to $115 million in two separate grants from the Japanese government. The grants were used to fund the construction of a factory and the purchase of capital equipment to support current Good Manufacturing Practice (cGMP) production of mRNA drug substance and mRNA drug product operations.

On October 4, 2023, we announced that ARCALIS was selected by the Japanese Ministry of Economy, Trade and Industry to receive additional financial support to construct a DNA template manufacturing facility along with new state-of-the-art equipment. DNA plasmid generated at this facility would be used as key starting material in the manufacture of mRNA drug substance at ARCALIS' neighboring mRNA drug substance facility, which was completed in July 2023. To date, approximately $165 million has been awarded to ARCALIS by the Japanese government, subject to certain terms and conditions, to build mRNA Drug Substance, mRNA Drug Product manufacturing capabilities and to construct a DNA template manufacturing facility.

On November 14, 2024, Meiji Seika Pharma announced its investment in ARCALIS. This investment will further strengthen the collaborative relationship between the two companies. The combination of ARCALIS' advanced technology and operations in mRNA pharmaceuticals and vaccines with Meiji Seika Pharma's expertise in manufacturing, post-marketing safety management and stable product supply is expected to significantly improve the supply of mRNA vaccines in Japan.

In January 2025, Meiji Seika Pharma, along with our manufacturing joint venture 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, are now able to be shipped for commercial use in Japan.

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, 2025, 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 process 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 2045, 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 under the STARR technology. 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 2044, 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.

Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial civil or criminal sanctions. FDA sanctions could include refusal to approve pending applications, withdrawal of an approval, clinical hold, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, debarment, restitution, disgorgement or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us. The process required by the FDA before a 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 audit 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. The conduct of the animal studies must comply with federal regulations and requirements including GLP. The sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. The IND automatically becomes effective thirty days after receipt by the FDA, unless the FDA imposes a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a drug candidate at any time before or during clinical trials due to safety concerns or non-compliance. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate such trial.

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. Each protocol must be submitted to the FDA as part of the IND. Clinical trials must be conducted in accordance with the FDA's regulations comprising the good clinical practices requirements. Further, each clinical trial must be reviewed and approved by an independent institutional review board ("IRB") at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the form and content of the

informed consent that must be signed by each clinical trial subject or his or her legal representative and provides oversight for the clinical trial until completed.

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.

Annual progress reports detailing the results of the clinical trials must be submitted to the FDA and written IND safety reports must be promptly submitted to the FDA and the investigators for serious and unexpected adverse events or any finding from tests in laboratory animals that suggests a significant risk for human subjects. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor or its data safety monitoring board may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients.

Concurrently with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final drug. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf life.

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.

In addition, under the Pediatric Research Equity Act ("PREA"), an NDA or BLA or supplement to an NDA or BLA must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers. Unless otherwise required by regulation, PREA does not apply to any drug for an indication for which orphan designation has been granted.

The FDA reviews all NDAs or BLAs submitted to determine if they are substantially complete before it accepts them for filing. If the FDA determines that an NDA or BLA is incomplete or is found to be non-navigable, the filing may be refused and must be re-submitted for consideration. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA or BLA. Under the goals and policies agreed to by the FDA under the

Prescription Drug User Fee Act ("PDUFA"), the FDA has 10 months from acceptance of filing in which to complete its initial review of a standard NDA or BLA and respond to the applicant, and six months from acceptance of filing for a priority NDA or BLA. The FDA does not always meet its PDUFA goal dates. The review process and the PDUFA goal date may be extended by three months or longer if the FDA requests or the NDA or BLA sponsor otherwise provides additional information or clarification regarding information already provided in the submission before the PDUFA goal date.

After the NDA or BLA submission is accepted for filing, the FDA reviews the NDA or BLA to determine, among other things, whether the proposed product is safe and effective for its intended use, and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, strength, quality and purity. The FDA may refer applications for novel drug or biological products or drug or biological products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. During the drug approval process, the FDA also will determine whether a risk evaluation and mitigation strategy ("REMS") is necessary to assure the safe use of the drug. If the FDA concludes a REMS is needed, the sponsor of the NDA or BLA must submit a proposed REMS; the FDA will not approve the NDA or BLA without a REMS, if required.

Before approving an NDA or BLA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. The FDA requires vaccine manufacturers to submit data supporting the demonstration of consistency between manufacturing batches, or lots. The FDA works together with vaccine manufacturers to develop a lot release protocol, the tests conducted on each lot of vaccine post-approval. Additionally, before approving an NDA or BLA, the FDA will typically inspect the sponsor and one or more clinical sites to assure that the clinical trials were conducted in compliance with IND study requirements. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable it will outline the deficiencies in the submission and often will request additional testing or information.

The NDA or BLA review and approval process is lengthy and difficult, and the FDA may refuse to approve an NDA or BLA if the applicable regulatory criteria are not satisfied or may require additional clinical data or other data and information. Even if such data and information are submitted, the FDA may ultimately decide that the NDA or BLA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data. The FDA will issue a complete response letter if the agency decides not to approve the NDA or BLA. The complete response letter usually describes all of the specific deficiencies in the NDA or BLA identified by the FDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may either submit new information, addressing all of the deficiencies identified in the letter, or withdraw the application.

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

Any drug or biological products for which we or our strategic alliance partners receive FDA approvals are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, complying with certain electronic records and signature requirements and complying with FDA promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, promoting drugs for uses or in patient populations that are not described in the drug's approved labeling (known as "off-label use"), industry-sponsored scientific and educational activities, and promotional activities involving the internet. Failure to comply with FDA requirements can have negative

consequences, including adverse publicity, enforcement letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties. Although physicians may prescribe legally available drugs for off-label uses, manufacturers may not market or promote such off-label uses.

Following approval, the FDA continues to monitor vaccine quality through real-time monitoring of lots by requiring manufacturers to submit certain information for each vaccine lot. Vaccine manufacturers may only distribute a lot following release by the FDA. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved NDA or BLA, including withdrawal of the product from the market. In addition, changes to the manufacturing process require notice to or prior approval from the FDA before being implemented and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

Regulation in Europe and Other Regions

In addition to regulations in the United States, we and our strategic alliance partners are subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products.

Whether or not we or our collaborators obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application much like the IND prior to the commencement of human clinical trials. Once the Clinical Trial Application ("CTA") is approved in accordance with a country's requirements, clinical trial development may proceed.

To obtain regulatory approval of an investigational drug or biological product under EU regulatory systems, we or our strategic alliance partners must submit a marketing authorization application. The application in the EU is similar to that required in the United States, with the exception of, among other things, region/country-specific document requirements.

For other countries outside of the EU, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical trials are conducted in accordance with GCPs and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. The regulatory approval of marketing authorization application of an investigational drug or biological product is similar to that required in the United States, with the exception of, among other things, country-specific document requirements.

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 I. 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.

LUNAR-COVID-19 Vaccine (KOSTAIVE®)

Our vaccine franchise is based on our self-amplifying and self-replicating 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, Janssen, AstraZeneca, Novavax, and HDT Bio. Dozens of other companies are continuing to develop COVID-19 vaccines. However, the majority of these companies use conventional mRNA (not self-amplifying) and egg-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, BioNTech, Moderna, Novavax, and Sanofi. The flu industry is rapidly shifting to utilizing mRNA-based platforms in addition to other non-egg based technologies and traditional (egg-based) technologies.

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 which is advancing a gene therapy program for OTC in clinical development, and Moderna which has a therapeutic candidate in pre-clinical 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, Eloxx Pharmaceuticals, Recode, 4DMT, Spirovant, SalioGen and Splisense.

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
    - BioNTech, in collaboration with Pfizer, has a marketed COVID-19 conventional mRNA vaccine, COMIRNATY® available in multiple geographies, and is developing mRNA flu vaccine and COVID-19/flu combination vaccine, as well as latent virus and other vaccines of global public health interest in early development.
    - Moderna manufactures the only other approved conventional mRNA based COVID-19 vaccine, Spikevax®, which is 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., CMV, EBV, HSV, etc.), and other virus vaccine candidates which are in the clinical stage of development; 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 II clinical development; COVID-19/flu combo is in Phase I. However, CureVac developed the RNA Printer®, an automated end-to-end system for manufacturing of GMP-grade mRNA vaccines and therapeutics which also has application in small-scale GMP manufacturing. In collaboration with Elon Musk and Tesla, CureVac plans to optimize and enhance their mRNA microscale manufacturing technology.

Human Capital

As of December 31, 2024, we had approximately 176 employees, of which 174 were full-time and 2 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.

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 exposed to interest rate risk, including under our loan agreements.*
- *Our debt contains customary default clauses, a breach of which may result in acceleration of the repayment of some or all of this debt.*
- *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.*
- *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, their 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.*
- *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.*
- *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.*
- *We have identified a material weakness in our internal control over financial reporting, and determined that our disclosure controls and procedures were not effective. If our remediations of this material weakness is not effective, or if we experience additional material weaknesses or otherwise fail to maintain an effective system of internal control over financial reporting or adequate disclosure controls and procedures, we may not be able to accurately and timely report our financial results, in which case our business may be harmed, investors may lose confidence in the accuracy and completeness of our financial reports, and the price of our common stock may decline.*

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 2024 we recognized a significant portion of our revenue from non-recurring milestone payments and license revenue under our collaboration agreement with CSL Seqirus. Our future payments from CSL Seqirus are dependent on our ability to execute by meeting key product development and other milestones within the contract. We have not recognized any revenue from product sales since our inception.

As of December 31, 2024, we had an accumulated deficit of $448.8 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, 2024, we had unrestricted cash and cash equivalents of $237.0 million, which we expect should be sufficient to fund currently planned operations for the near future. 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 2024 to fund our continued preclinical and clinical development activities for our pipeline, including manufacturing activities to support such development 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 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.

We are exposed to interest rate risk, including under our loan agreements.

We are exposed to market risk from changes in interest rates. Exposure to interest rate risk results from our debt obligations, including the credit agreement entered into on April 21, 2023 and amended on June 26, 2024 by our wholly-owned subsidiary, Arcturus Therapeutics, Inc., and Wells Fargo Bank, National Association (as amended, the "Credit Agreement"), providing for a revolving credit line evidenced by a revolving line of credit note (the "Note"). Borrowings under the Credit 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. All Loans shall bear interest during an Event of Default (as defined in the Credit Agreement) at a rate equal to 2.00% above the interest rate applicable immediately prior to the occurrence of the Event of Default (as defined in the Credit Agreement). As of December 31, 2024, we had no outstanding balance under the Credit Agreement.

Our indebtedness could materially and adversely affect our business, financial condition and results of operations.

Agreements with our lenders, including with Wells Fargo Bank, National Association, create several limitations on us, including but not limited to:

- limiting our flexibility in planning for, or reacting to, changes in our business and our industry;
- placing us at a competitive disadvantage compared to our competitors who may have less debt or comparable debt at more favorable interest rates or less strict covenants and other limitations or requirements;
- limiting our ability to incur specified types of additional indebtedness which may be desired for working capital, capital expenditures, research and development efforts, acquisitions, debt service requirements, execution of our business strategy or other purposes; and
- resulting in an acceleration of our obligations upon the occurrence of an event of default.

Our ability to comply with these covenants in future periods will depend on our financial and operating performance, which in turn will be subject to economic conditions and to financial, market and competitive factors, many of which are beyond our control. Any of these factors or others described in the Credit Agreement could materially and adversely affect our business, financial condition and results of operations.

Our debt contains customary default clauses, a breach of which may result in acceleration of the repayment of some or all of this debt.

The Credit Agreement contains customary default clauses. In the event we were to default on our obligations under our debt and were unable to cure or obtain a waiver of such default, the repayment of our debt may be accelerated. If such acceleration were to occur, we would be required to promptly secure alternative sources of equity or debt financing to be able to repay the debt. Alternative financing may not be available on terms satisfactory to us, or at all. New debt financing may require the cooperation and agreement of our existing lenders. If acceptable alternative financing were unavailable, we would have to consider alternatives to fund the repayment of the debt, which could materially and adversely affect our business, financial condition and results of operations.

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. It is uncertain if and to what extent various states will conform to the Tax Cuts and Jobs Act. 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 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.

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, or if CSL Seqirus terminates its collaboration agreement with us, it would negatively impact our ability to conduct our business and generate net product revenue. Failure by CSL Seqirus to perform its duties under its collaboration agreement with us may negatively affect us. The potential financial returns to us under our collaboration agreements with CSL Seqirus depends in large part on the achievement of milestones and generation of product sales. If CSL Seqirus fails to perform or satisfy its obligations under the collaboration agreement or if we otherwise encounter disagreement with CSL Seqirus regarding the satisfaction of milestones, the development and commercialization of the licensed programs could be delayed, hindered or may not occur and our business and prospects could be materially and adversely affected. The fulfillment of our obligations under the CSL Collaboration Agreement may require significant deployment of our resources, which could disrupt or delay our ability to pursue other programs, including our platform development and development of other product candidates.

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. As further COVID-19 vaccines are approved, production of existing COVID-19 vaccines improves and the COVID-19 impact transitions from pandemic to endemic stage, 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, 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 or other factors. Japanese regulatory agencies and purchasers might require involvement of Japanese companies in the domestic production of our COVID-19 vaccine, and our Japanese partners and contract manufacturers might not be able to scale up to commercial quantities. If any such Japanese companies do not participate or fail in such activities, then our and our partners' ability to commercialize our COVID-19 vaccine will be materially harmed. 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 are 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 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, their 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 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.

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 the FDA or other federal agencies could delay the approval or review processes for any of our products and product candidates, which could negatively impact our business and results of operations. In addition, the new presidential administration may institute policies, communications or programs that could negatively impact the biotechnology industry, vaccine products and our ability to raise additional financing.

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 we intend to make efforts to 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.

In addition, we cannot be certain if and when we will obtain formulary approval to allow us to sell any products into our target markets. Obtaining formulary approval from hospitals and from pharmacy benefits payors can be an expensive and time-consuming process. Failure to obtain timely formulary approval will limit our commercial success.

There have been a number of legislative and regulatory proposals to change the healthcare system in the United States and in some foreign jurisdictions that could affect our ability to sell products profitably. These legislative and/or regulatory changes may negatively impact the reimbursement for drug products, following approval. The availability of numerous generic treatments may also substantially reduce the likelihood of reimbursement for our future products. We expect to experience pricing pressures in connection with the sale of any products that we develop, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, and prescription drugs in particular, has and is expected to continue to increase in the future. For instance, government and private payors who reimburse patients or healthcare providers are increasingly seeking greater upfront discounts, additional rebates and other concessions to reduce prices for pharmaceutical products. If we fail to successfully secure and maintain sufficient reimbursement coverage for our future products or are significantly delayed in doing so, we will have difficulty achieving market acceptance of our future products and our business will be harmed.

In addition, in some non-U.S. jurisdictions, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the EU provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product, or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. If any country that has price controls or reimbursement limitations for pharmaceutical products does not allow favorable reimbursement and pricing arrangements for any of our products, our sales and profits from that product could be severely limited. Historically, products launched in the EU do not follow price structures of the U.S. and generally tend to be priced significantly lower.

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.

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.

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, 2024, we had approximately 176 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-E 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.

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.

We have identified a material weakness in our internal control over financial reporting, and determined that our disclosure controls were not effective as of December 31, 2023 and December 31, 2024. If our remediations of this material weakness are not effective, or if we experience additional material weaknesses or otherwise fail to maintain an effective system of internal control over financial reporting or adequate disclosure controls and procedures, we may not be able to accurately and timely report our financial results, in which case our business may be harmed, investors may lose confidence in the accuracy and completeness of our financial reports, and the price of our common stock may decline.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting and for evaluating and reporting on the effectiveness of our system of internal control. Our 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 reporting purposes in accordance with generally accepted accounting principles ("GAAP"). We are required to furnish annually a report by management of its assessment of the effectiveness of our internal control over financial reporting as of the end of our most recent fiscal year. In addition, our independent registered public accounting firm is required to provide a related attestation report on our internal control over financial reporting.

As previously reported, as part of our assessment of the effectiveness of our internal control over financial reporting as of December 31, 2023, management identified a material weakness related to information technology general controls ("ITGCs") for information systems and applications that are relevant to the preparation of the consolidated financial statements. Specifically, it was determined we did not design and maintain: (i) sufficient user access controls to ensure appropriate segregation of duties and adequately restrict user and privileged access to financial applications, programs and data to the appropriate personnel; (ii) program change management controls 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) computer operations controls to ensure that critical batch and interfaced jobs are monitored, privileges are appropriately granted, and data backups are authorized and monitored. Business process controls (automated and manual) that are dependent on the ineffective ITGCs, or that rely on data produced from systems impacted by the ineffective ITGCs, are also deemed ineffective. Management also identified a material weakness related to revenue recognition. Certain control activities within the area of revenue did not operate effectively, specifically controls over the review of costs incurred in satisfaction of our performance obligations under collaboration arrangements. Although we remediated the material weakness related to revenue recognition, management does not believe the corrective measures adopted in response to the ITGC-related material weakness have been fully implemented or operating for a sufficient period of time to enable management to conclude these internal controls over financial reporting are operating effectively and sufficiently to remediate this material weakness. As such, we concluded that our disclosure controls and procedures were not effective as of December 31, 2024.

If we are unable to successfully remediate our existing material weakness or any future material weakness or other deficiencies in our internal control over financial reporting: the accuracy and timing of our financial reporting may be adversely affected; our liquidity, our access to capital markets and the perceptions of our creditworthiness; we may be unable to maintain compliance with applicable securities laws, Nasdaq listing requirements, and the covenants under our debt instruments regarding the timely filing of periodic reports; we may be subject to regulatory investigations and penalties; and investors may lose confidence in our financial reporting. If any such event or circumstance were to occur, our stock price could decline and our business, financial condition and results of operations could be materially adversely affected.

Notwithstanding the identified material weakness, management does not believe that the deficiencies had an adverse effect on our reported operating results or financial condition, and management has determined that the financial statements and other information included in this report and other periodic filings present fairly in all material respects our financial condition and results of operations at and for the periods presented. The effectiveness of our internal control over financial reporting as of December 31, 2024 has been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report which is included elsewhere herein. For further discussion of the material weakness identified and our remedial efforts, see Item 9A. Controls and Procedures.

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. 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. In particular, the former shareholders, warrant holders and noteholders of Arcturus Therapeutics, Inc. received an aggregate of 6,631,712 of our common stock pursuant to the merger with Alcobra Ltd. in an unregistered transaction, which shares 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 not offered or sold any shares of common stock pursuant to 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 and our Vice President of Information Technology help 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 and 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, including, 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, asset management and tracking, systems monitoring, annual mandated employee training, penetration testing, cybersecurity insurance, and dedicated cybersecurity staff.

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 all determined 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 Vice President of IT, 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.

Governance

We have 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 Vice President of IT or the Chief Legal Officer as described below in "Management's Role Managing Risk."

Management's Role Managing Risk

The Vice President of IT, Chief Legal Officer ("CLO") and the Director of IT Infrastructure and Security, play a pivotal role in informing the Audit Committee on cybersecurity risks. They provide briefings to the Audit Committee on a regular basis, with a minimum frequency of once per year. The current Vice President of IT, 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 the Vice President of IT and the Director of IT Infrastructure and Security. 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 Vice President of IT 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 the Vice President of IT, the Director of IT Infrastructure and Security 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 Vice President of IT 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 Vice President of IT and the Director of IT Infrastructure and Security, in their respective capacity, inform the Chief Financial Officer (CFO) and Chief Legal Officer (CLO) 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 10628 Science Center Drive, Suite 250, and consists of approximately 24,700 square feet of office space and laboratory space leased through March 2027.

On September 29, 2021, we entered into a lease agreement for office, research and development, engineering and laboratory space located at 10285 Science Center Drive, San Diego, California. The additional space of approximately 43,234 square feet is leased for a term of 10 years and 8 months.

We believe that our properties are 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. We are not currently a party to any material legal proceedings.

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

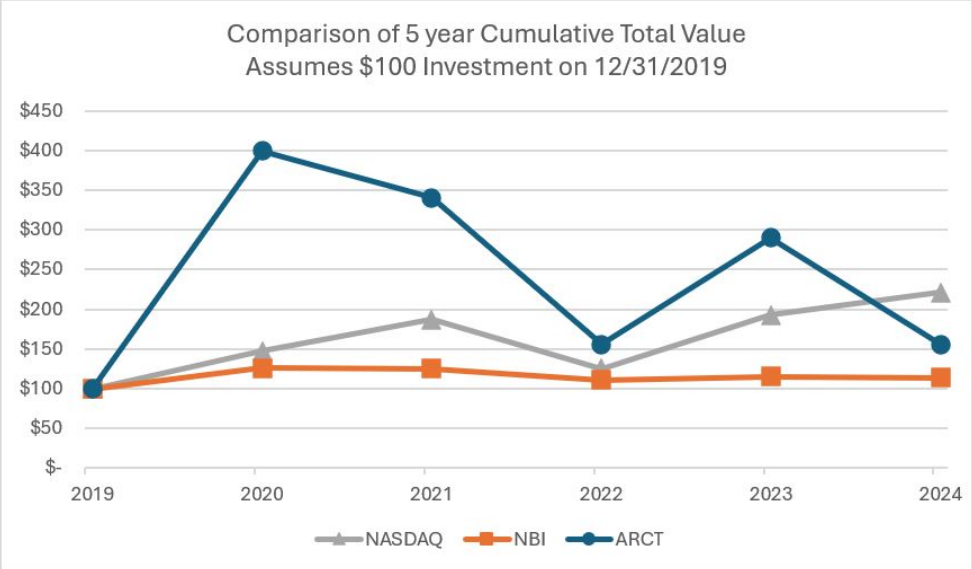
As of March 3, 2025, there were nine registered holders of record of our common stock. Because many of our outstanding shares are held in accounts with brokers and other institutions, the number of beneficial owners is significantly greater than the number of record holders. This number of holders of 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, 2019 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 2022 items and year-to-year comparisons between 2023 and 2022 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, 2023.

Overview

We are a messenger RNA medicines company focused on the development of infectious disease vaccines and opportunities within liver and respiratory rare diseases. We developed the world's first approved self-amplifying messenger RNA (sa-mRNA) vaccine, KOSTAIVE® ("KOSTAIVE"). KOSTAIVE achieved approval in Japan in 2023 as a vaccine against COVID-19. Sales of KOSTAIVE began in Japan in October 2024, marking our transition to a commercial stage company.

We have several key platform technologies that we leverage to develop and advance a pipeline of mRNA-based vaccines and therapeutics for infectious diseases and for rare genetic disorders with significant unmet medical needs. 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 believe we are among the world leaders in both areas. 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 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 therapeutics to disease-relevant target tissues. LUNAR may enable multiple nucleic acid medicines. The approval of KOSTAIVE in Japan was a significant milestone which validates our LUNAR and STARR platforms, as well as sa-mRNA more generally as a meaningful modality. Finally, we 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 Seqirus, Inc. ("CSL Seqirus"), a part of CSL Limited and one of the world's leading influenza vaccine providers, on the development and commercialization of mRNA vaccines for COVID-19, influenza and certain other infectious diseases.

We made significant progress in 2024. Commercial sales of KOSTAIVE began in October 2024 in Japan by Meiji Seika Pharma ("Meiji"), CSL Seqirus' exclusive partner in Japan, marking the first commercial sales of an Arcturus-developed product. In February 2025, we received approval of KOSTAIVE from the European Commission (EC), which provided further validation of our platform by another significant regulatory authority.

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.

We initiated dosing in a Phase 1 clinical trial of a novel seasonal influenza sa-mRNA vaccine candidate under our collaboration with CSL Seqirus in January 2024. 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").

In our OTC program, we completed dosing of eight subjects in August 2024 in a Phase 2 double-blind multiple-dose study of ARCT-810. In the second quarter of 2024, we expanded the Phase 2 clinical program of ARCT-810 with an open-label, multiple-dose study which initiated dosing in December 2024. ARCT-810 has

received Orphan Drug Designation from the FDA and Orphan Medicinal Product Designation from the European Medicines Agency (the "EMA") for treatment of OTC deficiency, as well as Fast Track Designation and Rare Pediatric Disease Designation from the FDA.

In our CF program, we initiated dosing in December 2024 in a Phase 2 multiple ascending dose study of ARCT-032 designed to identify a safe and effective dose in people with Class I (null) CFTR mutations and other CF patients who do not benefit from CFTR modulators. In July 2024, we completed dosing and follow-up visits for seven participants in a safety and tolerability Phase 1b clinical study in New Zealand of ARCT-032 in adults with CF. ARCT-032 has received Orphan Drug Designation by the FDA and Orphan Medicinal Product Designation by the EMA for the treatment of CF, and Rare Pediatric Disease Designation from the FDA.

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 potentially be useful for identification and development of additional products for our portfolio. Also, with our sourcing partners, we manufactured cGMP (current good manufacturing practices) batches yielding significant quantities of clinical trial materials for global studies of our candidates, and with our collaborator, CSL Seqirus, we have established commercial production processes for the COVID-19 vaccine program.

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, 2024, we had an accumulated deficit of $448.8 million.

Liquidity and Capital Resources

From the Company's inception through the year ended December 31, 2024, 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 2024, we received milestone payments totaling $96.0 million from CSL Seqirus. We expect to receive future payments from CSL Seqirus primarily by meeting future milestones related to the CSL Collaboration Agreement. At December 31, 2024, the Company's balance of cash and cash equivalents, including restricted cash, was $293.9 million.

CSL Seqirus, Inc. Collaboration and License Agreement

In 2022, we entered into the CSL Collaboration Agreement with CSL Seqirus, a part of CSL Limited, one of the world's leading influenza vaccine providers, for the global exclusive rights to research, develop, manufacture and commercialize mRNA vaccines.

CSL Seqirus received exclusive global rights to our technology for vaccines against SARS-CoV-2 (COVID-19), influenza and three other infectious diseases with non-exclusive rights to pandemic pathogens. We received an up-front payment of $200.0 million during the fourth quarter of 2022. We will be eligible to receive development milestones totaling more than $1.3 billion if all products are registered in the licensed fields. We will also be entitled to 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 and the other three specified infectious disease pathogens, as well as royalties on revenues from vaccines that may be developed for pandemic preparedness.

The CSL Collaboration Agreement sets forth how CSL Seqirus and we shall collaborate to research and develop vaccine candidates. In the COVID-19 field, we will lead activities for certain regulatory filings for ARCT-154 in the US and Europe and for research and development activities of a next-generation COVID vaccine candidate. CSL Seqirus will lead and be responsible for all other research and development in COVID-19, influenza and the other fields.

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. As of December 31, 2024, no borrowings were made against the Wells Fargo Loan.

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 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) occurs, then all Wells Fargo 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 original term of the agreement is 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 is no penalty for terminating the agreement. There is no penalty for terminating the facility prior to the maturity date of the Wells Fargo Loan. As collateral, the Company has 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.

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, 2024, the remaining available funding net of revenue earned was $40.0 million.

Vinbiocare Agreement

During 2021, we entered into a technology license and technical support agreement and the framework drug substance supply agreement with Vinbiocare, a member of Vingroup Joint Stock Company (collectively, the "Vinbiocare License & Supply Agreements"), whereby we would provide technical expertise and support services to Vinbiocare to assist in the build out of an mRNA drug product manufacturing facility in Vietnam. We received an upfront payment in aggregate of $40.0 million as part of the Vinbiocare License and Supply Agreements. In October 2022, in association with the termination of the Vinbiocare License and Supply Agreements, we signed the Vinbiocare Support Agreement with Vinbiocare which continues Vinbiocare's clinical obligations and reserved a portion of the original $40.0 million upfront payment received from the License and Supply Agreements to be paid over the future periods.

The Vinbiocare Support Agreement requires us to pay to Vinbiocare certain limited payments, including upon the occurrence of specified events through the first quarter of 2025. Vinbiocare is also eligible to receive a single digit percentage of amounts received by Arcturus on net sales, if any, of ARCT-154 (or next-generation COVID vaccine) up to a capped amount.

General Financial Resources

A portion of our current cash balance is expected to be utilized during fiscal year 2025 to fund (i) the continued Phase 2 trial of ARCT-810, our LUNAR-OTC candidate, (ii) advances to our LUNAR-CF program in clinical trials, (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 execute on milestones within the CSL Collaboration Agreement, 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, executing on milestones within the CSL Collaboration Agreement 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 LUNAR-COV19 and LUNAR-FLU vaccine 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, 2024 and 2023:

(in thousands)	Year Ended December 31, 2024	2023
Cash provided by (used in):		
Operating activities	$ (59,747)	$ (18,099)
Investing activities	(648)	(2,901)
Financing activities	5,418	(24,087)
Net decrease in cash and restricted cash	$ (54,977)	$ (45,087)

Operating Activities

Net cash used in operating activities was $59.7 million for the year ended December 31, 2024, compared to $18.1 million for the year ended December 31, 2023. The $41.6 million increase in cash used was primarily driven by a $93.8 million year-over-year impact from deferred revenue, as 2023 benefited from a $38.6 million deferred revenue inflow, while 2024 saw a $55.2 million outflow due to revenue recognition exceeding new milestone payments under the CSL collaboration agreement. Additionally, the increase in cash outflows was due to a higher net loss and the absence of a $34.0 million debt extinguishment gain recognized in 2023. These impacts were partially offset by a $57.4 million improvement in accounts receivable, as payments from CSL and BARDA were received in 2024 and a $6.5 million increase in accrued liabilities, primarily due to the timing of bonus accruals.

Investing Activities

Net cash used in investing activities of $0.6 million in 2024 and $2.9 million in 2023 reflected the acquisition of property and equipment.

Financing Activities

Net cash provided by financing activities was $5.4 million for the year ended December 31, 2024, compared to a net cash outflow of $24.1 million in 2023 ,representing a $29.5 million increase. The primary drivers of this increase were the repayments of the Singapore Loan and the Loan and Security Agreement with Western Alliance Bank during 2023, with no similar debt repayments occurring in 2024.

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:

(in thousands)	Years Ended December 31, 2024	2023	Change 2024 vs 2023 Change	%
Collaboration revenue	$ 138,389	$ 157,748	$ (19,359)	-12%
Grant revenue	13,921	9,051	4,870	54%
Total	$ 152,310	$ 166,799	$ (14,489)	-9%

Revenue decreased by $14.5 million during the year ended December 31, 2024 as compared to the year ended December 31, 2023. The decrease during 2024 primarily relates to a $15.9 million decrease in revenue related to the CSL collaboration agreement, primarily due to an $82.0 million decrease in milestone achievements during 2024 as compared to 2023, offset by a $23.4 million increase in revenue related to CSL commercial supply agreements and increased revenue recognition from amortization due to the progress of the CSL development programs during 2024. The remaining decrease is primarily due to a decrease of $1.8 million related to the completion of the amortization of the upfront payment during 2023 from the 2015 Research Collaboration and License Agreement with Ultragenyx

Pharmaceuticals, Inc., as well as $0.7 million less revenue in 2024 due the termination of the 2017 Research Collaboration and License Agreement with Janssen Pharmaceuticals, Inc. The decrease was primarily offset by an increase in the revenue of $4.8 million related to the increase in reimbursable research and development expenses for the grant agreement with BARDA.

Operating Expenses

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

	Years Ended December 31,		Change 2024 vs 2023	
(in thousands)	2024	2023	Change	%
Operating expenses:				
Research and development, net	$ 195,156	$ 192,133	$ 3,023	2%
General and administrative	52,823	52,871	(48)	0%
Total	$ 247,979	$ 245,004	$ 2,975	1%

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

Research and Development Expenses, net

	Year Ended December 31,		Change 2024 vs 2023	
(in thousands)	2024	2023	Change	%
LUNAR-COVID	$ 70,464	$ 81,262	$ (10,798)	-13%
LUNAR-OTC	9,509	9,315	194	2%
BARDA	7,807	5,465	2,342	43%
LUNAR-CF, net	17,227	14,666	2,561	17%
Early-stage programs	16,096	12,460	3,636	29%
Discovery technologies	6,278	6,405	(127)	-2%
Payroll and benefits	57,474	50,924	6,550	13%
Facilities and equipment	10,301	11,636	(1,335)	-11%
Total research and development expenses, net	$ 195,156	$ 192,133	$ 3,023	2%

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 $195.2 million for the year ended December 31, 2024, compared with $192.1 million for the year ended December 31, 2023, primarily reflecting increased payroll and benefits costs due to share-based compensation expense, progress within our BARDA, LUNAR-CF, and LUNAR-FLU programs, and clinical trial costs for the LUNAR-COVID program. The overall increase was offset by decreased manufacturing-related expenses due to lower costs associated with drug product supply agreements related to the LUNAR-COVID program during the year ended December 31, 2024. We expect that our research and development efforts and associated costs will continue to be substantial over the next several years as our pipeline progresses.

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. Although such expenses increased during 2024 as compared to 2023, we expect that they will not increase over the next twelve months due to reduced share-based compensation.

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 decreased during 2024 as compared to 2023 as we downsized from three to two facilities. Facilities and equipment expenses are not expected to increase during the next twelve months.

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 $52.8 million and $52.9 million for the years ended December 31, 2024 and 2023, respectively. We expect that general and administrative expenses will decrease slightly during the next twelve months due to reduced share-based compensation from fully vested stock options.

Finance income (expense), net

	Years Ended December 31,		Change 2024 vs 2023	
(in thousands)	2024	2023	Change	%
Interest income	$ 15,195	$ 17,359	$ (2,164)	-12%
Interest expense	-	(768)	768	-100%
Total	$ 15,195	$ 16,591	$ (1,396)	-8%

Interest income is generated on cash and cash equivalents. The decrease in interest income from 2023 to 2024 was the result of lower interest rates during the year ended 2024 and a decrease in cash and cash equivalents.

Interest expense decreased during the year ended 2024 as compared to the year ended 2023 as no interest expense has been incurred since to the first quarter of 2023. This was a result of the extinguishment of the Loan and Security Agreement dated October 12, 2018 with Western Alliance Bank, and forgiveness of the term loan from Economic Development Board of the Republic of Singapore pursuant to the Manufacturing Support Agreement dated November 7, 2020.

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 CDMOs. 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 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 Chief Financial Officer, with assistance from other members of management, have reviewed the effectiveness of our disclosure controls and procedures as of December 31, 2024, and, based on their evaluation, have concluded that the disclosure controls and procedures were not effective as of such date due to the material weakness in internal control over financial reporting, described below.

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.

Our management, under the supervision of and with the participation of the Chief Executive Officer and Chief Financial Officer, assessed the effectiveness of our internal control over financial reporting as of December 31, 2024. In making this assessment, management used the criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) ("the COSO criteria").

Based on our assessment under the COSO criteria, management concluded that our system of internal control over financial reporting was not effective due to the material weakness described below. However, after giving full consideration to the material weakness, and the additional analyses and other procedures we performed to ensure that our consolidated financial statements included in this Annual Report on Form 10-K were prepared in accordance with U.S. generally accepted accounting principles ("GAAP"), our management has concluded that our consolidated financial statements present fairly, in all material respects, our financial position, results of operations and cash flows for the periods disclosed in conformity with "GAAP".

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis.

Previously Reported Material Weaknesses and Remediation Plans

As reported in Part II, Item 9A. "Controls and Procedures" of our Annual Reports on Form 10-K for the fiscal year ended December 31, 2023, we identified a material weakness related to information technology general controls ("ITGCs") that support the financial reporting process. Specifically, the material weakness relates 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.

Management has made significant enhancements to the Company's process related to access provisioning and de-provisioning, program change management, as well as IT operations. Management has implemented or is in the process of implementing new or enhanced internal control procedures intended to both address the material weakness identified and strengthen our overall financial control environment, including:

- 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;
- developing and enhancing access administration controls over provisioning, deprovisioning, and authentication;
- developing and enhancing user access reviews for financially relevant IT systems;
- designing and refining 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.

While significant progress has been made to remediate this material weakness, management does not believe that these corrective measures have been either fully implemented or operating for a sufficient period of time to enable management to conclude that these internal controls over financial reporting are operating effectively and are fully implemented to remediate this material weakness. When fully implemented and operational, we believe the measures described above will remediate the material weakness. We are committed to making the necessary changes and improvements to our system of controls to address the material weakness in internal control over financial reporting described above.

In addition, 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, 2023, we identified a material weakness related to revenue recognition. Specifically, control activities related to the review of costs incurred in satisfaction of performance obligations under collaboration agreements did not operate effectively.

We have completed the execution of our remediation plan for this material weakness and, as of December 31, 2024, successfully remediated the material weakness by implementing the following measures:

- designed and implemented enhanced control activities over the identification of and accounting assessment of key terms and conditions of all revenue collaboration agreements;
- designed and implemented new control activities around the technical review of quarterly and annual revenue recognition; specifically, (i) verifying the completeness of revenue arrangements and collaboration agreements subject to quarterly measurement of progress toward the satisfaction of the relevant performance obligations and (ii) validating that the measurement of progress, including the measurement of costs incurred for satisfaction of performance obligations, are consistent with the technical conclusions reached within the corresponding technical memo;

- engaged a technical accounting consultant to review our revenue accounting and financial disclosures for collaboration arrangements, as needed; 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.

These steps are subject to ongoing senior management review, as well as oversight by the Audit Committee of our Board of Directors.

Our independent registered public accounting firm, Deloitte & Touche LLP, has issued a report on the effectiveness of our internal control over financial reporting as of December 31, 2024, which is included in Item 8 of this Annual Report on Form 10-K.

Changes in Internal Control over Financing Reporting

Other than the changes associated with the material weaknesses and remediation actions noted above, there have been no changes to our internal control over financial reporting that occurred during the year ended December 31, 2024.

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, 2024, 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, because of the effect of the material weakness identified below on the achievement of the objectives of the control criteria, the Company has not maintained effective internal control over financial reporting as of December 31, 2024, 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, 2024, of the Company and our report dated March 6, 2025, 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.

Material Weakness

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis. The following material weakness has been identified and included in management's assessment:

The Company identified a material weakness related to information technology general controls ("ITGCs") that support the financial reporting process. Specifically, the material weakness relates 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.

This material weakness was considered in determining the nature, timing, and extent of audit tests applied in our audit of the consolidated financial statements as of and for the year ended December 31, 2024, of the Company, and this report does not affect our report on such financial statements.

/s/ Deloitte & Touche LLP

San Diego, California

March 6, 2025

Item 9B. Other Information

Rule 10b5-1 Trading Plans

For the year ended December 31, 2024, 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, other than as follows:

- Keith C. Kummerfeld’s Rule 10b5-1 trading arrangement terminated on March 18, 2024 upon the effective date of his resignation.
- Lance Kurata, our Chief Legal Officer, adopted a Rule 10b5-1 trading arrangement as of June 12, 2024. Mr. Kurata's trading arrangement provides for the exercise options to purchase up to an aggregate of 35,000 shares of common stock and subsequent sale of such underlying shares of common stock, until June 12, 2025.
- Dr. Padmanabh Chivukula, Chief Scientific Officer and Chief Operating Officer, cancelled an existing Rule 10b5-1trading arrangement on November 11, 2024. Dr. Chivukula's trading arrangement provided for the sale of up to an aggregate of 152,000 shares of common stock. Subsequent to this, Dr. Chivukula entered into a new Rule 10b5-1 trading arrangement on November 20, 2024. The new trading arrangement provides for the sale of up to an aggregate of 120,000 shares, beginning on June 2, 2025 until November 10, 2025.

There were no "non-Rule 10b5-1 trading arrangements" (as defined in Item 408 of Regulation S-K of the Exchange Act) adopted or terminated during the year ended December 31, 2024 by our directors and officers.

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 2025 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2024. 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 2025 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2024. 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 2025 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2024. 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 2025 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2024. 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 2025 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2024. 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**	Loan and Security Agreement, dated October 12, 2018, by and between Western Alliance Bank and Arcturus Therapeutics, Inc. Incorporated by reference to Exhibit 10.1 to the Company's Report of Foreign Private Issuer on Form 6-K filed on October 15, 2018 (File No. 001-35932).
10.5**	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).
10.6**	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).
10.7**	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.

Exhibit Number	Description
10.8**	License Agreement, by and between Arcturus Therapeutics, Inc., as successor-in-interest to Marina Biotech, Inc., and Protiva Biotherapeutics Inc., dated as of November 28, 2012. Incorporated by reference to Exhibit 4.14 to Form 20-F/A filed on July 10, 2018 (File No. 001-35932).
10.9**	Amended and Restated Joint Venture, Research Collaboration and License Agreement, dated as of July 14, 2018 by and between Arcturus Therapeutics, Inc. and Providence Therapeutics, Inc. Incorporated by reference to Exhibit 10.14 to the Company's Amendment No. 1 to Annual Report on Form 10-K for the year ended December 31, 2018 filed on April 10, 2019 (File No. 001-35932).
10.10	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).
10.11	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).
10.12**	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).
10.13**	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).
10.14	Fourth Amendment to Loan and Security Agreement, dated December 1, 2020, by and between Arcturus Therapeutics, Inc. and Western Alliance Bank. Incorporated by reference to Exhibit 10.1 to Form 8-K filed on December 7, 2020 (File No. 001-38942).
10.15†	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).
10.16	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).
10.17	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).
10.18†	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).
10.19†	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)

Exhibit Number	Description
10.20†	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)
10.21†	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)
10.22†	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).
10.23	Fifth Amendment to Loan and Security Agreement, dated October 27, 2021, by and between Arcturus Therapeutics, Inc. and Western Alliance Bank. Incorporated by reference to Exhibit 10.34 to Form 10-Q filed on November 9, 2021 (File No. 001-38942).
10.24	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).
10.25	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).
10.26	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).
10.27	Sixth Amendment to Loan and Security Agreement, dated April 19, 2022, by and between Arcturus Therapeutics, Inc. and Western Alliance Bank. Incorporated by reference to Exhibit 10.36 to Quarterly Report on Form 10-Q filed on May 9, 2022 (File No. 001-38942).
10.28†	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).
10.29**	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).
10.30**	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).
10.31**	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).
10.32**	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).

Exhibit Number	Description
10.33**	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).
10.34**	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).
10.35**	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).
10.36**	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).
10.37**	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)
10.38**	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).
10.39	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).
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.

Exhibit Number	Description
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, 2024 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 6, 2025

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 6, 2025
/s/ Dr. Moncef Slaoui **Dr. Moncef Slaoui**	Chairman of the Board	March 6, 2025
/s/ Andrew Sassine **Andrew Sassine**	Director and Chief Financial Officer *(principal financial and accounting officer)*	March 6, 2025
/s/ Dr. Magda Marquet **Dr. Magda Marquet**	Director	March 6, 2025
/s/ James Barlow **James Barlow**	Director	March 6, 2025
/s/ Edward Holmes **Edward Holmes**	Director	March 6, 2025
/s/ Dr. Peter Farrell **Dr. Peter Farrell**	Director	March 6, 2025
/s/ Dr. John Markels **Dr. John Markels**	Director	March 6, 2025
/s/ Jing Marantz **Jing Marantz**	Director	March 6, 2025

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, 2024, the related consolidated statements of operations, comprehensive loss, stockholder's equity, and cash flows, for the year ended December 31, 2024, 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, 2024, and the results of its operations and its cash flows for the year ended December 31, 2024, 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, 2024, 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 6, 2025, expressed an adverse opinion on the Company's internal control over financial reporting because of a material weakness.

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

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.

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, 2024, Collaboration revenue was $138.4 million, of which $138.4 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 6, 2025

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 balance sheet of Arcturus Therapeutics Holdings Inc. and its subsidiaries (the Company) as of December 31, 2023, the related consolidated statements of operations and comprehensive income (loss), changes in stockholders' equity and cash flows for each of the two years in the period 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 financial position of the Company at December 31, 2023, and the results of its operations and its cash flows for each of the two years in the period 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 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.

/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, 2024	As of December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 237,028	$ 292,005
Restricted cash	55,000	55,000
Accounts receivable	3,974	32,064
Prepaid expenses and other current assets	9,977	7,521
Total current assets	305,979	386,590
Property and equipment, net	9,531	12,427
Operating lease right-of-use asset	26,674	28,500
Non-current restricted cash	1,885	1,885
Total assets	$ 344,069	$ 429,402
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 7,194	$ 5,279
Accrued liabilities	38,781	31,881
Deferred revenue	19,514	44,829
Total current liabilities	65,489	81,989
Deferred revenue, net of current portion	12,604	42,496
Operating lease liability, net of current portion	24,998	25,907
Other non-current liabilities	—	497
Total liabilities	103,091	150,889
Stockholders' equity:		
Common stock: $0.001 par value; 60,000 shares authorized; issued and outstanding shares were 27,000 at December 31, 2024 and 26,828 at December 31, 2023	27	27
Additional paid-in capital	689,758	646,352
Accumulated deficit	(448,807)	(367,866)
Total stockholders' equity	240,978	278,513
Total liabilities and stockholders' equity	$ 344,069	$ 429,402

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) INCOME

(in thousands, except per share data)	Year Ended December 31, 2024	2023	2022
Revenue:			
Collaboration revenue	$ 138,389	$ 157,748	$ 205,755
Grant revenue	13,921	9,051	244
Total revenue	152,310	166,799	205,999
Operating expenses:			
Research and development, net	195,156	192,133	147,751
General and administrative	52,823	52,871	46,071
Total operating expenses	247,979	245,004	193,822
(Loss) income from operations	(95,669)	(78,205)	12,177
Loss from equity-method investment	—	—	(515)
Loss from foreign currency	(471)	(229)	(598)
Finance income (expense), net	15,195	16,591	(420)
Gain on debt extinguishment	—	33,953	—
Net (loss) income before income taxes	(80,945)	(27,890)	10,644
(Benefit) provision for income taxes	(4)	1,835	1,295
Net (loss) income	(80,941)	(29,725)	9,349
Comprehensive (loss) income	$ (80,941)	$ (29,725)	$ 9,349
(Loss) earnings per share:			
Basic	$ (3.00)	$ (1.12)	$ 0.35
Diluted	$ (3.00)	$ (1.12)	$ 0.35
Weighted-average shares used in calculation of (loss) earnings per share:			
Basic	27,000	26,628	26,445
Diluted	27,000	26,628	27,093

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, 2021	**26,372**	**$ 26**	**$ 575,675**	**$ (347,490)**	**$ 228,211**
Share-based compensation	—	—	30,611	—	30,611
Issuance of common stock upon exercise of stock options	161	1	1,729	—	1,730
Issuance of common stock under equity plans	22	—	411	—	411
Net income	—	—	—	9,349	9,349
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**

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, 2024	2023	2022
Operating activities			
Net (loss) income	$ (80,941)	$ (29,725)	$ 9,349
Adjustments to reconcile net (loss) income to net cash (used in) provided by operating activities:			
Depreciation and amortization	3,544	2,957	1,527
Share-based compensation expense	37,988	34,649	30,611
Loss from equity-method investment	—	—	515
Gain on debt extinguishment	—	(33,953)	—
Foreign currency transaction loss	471	90	375
Other non-cash expenses	—	502	2,173
Changes in assets and liabilities:			
Accounts receivable	28,090	(29,300)	603
Prepaid expenses and other current assets	(2,456)	1,165	(3,584)
Right-of-use assets	4,562	4,045	3,264
Accounts payable	1,915	(2,238)	(3,112)
Accrued liabilities	5,932	(588)	9,443
Deferred revenue	(55,207)	38,606	(14,694)
Lease liabilities	(3,645)	(4,309)	(4,477)
Net cash (used in) provided by operating activities	(59,747)	(18,099)	31,993
Investing activities			
Acquisition of property and equipment	(648)	(2,901)	(7,726)
Net cash used in investing activities	(648)	(2,901)	(7,726)
Financing activities			
Proceeds from debt	—	20,000	—
Proceeds from exercise of stock options	4,736	2,668	1,730
Proceeds from issuance of common stock under equity plans	682	609	411
Payments on debt obligations	—	(47,364)	(5,000)
Net cash provided by (used in) financing activities	5,418	(24,087)	(2,859)
Net (decrease) increase in cash, cash equivalents and restricted cash	(54,977)	(45,087)	21,408
Cash, cash equivalents and restricted cash, beginning of year	348,890	393,977	372,569
Cash, cash equivalents and restricted cash, end of year	$ 293,913	$ 348,890	$ 393,977

	Year Ended December 31, 2024	2023	2022
Supplemental disclosure of cash flow information			
Cash paid for interest	$ —	$ 2,127	$ 813
Cash paid for income taxes	$ 1,407	$ —	$ —
Non-cash investing activities			
Right-of-use assets acquired through operating leases	$ 2,736	$ —	$ 30,191
Non-cash asset disposal	$ 473	$ —	$ —
Purchase of property and equipment in accounts payable and accrued expenses	$ —	$ 68	$ 573

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 infectious disease vaccines and opportunities within liver and respiratory rare diseases. Arcturus developed the world's first approved self-amplifying messenger RNA (sa-mRNA) vaccine, KOSTAIVE® ("KOSTAIVE"). KOSTAIVE achieved approval in Japan in 2023 as a vaccine against COVID-19. Sales of KOSTAIVE began in Japan in October 2024, marking the transition to a commercial stage company.

Recent Developments

See *"Note 3 Revenue – CSL Seqirus"* for further information on the agreement with Seqirus, Inc. ("CSL Seqirus"), whereby CSL Seqirus and the Company continue to collaborate on research and development, manufacturing and global commercialization of vaccines.

Liquidity

The Company has incurred significant operating losses since its inception. As of December 31, 2024 and 2023, the Company had an accumulated deficit of $448.8 million and $367.9 million, respectively.

The Company's activities since inception have consisted principally of research and development activities, general and administrative activities, and raising capital. The Company's activities are subject to significant risks and uncertainties, including failing to secure additional funding before the Company achieves sustainable revenues and profit from operations. From the Company's inception through the year ended December 31, 2024, the Company has funded its operations principally with the proceeds from revenues earned through collaboration agreements, including the $200.0 million upfront payment received from CSL Seqirus during 2022, the sale of capital stock and proceeds from long-term debt. During fiscal year 2024, the Company received milestone payments totaling $96.0 million from CSL Seqirus. At December 31, 2024, the Company's balance of cash and cash equivalents, including restricted cash, was $293.9 million.

Management believes that it has sufficient working capital on hand to fund operations through at least the next twelve months from the date these consolidated financial statements were available to be issued. There can be no assurance that the Company will be successful in acquiring additional funding, that the Company's projections of its future working capital needs will prove accurate, or that any additional funding would be sufficient to continue operations in future years.

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 collateral pledged and held at the Company's securities accounts pursuant to a security agreement with Wells Fargo Bank, National Association ("Wells Fargo") (*Note 7, Debt*). At December 31, 2024, such collateral amounted to $55.0 million.

Restricted cash also 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, 2024 and 2023, 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, 2024 or 2023.

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, 2024 and 2023, 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, 2024:

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

As of December 31, 2023:

- CSL – 74% of total accounts receivable
- BARDA – 23% 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, 2024:

- CSL – 91% of total revenue

For the year ended December 31, 2023:

- CSL – 92% of total revenue

For the year ended December 31, 2022:

- CSL – 75% of total revenue
- Vinbiocare – 12% 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 income (loss). As of December 31, 2024, the carrying value of the equity method investment in ARCALIS remained at zero as ARCALIS' cumulative losses exceeded any gains from dilution.

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, 2024, 2023 or 2022.

Comprehensive Income/Loss

Comprehensive income/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, 2024, 2023 or 2022.

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 income (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 income (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. For the nine months ended September 30, 2024, the expected volatility of stock options was based on the historical volatility of a peer group of publicly traded companies. For the three months ended December 31, 2024, the Company used its own historical volatility to estimate expected volatility, as it had accumulated sufficient historical stock price data. 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)	**2024**	**2023**	**2022**
Cash and cash equivalents	$ 237,028	$ 292,005	$ 391,883
Restricted cash - current	55,000	55,000	—
Non-current Restricted cash	1,885	1,885	2,094
Total cash, cash equivalents and restricted cash shown in the statement of cash flows	$ 293,913	$ 348,890	$ 393,977

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 credit 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) Income per Share

Basic net (loss) income per share is calculated by dividing the net (loss) income by the weighted-average number of shares of common stock outstanding for the period, without consideration for common stock equivalents. Diluted net (loss) income per share is calculated by dividing the net (loss) income 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, 2024 and 2023 were comprised of stock options and restricted stock units. Dilutive shares of stock for the years ended December 31, 2022 were comprised of stock options.

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. ASU 2023-07 is effective for annual reporting periods beginning after December 15, 2023, and for interim reporting periods beginning January 1, 2025. The Company adopted ASU 2023-07 for the annual reporting period beginning on January 1, 2024. See "*Note 12, Segment Information*" 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 and product revenue 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, 2024:

(in thousands)	December 31, 2023	Additions	Deductions	December 31, 2024
Contract Assets:				
Accounts receivable	$ 32,064	$ 98,430	$ (126,520)	$ 3,974
Contract Liabilities:				
Deferred revenue	$ 87,325	$ 97,599	$ (152,806)	$ 32,118

During the year ended December 31, 2024, the Company recognized $62.6 million in revenue from the deferred revenue balance as of December 31, 2023.

The following table summarizes the Company's revenue for the periods indicated. Approximately $138.4 million, $154.9 million and $192.7 million of total revenue represents revenue derived from foreign countries for the years ended December 31, 2024, 2023 and 2022, respectively.

	For the Year Ended December 31,		
(in thousands)	2024	2023	2022
Collaboration revenue:			
CSL Seqirus	$ 138,389	$ 154,264	$ 154,425
Vinbiocare	—	—	24,571
Janssen	—	660	9,201
Ultragenyx	—	1,837	3,739
Israel Ministry of Health	—	—	12,500
Other	—	987	1,319
Total collaboration revenue	$ 138,389	$ 157,748	$ 205,755
Grant revenue:			
BARDA	$ 13,921	$ 9,051	$ 244
Total grant revenue	$ 13,921	$ 9,051	$ 244

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 process. CSL Seqirus will lead 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.

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 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 against flu, pandemic preparedness and three other pathogens. During 2024, the Company achieved $72.2 million of development and regulatory milestones related to the CSL Collaboration Agreement, of which none was included in accounts receivable as of December 31, 2024.

In evaluating the CSL Collaboration Agreement in accordance with Accounting Standards Codification ("ASC") Topic 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 delivery of the vaccine license, research and development services for COVID and non-COVID vaccines

and regulatory activities for COVID 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, 2024, the transaction price primarily consisted of upfront consideration received and milestones achieved as of December 31, 2024. Additional variable consideration was not included in the transaction price at December 31, 2024 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 portion of the upfront payment that was allocated to 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 in 2024 reflects variable consideration added to the transaction price upon the achievement of milestones, attributable to the license granted in 2022 and research and development services provided through December 31, 2024.

Total deferred revenue as of December 31, 2024 and 2023 for the CSL Collaboration Agreement was $30.7 million and $87.1 million, respectively.

During 2023, the Company also received an advance payment of $23.6 million for the manufacturing and supply of ARCT-154 drug product. The advance payment was for specified manufacturing runs of ARCT-154 which include the drug substance utilized, as well as the reservation fees and related manufacturing requirements. The Company concluded that the promise to manufacture and supply ARCT-154 drug product is a customer option as part of the CSL Collaboration Agreement and is accounted for as a separate contract. The Company recognized $18.0 million in revenue related to this customer option during the second quarter of 2024. No amount related to this customer option remained in deferred revenue as of December 31, 2024.

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 year ended December 31, 2024, the Company recognized revenue of $12.0 million related to the performance obligation compared to $2.4 million during the year ended December 31, 2023. The remaining amount of $3.1 million is included in deferred revenue.

During the fourth quarter of 2023, the Company received an advance payment of $5.3 million from CSL Seqirus for manufacturing activities related to COVID-19 vaccine product. During the first quarter of 2024, the Company received an additional advance payment of $5.1 million from CSL Seqirus for manufacturing activities related to COVID-19 vaccine product. The Company concluded that the promise to perform manufacturing activities is a customer option as part of the CSL Collaboration Agreement and is accounted for as a separate contract. The Company recognized $5.3 million in revenue related to this customer option during the third quarter of 2024 upon the transfer of vaccine product to CSL Seqirus. The remaining $5.1 million is included in deferred revenue as of December 31, 2024 and will be recognized as revenue when the remaining vaccine product is transferred to CSL Seqirus.

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, (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.

Vinbiocare

During 2021 the Company entered into certain agreements with Vinbiocare, a member of Vingroup Joint Stock Company, whereby the Company would provide technical expertise and support services to Vinbiocare to assist in the build out of a mRNA drug product manufacturing facility in Vietnam. The Company received an upfront payment in aggregate of $40.0 million as part of the Vinbiocare Agreement. In October 2022, the Company and Vinbiocare executed a letter agreement terminating the Technology License and Technical Support Agreement and the Framework Drug Substance Supply Agreement (collectively, the "License & Supply Agreements"). The Company incurred no financial penalties in connection with the termination of the License & Supply Agreements and has no further financial obligations to Vinbiocare under these terminated agreements.

In October 2022, in association with the termination of the License & Supply Agreements, the Company signed the Study Support Agreement with Vinbiocare which provides that Vinbiocare shall continue to serve as the regulatory and financial sponsor of clinical studies conducted in Vietnam of ARCT-154 pursuant to the Company's arrangements with Vinbiocare (the "Study Support Agreement"). To support the continuing activities of these studies, the Study Support Agreement further provides for the Company to conduct certain services and to compensate Vinbiocare to help achieve the objectives of these studies. In February 2023, the Company agreed to provide additional financial support in the amount of approximately $2.1 million to allow Vinbiocare to provide additional study support duties related to the ARCT-154 clinical study. As a result, the Company reserved $11.8 million of the original upfront payment to be paid to Vinbiocare over the future periods pursuant to the Study Support Agreement by reclassifying a portion of the upfront payment received from Vinbiocare pursuant to the License & Supply Agreements, from deferred revenue to short-term and long-term liabilities, based on the anticipated timing of the payments to Vinbiocare, and removed that portion of the upfront payment from the transaction price of the modified arrangement. The transaction price was not adjusted for payments that are contingent upon the occurrence of future regulatory or sales-related events based on the information currently available to the Company.

The Company has concluded that it has no remaining performance obligations under its prior arrangements with Vinbiocare as summarized above as of December 31, 2024. As of December 31, 2024, the Company has accrued liabilities related to this arrangement of $2.4 million in current liabilities that will be paid upon the occurrence of specified events through the end of 2025. Vinbiocare is also eligible to receive a single digit percentage of amounts from net sales, if any, of ARCT-154 (or next-generation COVID vaccine) up to a capped amount of low single digit millions. The Company had no remaining deferred revenue as of December 31, 2024 or 2023.

BARDA Grant

In August 2022, the Company entered into a cost reimbursement 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 agreement with BARDA 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 consolidated statements of operations and comprehensive income (loss).

The Company recognized $13.9 million and $9.1 million of grant revenue during the years ended December 31, 2024 and 2023, respectively, which is included in revenue on the Company's consolidated statements of operations. As of December 31, 2024, the remaining available funding net of revenue earned was $40.0 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 carrying value of cash, restricted cash, accounts receivable, accounts payable, accrued liabilities and the Singapore loan approximate their respective fair values due to their relative short maturities. The carrying amounts of long-term debt for the amount drawn on the Company's debt facility approximates fair value as the interest rate is variable and reflects current market rates.

The Company's assets measured at fair value on a recurring basis consisted of money market funds. As of December 31, 2024, the Company's had money market funds with a fair value of $230.2 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)	**2024**	**2023**
Accrued compensation	$ 13,305	$ 5,918
Cystic Fibrosis Foundation liability	7,443	7,633
Income tax payable	—	641
Current portion of operating lease liability	3,552	4,309
Clinical trial accruals	2,828	2,333
Vinbiocare contractual liabilities	2,421	2,514
Legal accrual	130	177
Other accrued research and development expenses	9,102	8,356
Total	$ 38,781	$ 31,881

NOTE 6. Property and Equipment, Net

Property and equipment, net consisted of the following:

	December 31,	
(in thousands)	**2024**	**2023**
Research equipment	$ 16,864	$ 16,046
Computers and software	1,131	1,275
Office equipment and furniture	703	958
Leasehold improvements	2,644	2,655
Construction in progress	—	233
Total	$ 21,342	$ 21,167
Less accumulated depreciation and amortization	(11,811)	(8,740)
Property and equipment, net	$ 9,531	$ 12,427

Depreciation and amortization expense was $3.5 million, $3.0 million and $1.5 million for the years ended December 31, 2024, 2023 and 2022, respectively. Construction in progress is primarily comprised of research equipment not yet placed in service.

NOTE 7. Debt

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 (the "Credit Agreement") whereby Wells Fargo will make a $50.0 million revolving credit line available to the Company (the "Loan") and each Loan evidenced by a revolving line of credit note (the "Note"). On June 26, 2024, the parties entered into Amendment No. 1 to the Credit Agreement, 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 original term of the agreement is 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 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 at the Company's securities accounts with Wells Fargo Securities, LLC, an affiliate of Wells Fargo, pursuant to a security agreement. No amounts were outstanding as of December 31, 2024.

Manufacturing Supply Agreement

On November 7, 2020, the Company's wholly-owned subsidiary, Arcturus Therapeutics, Inc., entered into a Manufacturing Support Agreement (the "Support Agreement") with the Economic Development Board of the Republic of Singapore (the "EDB"). Pursuant to the Support Agreement, the EDB agreed to make a term loan (the "Singapore Loan") of S$62.1 million to the Company, subject to the satisfaction of customary deliveries, to support the manufacture of the LUNAR-COV19 vaccine candidate (ARCT-021). The Singapore Loan accrues interest at a rate of 4.5% per annum calculated on a daily basis. The Company elected to borrow the full amount available under the Support Agreement of S$62.1 million ($46.6 million) on January 29, 2021.

During the first quarter of 2023, the EDB agreed to an extension of the reconciliation period to March 22, 2023, with unused funds not utilized for the manufacture of ARCT-021 as of such date returned to the EDB. As of December 31, 2022, the outstanding balance of the Singapore Loan, which includes accrued interest, was $50.4 million of which the Company paid S$22.8 million ($17.1 million) in March 2023. During the first quarter of 2023, the remaining principal portion of the Singapore Loan plus accrued interest, totaling $34.0 million, was forgiven and recorded as a gain on debt extinguishment in the consolidated statement of operations and comprehensive loss.

No interest expense was incurred on the Singapore Loan for the year ended December 31, 2024, and $0.5 million and $2.1 million of interest expense was incurred for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023, the Company no longer had debt or interest related to this agreement.

Termination of Agreement with Western Alliance Bank

On March 14, 2023, the Loan and Security Agreement, dated as of October 12, 2018 (as amended and supplemented, the "Western Alliance Agreement") with Western Alliance Bank, an Arizona corporation ("Western Alliance"), was terminated (the "Termination") upon the receipt by Western Alliance of a payoff amount of approximately $7.4 million from the Company. The Western Alliance Agreement provided for a collateralized term loan in the aggregate principal amount of up to $15.0 million, with interest at a floating rate ranging from 1.25% to 2.75% above the prime rate and a maturity date of October 30, 2023. The payoff amount was made by the Company to Western Alliance from available cash on hand, pursuant to a payoff letter, and included payment of (i) approximately $7.0 million in principal and interest, (ii) $0.3 million fee payable upon prepayment as a result of prior FDA approval of an IND and (iii) de minimis amounts in prepayment charges and various operational fees. The Company was released from all liens under the Western Alliance Agreement.

The Company recorded no interest expense for the year ended December 31, 2024, and for the years ended December 31, 2023 and 2022, the Company recorded interest expense of $0.3 million and $0.9 million, respectively.

NOTE 8. Stockholders' Equity

Net (Loss) Income Per Share

Potentially dilutive securities that were not included in the calculation of diluted net loss per share for the year ended December 31, 2024 and 2023 as they were anti-dilutive totaled 1.4 million and 0.8 million, respectively. Potentially dilutive securities that were not included in the calculation of diluted earnings per share for the year ended December 31, 2022 as they were anti-dilutive totaled 3.7 million.

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, 2024, a total of 1,834,158 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. As of December 31, 2024, a total of 124,697 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,		
	2024	2023	2022
Expected life (in years)	5.88	6.04	6.05
Expected volatility	91.4%	76.1%	82.1%
Expected dividend yield	—%	—%	—%
Risk-free interest rate	4.24%	3.91%	2.93%
Grant date weighted average fair value	$ 22.62	$ 18.87	$ 15.56

The following table summarizes the Company's stock option activity for the year ended December 31, 2024:

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding – December 31, 2023	7,971,127	$ 33.55	7.9 years	$ 53,295
Granted	740,594	$ 22.62		
Exercised	(228,328)	$ 20.74		
Forfeited/cancelled	(404,641)	$ 42.43		
Outstanding – December 31, 2024	8,078,752	$ 32.38	7.2 years	$ 9,247
Exercisable – December 31, 2024	4,983,108	$ 37.27	6.4 years	$ 8,796
Exercisable and expected to vest – December 31, 2024	8,078,752	$ 32.38	7.2 years	$ 9,247

At December 31, 2024, the total unrecognized compensation cost of $48.5 million will be recognized over the weighted-average remaining service period of approximately 2.6 years. The fair value of the options vested during the years ended December 31, 2024 , 2023 and 2022 was $40.5 million, $35.3 million and $39.2 million, respectively. The total intrinsic value of options exercised during the years ended December 31, 2024, 2023 and 2022 was $3.3 million, $4.3 million and $1.6 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, 2024:

	Number of Shares	Weighted-Average Grant Date Fair Value
Outstanding – December 31, 2023	18,786	$ 34.92
Awarded	-	
Released	-	
Forfeited	-	
Outstanding – December 31, 2024	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, 2024, 2023 and 2022 were:

	For the Year Ended December 31,		
(in thousands)	2024	2023	2022
Research and development	$ 18,456	$ 14,950	$ 14,081
General and administrative	19,532	19,699	16,530
Total	$ 37,988	$ 34,649	$ 30,611

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)	2024	2023	2022
United States	$ 81,050	$ (27,890)	$ 10,644
Foreign	—	—	—
Total (loss) income before income taxes	$ 81,050	$ (27,890)	$ 10,644

A reconciliation of income tax (benefit) expense for the years ended December 31, 2024, 2023 and 2022 is as follows:

	For the Year Ended December 31,		
	2024	2023	2022
Current:			
Federal	$ (11)	$ 1,246	$ 1,121
State	7	589	174
Foreign	—	—	—
Total current income tax (benefit) expense	$ (4)	$ 1,835	$ 1,295
Deferred:			
Federal	$ —	$ —	$ —
State	—	—	—
Foreign	—	—	—
Total deferred income tax expense	—	—	—
Total income tax (benefit) expense	$ (4)	$ 1,835	$ 1,295

A reconciliation of the federal statutory income tax rate to the Company's effective income tax rate is as follows:

	For the Year Ended December 31,		
	2024	2023	2022
Federal statutory income tax rate	21.0%	21.0%	21.0%
State income taxes, net of federal benefit	1.9%	1.9%	7.2%
Share-based compensation	(1.9%)	(2.5%)	16.1%
Officers compensation	(3.4%)	(7.4%)	21.8%
Research and development credits	24.0%	20.0%	(40.3%)
Uncertain tax positions	(3.7%)	(2.4%)	9.0%
Change in tax rate	(1.4%)	0.2%	(12.6%)
Change in valuation allowance	(36.1%)	(36.5%)	(9.4%)
Other	(0.2%)	(0.3%)	(1.0%)
Permanent differences	(0.2%)	(0.7%)	0.4%
Provision for income taxes	0.0%	(6.7)%	12.2%

The significant components of deferred income taxes are as follows:

	December 31,	
(in thousands)	2024	2023
Deferred tax assets:		
Net operating loss	$ 25,413	$ 19,147
Tax credits	27,472	10,723
Accrued liabilities	2,966	943
Deferred revenue	5,515	7,014
Inventory	—	15,961
Basis difference in equity investments	2,127	2,202
Capitalized R&D	60,104	41,971
Right-of-use lease liability	6,601	7,233
Share-based compensation	14,872	11,618
Total gross deferred tax assets	145,070	116,812
Deferred tax liabilities:		
Depreciation and amortization	(858)	(1,184)
Right-of-use asset	(6,168)	(6,822)
Total gross deferred tax liabilities	(7,026)	(8,006)
Valuation allowance	(138,044)	(108,806)
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, 2024 and 2023, the Company recorded a valuation allowance of $138.0 million and $108.8 million, respectively. The valuation allowance changed by $29.2 million and $10.2 million for the years ended December 31, 2024 and 2023, respectively.

At December 31, 2024, the Company has federal and state net operating losses, or NOL, carryforwards of approximately $47.5 million and $223.5 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 $0.4 million of losses that can be carried forward indefinitely. The remaining state net operating losses begin to expire in 2039.

At December 31, 2024, the Company has federal and state research and development credit carryforwards of approximately $19.8 million and $11.5 million, respectively. The federal credit carryforwards begin to expire in 2037, and the state credits carry forward indefinitely. $0.8 million of the state credit begin to expire in 2037 and the remainder carryforward indefinitely. Additionally, the Company has an Orphan Drug Credit of $4.7 million as of December 31, 2024 which will begin to expire in 2042 unless previously utilized.

Pursuant to Internal Revenue Code (IRC) Sections 382 and 383, annual use of the Company's federal and California net operating loss and research and development credit carryforwards may be limited in the event a cumulative change in ownership of more than 50% occurs within a three-year period. The Company has completed an IRC Section 382 analysis through December 31, 2024 regarding the limitation of net operating loss carryforwards and other tax attributes. The Company experienced ownership changes in 2018 and 2020; however, the Company estimates that all tax attributes can be utilized. 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.

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 millions):

	December 31,	
	2024	2023
Beginning balance of unrecognized tax benefits	$ 3.6	$ 2.9
Decrease for prior period tax positions	1.2	0.1
Increase for current period tax positions	2.0	0.6
Ending balance of unrecognized tax benefits	$ 6.8	$ 3.6

Amounts in the summary rollforward would not impact the effective tax rate 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 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, 2024, 2023 and 2022.

The Company does not anticipate any material changes to its unrecognized tax benefits within the next twelve months.

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, (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, 2024, 2023 and 2022, the Company recognized contra expense of $0.2 million, $1.4 million and $5.2 million, respectively. As of December 31, 2024, $7.4 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. In March 2024, the Company negotiated with the lessor to extend the lease through March 2027.

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 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 31, 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. As a result, no lease liability remains as of December 31, 2024.

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, 2024, the remaining payments of the operating lease liability were as follows:

(in thousands)	Remaining Lease Payments
2025	$ 4,811
2026	5,274
2027	4,132
2028	3,822
2029	3,937
Thereafter	11,813
Total remaining lease payments	33,789
Less: imputed interest	(5,239)
Total operating lease liabilities	$ 28,550
Weighted-average remaining lease term (in years)	7.2
Weighted-average discount rate	4.7%

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 $4.5 million, $5.6 million and $4.7 million for the years ended December 31, 2024, 2023 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) income 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 income, and significant segment expenses:

	For the Year Ended December 31,		
(in thousands)	**2024**	**2023**	**2022**
Revenues	$ 152,310	$ 166,799	$ 205,999
Less:			
Research and development:			
LUNAR-COVID	70,464	81,262	65,136
LUNAR-OTC	9,509	9,315	8,898
BARDA	7,807	5,465	95
LUNAR-CF, net	17,227	14,666	6,931
Early-stage programs	16,096	12,460	9,681
Discovery technologies	6,278	6,405	6,082
Payroll and benefits	57,474	50,924	42,466
Facilities and equipment	10,301	11,636	8,462
Total research and development	195,156	192,133	147,751
General and administrative	52,823	52,871	46,071
Other [(1)]	(14,728)	(48,480)	2,828
Net (loss) income	$ (80,941)	$ (29,725)	$ 9,349

(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.

Exhibit 4.1

ARCTURUS THERAPEUTICS HOLDINGS INC.
DESCRIPTION OF SECURITIES

Arcturus Therapeutics Holdings Inc. ("we," "our," "us," or the "Company") has one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended: our common stock. The following description summarizes important terms of our common stock. For a complete description, you should refer to our certificate of incorporation and bylaws, each as amended or may be amended from time to time, which are incorporated by reference as exhibits to the Annual Report on Form 10-K of which this exhibit is a part, as well as the relevant portions of the Delaware General Corporation Law (the "DGCL").

Common Stock
As of the date of this Annual Report on Form 10-K, we are authorized to issue up to 60,000,000 shares of common stock. As of March 4, 2025, there were 26,915,243 shares of common stock outstanding. The holders of our common stock are entitled to one vote for each share held of record on all matters submitted to a vote of the stockholders. The holders of common stock are not entitled to cumulative voting rights with respect to the election of directors, and as a consequence, minority stockholders will not be able to elect directors on the basis of their votes alone. Subject to preferences that may be applicable to any then outstanding shares of preferred stock, holders of common stock are entitled to receive ratably such dividends as may be declared by the board of directors out of funds legally available therefor. In the event of a liquidation, dissolution or winding up of us, holders of the common stock are entitled to share ratably in all assets remaining after payment of liabilities and the liquidation preferences of any then outstanding shares of preferred stock. Holders of common stock have no preemptive rights and no right to convert their common stock into any other securities. There are no redemption or sinking fund provisions applicable to our common stock. All outstanding shares of common stock are fully paid and non-assessable. The rights, preferences and privileges of holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any of our outstanding preferred stock.

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

Transfer Agent and Registrar
The transfer agent and registrar for our common stock is Continental Stock Transfer & Trust.

Dividends
We have not declared any cash dividends on our common stock since inception and we do not anticipate paying any cash dividends on our common stock in the foreseeable future.

Possible Anti-Takeover Effects of Delaware Law and our Charter Documents
Provisions of the DGCL, our certificate of incorporation, and our bylaws, could make it more difficult to acquire us by means of a tender offer, a proxy contest or otherwise, or to remove incumbent officers and directors. These provisions, summarized below, are expected to discourage certain types of coercive takeover practices and takeover bids that our board of directors may consider inadequate and to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe that the benefits of increased protection of our ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging takeover or acquisition proposals because, among other things, negotiation of these proposals could result in an improvement of their terms.

Delaware Anti-Takeover Statute
We are subject to Section 203 of the DGCL, an anti-takeover statute. In general, Section 203 of the DGCL prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years following the time the person became an interested stockholder, unless the business combination or the acquisition of shares that resulted in a stockholder becoming an interested stockholder is approved in a prescribed manner. Generally, a "business combination" includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. Generally, an "interested stockholder" is a person who, together with affiliates and associates, owns (or within three years prior to the determination of

interested stockholder status did own) 15% or more of a corporation's voting stock. The existence of this provision would be expected to have an anti-takeover effect with respect to transactions not approved in advance by our board of directors, including discouraging attempts that might result in a premium over the market price for the shares of common stock held by our stockholders.

Election and Removal of Directors

Our board of directors is elected annually by all holders of our capital stock. The stockholders may nominate one or more persons for election as directors at an annual meeting of stockholders, but only if written notice of such stockholder's intent to make such nomination or nominations has been received by the Secretary of the Company not less than forty-five (45) nor more than seventy-five (75) days prior to the first anniversary of the preceding year's annual meeting of stockholders. Any vacancy on the board of directors resulting from death, resignation,

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removal or otherwise or newly created directorships may be filled by the vote of the majority of directors then in office, although less than a quorum, or by a sole remaining director.

Amendment

The affirmative vote of a majority of the entire board of directors may amend and repeal the bylaws. The bylaws may be altered, amended or repealed, and new bylaws may be adopted, at any annual meeting of the stockholders (or at any special meeting thereof duly called for that purpose) by a majority of the combined voting power of the then outstanding shares of capital stock of all classes and series of the Company entitled to vote generally in the election of directors, voting as a single class, provided that, in the notice of any such special meeting, notice of such purpose shall be given.

Size of Board and Vacancies

Pursuant to our certificate of incorporation, and our bylaws, the number of directors constituting the board shall be at least one and no more than nine and our board of directors has the exclusive right to fix the size of the board and to fill any vacancies resulting from death, resignation, disqualification or removal as well as any newly created directorships arising from an increase in the size of the board.

Special Stockholder Meetings

Our bylaws provide that special meetings of stockholders can be called only by the board of directors, the chairman of the board of directors or the chief executive officer. Stockholders are not permitted to call a special meeting and cannot require the board of directors to call a special meeting. There is no right of stockholders to act by written consent without a meeting.

Requirements for Advance Notification of Stockholder Nominations and Proposals

Our bylaws establish advance notice procedures with respect to stockholder proposals and nomination of candidates for election as directors other than nominations made by or at the direction of our board of directors or a committee of our board of directors.

No Cumulative Voting

The DGCL provides that stockholders are denied the right to cumulate votes in the election of directors unless our certificate of incorporation provides otherwise. Our amended and certificate of incorporation does not provide for cumulative voting.

Authorized but Unissued Shares

Our authorized but unissued shares of common stock and preferred stock will be available for future issuance without stockholder approval. We may use additional shares for a variety of purposes, including future public offerings to raise additional capital, to fund acquisitions and as employee compensation. The existence of authorized but unissued shares of undesignated preferred stock may enable our board of directors to render more difficult or to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise. For example, if in the due exercise of its fiduciary obligations, our board of directors were to determine that a takeover proposal is not in the best interests of us or our stockholders, our board of directors could cause shares of preferred

stock to be issued without stockholder approval in one or more private offerings or other transactions that might dilute the voting or other rights of the proposed acquirer, stockholder or stockholder group. The rights of holders of our common stock described above will be subject to, and may be adversely affected by, the rights of any preferred stock that we may designate and issue in the future. The issuance of shares of undesignated preferred stock could decrease the amount of earnings and assets available for distribution to holders of shares of common stock. The issuance may also adversely affect the rights and powers, including voting rights, of these holders and may have the effect of delaying, deterring or preventing a change in control of us.

Director Liability

Our bylaws limit the extent to which our directors are personally liable to us and our stockholders, to the fullest extent permitted by the DGCL. The inclusion of this provision in our bylaws may reduce the likelihood of derivative litigation against directors and may discourage or deter stockholders or management from bringing a lawsuit against directors for breach of their duty of care.

Exhibit 19.1

Effective January 1, 2024

ARCTURUS THERAPEUTICS HOLDINGS INC. INSIDER TRADING POLICY
and Guidelines with Respect to Certain Company Information and Certain Transactions in Company Securities

Purpose

This Insider Trading Policy (this "***Policy***") provides guidelines with respect to transactions in the securities of Arcturus Therapeutics Holdings Inc. (including subsidiaries where applicable, the "Company") and the handling of material confidential information about the Company and the companies with which the Company engages in transactions or does business. The Company's Board of Directors has adopted this Policy to promote compliance with U.S. federal, state and foreign securities laws that prohibit certain persons who are aware of material nonpublic information about a company from: (i) trading in securities of that company; or (ii) providing material nonpublic information to other persons who may trade based on that information.

Persons Subject to the Policy

This Policy applies to (each of the following, a "***Covered Person***"):

- officers of the Company;
- the Company's Board of Directors;
- employees of the Company;
- consultants and independent contractors of the Company who receive or have access to material nonpublic information;
- Family Members and Controlled Entities, each as defined below; and
- any other persons who receive or have access to material nonpublic information that the Company designates as subject to this Policy.

Transactions Subject to the Policy

This Policy applies to transactions in the Company's securities (collectively referred to in this Policy as "***Company Securities***"), including the Company's common stock, options to purchase common stock, or any other type of securities that the Company may issue, including (but not limited to) preferred stock, convertible debentures and warrants, as well as derivative securities that are not issued by the Company, such as exchange-traded put or call options or swaps relating to the Company's Securities. Transactions subject to this Policy include purchases, sales and *bona fide* gifts of Company Securities.

Individual Responsibility

Persons subject to this Policy have ethical and legal obligations to maintain the confidentiality of information about the Company and to not engage in transactions in Company Securities while in possession of material nonpublic information. Persons subject to this policy must not engage in illegal trading and must avoid the appearance of improper trading.

Each individual is responsible for making sure that he, she or they complies with this Policy, and that any Family Member or Controlled Entity whose transactions are subject to this Policy, also complies with this Policy. In all cases, the responsibility for determining whether an individual is in possession of material nonpublic

information rests with that individual, and any action on the part of the Company, the Compliance Officer or any other employee or director pursuant to this Policy (or otherwise) does not in any way constitute legal advice or

insulate an individual from liability under applicable securities laws. You could be subject to severe legal penalties and disciplinary action by the Company for any conduct prohibited by this Policy or applicable securities laws, as described below in more detail under the heading "Consequences of Violations."

Administration of the Policy

For the purposes of this Policy, the Chief Legal Officer of the Company shall serve as the "***Compliance Officer***." The Compliance Officer shall be responsible for administration of this Policy. In the absence of the Chief Legal Officer of the Company, the Chief Compliance Officer of the Company (or such other officer of the Company that has been designated by the Chief Legal Officer of the Company in advance of such absence) shall serve as the "Compliance Officer" for purposes of this Policy during such absence. All determinations and interpretations by the Compliance Officer shall be final and not subject to further review.

Statement of Policy

Company Securities. No director, officer, employee, consultant, or independent contractor of the Company (or any other person designated by this Policy or by the Compliance Officer as subject to this Policy) who is aware of material nonpublic information relating to the Company may, directly, or indirectly through family members or other persons or entities:

1. Engage in transactions in Company Securities, except as otherwise specified in this Policy under the headings "Transactions Under Company Plans" and "Rule 10b5-1 Plans;"

2. Recommend that others engage in transactions in any Company Securities;

3. Disclose material nonpublic information to persons within the Company whose jobs do not require them to have that information, or outside of the Company to other persons, including, but not limited to, family, friends, business associates, investors and expert consulting firms, unless any such disclosure is made in accordance with the Company's policies regarding the protection or authorized external disclosure of information regarding the Company; or

4. Assist anyone engaged in the above activities.

Securities of Third Parties. In addition, it is the policy of the Company that no director, officer, employee, consultant, or independent contractor of the Company (or any other person designated as subject to this Policy) who, in the course of working for the Company, learns of material nonpublic information about another company (1) with which the Company does business, such as the Company's distributors, vendors, customers and suppliers, or (2) that is involved in a potential transaction or business relationship with Company, may engage in transactions in that other company's securities until the information becomes public or is no longer material.

Confidentiality Obligation. Everyone associated with the Company has a duty to protect the confidential information, including material nonpublic information, of the Company. Nonpublic information relating to the Company is the property of the Company and the unauthorized disclosure of such information is forbidden.
Accordingly, such information must be strictly safeguarded and not shared with unauthorized third parties including family members, household members and controlled entities, as described below. In the event any officer, director or employee of the Company receives any inquiry from outside the Company, such as a stock analyst, for information (particularly financial results and/or projections) that may be material nonpublic information, the inquiry should be referred to the Chief Executive Officer or Chief Financial Officer and to the other appropriate Company officers, as provided for in the Investor Relations Policy of the Company.

Limited Exceptions. There are no exceptions to this Policy, except as specifically noted herein. Transactions that may be necessary or justifiable for independent reasons (such as the need to raise money for an emergency expenditure), or small transactions, are not excepted from this Policy. The securities laws do not recognize any

mitigating circumstances, and, in any event, even the appearance of an improper transaction must be avoided to preserve the Company's reputation for adhering to the highest standards of conduct.

Definition of Material Nonpublic Information

Material Information. Information is considered "material" if a reasonable investor would consider that information important in making a decision to buy, hold or sell securities. Any information that could be expected

to affect a company's stock price, whether it is positive or negative, should be considered material. There is no bright- line standard for assessing materiality; rather, materiality is based on an assessment of all of the facts and circumstances, and is often evaluated by enforcement authorities with the benefit of hindsight. While it is not possible to define all categories of material information, some examples of information that ordinarily would be regarded as material are:

- Projections of future earnings or losses, or other earnings guidance;
- Changes to previously announced earnings guidance, or the decision to suspend earnings guidance;
- Clinical data or significant regulatory updates, approvals or rejections;
- A pending or proposed merger, acquisition or tender offer;
- A pending or proposed significant collaboration or joint venture;
- A Company restructuring;
- A pending or proposed offering of additional securities;
- Bank borrowings or other financing transactions out of the ordinary course;
- A change in executive management;
- A change in auditors or notification that the auditor's reports may no longer be relied upon;
- Pending or threatened significant litigation, or the resolution of such litigation;
- Impending bankruptcy or the existence of severe liquidity problems;
- The gain or loss of a significant customer or supplier;
- A significant cybersecurity incident, such as a data breach, or any other significant disruption in the company's operations or loss, potential loss, breach or unauthorized access of its property or assets, whether at its facilities or through its information technology infrastructure; or
- The imposition of an event-specific restriction on trading in Company Securities or the securities of another company or the extension or termination of such restriction.

The foregoing list is illustrative only and is not intended to provide a comprehensive list of all circumstances that could give rise to material information.

When Information is Considered Public. Information that has not been disclosed to the public is generally considered to be nonpublic information. In order to establish that the information has been disclosed to the public, it may be necessary to demonstrate that the information has been widely disseminated. Information generally would be considered widely disseminated if it has been disclosed through the newswire services, a broadcast on widely-

available news programs, publication in a widely-available news source, or public disclosure documents filed with the Securities and Exchange Commission (the "***SEC***") that are available on the SEC's website. By contrast, information would likely not be considered widely disseminated if it is available only to the Company's employees, or if it is only available to a select group of analysts, brokers and institutional investors.

Once information is widely disseminated, it is still necessary to provide the investing public with sufficient time to absorb the information. As a general rule, information should not be considered fully absorbed by the market until after the second Trading Day after the day on which the information is publicly released. As used herein, the term "***Trading Day***" shall mean any day on which the Nasdaq Stock Market LLC (the "***Nasdaq***") or, if the Company's common stock is not then traded on the Nasdaq, the principal national securities exchange, automated quotation system or other trading market where the Company's common stock is then listed, quoted or traded, is open for

trading. Nasdaq or such other principal national securities exchange, automated quotation system or other trading market where the Company's common stock is then listed, quoted or traded is herein referred to as the "***Principal Market***". If, for example, the Company were to make a public announcement of previously material nonpublic information on a Monday that is a Trading Day (at any time after market open), the information would not be considered fully absorbed by the market until the close of the second daily trading session on the Principal Market following such public announcement, i.e., the close of trading on Wednesday (assuming Tuesday and Wednesday are Trading Days). However, if, for example, the Company were to make an announcement pre-market on a Monday that is a Trading Day, the information would not be considered fully absorbed by the market until the close of the second daily trading session on the Principal Market following such public announcement, i.e., the close of trading on Tuesday (assuming Tuesday is also a Trading Day). Although such circumstances are likely to be rare, depending on the particular circumstances, the Compliance Officer may determine that a longer or shorter absorption period should apply following public release of specific material nonpublic information. For the avoidance of doubt, the persons designated by the Compliance Officer as being subject to pre-clearance procedures (as described under the heading "Additional Procedures") may not engage, or allow their Family Members or Controlled Entities to engage, in any transaction in Company Securities without first obtaining pre-clearance of the transaction from the Compliance Officer in accordance with the terms of this Policy, even after information is considered to be fully absorbed by the market, as set forth above.

Transactions by Family Members and Others

In addition to all directors, officers, employees, consultants, and independent contractors of the Company (or any other person designated as subject to this Policy) ("***you***"), this Policy applies to all family members who reside with you (including a spouse, a child, a child away at college, stepchildren, grandchildren, parents, stepparents, grandparents, siblings and in-laws), anyone else who lives in your household, and any family members who do not live in your household but whose transactions in Company Securities are directed by you or are subject to your influence or control, such as parents or children who consult with you before they trade in Company Securities (collectively referred to as "***Family Members***"). You are responsible for the transactions of these other persons and therefore should make them aware of the need to confer with you before they trade in Company Securities, and you should treat all such transactions for the purposes of this Policy and applicable securities laws as if the transactions were for your own account. This Policy does not, however, apply to personal securities transactions of Family Members where the purchase or sale decision is made by a third party not controlled by, influenced by or related to you or your Family Members.

Transactions by Entities that You Influence or Control

This Policy applies to any entities that you influence or control, including any corporations, companies, partnerships or trusts (collectively referred to as "***Controlled Entities***"), and transactions by these Controlled Entities should be treated for the purposes of this Policy and applicable securities laws as if they were for your own account.

Transactions Under Company Plans

This Policy does not apply in the case of the following transactions, except as specifically noted:

Stock Option Exercises. This Policy does not apply to the ***exercise*** of an employee stock option acquired pursuant to the Company's plans, or to the exercise of a tax withholding right pursuant to which a person

has elected to have the Company withhold shares subject to an option to satisfy tax withholding requirements. This Policy does apply, however, to any sale of stock as part of a broker-assisted cashless exercise of an option, or any other market sale for the purpose of generating the cash needed to pay the exercise price of an option.

Restricted Stock Awards. This Policy does not apply to the vesting of restricted stock, or the exercise of a tax withholding right pursuant to which you elect to have the Company withhold shares of stock to satisfy tax withholding requirements upon the vesting of any restricted stock. The Policy does apply, however, to any market sale of restricted stock.

401(k) Plan. This Policy does not apply to purchases of Company Securities in the Company's 401(k) plan, if any, resulting from your periodic contribution of money to the plan pursuant to your payroll deduction election. This Policy does apply, however, to certain elections you may make under the 401(k) plan, if any, including: (a) an election to increase or decrease the percentage of your periodic contributions that will be allocated to the Company Securities fund; (b) an election to make an intra-plan transfer of an

existing account balance into or out of the Company Securities fund; (c) an election to borrow money against your 401(k) plan account if the loan will result in a liquidation of some or all of your Company Securities fund balance; and (d) an election to pre-pay a plan loan if the pre-payment will result in allocation of loan proceeds to the Company stock fund. It should be noted that sales of Company Securities from a 401(k) account are also subject to Rule 144, and therefore affiliates should ensure that a Form 144 is filed when required.

Employee Stock Purchase Plan. This Policy does not apply to purchases of Company Securities in the Company's employee stock purchase plan, if any, resulting from your periodic contribution of money to the plan pursuant to the election you made at the time of your enrollment in the plan, if any. This Policy also does not apply to purchases of Company Securities resulting from lump sum contributions to the plan, if any, provided that you elected to participate by lump sum payment during the applicable enrollment period. This Policy does apply, however, to your sales of Company Securities purchased pursuant to the plan, if any.

Other Similar Transactions. Any other purchase of Company Securities from the Company or sales of Company Securities to the Company are not subject to this Policy.

Special and Prohibited Transactions

The Company has determined that there is a heightened legal risk and/or the appearance of improper conduct if the persons subject to this Policy engage in certain types of transactions. It therefore is the Company's policy that any persons covered by this Policy may not engage in any of the following transactions:

Short Sales. Short sales of Company Securities (*i.e.*, the sale of a security that the seller does not own) may evidence an expectation on the part of the seller that the securities will decline in value, and therefore have the potential to signal to the market that the seller lacks confidence in the Company's prospects. In addition, short sales may reduce a seller's incentive to seek to improve the Company's performance. For these reasons, short sales of Company Securities are prohibited. In addition, Section 16(c) of the Exchange Act of 1934, as amended (the "Exchange Act"), prohibits officers and directors from engaging in short sales. (Short sales arising from certain types of hedging transactions are governed by the paragraph below captioned "Hedging Transactions.")

Publicly-Traded Options. Given the relatively short term of publicly-traded options, transactions in options may create the appearance that a director, officer, employee, consultant, or independent contractor is trading based on material nonpublic information and focus a director's, officer's, employee's, consultant's, or independent contractor's attention on short-term performance at the expense of the Company's long-term objectives. Accordingly, transactions in put options, call options or other derivative securities, on an exchange or in any other organized market, are prohibited by this Policy. (Option positions arising from certain types of hedging transactions are governed by the next paragraph below.)

Hedging Transactions. Hedging or monetization transactions can be accomplished through a number of possible mechanisms, including through the use of financial instruments such as prepaid variable forwards, equity swaps, collars and exchange funds. Such transactions may permit a director, officer, employee, consultant, or independent contractor to continue to own Company Securities obtained through employee benefit plans or otherwise, but without the full risks and rewards of ownership. When that occurs, the director, officer, employee, consultant, or independent contractor may no longer have the same objectives as the Company's other shareholders. Therefore, Covered Persons are prohibited from engaging in any such transactions.

Margin Accounts and Pledged Securities. Securities held in a margin account as collateral for a margin loan may be sold by the broker without the customer's consent if the customer fails to meet a margin call.
Similarly, securities pledged (or hypothecated) as collateral for a loan may be sold in foreclosure if the borrower defaults on the loan. Because a margin sale or foreclosure sale may occur at a time when the pledgor is aware of material nonpublic information or otherwise is not permitted to trade in Company Securities, Covered Persons are prohibited from holding Company Securities in a margin account or otherwise pledging Company Securities as collateral for a loan. (Pledges of Company Securities arising from certain types of hedging transactions are governed by the paragraph above captioned "Hedging Transactions.").

Standing and Limit Orders. Standing and limit orders (except standing and limit orders under approved

Rule 10b5-1 Plans, as described below) create heightened risks for insider trading violations similar to the use of margin accounts. There is no control over the timing of purchases or sales that result from standing instructions to a broker, and as a result the broker could execute a transaction when a director, officer, employee, consultant, or independent contractor is in possession of material nonpublic information. The Company therefore prohibits Covered Persons from placing standing or limit orders on Company Securities. If a person subject to this Policy determines that they must use a standing order or limit order, the order should be limited to short duration and should otherwise comply with the restrictions and procedures outlined below under the heading "Additional Procedures." A person who has placed a limit order or open instruction to buy or sell Company securities shall bear responsibility for canceling such instructions immediately upon becoming in possession of material nonpublic information.

Additional Procedures

The Company has established additional procedures in order to assist the Company in the administration of this Policy, to facilitate compliance with laws prohibiting insider trading while in possession of material nonpublic information, and to avoid the appearance of any impropriety. These additional procedures are applicable only to those individuals described below.

Pre-Clearance Procedures for Deemed Insiders. Officers and directors of the Company, as well as the Family Members and Controlled Entities of such persons, and any other person that the Compliance Officer designates (collectively, "***Deemed Insiders***"), may not engage in any transaction in Company Securities without first obtaining pre-clearance of the transaction from the Compliance Officer. Any Deemed Insider seeking to request pre-clearance can obtain the Company's **pre-clearance form** upon request from the Compliance Officer. A request for pre-clearance should be submitted to the Compliance Officer at least two Trading Days in advance of the proposed transaction. The Compliance Officer is under no obligation to approve a transaction submitted for pre-clearance, and may determine not to permit the transaction. If a person seeks pre-clearance and permission to engage in the transaction and such pre-clearance is not received, then he or she should refrain from initiating any transaction in Company Securities, and should not inform any other person of the restriction.

When a request for pre-clearance is made, the requestor should carefully consider whether he or she may be aware of any material nonpublic information about the Company. The requestor should also indicate whether he or she has effected any non-exempt "opposite-way" transactions within the past six months, and should be prepared to report the proposed transaction on an appropriate Form 4 or Form 5. The requestor should also be prepared to comply with SEC Rule 144 and file a Form 144, if necessary, at the time of any sale.

Any pre-cleared transaction must be effected within the period of time indicated on the pre-clearance form as approved by the Compliance Officer (typically not to exceed 10 Trading Days), unless a different period of time is specified by the Compliance Officer. Transactions not effected within such specified period shall be subject to pre-clearance again before a trade can be effected.

Quarterly Trading Restrictions. No Covered Person may conduct any transactions involving the Company's Securities (other than as specified by this Policy), during a "Quarterly Restricted Period" beginning 14 calendar days prior to the end of each fiscal quarter and ending at the close of the second daily trading session on the Principal Market following the public release of the Company's earnings results for that quarter. In other words, Covered Persons may only conduct transactions in Company Securities during the "***Window Period***" beginning after the close of the second daily trading session on the Principal Market following the public release of the Company's earnings results for that quarter and ending 14 calendar days prior to the close of the next fiscal quarter. It should be noted that preliminary guidance with respect to the quarterly results generally will not suffice to end the Quarterly Restricted Period.

To illustrate the commencement of a Quarterly Restricted Period, if the Company's fourth fiscal quarter ends immediately following 11:59 p.m., Eastern time, on December 31st, the corresponding Quarterly Restricted Period would begin immediately following 11:59 p.m., Eastern time, on December 17th.

To illustrate the commencement of the Window Period, if the Company publicly announces its earnings results intra-day or post-market, for example, on Monday, March 8th, then the Window Period shall begin after the close of the daily trading session on the Principal Market on Wednesday, March 10th. However, if the Company publicly announces its earnings results pre-market, for example, on Monday, March 8th, then the Window Period shall begin after the close of the daily trading session on the Principal Market on

Tuesday, March 9th.

The foregoing calculation of the two-daily trading session period required prior to commencement of a Window Period assumes all relevant days are Trading Days and is made using the same method of calculating the two-daily trading session period as set forth under the heading "When Information is Considered Public".

For the avoidance of doubt, all persons designated by the Compliance Officer as being subject to pre- clearance procedures, as well as the Family Members and Controlled Entities of such persons, may not engage in any transaction in Company Securities without first obtaining pre-clearance of the transaction from the Compliance Officer in accordance with the terms of this Policy, even during a Window Period.

Under certain very limited circumstances, a person subject to a Quarterly Restricted Period may be permitted to trade during such Quarterly Restricted Period, but only if the Compliance Officer concludes that the person is not aware of material nonpublic information. Persons wishing to trade during a Quarterly Restricted Period must contact the Compliance Officer for approval at least two Trading Days in advance of any proposed transaction involving Company Securities.

Event-Specific Restricted Periods. From time to time, an event may occur that is material to the Company and is known by only a few directors, officers, employees, consultants, and independent contractors. So long as the event remains material and nonpublic (the "Event-Specific Restricted Period"), the persons designated by the Compliance Officer may not engage in transactions in Company Securities. In addition, the Company's financial results may be sufficiently material in a particular fiscal quarter that, in the judgment of the Compliance Officer, designated persons should refrain from engaging in transactions in Company Securities even sooner than the Quarterly Restricted Period described above. In that situation, the Compliance Officer may notify these persons that they should not trade in the Company's Securities, without disclosing the reason for the restriction. The existence of an Event-Specific Restricted Period or the extension of a Quarterly Restricted Period will not be announced to the Company as a whole, and should not be communicated to any other person. Even if the Compliance Officer has not designated you as a person who should not engage in transactions in Company Securities due to an Event-Specific Restricted Period, you should not trade while aware of material nonpublic information. Exceptions will not be granted during an Event-Specific Restricted Period.

Closed Window. From time to time, there may be a risk that material nonpublic information is known widely within the Company during a Window Period such that the Compliance Officer determines to close that Window Period for all Covered Persons. In such event, the Window Period is treated as a Quarterly Restricted Period and no Covered Person may conduct any transactions involving the Company's Securities, unless and until the Compliance Officer determines to open the Window Period.

Exceptions. The quarterly trading restrictions and event-specific trading restrictions do not apply to those transactions to which this Policy does not apply, as described above under the heading "Transactions Under Company Plans." Further, the requirement for pre-clearance, the quarterly trading restrictions and event- specific trading restrictions do not apply to transactions conducted pursuant to approved Rule 10b5-1 plans, described under the heading "Rule 10b5-1 Plans."

Rule 10b5-1 Plans

Rule 10b5-1 under the Exchange Act provides a defense from insider trading liability under Rule 10b-5. In order to be eligible to rely on this defense, a person subject to this Policy must enter into a Rule 10b5-1 plan for transactions in Company Securities that meets certain conditions specified in the Rule (a "***Rule 10b5-1 Plan***") and must be in accordance with the Company's "**Guidelines for Rule 10b5-1 Plans**" that is attached to this Policy as Attachment
A. If the plan meets the requirements of Rule 10b5-1, transactions in Company Securities may occur even when the person who has entered into the plan is aware of material nonpublic information.

To comply with the Policy, a Rule 10b5-1 Plan must be approved by the Compliance Officer and meet the requirements of Rule 10b5-1 and the Company's "Guidelines for Rule 10b5-1 Plans". In general, a Rule 10b5-1 Plan must be entered into during a Window Period when the person entering into the plan is not aware of material nonpublic information. Once the plan is adopted, the person must not exercise any influence over the amount of securities to be traded, the price at which they are to be traded or the date of the trade. The plan must either specify the amount, pricing and timing of transactions in advance or delegate discretion on these matters to an independent third party. The plan must include a cooling-off period before trading can commence that, for directors or officers,

ends on the later of 90 days after the adoption of the Rule 10b5-1 Plan or two Trading Days following the disclosure of the Company's financial results in an SEC periodic report for the fiscal quarter in which the plan was adopted (but in any event, the required cooling-off period is subject to a maximum of 120 days after adoption of the plan), and for persons other than directors or officers, 30 days following the adoption or modification of a Rule 10b5-1 Plan. A person may not enter into overlapping Rule 10b5-1 plans (subject to certain exceptions) and may only enter into one single-trade Rule 10b5-1 Plan during any 12-month period. Directors and officers must include a representation in their Rule 10b5-1 Plan certifying that: (i) they are not aware of any material nonpublic information; and (ii) they are adopting the plan in good faith and not as part of a plan or scheme to evade the prohibitions in Rule 10b-5. All persons entering into a Rule 10b5-1 Plan must act in good faith with respect to that plan.

Any Rule 10b5-1 Plan must be submitted for approval at least five days prior to the entry into the Rule 10b5-1 Plan. No further pre-approval of transactions conducted pursuant to the Rule 10b5-1 Plan will be required.

Notwithstanding anything contained herein to the contrary, it is the Company's policy that no officer or director, or Family Members or Controlled Entities of any such person, may enter into any transaction in Company Securities while such person has a Rule 10b5-1 Plan that is in effect; provided, however, that the foregoing shall only apply to a Rule 10b5-1 Plan adopted or modified by such person on or after January 1, 2024.

Post-Termination Transactions

This Policy continues to apply to transactions in Company Securities even after termination of service to the Company. If an individual is in possession of material nonpublic information when his or her service terminates, that individual may not engage in transactions in Company Securities until that information has been publicly announced or is no longer material. The pre-clearance procedures specified under the heading "Additional Procedures" above, however, will cease to apply to transactions in Company Securities upon the expiration of any Quarterly Restricted Period, Event-Specific Restricted Period, or other Company-imposed trading restrictions applicable at the time of the termination of service.

Consequences of Violations

The purchase or sale of securities while aware of material nonpublic information, or the disclosure of material nonpublic information to others who then engage in transactions in the Company's Securities, is prohibited by the federal and state laws. Insider trading violations are pursued vigorously by the SEC, U.S. Attorneys and state enforcement authorities, as well as enforcement authorities in foreign jurisdictions. Punishment for insider trading violations is severe, and could include significant fines and imprisonment. While the regulatory authorities concentrate their efforts on the individuals who trade, or who tip inside information to others who trade, the federal securities laws also impose potential liability on companies and other "controlling persons" if they fail to take reasonable steps to prevent insider trading by company personnel.

In addition, an individual's failure to comply with this Policy may subject the individual to Company-imposed sanctions, including dismissal for cause, whether or not the employee's failure to comply results in a violation of law. Needless to say, a violation of law, or even an SEC investigation that does not result in prosecution, can tarnish a person's reputation and irreparably damage a career.

Persons located or engaged in dealings outside the United States should be aware that laws regarding insider trading and similar offenses differ from country to country. Employees must abide by the laws in the country where they are located. However, all persons subject to this Policy are required to comply with this Policy even if applicable local law is less restrictive. If a local law conflicts with this Policy, consult the Compliance Officer.

Reporting

Consistent with the Company's Code of Conduct, it is the responsibility of all directors, officers and employees of the Company to report any violation of this Policy to the Compliance Officer. This reporting duty should be broadly construed to include any inappropriate conduct by their Family Members and Controlled Entities in respect of trading in the securities of the Company, as well as the sharing or misuse of the confidential information of the Company and any material nonpublic information.

Company Assistance

Any person who has a question about this Policy or its application to any proposed transaction may obtain additional

guidance from the Compliance Officer.

Prior to disclosure to any third party, any officer, director or employee of the Company who is aware of any material nonpublic information concerning the Company that has not been disclosed to the public should report the intention to disclose such information promptly to the Compliance Officer and obtain approval to do so, or otherwise act in accordance with the Company's Investor Relations Policy.

Certification

All persons subject to this Policy must certify their understanding of, and intent to comply with, this Policy.

CERTIFICATION

I certify that:

1. I have read and understand the Policy. I understand that the Compliance Officer is available to answer any questions I have regarding the Policy.

2. Since the date that the Policy became effective, or such shorter period of time that I have been an employee of the Company, I have complied with the Policy.

3. I will continue to comply with the Policy for as long as I am subject to the Policy.

Print name:___

Signature:____

Date:____

Attachment A to Insider Trading Policy

Guidelines for Rule 10b5-1 Plans

Rule 10b5-1 under the Exchange Act provides a defense from insider trading liability under Rule 10b-5. In order to be eligible to rely on this defense, a person subject to this Policy must enter into a Rule 10b5-1 plan for transactions in Company Securities (as defined in the Insider Trading Policy) that meets certain conditions specified in the Rule (a "Rule 10b5-1 Plan"). If the plan meets the requirements of Rule 10b5-1, transactions in Company Securities may occur without regard to certain insider trading restrictions. In general, a Rule 10b5-1 Plan must be entered into at a time when the person entering into the plan is not aware of material nonpublic information. Once the plan is adopted, the person must not exercise any influence over the amount of securities to be traded, the price at which they are to be traded or the date of the trade. The plan must either specify the amount, pricing and timing of transactions in advance or delegate discretion on these matters to an independent third party.

A Rule 10b5-1 plan must include a cooling-off period before trading can commence that, for directors or officers, ends on the later of 90 days after the adoption of the Rule 10b5-1 plan or two Trading Days following the disclosure of the Company's financial results in an SEC periodic report for the fiscal quarter in which the plan was adopted (but in any event, the required cooling-off period is subject to a maximum of 120 days after adoption of the plan), and for persons other than directors or officers, 30 days following the adoption or modification of a Rule 10b5-1 plan. A person may not enter into overlapping Rule 10b5-1 plans (subject to certain exceptions) and may only enter into one single-trade Rule 10b5-1 plans during any 12-month period (subject to certain exceptions). Directors and officers must include a representation in their Rule 10b5-1 plan certifying that: (i) they are not aware of any material nonpublic information; and (ii) they are adopting the plan in good faith and not as part of a plan or scheme to evade the prohibitions in Rule 10b-5. All persons entering into a Rule 10b5-1 plan must act in good faith with respect to that plan.

As specified in the Company's Insider Trading Policy, a Rule 10b5-1 Plan must be approved by the Compliance Officer and meet the requirements of Rule 10b5-1 and these guidelines. Any Rule 10b5-1 Plan must be submitted for approval five days prior to the entry into the Rule 10b5-1 Plan. No further pre-approval of transactions conducted pursuant to the Rule 10b5-1 Plan will be required.

The following guidelines apply to all Rule 10b5-1 Plans:

- You may not enter into, modify or terminate a trading program during a Restricted Period, or Event-Specific Restricted Period or otherwise while you are aware of material nonpublic information.
- All Rule 10b5-1 Plans must have a duration of at least six (6) months and no more than two (2) years.
- For officers and directors, no transaction may take place under a Rule 10b5-1 Plan until the later of (a) 90 days after adoption or modification of the Rule 10b5-1 Plan or (b) two Trading Days following the disclosure of the Company's financial results in a Form 10-Q or Form 10-K for the fiscal quarter (the Company's fourth fiscal quarter in the case of a Form 10-K) in which the Rule 10b5-1 Plan was adopted or modified (but in any event, the cooling-off period is subject to a maximum of 120 days after adoption of the plan).
- For persons other than officers and directors, no transaction may take place under a Rule 10b5-1 Plan until 30 days following the adoption or modification of a Rule 10b5-1 plan.
- Subject to certain limited exceptions specified in Rule 10b5-1, you may not enter into more than one Rule 10b5-1 Plan at the same time;
- Subject to certain limited exceptions specified in Rule 10b5-1, you are limited to only one Rule 10b5-1 designed to effect an open market purchase or sale of the total amount of securities subject to the Rule 10b-1 Plan as a single transaction in any 12-month period;
- You must act in good faith with respect to a Rule 10b5-1 Plan. A Rule 10b5-1 Plan cannot be entered into as part of a plan or scheme to evade the prohibition of Rule 10b¬5. Therefore, although modifications to an existing Rule 10b5-1 Plan are not prohibited, a Rule 10b5-1

Plan should be adopted with the intention that it will not be amended or terminated prior to its expiration.

- Officer and directors must include a representation to the Company at the time of adoption or modification of a Rule 10b5-1 Plan that (i) the person is not aware of material nonpublic information about the Company or Company Securities and (ii) the person is adopting the plan in good faith and not as part of plan or scheme to evade the prohibitions of Rule 10b-5.

- No officer or director, or Family Members or Controlled Entities of such person, may enter into any transaction in Company Securities while any such person has a Rule 10b5-1 Plan that is in effect; provided, however, that the foregoing shall only apply to a Rule 10b5-1 Plan adopted by such person(s) on or after January 1, 2024.

The Company and the Company's officers and directors must make certain disclosures in SEC filings concerning Rule 10b5-1 Plans. Officers and directors of the Company must undertake to provide any information requested by the Company regarding Rule 10b5-1 Plans for the purpose of providing the required disclosures or any other disclosures that the Company deems to be appropriate under the circumstances.

Each director, officer and other Section 16 insider understands that the approval or adoption of a pre-planned selling program in no way reduces or eliminates such person's obligations under Section 16 of the Exchange Act, including such person's disclosure and short-swing trading liabilities thereunder. If any questions arise, such person should consult with their own counsel in implementing a Rule 10b5-1 Plan.

As of January 1, 2024, the Company has a relationship with ETrade (through Morgan Stanley) that includes administration of the Company's Employee Stock Purchase Plan. Employees can contact ETrade at 10b51@etrade.com to help establish a Rule 10b5-1 Plan, or can use the employee's separate broker.

Exhibit 21.1

Subsidiaries of the Registrant

Set forth below is a list of subsidiaries of Arcturus Therapeutics Holdings Inc. (the "Registrant") All of the subsidiaries listed below are wholly-owned subsidiaries of the Registrant and are owned directly by the Registrant.

Subsidiary	Jurisdiction of Formation
Arcturus Therapeutics, Inc.	Delaware
Arcturus Therapeutics Asia Pte. Ltd.	Singapore
Arcturus Therapeutics Europe B.V.	Netherlands

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Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form S-4 No. 333-230353) of Arcturus Therapeutics Holdings Inc.,

(2) Registration Statement (Form S-8 No. 333-232272) pertaining to the Arcturus Therapeutics Holdings Inc. 2019 Omnibus Equity Incentive Plan,

(3) Registration Statement (Form S-8 No. 333-280860) pertaining to Arcturus Therapeutics Holdings Inc. 2019 Omnibus Equity Incentive Plan,

(4) Registration Statement (Form S-8 No. 333-265925) pertaining to the Arcturus Therapeutics Holdings Inc. 2019 Omnibus Equity Incentive Plan, as amended,

(5) Registration Statement (Form S-8 No. 333-240397) pertaining to the Arcturus Therapeutics Holdings Inc. Amended and Restated 2019 Omnibus Equity Incentive Plan,

(6) Registration Statement (Form S-8 No. 333-240392) pertaining to the Arcturus Therapeutics Holdings Inc. 2020 Employee Stock Purchase Plan,

(7) Registration Statement (Form S-8 No. 333-260391) pertaining to the Arcturus Therapeutics Holdings Inc. 2021 Inducement Equity Incentive Plan,

(8) Registration Statements (Form S-3 Nos. 333-235475 and 333-269003) of Arcturus Therapeutics Holdings Inc.

of our report dated March 14, 2024 (except Note 12, as to which the date is March 6, 2025) with respect to the consolidated financial statements of Arcturus Therapeutics Holdings Inc. included in this Annual Report (Form 10-K) of Arcturus Therapeutics Holdings, Inc. for the year ended December 31, 2024.

/s/ Ernst & Young LLP
San Diego, California
March 6, 2025

Exhibit 23.2

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement Nos. 333-235475 and 333-269003 on Form S-3; Registration Statement No. 333-230353 on Form S-4; and Registration Statement Nos. 333-232272, 333-240397, 333-240392, 333-260391, 333-265925, and 333-280860 on Form S-8 of our reports dated March 6, 2025, relating to the financial statements of Arcturus Therapeutics Holdings, Inc. and the effectiveness of Arcturus Therapeutics Holdings, Inc. internal control over financial reporting appearing in this Annual Report on Form 10-K for the fiscal year ended December 31, 2024.

/s/ Deloitte & Touche LLP

San Diego, California
March 6, 2025

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a)

I, Joseph E. Payne, certify that:

1. I have reviewed this Annual Report on Form 10-K of Arcturus Therapeutics Holdings Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

   c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 6, 2025

By: /s/ Joseph E. Payne

Joseph E. Payne
President, Chief Executive Officer and Director
(principal executive officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a)

I, Andrew Sassine, certify that:

1. I have reviewed this Annual Report on Form 10-K of Arcturus Therapeutics Holdings Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

   c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 6, 2025

By: /s/ Andrew Sassine

Andrew Sassine
Director and Chief Financial Officer
(principal financial and accounting officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350

In connection with the Annual Report of Arcturus Therapeutics Holdings Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2024 (the "Report"), I, Joseph E. Payne, President, Chief Executive Officer and Director of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 6, 2025

By: /s/ Joseph E. Payne

Joseph E. Payne
President, Chief Executive Officer and Director
(principal executive officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350

In connection with the Annual Report of Arcturus Therapeutics Holdings Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2024 (the "Report"), I, Andrew Sassine, Chief Financial Officer and Director of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 6, 2025

By: /s/ Andrew Sassine
Andrew Sassine
Director and Chief Financial Officer
(principal financial and accounting officer)

Exhibit 97.1

ARCTURUS THERAPEUTICS HOLDINGS INC. CLAWBACK POLICY

1. Introduction

Arcturus Therapeutics Holdings Inc. (the "Company") believes that it is in the best interests of the Company and its stockholders to create and foster a culture of business ethics, integrity and accountability, and that, among other purposes, reinforces the Company's incentive compensation philosophy.

The Board of Directors (the "Board") therefore adopts this policy to provide for the Company's recovery of certain compensation in the event of an accounting restatement of the Company's financial statements resulting from material noncompliance with applicable financial reporting requirements under the federal securities laws (this "Policy").

This Policy is designed to comply with Section 10D of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and the rules and regulations promulgated thereunder.

2. General Administration

This Policy shall be administered by the Board or, if so designated by the Board, the Compensation Committee of the Board, in which case references herein to the Board shall be deemed to be references to the Compensation Committee of the Board. Any determinations made by the Board in respect of this Policy, or to matters as to this Policy's amendment, enforcement, or otherwise, shall be final and binding on all individuals governed under this Policy as well as any related actions or procedures carried out by the Company's Executive Officers (as defined herein) that are deemed necessary, appropriate, or advisable to effectuate the purposes of this Policy.

3. Applicability

This Policy applies to the Company's current and former Executive Officers, as determined by the Board in accordance with Section 10D of the Exchange Act and the listing standards of the national securities exchange on which the Company's securities are listed (such as Section 303A.14 of the New York Stock Exchange's listing standards or Rule 5608 of Nasdaq's listing rules, which are each approved by the U.S. Securities and Exchange Commission (the "SEC") to implement Rule 10D-1 promulgated under the Exchange Act).

For purposes of this Policy, "Executive Officer" means the Company's president, principal financial officer, principal accounting officer (or, if there is no such accounting officer, the controller); any vice president of the Company in charge of a principal business unit, division, or function (such as sales, administration, or finance); any other officer who performs a policy-making function; and any other person who performs a function similar to a policy-making function on behalf of the Company. Executive officers of the Company's parent(s) or subsidiaries are deemed Executive Officers of the Company if they perform such policy-making or similar functions for or on behalf of the Company.

This Policy also applies to other senior executives, employees, or classes of employees of the Company as may be determined by the Board in its sole discretion from time to time (together with Executive Officers, "Covered Persons").

4. **Recoupment**

If the Company is required to prepare an accounting restatement of its financial statements due to the Company's material noncompliance with financial reporting requirements under the applicable federal securities laws (including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period) (an "Accounting Restatement"), without regard to any fault or misconduct of a Covered Person, then, the Board shall mandate the Company's recovery, in the form of reimbursement, or forfeiture, as applicable ("Recoupment"), of any Excess Incentive Compensation (as defined herein) received by a Covered Person, *provided that*:

(a) the receipt of any such Excess Incentive Compensation by a Covered Person occurred after the Covered Person became a Covered Person;

(b) the Covered Person served as a Covered Person at any time during the performance period applicable to the Covered Person's Incentive Compensation (as defined herein);

(c) the Company had a class of securities listed on a national securities exchange or a national securities association during the Covered Person's service as a Covered Person and during the performance period applicable to the Covered Person's Incentive Compensation; and

(d) the receipt of the Excess Incentive Compensation by the Covered Person occurred during the three completed fiscal years immediately preceding the date that the Company is required to prepare an Accounting Restatement, or during any transition period (that results from a change in the Company's fiscal year) within or immediately following such three completed fiscal years.

For purposes of this Policy, a transition period between the last day of the Company's previous fiscal year end and the first day of its new fiscal year that comprises a period of nine to 12 months is a completed fiscal year.

For purposes of this Policy, any Incentive Compensation is deemed to be "received" by a Covered Person *at the point in time when a Financial Reporting Measure* (as defined herein), as specified in a Covered Person's incentive compensation agreement (or other equity or incentive compensation plan of the Company) providing for a Covered Person's compensation that is contingent upon or tied to the attainment of such Financial Reporting Measure, *is attained during the relevant fiscal period of the Company*.

Therefore, under this Policy, a Covered Person is deemed to receive Incentive Compensation even if, for instance, the payment or grant of Incentive Compensation occurs after the end of the relevant fiscal period of the Company.

For purposes of this Policy, the date on which the Company is required to prepare an Accounting Restatement is deemed to have occurred on the earlier of (i) the date the Board concludes, or reasonably should have concluded, that the Company's previously issued financial statements contain a material error and (ii) the date a court, regulator, or other legally authorized body directs the Company to restate its previously issued financial statements to correct a material error.

The Company's obligation to seek Recoupment of a Covered Person's Excess Incentive Compensation is *not* dependent on whether or when the restated financial statements are filed with the SEC.

5. **Incentive Compensation; Financial Reporting Measures**

For purposes of this Policy, "Incentive Compensation" means any compensation that is granted, earned, or vested based wholly or in part upon the attainment of a Financial Reporting Measure.

Incentive Compensation may include (but is not limited to):

- Annual bonuses and other short- and long-term cash incentives;
- Stock options;
- Stock appreciation rights;
- Restricted stock;
- Restricted stock units;
- Performance shares; and
- Performance units.

For purposes of this Policy, "Financial Reporting Measure" means a measure that is determined and presented in accordance with the generally accepted accounting principles used in preparing the Company's financial statements, or any measure that is derived wholly or in part therefrom. For avoidance of doubt, a Financial Reporting Measure need not be presented within the Company's financial statements or included in a filing with the SEC.

Financial Reporting Measures may include (but are not limited to):

- Company stock price;
- Total shareholder return;
- Revenues;
- Net income;
- Earnings before interest, taxes, depreciation and amortization, EBITDA, or adjusted EBITDA;
- Funds from operations;
- Liquidity measures, such as working capital or operating cash flow;
- Return measures, such as return on invested capital or return on assets; and
- Earnings measures, such as earnings per share.

6. **Excess Incentive Compensation**

The amount subject to Recoupment is any Incentive Compensation received by a Covered Person that is determined by the Board, in good faith and upon the exercise of due care, to have been based on erroneous

information that caused the Company's material noncompliance with financial reporting requirements under the federal securities laws (without regard to any fault or misconduct of a Covered Person), which would not have been received by a Covered Person had the Incentive Compensation of a Covered Person been based on the restated financial statements' results ("Excess Incentive Compensation").

If the Board cannot calculate Excess Incentive Compensation received by a Covered Person from the information in an Accounting Restatement (i.e., the amount of Excess Incentive Compensation is not subject to mathematical recalculation directly from the information in an Accounting Restatement), then, the Board shall determine such Excess Incentive Compensation based on a reasonable estimate of the effect of such Accounting Restatement on the applicable Financial Reporting Measures upon which the Excess Incentive Compensation was received and in consideration of all facts relevant to the Company's Recoupment of Excess Incentive Compensation received by a Covered Person in the circumstances.

The Company shall maintain documentation of any such reasonable estimates and provide such documentation, when and if reasonably requested, to the applicable national securities exchange on which the Company's securities are listed in accordance with the applicable standards or rules of the national securities exchange.

With respect to Incentive Compensation based in part or whole on stock price or measures of shareholder return, the Board shall calculate Excess Incentive Compensation relating thereto in such manner as the Board deems appropriate or reasonable.

In no event shall the Company be required to award a Covered Person additional Incentive Compensation if the restated financial statements' results would have resulted in the provision of Incentive Compensation that is higher in monetary value relative to the monetary value received by a Covered Person prior to the Accounting Restatement.

7. **Recoupment Method**

The Board shall determine in its sole discretion, to be exercised in good faith, and not inconsistent with applicable law, the method for Recoupment of a Covered Person's Excess Incentive Compensation, which may include, without limitation, one or more of the following acts:

(a) mandating reimbursement of cash-based Incentive Compensation previously paid to a Covered Person;

(b) seeking recovery of any gain realized on the vesting, exercise, settlement, sale, transfer, or other disposition of any equity-based Incentive Compensation of a Covered Person;

(c) offsetting the recouped amount from any compensation otherwise owed by the Company to a Covered Person;

(d) cancelling outstanding vested or unvested equity-based Incentive Compensation of a Covered Person; and

(e) taking any other remedial and recovery action not disallowed by applicable law, as determined by the Board, consistent with Sections 4, 6, 10, and 13 under this Policy.

The Board shall, in the exercise of its fiduciary duty to safeguard the assets of the Company (including the time value of any potentially recoverable Incentive Compensation), and, in the light of the particular facts and circumstances of a Covered Person who is determined by the Board to owe Excess Incentive

Compensation to the Company, pursue the most appropriate balance of cost and speed in determining the means to seek Recoupment of a Covered Person's Excess Incentive Compensation.

Consistent with this Section 7 and Rule 10D-1 of the Exchange Act, regardless of the means of Recoupment used, the Board intends that Recoupment of a Covered Person's Excess Incentive Compensation shall be effected by the Company reasonably promptly. The Board further intends that the administration of this Policy shall abide by the Company's recognition that what is reasonable may depend on the additional cost incident to Recoupment.

8. **No Indemnification**

In no event shall the Company indemnify any Covered Persons against the loss of any incorrectly awarded Incentive Compensation pursuant to Rule 10D-1 and applicable stock exchange listing rules.

9. **Cooperation**

Covered Persons shall facilitate the Company's compliance with its disclosure obligations relating to this Policy in accordance with the requirements of the federal securities laws and applicable stock exchange listing rules.

10. **Interpretation**

Consistent with Section 2 of this Policy, the Board shall be authorized to construe and interpret this Policy and to make all determinations necessary, appropriate, or advisable for the administration of this Policy in accordance with the Company's constitutional documents.

This Policy memorializes the Board's intention that this Policy be interpreted in a manner that is consistent with Section 10D of the Exchange Act and any applicable rules, regulations, or standards adopted by the SEC (such as Rule 10D-1) and those adopted by the national securities exchange on which the Company's securities are listed as well as any other relevant law, in each case as in effect from time to time (the "Applicable Rules").

To the extent the Applicable Rules require recovery of Incentive Compensation in additional circumstances beyond those specified above, nothing in this Policy shall be deemed to limit or restrict the right or obligation of the Company to recover Incentive Compensation to the fullest extent required by the Applicable Rules.

11. **Effective Date**

This Policy is effective as of October 2, 2023 (the "Effective Date") and shall be duly adopted by the Board in accordance with the Company's constitutional documents. This Policy shall apply to all Incentive Compensation that is received by Covered Persons on or after the Effective Date.

12. **Amendment; Termination**

Consistent with Section 2 of this Policy, the Board may amend this Policy from time to time in its sole discretion and shall amend this Policy as the Board deems necessary or proper to (i) reflect any modification to the rules and regulations adopted by the SEC interpreting Section 954 of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 and the rules and regulations adopted by the SEC under Section 10D of the Exchange Act and to (ii) comply with any rules or standards adopted by a national securities exchange on which the Company's securities are listed.

The Board may, but is not required to, reassess the contents of this Policy on a yearly basis as part of the Company's analysis of material risks.

The Board may terminate this Policy at any time.

13. **Other Recoupment Rights**

The Board intends that this Policy shall be applied to the fullest extent of the law.

In the Board's good-faith determination, the Board may require that any employment agreement, equity award agreement, or similar enforceable agreement by and between the Company and a Covered Person entered into on or after the Effective Date shall, as a condition to the grant of any benefit thereunder, be amended and restated, or otherwise validly modified or supplemented, under the governing law of any such agreement, to require a Covered Person to agree to abide by the terms of this Policy.

All of the Company's actions or powers associated with Recoupment contemplated by this Policy are in addition to, and not in lieu of, any contract or other rights of a compensation-recovery nature that may be available to the Company (including, without limitation, any right of repayment, forfeiture, or right of offset against any employees that is required pursuant to any statutory repayment requirement (regardless of whether implemented at any time prior to or following the adoption or amendment of this Policy), including Section 304 of the Sarbanes-Oxley Act of 2002 ("SOX")).

Any amounts paid to the Company in accordance with Section 304 of SOX shall be considered by the Company in determining any amounts recovered under this Policy.

The application and enforcement of this Policy does not preclude the Company from taking any other action to enforce a Covered Person's obligations to the Company, including termination of employment or institution of legal proceedings. Nothing in this Policy restricts the Company from seeking Recoupment under any other compensation recoupment-based policy or any applicable provisions in plans, agreements, awards, or other arrangements that contemplate the recovery of compensation from a Covered Person.

If a Covered Person fails to repay Excess Incentive Compensation that is owed to the Company under this Policy, then, the Company shall take all appropriate action to recover such Excess Incentive Compensation from the Covered Person, and the Covered Person shall be required to reimburse the Company for all expenses (including legal expenses) incurred by the Company in recovering such Excess Incentive Compensation.

14. **Impracticability**

The Board shall mandate Recoupment of any Excess Incentive Compensation of a Covered Person in accordance with this Policy *unless* effecting Recoupment would be impracticable, as the Compensation Committee of the Board may so determine (i) in consistence with its fiduciary duties owed to the Company's shareholders and (ii) in accordance with Rule 10D-1 of the Exchange Act and the applicable listing standards of the national securities exchange on which the Company's securities are traded.

Under Rule 10D-1 of the Exchange Act, a company's obligation to recover any erroneously awarded compensation is subject only to the following limited instances in which recovery would be considered impracticable:

(a) The direct expense paid to a third party to assist in enforcing the policy would exceed the amount to be recovered after a company has made and documented a reasonable attempt to recover;

(b) Recovery would violate home country law where that law was adopted prior to November 28, 2022, and the issuer provides an opinion of home country counsel to the exchange; or

(c) Recovery would likely cause an otherwise tax-qualified retirement plan to fail to meet the requirements of the Internal Revenue Code of 1986, as amended.

Therefore, the Board intends that this Policy shall be implemented in a manner that follows the aforementioned exceptions (as applicable to the Company), and that Recoupment of any Excess Incentive Compensation of a Covered Person under this Policy shall be mandatory unless one of the exceptions under Rule 10D-1 apply.

15. **Severability**

If any provision of this Policy or the application of such provision to any Covered Person shall be adjudicated to be invalid, illegal, or unenforceable in any respect, such invalidity, illegality, or unenforceability shall not affect any other provisions of this Policy, and the invalid, illegal, or unenforceable provisions shall be deemed amended to the minimum extent necessary to render any such provision (or the application of such provision) valid, legal or enforceable.

16. **Successors**

This Policy shall be binding and enforceable against all Covered Persons and their beneficiaries, heirs, executors, administrators, or other legal representatives.

ARCTURUS THERAPEUTICS HOLDINGS INC. CLAWBACK POLICY
ACKNOWLEDGEMENT AND AGREEMENT FORM

By signing below, the undersigned acknowledges and confirms that the undersigned has received and reviewed a copy of the Arcturus Therapeutics Holdings Inc. (the "Company") Clawback Policy (the "Policy").

By signing this Acknowledgement and Agreement Form, the undersigned acknowledges and agrees that the undersigned is and will continue to be subject to the Policy, and that the Policy will apply both during and after the undersigned's employment with the Company. Further, by signing below, the undersigned agrees to abide by the terms of the Policy, including, without limitation, by returning any Excess Incentive Compensation (as defined in the Policy) reasonably promptly to the Company to the extent required by, and in a manner consistent with, the Policy.

In addition, by signing below, the undersigned acknowledges that the Policy applies to all Incentive Compensation (as defined in the Policy); agrees to waive any legal right that might conflict or otherwise interfere with the Company's Recoupment (as defined in the Policy) of any Excess Incentive Compensation in consistence with the terms of the Policy; and acknowledges that the Company may seek Recoupment of any Excess Incentive Compensation through any method of recovery it deems appropriate or necessary under the circumstances (which may include offsetting against any compensation payable to the undersigned, among other methods of recovery), as contemplated by Sections 7 and 13 under the Policy.

The undersigned acknowledges and agrees that by signing below, the undersigned agrees that any and all agreements and understandings between the undersigned and the Company are hereby amended and modified by and subject to this Policy.

COVERED PERSON

Signature

Printed Name

Date