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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2020

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE TRANSITION PERIOD FROM TO**

Commission File Number 001-38942

ARCTURUS THERAPEUTICS HOLDINGS INC.

(Exact name of Registrant as specified in its Charter)

Delaware **(State or other jurisdiction of incorporation or organization)**	**32-0595345** **(I.R.S. Employer Identification No.)**
10628 Science Center Drive, Suite 250 **San Diego, California** **(Address of principal executive offices)**	**92121** **(Zip Code)**

Registrant's telephone number, including area code: (858) 900-2660

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 ☐

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, 2020 was $701.4 million.

As of February 24, 2021, the registrant had 26,280,275 shares of voting common stock outstanding.

Documents Incorporated by Reference: Certain portions of the registrant's definitive Proxy Statement for its 2021 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.

Table of Contents

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 3.D, "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:

- the initiation, cost, timing, progress 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;
- our ability to obtain and maintain regulatory approval of our product candidates, and any related restrictions, limitations, and/or warnings in the label of an approved product candidate;
- our ability to obtain and deploy funding for our operations;
- our ability to continue as a going concern;
- our plans to research, develop and commercialize 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 avoid, settle or be victorious at costly litigation with shareholders, former executives or others, should these situations arise;
- our ability to obtain and maintain intellectual property protection for our product candidates;
- the size and growth potential of the markets for our product candidates, and our ability to serve those markets;
- our ability 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;
- our ability to develop sales and marketing capabilities, whether alone or with potential future collaborators;
- regulatory developments in the United States and foreign countries;
- our ability to attract and retain experienced and seasoned scientific and management professionals to lead the Company;
- the performance of our third-party suppliers and manufacturers;
- the success of competing therapies that are or may become available; and
- the accuracy of our estimates regarding future expenses, future revenues, capital requirements and need for additional financing.

Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results or performance to differ materially from those projected. These 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, or 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 believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance, or achievements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

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) 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 and Forecasts

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.

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. We are responsible for all of the disclosure in this Annual Report on Form 10-K.

PART I

Item 1. Business

Overview

We are a global clinical-stage messenger RNA medicines company focused on the development of infectious disease vaccines and significant opportunities within liver and respiratory rare diseases. In addition to our messenger RNA ("mRNA") platform, our proprietary lipid nanoparticle ("LNP") delivery system, LUNAR, has the potential to enable multiple nucleic acid medicines, and our proprietary Self-Transcribing and Replicating RNA ("STARR") technology has the potential to provide longer-lasting RNA and sustained protein expression.

We are leveraging our proprietary platform relating to LUNAR and our nucleic acid technologies to develop and advance a pipeline of mRNA-based vaccines and therapeutics for infectious diseases and rare genetic disorders with significant unmet medical needs. Our key proprietary technology has the potential to address the major hurdles in RNA development, namely the effective and safe delivery of RNA therapeutics to disease-relevant target tissues. We believe the versatility of our platform to target multiple tissues, its compatibility with various nucleic acid therapeutics, and our expertise in developing scalable manufacturing processes puts us in a leading position to deliver on the next generation of nucleic acid medicines.

We are a clinical stage company with the commencement of clinical trials in two of our programs and further expanded our pipeline with the initiation of our COVID-19 and flu vaccine programs. We continued to progress our existing pipeline and collaborations, and have, with our manufacturing partners, manufactured current good manufacturing practice ("cGMP") batches yielding significant quantities of clinical trial materials for ARCT-810 (LUNAR-OTC) and ARCT-021 (LUNAR-COV19 Vaccine), which includes lyophilized vaccine.

We intend to advance ARCT-021(LUNAR-COV19 Vaccine) into Phase 3 and to request Emergency Use Authorization ("EUA"), commence a Phase 2 multiple-dose study of ARCT-810 in OTC-deficient patients in mid-2021, file an Investigational New Drug ("IND") or Clinical Trial Application ("CTA") for a first in human study in Q4 2021 for ARCT-032 (LUNAR-CF), and evaluate in preclinical studies the efficacy and safety of a seasonal influenza vaccine. We are focused on expanding our portfolio of internally-owned and partnered programs to advance our clinical and preclinical candidates in a timely and cost-effective manner.

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.

Recent Business Development Activities

In March 2020, we partnered with Duke-NUS Medical School to develop a COVID-19 vaccine for the Singapore Economic Development Board ("EDB") based on the Company's STARR Technology and designated the vaccine candidate LUNAR-COV19 (ARCT-021). Duke-NUS Medical School is a graduate entry medical school in Singapore, established in 2005 through a partnership between Duke University School of Medicine and the National University of Singapore ("NUS").

On March 4, 2020, we were awarded a grant of S$14.0 million (approximately US$10.0 million using the exchange rate at the time the grant contract was entered into) from the EDB to support the co-development of ARCT-021 with Duke-NUS Medical School. In exchange for the grant, we agreed to supply ARCT-021 to the EDB for use within Singapore and we retained the right to sell and market ARCT-021 outside of Singapore. We have agreed to pay Duke-NUS Medical School a low single digit royalty based on annual net sales of the vaccine in markets or jurisdictions outside of Singapore.

On August 17, 2020, we entered into a definitive Supply Agreement (the "Supply Agreement") with the Israeli Ministry of Health ("MOH") which provides for the supply of ARCT-021 to the MOH. The MOH has elected to reserve delivery by us of doses of ARCT-021 for an initial 500,000 vaccinations (the "Initial Reserve Doses"). The Supply Agreement also provides the MOH with the right to elect, in its discretion, to purchase additional doses of ARCT-021 upon notice to us prior to specified dates at specified purchase prices. On October 14, 2020, we received a non-refundable first reserve payment of $12.5 million from the MOH. This payment serves as partial

payment for the Initial Reserve Doses. The Supply Agreement is described more fully below in the section titled “Other Material Agreements.”

On October 2, 2020, we were awarded a grant from the EDB to support the further development of our LUNAR-COV19 vaccine candidate. The grant provides for up to S$9.3 million (approximately US$6.7 million) to support the development of the vaccine candidate. The grant is payable in two installments upon the achievement of certain milestones related to the progress of the development of the vaccine candidate. The Company received the first installment of approximately $3.6 million in the fourth quarter of 2020.

In November 2020, we announced a manufacturing support agreement with the EDB that includes a limited recourse loan of up to S$62.1 million, which was subsequently borrowed in full during January 2021 in an amount equivalent to $46.6 million. The manufacturing support agreement is described more fully below in the section titled “Other Material Agreements.”

In February 2021, we entered into an exclusive license agreement with Alexion Pharmaceuticals, Inc. (“Alexion”) pursuant to which Alexion granted to us an exclusive, worldwide license to exploit certain specified Alexion patents. The exclusive license agreement is described more fully below in the section titled “Other Material Agreements.”

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 this class of therapeutics are being developed by public and private companies. These therapies have three general objectives:

- to reduce the amount of a target protein in a patient by binding to and destroying the associated target mRNA (antisense and small interfering RNA (“siRNA”));
- to increase the amount of a functioning target protein by introducing a functional gene or mRNA that encodes for a protein that replaces a malfunctioning protein (mRNA therapy, CRISPR, gene therapy, replicon); and
- to introduce proteins from viruses or malfunctioning proteins in certain cancers to train the immune system to recognize and clear these proteins (nucleic acid vaccines).

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. We have developed a novel lipid-mediated delivery system called LUNAR. LUNAR is a multi-component drug delivery system that incorporates a mixture of novel biodegradable 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, certain vitamins (such as A, D, E and K), hormones and most of the cell membrane that is not made up of protein. LUNAR is designed to address technical challenges facing the delivery of nucleic acid medicines into cells. We continue to expand our library of proprietary lipids, with over 200 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 formulation process is scalable and reproducible. Our LUNAR platform is described in more detail below.

STARR™

Our STARR technology platform combines self-replicating RNA with our lipid-mediated delivery system, LUNAR, into a single solution to produce proteins inside the human body. The STARR technology has the potential to generate a protective immune response or drive therapeutic protein expression to potentially prevent against or

treat a variety of diseases. Self-replicating RNA-based prophylactic vaccines developed with STARR have the potential to trigger rapid and prolonged antigen expression within host cells resulting in protective immunity against infectious pathogens. We believe this combination of LUNAR and STARR technology may provide lower dose requirements due to superior immune response, sustained protein expression compared to non-self-replicating RNA-based vaccines and potentially enable us to produce vaccines more quickly and simply. Our STARR platform is described in more detail below.

Our Development Programs

Arcturus' Internal Programs Pipeline

Franchise	Product Name	Indication	Route of Administration	Cell Target	Prevalence Worldwide	Stage	Anticipated Milestones
VACCINES	**LUNAR-COV19** (ARCT-021)	COVID-19	Intramuscular	Myocytes & Dendritic Cells	Global	Phase 2	Phase 3 Initiation Q2 EUA H2 2021
	LUNAR-FLU	Influenza	Intramuscular	Myocytes & Dendritic Cells	Global	Preclinical	IND/CTA H1 2022
HEPATIC	**LUNAR-OTC** (ARCT-810)	Ornithine Transcarbamylase Deficiency	Intravenous	Periportal Hepatocytes	> 10,000	Phase 1b	Phase 2 Multiple Dose Study CTA Q2 2021
RESPIRATORY	**LUNAR-CF** (ARCT-032)	Cystic Fibrosis	Inhaled	Bronchial Epithelial Cells	> 70,000	Preclinical	CTA Q4 2021

EUA = Emergency Use Authorization; CTA = Clinical Trial Application; IND = Investigational New Drug Application

Vaccines to Prevent Infectious Disease

According to the National Foundation for Infectious Diseases in a typical year, over 50,000 people die each year due to vaccine-preventable diseases in the United States alone. According to the Centers for Disease Control and Prevention, influenza and pneumonia cases alone approach this number of deaths each year. With the SARS-CoV-2 pandemic, more than 500,000 US citizens have died of COVID 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 current pandemic has highlighted the efficacy, safety, and rapidity in which nucleic acid medicines can be used to vaccinate vulnerable populations. We are a leader in self-amplifying mRNA vaccine development. In 2020, we progressed the rapid development of a self-amplifying mRNA vaccine to the Coronavirus that showed favorable safety and immunogenicity in Phase 1/2 trials after a single dose and have begun dosing in a Phase 2 trial. Other pharmaceutical companies are clinically investigating self-amplifying mRNA SARS-CoV-2 vaccines as well, including GSK (Phase 1), and Pfizer (Phase 1). We have also expanded our vaccine program to include seasonal influenza with a goal of beginning safety and immunogenicity trials in humans during the 2021/2022 influenza season.

Out internal programs include our LUNAR-COV19 and LUNAR-FLU vaccine programs as further described below. The recent coronavirus pandemic has proven that mRNA vaccines can be highly efficacious and nimble, allowing for adjustments in antigenic sequences in record time.

ARCT-021 (LUNAR-COV19 Vaccine)

Coronaviruses are a family of viruses that can lead to respiratory illness, including Middle East Respiratory Syndrome (MERS-CoV) and Severe Acute Respiratory Syndrome (SARS-CoV). Coronaviruses are transmitted between animals and people and can evolve into strains not previously identified in humans. On January 7, 2020, a novel coronavirus was identified as the cause of pneumonia cases in Wuhan City, Hubei Province of China. On February 11, 2020, the World Health Organization announced the official name for the disease caused by SARS-CoV-2 virus (2019 novel coronavirus outbreak) as coronavirus disease 2019, commonly abbreviated as COVID-19. The spread of COVID-19 has resulted in more than two million disease-related deaths across the globe.

Swift alert by health authorities and broad measures to contain the virus have not been entirely successful. The development of effective vaccines and swift implementation of vaccinations will be key in stopping the spread of the COVID-19 pandemic. Recent EUAs for COVID-19 vaccines from other companies have been backed by data from clinical trials supporting vaccine efficacy. Durability of COVID-19 vaccines, including capability to prevent disease covered by SARS-CoV-2 variants, is an important consideration. We expect both humoral and cellular immunogenicity to play a key role in providing durable and broad protection against COVID-19 and its variants.

Our COVID-19 vaccine candidate, ARCT-021, developed in conjunction with Duke-NUS Medical School, is based on our STARR technology platform. The vaccine is designed to promote immune responses to the spike protein of the SARS-CoV-2 virus, which is the critical part of the virus that allows infection to occur.

We have commenced dosing with the ARCT-021 candidate in three clinical trials: one first-in-human Phase 1/2 study (ARCT-021-01), one open label extension study to the same study (ARCT-021-02), and a Phase 2 study (ARCT-021-04).

The first of these studies (ARCT-021-01) was a randomized, blinded, placebo-controlled study exploring single and two-dose regimens of ARCT-021 (dose range: 1 to 10 µg ARCT-021 single dose, 3 to 5 µg ARCT-021 two dose) in younger and older healthy adults. This study enrolled participants in a series of cohorts based on participant age, intended ARCT-021 dose for study, and based on one or two-dose administrations. The study has completed enrollment of 106 participants, and some of these participants have transitioned to the ARCT-021-02 study, which is actively enrolling and is expected to complete in 2022. An interim analysis was perfomed based on unaudited data from the single dose cohorts and the 5µg two-dose older and younger adult cohorts. At the time of the analysis all included participants had completed at least 28 days after their last dose of study vaccine.

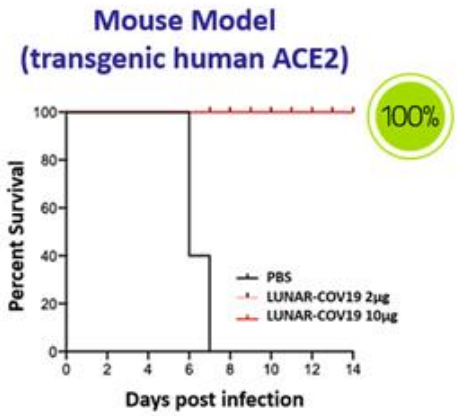
The interim analysis data from the ARCT-021-01 study were submitted to the Singaporean Health Science Authority (“HSA”) and the US FDA prior to approval to initiate enrollment in the Phase 2 study (ARCT-021-04).

Key findings from the ARCT-021-01 interim analysis include: primarily mild-to-moderate adverse events following vaccination in younger and older adults, no vaccine-related serious adverse events, dose-related increases in binding antibody responses after single dose administration in younger and older adults at all doses evaluated, demonstration of neutralizing antibody responses after single dose administration in younger and older adults that fell within the range of titers from COVID-19 convalescent antibody responses measured on the same assay (PRNT50), and Th1- biased T cell activation following single dose administration in younger and older adults.

The Phase 2 study (ARCT-021-04) is a randomized, placebo-controlled study designed to evaluate the safety and immunogenicity of three different dosing schedules in a broader population of healthy younger and older adults. The doses and schedules for additional exploration include: 5 µg ARCT-021, two dose regimen and 7.5 µg ARCT-021, as one- and two-dose regimens. We have dosed over 500 participants across the United States and Singapore.

The next planned clinical study is the Phase 3, placebo-controlled efficacy study of ARCT-021 (ARCT-021-05). We are presently preparing to advance with a 5 µg single dose regimen, to be confirmed based on pending Phase 2 data. We expect that this study will initiate enrollment in Q2 2021 and will be executed in several countries with significant SARS-CoV-2 outbreaks. Based on study recruitment and occurrence of COVID-19 cases in enrolled participants, we expect data establishing vaccine efficacy to prevent COVID-19 to be available in the latter part of 2021 and expect to analyze and submit an application seeking an EUA in one or more jurisdictions based on this data. We plan for the study to continue execution into 2022, at which point we expect to use the data to seek full licensure of the ARCT-021 study.

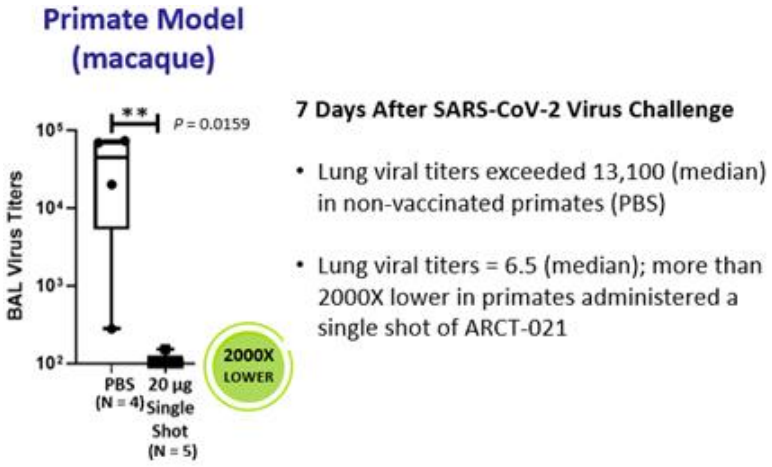
ARCT-021 Significantly Effective in Challenge Models



ARCT-021 was shown to be significantly effective in a virus challenge study in the human ACE2 transgenic mouse model. The single dose provided complete protection from SARS-CoV-2 infection and death, compared to control mice which experienced 100% mortality.

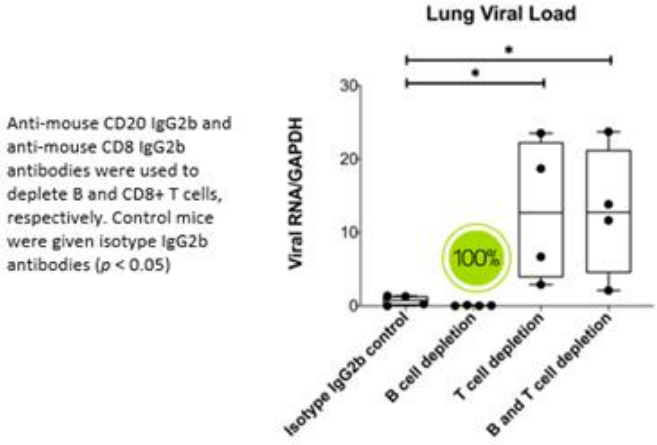
Transgenic mice expressing a human ACE2 receptor received a single vaccination of either 2 µg or 10 µg of ARCT-021 RNA. Mice were challenged with a lethal dose of SARS-CoV-2 clinical isolate 28 days after vaccination. 100% of vaccinated by at both doses survived for at least 14 days after challenge whereas unvaccinated mice died by day 7. The vaccinated mice showed absolutely no clinical signs up to day 14 post challenge which was the study termination date.

In September 2020, a rhesus macaque immunogenicity and a SARS-CoV-2 virus challenge study sponsored by the National Institutes of Health ("NIH") and the National Institute of Allergy and Infectious Diseases was initiated. Non-human primates were immunized with either a single injection of 20 µg or 40 µg RNA dose, or two injections of a 5 µg or 20 µg RNA dose administered 28 days apart, and challenged with SARS-CoV-2 virus 42 days post single vaccination and 14 days post boost vaccination. A single vaccination of 20 µg RNA dose yielded a >1,000 fold reduction in virus in the lungs. Two injections of 5 µg reduced virus infection by >5,000 fold and virus was undetectable in non-human primates after two injections of 20 µg RNA. The amount of virus in the lungs from bronchioalveolar lavage vs. RNA dose is shown in the figure below.



The results showed that a single administration of ARCT-021 was significantly effective in the primate model (macaque); vaccinated macaques show substantial (3.30 log lower) reduction in median lung viral titers.

T Lymphocyte Mediated Immunity Is the Major Contributor to Protective Immunity Against Virus Challenge in Transgenic Mouse Model



Human ACE2 receptor transgenic mice were vaccinated with a single 1 µg dose and challenged with sublethal virus load 21 days post vaccination. In one treatment group, B lymphocytes, responsible for producing virus neutralizing antibodies, were depleted three days prior to vaccination. In a second group, T lymphocytes, responsible for killing cells infected with virus, were depleted three days prior to virus challenge. In a third group, B cells were depleted 3 days prior to vaccination and T cells were depleted three days prior to virus challenge. The above figure shows that no virus was detected in the lungs of mice depeted of B cells, marked as 100%, whereas mice depleted of T cells had an equivalent amount of virus as mice with depleted B cells and T cells, demonstrating that ARCT-021 induced cell mediated immunity plays a major role in conveying protective immunity against SARS-CoV-2 infection.

Studies have shown T cells to be more durable (approximately six times longer-lasting) than antibodies (Bert, et al. *Nature*, 2020). In another study performed by Public Health England, T cell counts of thousands of frontline workers were monitored for four months. High T cell activities significantly correlated (p =0.0006) with protection from COVID-19 infection even when no antibodies against SARS-CoV-2 could be detected.

mRNA platforms have the advantage of being able to more nimbly adapt to new viral strains. We are closely evaluating COVID-19 variants, especially those strains that appear to evade the neutralizing antibodies to the original Wuhan strain such as the South African variant (B.1.351). A study in non-human primates conducted by Dan Barouch (et al) of Harvard Medical School found that T-cell responses are important for COVID-19 vaccines, and in particular for strains that evade the neutralizing antibodies to the original Wuhan strain. As shown above, ARCT-021 has shown robust cellular immunity, and we will gain a better understanding of ARCT-021's coverage of COVID-19 variants as we continue to collect clinical data.

LUNAR-FLU

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 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 program has the objective of producing a safe and effective seasonal 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. Also, mRNA vaccines do not face the challenge from mutations common to egg-grown vaccines.

LUNAR-FLU candidates will be evaluated preclinically in 2021 to support the goal of IND/CTA submission in the first half of 2022.

Rare Disease Medicines in Development

The Orphan Drug Act defines a rare disease as a disease or condition affecting fewer than 200,000 individuals in the United States. According to the NIH, there are approximately 7,000 such diseases, that together affect nearly 30 million people in the United States. The European Union defines a rare disease as having a prevalence of fewer than 5 in 10,000 people. Collectively, these disorders affect between six and seven percent of the population in the developed world.

There is a pressing need for new medicines for rare diseases as few of the 7,000 rare diseases have approved treatments. Biopharmaceutical industry researchers are making great progress in the fight against rare diseases as innovative science has opened new opportunities. There have been incredible advances in the development of medicines to treat patients with rare diseases as researchers uncover the molecular and genomic drivers of many conditions. More than 770 medicines have been approved by the FDA since the enactment of the Orphan Drug Act in 1983 and more than 800 medicines are currently in clinical development. Despite recent progress, there is still much more work to be done.

Developing medicines to treat rare diseases presents scientific and operational challenges. We believe our technology provides an excellent platform to address genetically inherited rare diseases, and we are focusing on development of medicines to treat people with rare respiratory and liver diseases who currently have limited or no treatment options.

ARCT-810 (LUNAR-OTC)

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

OTC deficiency causes the body to accumulate ammonia, which is neurotoxic and harmful to the liver. OTC deficiency is the most common of the urea cycle disorders, a group of inherited metabolic disorders that make it difficult for affected patients to remove toxic waste products as proteins are broken down. OTC deficiency is a life-threatening genetic disease. OTC is a critical enzyme in the urea cycle, which takes place in liver cells, and converts ammonia to urea. This conversion does not occur properly in patients with OTC deficiency and ammonia accumulates in their blood, acting as a neurotoxin and liver toxin. High ammonia levels in the blood can cause severe symptoms including vomiting, headaches, coma and death. OTC deficiency is an inherited disease that can cause developmental problems, seizures and death in newborn babies. It is an X-linked disorder, and consequently more common in males. 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 risk of complications such as organ rejection, and transplant recipients must take immunosuppressant drugs for the rest of their lives. Current standard of care for OTC patients is a low-protein diet, dietary supplements and ammonia scavengers to try and prevent accumulation of ammonia. Life-threatening episodes of high ammonia levels can 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, where OTC is produced and functions, to 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. LUNAR-OTC has received orphan drug designation from the FDA for treatment of OTC deficiency. Worldwide development and commercialization rights to ARCT-810 are entirely held by Arcturus.

Preclinical data in OTC deficiency murine models has demonstrated that dosing of LUNAR-OTC results in robust OTC protein expression and activity, thereby improving ureagenesis, reducing plasma ammonia and increasing survival. We submitted an IND application to the FDA for a Phase 1b study in patients with OTC deficiency, and an additional CTA for a Phase 1 study in healthy volunteers was approved by the New Zealand Medicines and Medical Devices Safety Authority. In April 2020, we announced that we were deemed allowed to proceed with the studies.

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

A Phase 1b study in OTC-deficient patients in the United States opened for enrollment, with dosing initiated in the first subject in December 2020. The trial will enroll approximately 12 patients and is designed to assess safety, tolerability and pharmacokinetics, as well as various exploratory biomarkers of drug activity. The trial currently consists of nine sites in the United States. We have received approval from Health Canada to conduct the trial in Canada and are working with sites in Canada in preparation for enrollment. We intend to commence a Phase 2 multiple-dose study of ARCT-810 in OTC-deficient patients in mid-2021.

ARCT-032 (LUNAR-CF)

The LUNAR-CF program addresses cystic fibrosis lung disease, a progressive lung disease caused by mutations in the cystic fibrosis transmembrane conductance regulator ("CFTR") gene. In December 2020, we announced the selection and advancement of ARCT-032 as a development candidate for treatment of cystic fibrosis. ARCT-032 uses our LUNAR platform to deliver codon-optimized CFTR mRNA into airway epithelial cells. This allows airway cells to produce functional CFTR protein using their native translational machinery and protein trafficking pathways. This approach has the potential to treat the underlying defect that causes CF lung disease,

regardless of what mutation type a patient has. The Cystic Fibrosis Foundation ("CFF") has recognized the potential of the LUNAR-CF program and has partnered with us to develop this important therapy. ARCT-032 represents the first LUNAR-based mRNA therapeutic that will be delivered by the inhaled route, offering direct delivery to the affected airways with the potential to restore functional CFTR. We received encouraging pre-IND feedback on our proposed non-clinical and clinical development program in January 2021. We anticipate filing a CTA for a first in human study in Q4 2021.

According to the NIH, cystic fibrosis is the most common rare disease in the world, with an estimated 30,000 diagnosed cases in the United States and 85,000 worldwide. Approximately 1,000 people are newly-diagnosed with cystic fibrosis each year. Cystic fibrosis is caused by one of 2,000 known mutations in the CFTR gene, which have been grouped into several different classes based on the mechanism of how they cause reduction in the production and/or function of the CFTR protein.

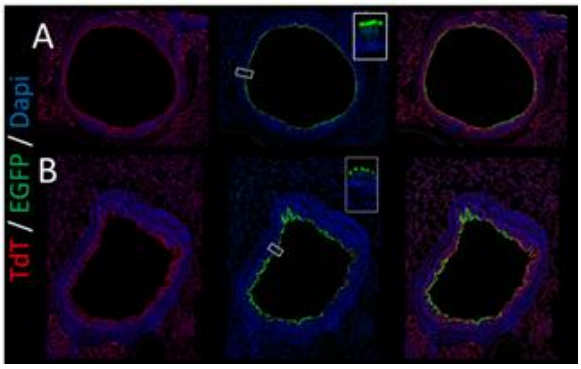
The CFTR protein is a cAMP-activated transmembrane protein that controls chloride and bicarbonate flow and is critical for lung homeostasis. When CFTR is not present in the membrane or does not function properly, there is a deficit in the release of chloride and bicarbonate anions into the airways, and an associated increase of sodium uptake by the cells, thus dehydrating the airway surfaces and causing accumulation of a thick mucus layer. This mucus causes clogging of the airways, a negative impact on breathing quality, and decreases the clearance of pathogens which accumulate in the airways, causing chronic infections, exaggerated inflammation, structural airway damage, and other serious complications not only related to the lung but to other organs such as pancreas and liver. The median lifespan of CF patients in the United States is <40 years, and the cause of death is usually lung-related.

The daily standard-of-care for CF lung disease includes palliative treatments meant to treat existing lung disease and 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 the mutant CFTR protein to reach the cell membrane and/or increase functional ion channel activity. The CFTR modulators, while effective in some patients, are mutation-specific and therefore are not effective in all people 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 focusing our LUNAR-CF program on these groups of patients, as they currently have the highest unmet need for CF therapies.

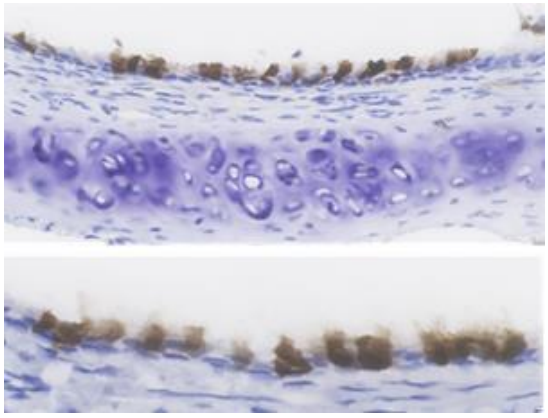
We presented data that demonstrated the significant potential for LUNAR-CF as a disease-modifying treatment at The American Society for Gene and Cell Therapy Conference in May 2020, and the North American Cystic Fibrosis Conference in October 2020. The data presented demonstrated that (i) aerosolized LUNAR-mRNA formulation properties are optimal for lung therapeutics, (ii) codon optimized mRNAs produce a functional protein that can generate chloride channel activity in FRT cells, and can also restore chloride channel activity (measured by nasal potential difference) in a Class I CFTR-knockout mouse model, and (iii) aerosolized LUNAR can efficiently deliver mRNA to epithelial airways across species, including rodents and non-rodents (ferrets, non-human primates). Taken together, these data demonstrate the proof of principle to validate LUNAR-CF, as we continue investigating various aspects of LUNAR-CF in several disease models of CF.

LUNAR construct with mRNA of CRE protein efficiently transduces epithelial airways in a non-rodent model (Ferret)



In ferret, a 0.6 mg/ml dose of a LUNAR construct loaded with mRNA of the CRE protein was delivered to the airways of the ROSA26TG model. Upon CRE-recombination, a robust conversion of the TdTomato (red) into EGFP (green) was observed by immunohistochemistry analysis of the ferret lungs. Panels A and B show large and small airways, respectively. Boxed area in EGFP (green) images show high magnification of the highly efficient delivery into ferret airways. DAPI is shown as counterstaining.

Aerosolized LUNAR construct with Tdtomato mRNA efficiently delivers to epithelial airways in Non-human Primates (NPHs)



In NHP, a 1 mg/ml dose of a LUNAR construct loaded with TdTomato mRNA was aerosolized using a face mask exposure system. A robust expression of TdTomato protein was observed by immunohistochemistry analysis of the NHP lungs. The panel shows detailed TdTomato staining in bronchial epithelial cells across different lung levels.

Platform Technology Overview

Current Technologies and Limitations

mRNA therapeutics offer an attractive promise that other RNA medicines cannot provide – to increase the production of a protein in the body that is either defective or expressed at low levels to improve symptoms of a genetic disease without interacting with the patient's genetic code. The promise of mRNA therapies is only beginning to be realized with the approval of the first two mRNA vaccine therapies in 2020. Developers of mRNA therapies should strive to improve ways to address the following hurdles:

- delivery of an intact mRNA, which is much larger than other RNA drugs (e.g., small interfering RNA, siRNA) to the target organ and cell type needed for a therapeutic effect;
- inefficient translation into the therapeutic protein;
- short duration of effect of the mRNA medicine; and
- tolerability issues associated with therapeutic RNAs.

The first-generation lipid nanoparticle technology used to deliver mRNA therapeutics is also limited by their propensity to cause immune responses. This decreases the tolerability of the medicine. Many of these delivery systems biodegrade slowly, which causes accumulation of these lipids in cells upon repeat dosing. Each of these aspects of current lipid nanoparticle delivery systems is expected to ultimately limit the utility and therapeutic reach of the RNA therapies they deliver.

Arcturus aims to mitigate the immune response and tolerability issues associated with the LNP mRNA delivery with the development of both less immunogenic mRNAs and more rapidly biodegradable lipids. The Company has developed processes for the scale up of LNP-mRNA therapeutics to support clinical development. As described below, Arcturus' lipid-mediated delivery platform is designed to address many of the technical issues encountered to date for this very promising area of RNA medicines.

Our Delivery Solutions

Our LUNAR lipid-mediated delivery technology includes a diverse, growing library of over 200 proprietary lipids that we are rationally designing to be versatile, maximizing potential efficacy and improving tolerability of a diverse selection of nucleic acids, target cell types and 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 experienced team continues to innovate in the area of producing LUNAR lipid formulated nucleic acid product candidates in a scalable and highly reproducible manner, reducing the costs of goods for the therapies in our pipeline.

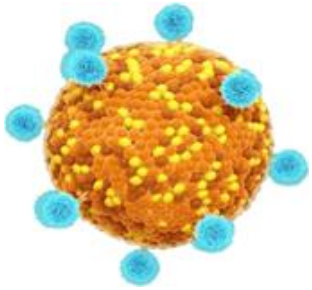
In addition to our LUNAR lipid-mediated delivery technology, we believe we have created innovative, proprietary advancements in producing mRNA medicines, including improvements that increase purity, scalability, efficiency in production times, and adaptability to different mRNA modification strategies.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

We continue to invest in our LUNAR lipid-mediated delivery of mRNA (encoding CRISPR, TALEN, zinc finger proteins, and meganucleases), siRNA, DNA, microRNA, and antisense oligonucleotide technology platforms to improve their efficacy and safety profile, further expanding their applications. This investment has led to key innovations ensuring optimal characteristics of our LUNAR formulated drug product candidates are attained, which we believe sets us apart from other nucleic acid therapeutics and lipid-mediated delivery platforms. As such, we consider ourselves a leader in systemically administered mRNA therapeutics.

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. See below for a graphic representation of our LUNAR formulation, where blue spheres represent polyethylene glycol lipids and the orange, darker orange, and yellow spheres represent the proprietary "ATX" lipid excipient and other structural components (phospholipid and cholesterol).

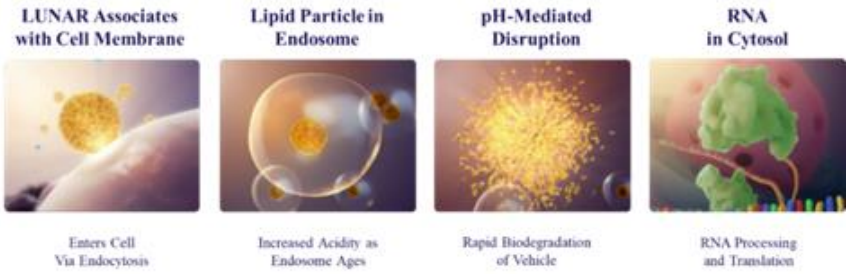
Graphic of LUNAR



LUNAR formulations are a multi-component, lipid-mediated drug delivery system that utilizes our proprietary lipids, called ATX lipids. Each of our ATX lipids contains an amino head group and a biodegradable lipid backbone. The amino 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 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), 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 amino head group again becomes positively charged, disrupting the endosome and the LUNAR particle, and releasing the nucleic acid therapeutic into the cell.

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 Company’s development of its LUNAR platform is focused on continuous innovation and advancement in the following areas:

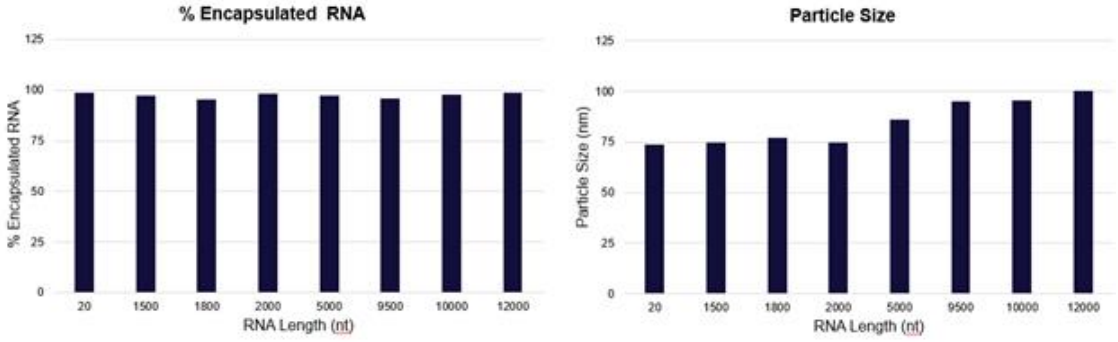
- Design and incorporate novel ATX lipids and formulations to enrich our library of proprietary ATX lipids for target cell/tissue specificity, improved tolerability and translatability to larger species;
- Develop and improvise manufacturing processes for LUNAR formulations to ensure RNA encapsulation across compositions and scales;
- Develop stabilization strategies (e.g. lyophilized presentation) for LUNAR formulation to mitigate frozen storage; and

- Continually assess and improvise LUNAR screening funnel to enable rigorous selection of ATX lipids for various programs.

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

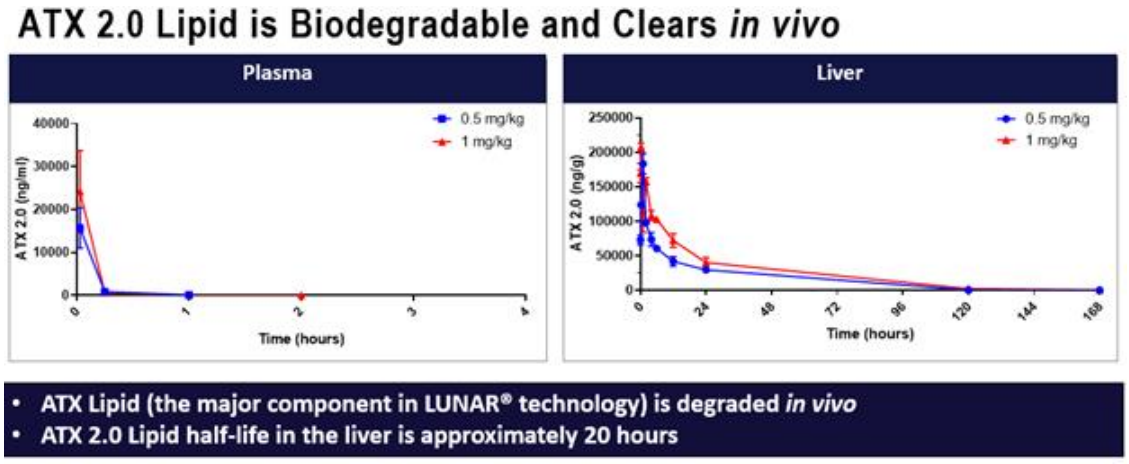
LUNAR compatibility with nucleic acids of various size

We have generated a growing library of over 200 proprietary ATX lipids. ATX lipids are rationally designed to fit the application 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 and LUNAR composition for the particular nucleic acid therapeutic candidate, the desired route of administration and target cell type. We have demonstrated high encapsulating efficiency when formulating a wide range of nucleic acid sizes, 20 to 12,000 nucleotides in length (figure below, left), and particle size was within the acceptable range to maximize targeting and efficacy (figure below, right).



LUNAR Biodegradability

Although all ATX lipids are designed with biodegradable ester bonds in their backbone, one of the key platform learnings is the understanding of the relationship between positioning of these ester bonds and their clearance profile *in vivo*. *In vitro* and *in vivo* screening assays are utilized in our LUNAR screening cascade to enable ranking of ATX lipids based on their esterase susceptibility. These new assays have enabled a more rigorous selection of ATX lipids. New ATX lipids with optimal biodegradability and potency continue to be identified and further characterized for potential application to upcoming therapeutic and vaccines programs.



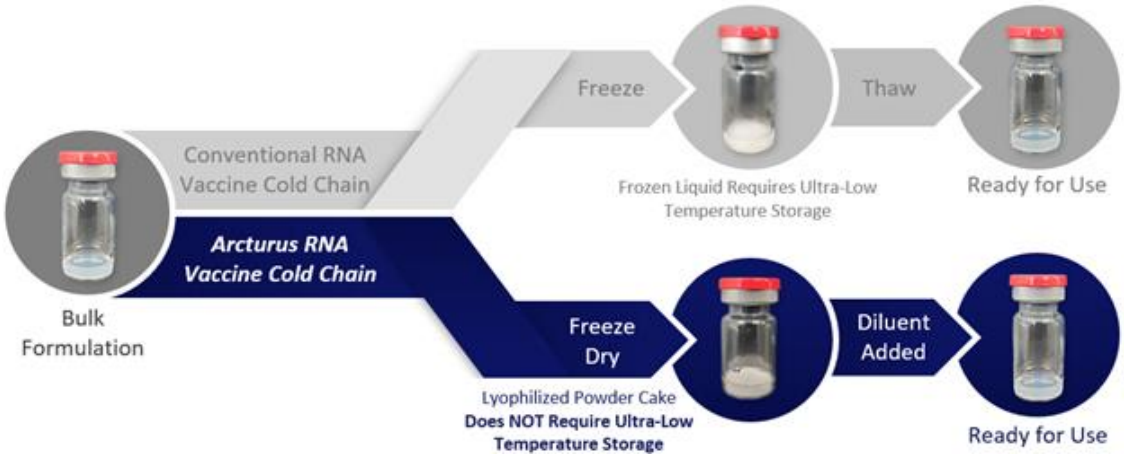
LUNAR Scalability and Reproducibility

We have demonstrated scalability and reproducibility of LUNAR. Multiple non-GMP and GMP batches of mRNA drug substance have been successfully produced from 0.5 to 30 gram scales with equivalent yield and purity.

Additionally, we have demonstrated scalability of our LUNAR-mRNA platform from milligram to multigram scales. LUNAR-mRNA batches have been successfully produced at scales from 0.1 to 15 grams while retaining key physicochemical attributes of particles.

Lyophilization Process Advantages Over Conventional Frozen Liquid

We have engaged in focused efforts to develop lyophilized LUNAR formulations, in order to mitigate challenges associated with cold chain logistics of a -70°C frozen product. A lyophilized product allows for simpler handling, such as no dry ice at point of care and lower risk of degradation from uncontrolled temperature fluctuations.



The results of these efforts have yielded a lyophilized version of ARCT-021 that maintains key quality attributes of the frozen liquid equivalent. We are collecting stability data at -20°C, 2-8°C, and room temperature.

Targeting Capabilities

As proof of concept for augmenting LUNAR targeting capabilities for specific tissues and even cell types within those tissues, we are developing LUNAR formulations containing a propriety hepatocyte targeting agent. Traditional lipid nanoparticle mediated delivery to hepatocytes occurs via uptake via the low-density lipoprotein receptor (“LDLR”). To evaluate this targeting agent, we ran studies in a mouse model that is LDLR deficient. Only the LUNAR formulations with this targeting agent were able to deliver mRNA to the hepatocytes, as compared to LUNAR formulations that did not contain the targeting agent. Based on this promising data, we are expanding these platform development efforts.

Our Proprietary mRNA and Protein Design Technology

The mRNA programs in our pipeline are benefited by 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 (conversion from mRNA to protein) 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 approaching 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.

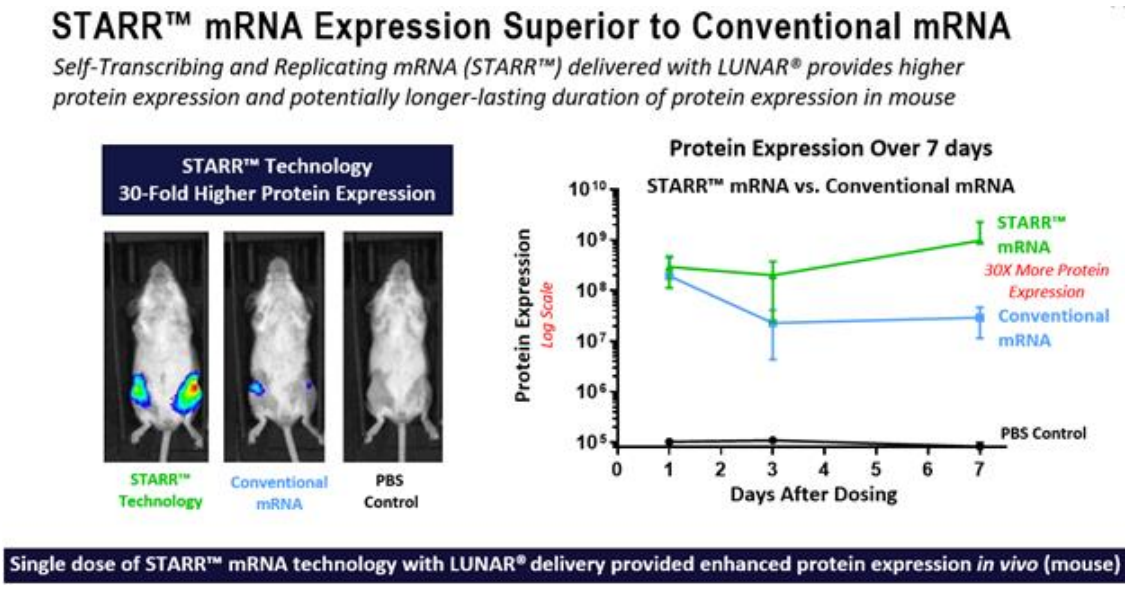
In addition to these platform technologies, we have developed a proprietary tool to aid our team in the efficient design and development of new mRNA drug candidates. Our mRNA Design Suite is a cloud-based software suite with a collection of proprietary bioinformatic algorithms aimed at achieving highly 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 QC 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

STARR is designed to increase the amount and duration of protein antigen expression compared to conventional mRNA. This is achieved by constructing an RNA that encodes for a replicon and a pathogenic protein antigen. The replicon segment encodes for genes derived from an alpha-virus, specifically Venezuela Equine Encephalitis Virus, that is responsible for amplifying the production of the pathogenic protein antigen mRNA. These are non-structural viral proteins, meaning they are not included in any virus particle and are completely incapable of producing any virus. However, upon translation they produce multiple copies of the pathogenic protein antigen which increases production of the protein. In addition, during the course of protein antigen mRNA replication, a short-lived double-stranded RNA intermediate is produced which activates the innate immune system. This activation transitions to an adaptive immune response resulting in the specific programming of the immune system, both neutralizing antibody production and T lymphocyte activation, which are important in preventing pathogen infection. The activation of the innate immune system by the double-stranded RNA intermediate serves as a self-adjuvanting feature, thus eliminating the need for the addition of an adjuvant to the vaccine.

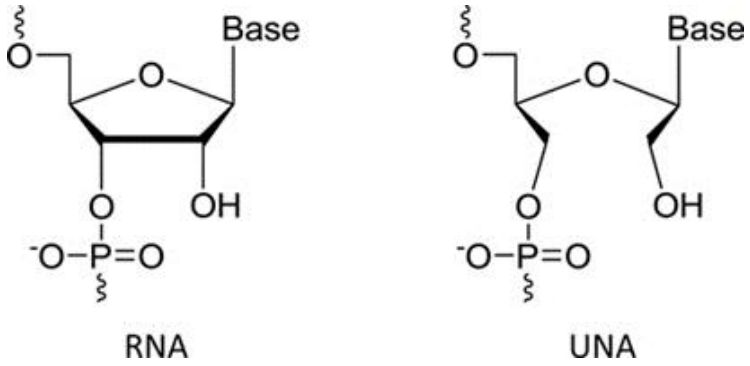
An example of generating a protected immune response is shown in the graphic below. The self-replicating RNA-based therapeutic vaccine triggers rapid and prolonged antigen expression within host cells resulting in protective immunity against infectious pathogens. We believe the combination of LUNAR and STARR technology could provide lower dose requirements due to superior immune response and sustained protein expression as compared to non-self-replicating RNA-based vaccines. We believe this may enable us to simplify and increase the speed of vaccine production.



Our Unlocked Nucleic Acid (UNA) Oligomer Chemistry

UNAs are RNA analogues in which the C2'-C3' bond of the ribose ring is absent (figure below). UNA chemistry technology can potentially be applied to multiple types of RNA medicines including mRNA, siRNA, microRNA and guide RNAs for gene editing. One or more UNAs can be positioned strategically along a nucleic acid strand to manipulate the chemical properties of the molecule.

RNA structure compared with UNA structure



UNAs can potentially improve the efficiency and specificity of siRNA-mediated protein suppression.

siRNAs are short double-stranded RNA molecules. Once inside the cell, they become part of the RNA-induced silencing complex (“RISC”) and are split into two single siRNA strands. One of these strands stays with RISC and binds to any mRNA with a complementary sequence. If the wrong siRNA strand stays with RISC, it can bind to different mRNAs than the target mRNA and therefore inhibit translation of other proteins. This is an undesired off-target effect and is one of the major barriers to developing effective siRNA medicines. Incorporating a single UNA into siRNA molecules can make one of the strands preferentially bind to RISC, which improves specificity. Additionally, incorporation of UNA modifications can reduce susceptibility of the siRNA to nuclease degradation, which improves the efficiency of siRNA-mediated protein suppression.

We own a comprehensive suite of UNA technology patents for therapeutic and reagent use, enabling us to operate freely and to independently pursue nucleic acid therapeutic candidates incorporating this technology. We are also actively pursuing other novel chemistry technologies with the aim of overcoming the development and therapeutic challenges of nucleic acid medicines. Our goal is to expand our nucleic acid technology portfolio and strengthen our ability to develop safer and more effective nucleic acid therapeutic candidates.

Supply and Manufacturing

We have built out robust manufacturing capabilities designed to meet global supply needs for clinical trials and future commercialization, with a network of established contract manufacturing organizations (“CMOs”) for producing critical raw materials, drug substance, and finished and packaged drug product. We have developed, and continue to dedicate resources to advance, our sophisticated manufacturing know-how, including with respect to formulation of lipid nanoparticles, which improves manufacturing efficiency and capacity. We are strategically exploring options to build our internal manufacturing capabilities for drug substance and finished drug product.

To date, we have manufactured and supplied gram quantities of drug substance, scaled up finished drug products through our CMOs for preclinical and clinical studies. For the near future, we expect to continue to rely on third-party CMOs for the supply of drug substance and finished drug product for our current product candidates, including to support the launch of our first commercial products.

Our CMOs are compliant with cGMPs and other rules and regulations prescribed by foreign regulatory authorities. We believe we have established sufficient manufacturing capacity through our CMOs 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.

Collaboration Arrangements

In addition to our internal development programs, we have a number of development partnerships structured where we work to discover mRNA or siRNA therapeutic candidates formulated for our LUNAR lipid-mediated delivery system. Among other collaboration agreements,

- we are partnering with Janssen to develop nucleic acid-based therapeutic candidates for the treatment of HBV, and potentially for other infectious or respiratory diseases;
- we are partnering with Takeda to develop nucleic acid-based therapeutic candidates, primarily for the treatment of nonalcoholic steatohepatitis ("NASH"), as well as other gastrointestinal disorders;
- we are partnering with Ultragenyx to develop mRNA therapeutic candidates for rare disease targets;
- we are partnering with CureVac to develop mRNA therapeutic and vaccine candidates for various indications;
- we have received funding from the CFF to support our LUNAR-CF development program; and
- we are partnering with the Singapore Economic Development Board and Duke-NUS Medical School to develop a potential vaccine for the Coronavirus outbreak.

Janssen Agreement

On October 18, 2017, we entered into a Research Collaboration and License Agreement with Janssen (the "Janssen Agreement") to collaborate on developing candidates for treating HBV with RNA therapeutics. Under the Janssen Agreement, Janssen and the Company will carry out their respective research obligations pursuant to agreed-upon joint research plans, and we may not engage in HBV-related research independent of the Janssen Agreement.

The Janssen Agreement provides that Janssen will develop the candidates licensed pursuant to the agreement, obtain certain regulatory approvals, and commercialize products containing the development candidates. Under the Janssen Agreement, both parties granted each other certain non-exclusive, royalty-free licenses to conduct the research covered by the agreement.

Under the Janssen Agreement, Janssen paid us an upfront fee of $7.7 million. On a development candidate-by-development candidate basis, Janssen will pay us certain development milestone payments of up to $56.5 million for each of the first two products to treat HBV and in each indication for which Janssen exercises its option to license certain therapeutics from us. In addition, on a research program-by-research program basis, Janssen will pay us between $20 million and $40 million in multiple sales milestone payments if they achieve certain annual net sales milestones in the first calendar year in which such milestones are achieved. Janssen will also pay between $1 million and $5 million in option exercise fees, with the precise amount depending on when Janssen exercises its license option. In addition, Janssen will pay royalties on annual net sales of licensed products up to a mid-single digit percentage, subject to (i) reduction on a country-by-country and licensed-product-by-licensed-product basis and (ii) certain events, such as expiration of program patents.

The Janssen Agreement will terminate when no further royalty payments on any licensed products are payable. Janssen may terminate the Janssen Agreement at any time on a licensed product-by-licensed product and country-by-country basis, or in its entirety, in each case upon 60 days' written notice.

Ultragenyx Agreement

On October 26, 2015, we entered into a Research Collaboration and License Agreement with Ultragenyx, which was later amended on October 17, 2017 and April 20, 2018 (as amended, the "Ultragenyx Agreement"). Ultragenyx initially selected two development targets, including Glycogen Storage Disease Type III, and the parties initially agreed to a list of eight additional reserved rare disease targets which Ultragenyx has an exclusive option to

select for collaborative development. The Ultragenyx Agreement provides for an exclusivity period, during which Ultragenyx may substitute a reserved target for a selected target, in which case such reserved target will be deemed an additional target and will preclude an additional reserved target in place of the newly reserved target. Further, during the exclusivity period, Ultragenyx may replace a reserved target with a proposed new target, subject to certain conditions, including whether we have the ability to partner with respect to such new target.

Under the Ultragenyx Agreement, we have granted Ultragenyx exclusivity (i) with respect to development targets, to the development and commercialization of products containing nucleic acid technology, and (ii) with respect to reserved targets and subject to the right of first negotiation described below, the development and commercialization of any product containing nucleic acid products or utilizing LUNAR lipid-mediated delivery technology.

During the reserved target exclusivity period and with respect to reserved targets, Ultragenyx has a right of first negotiation for any nucleic acid product utilizing LUNAR lipid-delivery technology with respect to such reserved targets. These restrictions terminate upon expiration of the reserved target exclusivity period for each target, which may be extended on a reserved target-by-reserved target basis upon payment of an exclusivity extension fee.

Following the reserved target exclusivity period and on a reserved target-by-reserved target basis, Ultragenyx has an exclusive right of first negotiation to obtain an exclusive license to exploit RNA products with respect to such reserved target. If we have not entered into an agreement with Ultragenyx by the time its exclusive right of first negotiation expires, its rights with respect to such reserved target terminate and we may grant a license or enter into an arrangement with a third-party with respect to such reserved target.

Under the Ultragenyx Agreement, we have granted Ultragenyx a co-exclusive, royalty-free, sublicensable license of our technology for conducting collaborative development of development targets, compounds and products. The license remains in effect for a specified option period based upon achievement of milestones with respect to development targets and reserved targets, and development of compounds and products with respect to such development targets and reserved targets. If Ultragenyx exercises its option with respect to a development target and we enter into a license with them, it will receive an exclusive, royalty bearing, sublicensable (subject to certain limitations) license to our technology to exploit compounds and products with respect to such development target.

For development targets and reserved targets that revert to us (“Discontinued Targets”), Ultragenyx will grant us an exclusive, worldwide, perpetual license to all technology developed pursuant to the Ultragenyx Agreement with respect to such Discontinued Targets. We will pay Ultragenyx royalties on net sales related to Discontinued Targets on a country-by-country basis until the expiration of the last valid claim, product-specific patents or patent rights covering such Discontinued Targets that we have licensed from Ultragenyx. The amount of any such royalties will depend on the state of development of the subject Discontinued Target and will be a low-single digit percentage.

In connection with the execution of the Ultragenyx Agreement, Ultragenyx paid us an upfront fee of $10 million. We are entitled to certain additional payments (i) for costs we incur in connection with our activities under agreed-upon collaborative development plans, and (ii) if Ultragenyx exercises its option to select additional reserved rare disease targets for collaborative development. For each development target for which Ultragenyx exercises this option, it will pay us a one-time option exercise fee, which will vary depending on the total number of development targets for which it has exercised such option. The option exercise fee is subject to reduction if a development target does not utilize certain of our patented RNA-delivery technology or nucleic acid chemistry technology.

Ultragenyx will also pay us certain milestone payments with respect to clinical/regulatory development (not to exceed $49 million per development target), and commercialization (not to exceed $90 million per development target), in each case subject to reduction if the relevant development program does not utilize technology covered by certain of our patents.

During the applicable royalty term, Ultragenyx will also pay royalties as a percentage of net sales (not to exceed 10%) on a product-by-product and country-by-country basis.

The Ultragenyx Agreement provides that each party owns any intellectual property that it develops independently, and that any intellectual property developed jointly on behalf of both parties will be owned jointly, provided that (i) Ultragenyx will own all collaboration technology that specifically relates to (i) the composition or

formulation of a particular compound or product, or (ii) any method of using, making or administering a particular compound or product, and (ii) we will own all improvements to LUNAR lipid-mediated delivery technology and/or UNA oligomer chemistry.

Unless terminated earlier, the Ultragenyx Agreement expires upon the expiration of the last-to-expire royalty term for any product, on a development target-by-development target basis. Upon expiration with respect to a particular development target, our license of technology to Ultragenyx to exploit products with respect to the relevant development target will become fully paid-up, irrevocable and exclusive. On a target-by-target basis, Ultragenyx has the right to terminate for convenience upon 60 days' written notice.

On June 18, 2019, we expanded our collaboration with Ultragenyx and entered into a third amendment (the "Third Amendment") to the Ultragenyx Agreement. Pursuant to the Third Amendment, the total number of targets was increased from 10 to 12, and we granted Ultragenyx exclusivity to development targets for four years at no additional cost. In connection with the Third Amendment, Ultragenyx purchased 2.4 million shares of our common stock for $24.0 million and made a one-time upfront payment of $6.0 million. Ultragenyx also received a two-year option to purchase an additional 600,000 shares of our common stock at a price of $16.00 per share.

Additionally, until the later of (i) the first anniversary of the closing date or (ii) the date on which Ultragenyx beneficially owns less than 8.0% of the total voting power of the Company, at each annual shareholders' meeting or any shareholders' meeting at which board members are to be elected, we must nominate one director designated by Ultragenyx (the "Ultragenyx Designee"). Additionally, the Ultragenyx Designee is required to be appointed to all board committees (subject to applicable Nasdaq rules). Ultragenyx also has the right to have its designee attend board meetings as a non-voting observer. Karah Parschauer, the Executive Vice President and Corporate Counsel of Ultragenyx, joined the board in June 2019 as the Ultragenyx Designee.

On June 18, 2019, we entered into an Equity Purchase Agreement with Ultragenyx. Pursuant to this agreement, we granted Ultragenyx a two-year option to purchase up to 600,000 additional shares of our common stock at a price of $16.00 per share. On May 20, 2020, Ultragenyx completed the exercise of this option to purchase an additional 600,000 shares of common stock in accordance with the terms of the agreement. The issuance of the additional 600,000 shares closed on May 20, 2020.

CureVac Agreement

On January 1, 2018, we entered into a Development and Option Agreement with CureVac, which was amended on May 3, 2018 and later restated on September 28, 2018 (as amended and restated, the "Development and Option Agreement"). Under the terms of the Development and Option Agreement, CureVac and Arcturus agreed to conduct joint preclinical development programs and we granted CureVac a license to develop and commercialize certain products incorporating certain of our technology (the "Arcturus LMD Technology") and CureVac technology. The products subject to the Development and Option Agreement relate to certain targets to be identified during the term of the agreement. In consideration for the rights granted under the Development and Option Agreement, we received an upfront fee from CureVac.

In connection with the Development and Option Agreement, we granted CureVac a worldwide, non-exclusive, sublicensable license to use the Arcturus LMD Technology for the purpose of conducting research and preclinical development activities, subject to certain limitations. In addition, CureVac granted to us a worldwide, non-exclusive license to its mRNA technology to the extent necessary for us to execute the activities contemplated by the Development and Option Agreement. Subject to certain restrictions, the Company and CureVac each have an undivided one-half interest in the patents and know-how developed jointly during the course of the Development and Option Agreement. The amended and restatement of the Development and Option Agreement provided for (i) an increase in the number of targets available to CureVac and (ii) agreed-upon license forms to be executed upon selection of targets by CureVac.

Subject to certain limitations, CureVac may designate certain targets as reserved targets. To the extent a reserved target is only available on a non-exclusive basis, CureVac may elect to enter into a non-exclusive license agreement on a pre-negotiated form to be executed upon identification of the relevant target. CureVac is required to pay us a fee for any license (exclusive or non-exclusive), the amount of which depends on whether the target involves a rare or non-rare disease. Each development program with CureVac is subject to the terms of a work plan, pursuant to which the Company and CureVac will work to develop certain products.

Pursuant to the form of license agreement, if CureVac achieves all development and commercialization milestones with respect to the licensed product developed for an identified target, it is required to (i) pay certain development and regulatory approval milestones, the amount of which depends on whether the target involves a rare or non-rare disease, and (ii) royalties in a low-single digit percentage on the net sales of each product subject to a license agreement on a country-by-country and product-by-product basis. Such royalties are subject to reduction for third-party payments with respect to licensed products or if there is no valid claim under the licensed patents, but may not fall below a specified percentage if the licensed product during the royalty term is not covered by a licensed patent. Further, if within 24 months after the license agreement effective date, CureVac grants a sublicense to a third party for the development and commercialization of the licensed products, then CureVac will pay us a single-digit percentage of the total sublicense income that it receives to the extent that such income exceeds (i) the fee paid by CureVac under the Development and Option Agreement to identify a target for such license agreement and (ii) the milestone payments paid by CureVac under such license agreement. The fees, milestones and royalty payments for a non-exclusive license are 50% of the corresponding payments for an exclusive license.

The Development and Option Agreement had an initial term of eight years, unless earlier terminated or extended in accordance with its terms. Within 60 days prior to the expiration of the initial term, CureVac has the option to extend the initial term of the agreement on an annual basis for up to a total of three successive years upon payment of an annual non-refundable extension fee. CureVac has the right to terminate the agreement in full or on a program-by-program basis (i) upon a material breach by us that is not cured within a certain period, (ii) upon a change in control of Arcturus, or (iii) without cause upon 60 days' notice to us. We have the right to terminate the agreement upon material breach by CureVac that is not cured within a certain period. Upon termination, all licenses granted under the Development and Option Agreement will terminate, but any license agreement entered into pursuant upon the identification of a target will remain in effect.

On February 11, 2019, we announced the termination of our obligations to CureVac for the preclinical development of ARCT-810, effective August 4, 2019, and the re-assumption of our worldwide rights thereto. On July 24, 2019, the Company and CureVac entered into an amendment to the Development and Option Agreement, pursuant to which we agreed to (i) shorten the time period during which CureVac may select potential targets to be licensed from the Company from eight years to four years, and (ii) reduce the overall number of maximum targets to be reserved and licensed to 10 targets. Additionally, we canceled our related Co-Development and Co-Commercialization agreement for developing and commercializing ARCT-810.

Other Collaboration Agreements

On December 6, 2016, we entered into a Research Agreement (as amended, the "Takeda Agreement") with Takeda. Under the Takeda Agreement, we conducted a joint research program (the "Research Program") with Takeda to discover siRNA medicines for the treatment of NASH. The program involved development of siRNA compounds formulated in LUNAR lipid-mediated delivery technology for *in vivo* studies. Pursuant to the Takeda Agreement, Takeda had a non-exclusive, worldwide sublicensable license to our technology until December 20, 2018 (the "Research Term") for the purpose of conducting the Research Program. We also agreed not to engage in any research or development activities involving LUNAR and UNA oligomers for any NASH targets involved in the Research Program for two years after the Research Term.

On March 8, 2019, we entered into a subsequent Research Agreement with Takeda, which was subsequently amended on June 3, 2019 (as amended, the "New Takeda Agreement"). Under the New Takeda Agreement, Takeda received a non-exclusive, worldwide, sublicensable license to certain of our technology, including mRNA compounds formulated for LUNAR lipid-mediated delivery technology, for the purpose of conducting a joint research program on additional targets in in vitro and *in vivo* models of liver diseases (including NASH). Both Arcturus and Takeda have agreed not to participate in other research, internally or with a third party, on therapeutic mRNA molecules designed to express the selected targets. We also granted Takeda an exclusive option to negotiate a license to the product candidates determined to be of potential relevance as a result of the joint research program. The option lasts for a certain period of time following the delivery of the results of the research program. Funds remaining from the Takeda Agreement will be transferred to cover our activities under the New Takeda Agreement. If any remaining funds are unspent or uncommitted for expenditure upon completion of the current research program, then we will retain such funds.

We have a Research Collaboration and License Agreement with Providence Therapeutics Inc. (the "Providence Agreement"). The Providence Agreement provides for collaborative efforts to identify and optimize microRNA modulators or mimetics for the treatment of neoplastic diseases. In April 2017, the Providence

Agreement was amended to include mRNA for the treatment of neoplastic disease. In July 2018, the Providence Agreement was amended and restated to cover brain neoplasms, breast neoplasms and ovarian neoplasms.

Additionally, we have a Research and Nonexclusive License Agreement with Synthetic Genomics, Inc. ("Synthetic Genomics"), pursuant to which we granted Synthetic Genomics a nonexclusive, worldwide license to use our LUNAR lipid-mediated delivery to research, develop, manufacture and commercialize vaccines, but expressly excluding diagnosis, prophylaxis and treatment of respiratory disease viruses other than influenza. During 2019 Synthetic Genomics exercised its right to sublicence the LUNAR technology subject to the license to certain third parties.

Other Material Agreements

Protiva Agreement

On August 9, 2013, we entered into a Patent Assignment and License Agreement with Marina Biotech, Inc. ("Marina"), pursuant to which Marina assigned to us certain intellectual property, including patents, inventions and information related to UNA oligonucleotide therapeutics, as well as Marina's rights and obligations under a License Agreement (the "Protiva Agreement") with Protiva Biotherapeutics Inc. ("Protiva"), a wholly-owned subsidiary of Arbutus Biopharma Corporation. The intellectual property licensed from Marina is a significant component of our UNA oligomer chemistry platform. As partial consideration for the assignment from Marina, we granted Marina a royalty-free, fully-paid, irrevocable, worldwide, non-exclusive license to use the inventions, ideas and information embodied in the assigned patents to develop, make, use and sell chemical compounds intended for human and animal therapeutic uses (including certain rights to sublicense in connection with continuing research, development and/or commercialization). We also paid an upfront fee to Marina and agreed to maintain the assigned patents in certain countries.

Under the assigned Protiva Agreement, we granted Protiva a non-exclusive, irrevocable, perpetual, worldwide license with certain rights to sublicense (in connection with continuing research, development and/or commercialization) to exploit our patents, know-how and inventions relating to our technology for purposes of the development of human therapeutics. Upon achievement of certain development milestones with respect to each Protiva product directed to a specific gene target, Protiva will pay us milestone payments with an aggregate value of up to $3.25 million for each such product and target. If Protiva instead sublicenses the commercialization rights for a Protiva product, then it will pay us a percentage of sublicense revenues it receives from sublicensees, the amount of which payment depends on the development stage of such Protiva product at the time of sublicense. In addition, Protiva will pay us royalties on net sales of Protiva products during the royalty term. The royalties depend on the type of product and are on a country-by-country basis. For licensed Protiva products, royalties will be paid in a low single digit percentage on net sales for such product, subject to reduction on net sales in the event there is no patent coverage or generic products are introduced with respect to such product. A royalty reduction will apply if Protiva is required to license third party intellectual property to commercialize such product, subject to a cap on such reductions.

The Protiva Agreement for a particular Protiva product in a particular country will expire on a country-by-country basis upon the earlier of (i) the expiration of the royalty term for such product in such country, or (ii) the end of the calendar quarter in which sales in such country of generic products exceed sales of Protiva products in such country by a certain amount. Unless earlier terminated by its terms, the Protiva Agreement will expire in its entirety upon expiration of the last royalty term for any of our patents with respect to which Protiva has a license under the agreement. Protiva may terminate the Protiva Agreement for convenience in its entirety, or for a particular country or countries, upon ninety days' prior written notice to us.

Alexion License Agreement

On February 17, 2021, we entered into an exclusive license agreement with Alexion Pharmaceuticals, Inc. ("Alexion") pursuant to which Alexion granted to Arcturus Therapeutics, Inc. an exclusive, worldwide license to exploit certain specified Alexion patents. In accordance with the terms of the license agreement, and in exchange for the license, we issued 74,713 shares of our common stock to Alexion on February 19, 2021, which number of shares was based on a price of $66.92 per share. The price was determined based on the volume weighted average closing price of the Company's common stock on The NASDAQ Global Market for the thirty trading days ending on February 17, 2021.

Cystic Fibrosis Foundation Agreement

On May 16, 2017, pursuant to a Development Program Letter Agreement (the "CFF Agreement"), CFF awarded us approximately $3.1 million to fund 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 "CFF Agreement"). The award will be received according to a milestone schedule and unused funds will be retained by CFF. We will use commercially reasonable efforts to conduct the development program and develop the product thereafter. 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 of transfer payments actually received by us or our shareholders (subject to a royalty cap).

Pursuant to CFF's interruption license right under the CFF Agreement, if we fail to use commercially reasonable efforts to develop a product for a certain time period before the first commercial sale of such product, CFF may, upon written notice and our failure to effectively deny or cure such interruption (as set forth in the CFF Agreement), exercise certain rights pursuant to procedures set forth in the CFF Agreement. CFF's rights include, in certain cases, payments from us to CFF, or the grant of an exclusive (even as to us), worldwide license to CFF under our development program technology solely to the extent necessary to manufacture, have manufactured, license, use, sell, offer to sell, and support the product in the field of treatment of cystic fibrosis and other pulmonary diseases.

All inventions, data, know-how, information, results, analyses and other intellectual property rights resulting from the development program will be owned by us, and subject to certain exceptions, CFF has assigned and transferred to us all of its right, title, and interest in and to all inventions and other intellectual property resulting from the development program.

Either party may terminate the CFF Agreement for cause (e.g., material breach by the other party of its covenants or obligations).

On August 1, 2019, the Company and CFF amended the CFF Agreement. Pursuant to the amendment, (i) CFF will increase the amount it will award to advance LUNAR-CF to $15.0 million from approximately $3.2 million, (ii) the Company will provide $5.0 million in matching funds for remaining budgeted costs, (iii) the related disbursement schedule from CFF to us will be modified such that (a) $4.0 million was disbursed upon execution of the amendment, (b) $2.0 million will be disbursed within 30 days of the first day of each of January, April, July and October 2020 upon us invoicing CFF to meet project goals, and (c) the last payment of $3.0 million less the prior award previously paid out (approximately $2.3 million) will be disbursed upon us invoicing CFF to meet good manufacturing practices and submitting an IND application. The funds received from CFF will be recognized as contra research and development expense in proportion to the percentage covered by CFF of the overall budget.

Singapore Economic Development Board

On March 4, 2020, we were awarded a grant from the EDB to support the co-development of ARCT-021 with Duke-NUS Medical School. In exchange for the grant, we agreed to supply ARCT-021 to the EDB for use within Singapore and we retained the right to sell and market ARCT-021 outside of Singapore. We have agreed to pay Duke-NUS Medical School a low single digit royalty based on annual net sales of the vaccine in markets or jurisdictions outside of Singapore.

On October 2, 2020, we were awarded a grant from the EDB to support the further development of our LUNAR-COV19 vaccine candidate. The Grant provides for up to S$9.3 million (approximately US$6.7 million) to support the development of the vaccine candidate. The Grant is payable in two installments upon the achievement of certain milestones related to the progress of the development of the vaccine candidate. We received the first installment of approximately $3.6 million in the fourth quarter of 2020.

On November 7, 2020, we entered into a Manufacturing Support Agreement (the "Support Agreement") with the EDB pursuant to which they agreed to make a term loan of up to S$62.1 million (subject to adjustment based on exchange rates) to the Company, subject to the satisfaction of customary deliveries, to support the development of

the LUNAR-COV19 vaccine candidate (the "Singapore Loan"). We elected to borrow the full amount available under the Support Agreement of S$62.1 million, or $46.6 million as a result of applicable exchange rates, on January 29, 2021. Subject to certain exceptions, the Singapore Loan is a limited recourse loan that is intended to be repaid solely through a royalty payment on sales of the LUNAR-COV19 vaccine candidate, with a portion of the proceeds on all such vaccine sales being applied on a quarterly basis to prepay outstanding principal and interest under the Singapore Loan. However, all unpaid principal and interest under the Singapore Loan will be due and payable five years after draw date, if net sales of the LUNAR-COV19 vaccine exceed a certain minimum threshold during this five year period or the Company obtains clearance to sell the vaccine in specified jurisdictions. Unpaid principal and interest under the Singapore Loan will also become due and payable upon an event of default under the Support Agreement. If any portion of the Singapore Loan is required to be forgiven pursuant to the terms of the Support Agreement, the EDB has the right to take ownership of certain raw materials and equipment that were purchased by the Company with proceeds of the Singapore Loan (the "Specified Assets") and entered into a security agreement for the benefit of the EDB to provide that repayment of the Singapore Loan and related obligations are secured by a lien on the Specified Assets.

Israel Supply Agreement

On August 17, 2020, our wholly owned subsidiary entered into a definitive Supply Agreement (the "Supply Agreement") with the Israeli MOH which provides for the supply of LUNAR-COV19 to the MOH. The MOH has elected to reserve delivery by us of doses of LUNAR-COV19 for an initial 500,000 vaccinations (the "Initial Reserve Doses"). The Supply Agreement also provides the MOH with the right to elect, in its discretion, to purchase additional doses of LUNAR-COV19 upon notice to us prior to specified dates at specified purchase prices. On October 14, 2020, we received a non-refundable first reserve payment of $12.5 million from the MOH. This first reserve payment is associated with a specified clinical trial milestone and was provided after a data review process during which the MOH had access to material preclinical and clinical data for our LUNAR-COV19 vaccine candidate.

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 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 March 1, 2021, we are the sole owner of over 209 patents and pending patent applications including 33 U.S. patents, 29 pending U.S. patent applications, 7 pending international applications under Patent Cooperation Treaty ("PCT"), 68 foreign patents and 72 pending foreign 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, the use of UNA oligomers for therapeutics and reagents, the use of LNA oligomers for therapeutics, 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, HBV, and COVID-19. Our issued patents are expected to expire between 2028 and 2038, without taking into account any possible patent term extensions.

Our patent portfolio includes the following patents and pending patent applications for LUNAR, UNA and the use of LNA in certain RNA medicines:

- LUNAR – As of March 1, 2021, we own 16 U.S. patents, 9 U.S. pending patent applications, 2 international patent application ("PCT"), 11 foreign granted patents, and 38 foreign pending patent applications covering the composition of matter, manufacture of lipid nanoparticles (including lyophilization), and use of our LUNAR technology for nucleic acid delivery and drug delivery.

- UNA, mRNA and LNA – As of March 1, 2021, we own 147 U.S. patents, 10 U.S. pending patent applications, 3 PCT applications, 57 foreign patents and 32 foreign pending patent applications covering methods and uses of LNA, UNA oligomer and mRNA therapeutics, and compositions of UNA oligomers or mRNA to treat specific target diseases.
- 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-replicating RNA. As noted above, our robust LUNAR portfolio of over 60 patents and patent applications, provides protection for delivery vehicles that can enable specific and effective delivery of STARR drug substances. In particular, we own one pending U.S. patent application directed to the manufacture of compositions that can comprise STARR RNA in a lipid delivery vehicle. In addition, we have begun to develop our STARR patent portfolio, and as of March 1, 2021, we own one pending U.S. patent application 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 patents covering these developments in our STARR platform will last until 2041, 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 also rely on trade secrets to protect our product candidates. 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.

Certain Risks to Intellectual Property

We also 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 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. 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;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the drug is produced to assess 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 laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the drug candidate. The conduct of the preclinical tests 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 30 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 provide 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 is 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.

EUA Approval

The Commissioner of the FDA, under delegated authority from the Secretary of the U.S. Department of Health and Human Services ("DHHS") may, under certain circumstances, issue an EUA that would permit the use of an unapproved drug product or unapproved use of an approved drug product. Before an EUA may be issued, the Secretary must declare an emergency based on one of the following grounds:

- a determination by the Secretary of the Department of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a specified biological, chemical, radiological, or nuclear agent or agents;
- a determination by the Secretary of the Department of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to U.S. military forces of attack with a specified biological, chemical, radiological, or nuclear agent or agents; or
- a determination by the Secretary of the DHHS that a public health emergency that affects, or has the significant potential to affect, national security and that involves a specified biological, chemical, radiological, or nuclear agent or agents, or a specified disease or condition that may be attributable to such agent or agent.

In order to be the subject of an EUA, the FDA Commissioner must conclude that, based on the totality of scientific evidence available, it is reasonable to believe that the product may be effective in diagnosing, treating or preventing a disease attributable to the agents described above, that the product's potential benefits outweigh its potential risks and that there is no adequate approved alternative to the product.

Although an EUA cannot be issued until after an emergency has been declared by the Secretary of DHHS, the FDA strongly encourages an entity with a possible candidate product, particularly one at an advanced stage of development, to contact the FDA center responsible for the candidate product before a determination of actual or potential emergency. Such an entity may submit a request for consideration that includes data to demonstrate that, based on the totality of scientific evidence available, it is reasonable to believe that the product may be effective in diagnosing, treating, or preventing the serious or life-threatening disease or condition. This is called a pre-EUA submission and its purpose is to allow FDA review considering that during an emergency, the time available for the submission and review of an EUA request may be severely limited.

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.

Manufacturers of our product candidates are required to comply with applicable FDA manufacturing requirements contained in the FDA's cGMP regulations. cGMP regulations require among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation. 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 generally require prior FDA approval before being implemented and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

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. In the European Union, for example, a CTA must be submitted to each country's national health authority and an independent ethics committee, much like the FDA and IRB, respectively. Once the CTA is approved in accordance with a country's requirements, clinical trial development may proceed.

The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, 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.

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

For other countries outside of the European Union, 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.

Competition

Our Business in General

We believe that our scientific knowledge and expertise in nucleic acid-based therapies provide us with competitive advantages over the various companies and other entities that are attempting to develop similar treatments. However, 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 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.

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. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, are more convenient or are less expensive than any products we may develop.

We are aware of several other companies that are working to develop nucleic acid medicines, including gene therapy, gene editing, mRNA, siRNA, and antisense therapeutics. Many of these companies, such as the newly formed Genevant, 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.

ARCT-021 (LUNAR-COV19 Vaccine)

We consider the following medicines as competitors or future competitors to ARCT-021.

Drug	Company	Drug Description	Phase	Administration/Dosing	Number of Doses
Comirnaty (BNT162b2)	Pfizer, BioNTech, Fosun Pharma	mRNA-based Vaccine	Phase 3 and EUA	i.m.	2(1)
mRNA-1273	Moderna	mRNA-based Vaccine	Phase 3 and EUA	i.m.	2(1)
Covishield (AZD1222)	AstraZeneca	Non-replicating Chimpanzee Adenovirus vaccine	Phase 3 and EUA	i.m.	2
JNJ-78436735 or Ad26.COV2.S	JNJ/Janssen	Non-replicating Adenoviral vector-Ad26	Phase 3	i.m.	1
Sputnik V (Gam-COVID-Vac)	Russian (Gamaleya National Research Centre for Epidemiology and Microbiology)	Heterologous non-replicating adeno viral vectors Ad26 prime/Ad5 boost	Phase 3 and EU	i.m.	2
CoronaVac	Sinovac	Inactivated vaccine (formalin with alum adjuvant)	Approved in China, Phase 3, EUA	i.m.	2
NVX-CoV2373	Novavax	Recombinant nanoparticle technology	Phase 3	i.m.	2

(1) Comirnaty (Pfizer, BioNTech, Fosun Pharma) is a two-dose regimen at 30 µg per dose. mRNA-1273 (Moderna) is a two-dose regimen at 100 µg per dose. In our current Phase 2 trial for ARCT-021, we are exploring the following doses and regimens: 5 µg ARCT-021, two dose regimen and 7.5 µg ARCT-021, as one- and two-dose regimens.

Despite the receipt of emergency use approval (EUA) by several of our competitors for their COVID-19 vaccine, we believe there are significant commercial opportunities globally.

ARCT-810 (LUNAR-OTC)

We consider the following medicines as competitors or future competitors to ARCT-810.

Drug	Company	Drug Description	Phase	Administration/Dosing
DTX-301	Ultragenyx Pharmaceuticals	OTC gene in AAV8 vector	Phase 1/2	IV, single dose

ARCT-032 (LUNAR-CF)

We consider the following medicines as competitors or future competitors to ARCT-032.

Drug	Company	Drug Description	Phase	Administration/Dosing
MRT5005	Translate Bio	CFTR-encoded mRNA	Phase 1/2	Weekly or daily inhalation
ELX-02	Eloxx Pharmaceuticals	Readthrough agent for premature stop codons	Phase 2, G542X mutation	Daily SC

Employees

As of December 31, 2020, we had 118 employees, all of which were full-time. None of our employees are represented by a labor union or covered by a collective bargaining agreement. We consider our relationship with our employees to be good.

Available Information

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 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 and anticipate that we will continue to incur significant losses for the foreseeable future.

We have never generated any revenue from product sales, have generated only limited revenue since inception, and may never be profitable.

The recent coronavirus outbreak has caused interruptions or delays of our business plan and may have a significant adverse effect on our business.

We may need to seek and secure significant funding through financings or from other sources to complete Phase 3 studies of ARCT-021, our LUNAR-COV19 vaccine candidate.

If we are unable to generate successful results in our Phase 2 clinical trial for ARCT-021, our LUNAR-COV19 vaccine candidate, or experience significant delays in doing so, or are unable to develop a vaccine that does not require a booster shot, we may be unable to market and sell a COVID-19 vaccine.

There is significant competition in the development of a vaccine against COVID-19, and many of our competitors have substantially greater financial, scientific and other resources than us.

We are relying on advance purchase commitments of ARCT-021, our LUNAR-COV19 vaccine candidate, from certain foreign governmental agencies.

Our ability to produce a successful vaccine may be curtailed by one or more government actions or interventions, which may be more likely during a global health crisis such as COVID-19.

Our business may be harmed if we are unable to generate successful and timely clinical trials for our product candidates.

The approach we are taking to discover and develop drugs is novel and may never lead to marketable products.

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

We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates if our clinical trials are not successful.

We may find it difficult to identify and enroll patients in our clinical studies due to the rollout of competing vaccines for COVID-19. In addition, the rollout of competing vaccines for COVID-19 may make it more difficult for us to achieve approval of certain clinical trial designs for our LUNAR-COV19 vaccine. Difficulty in enrolling patients, or in seeking approval for certain clinical trial designs could delay or prevent clinical studies of certain of our product candidates.

Any of our product candidates may cause undesirable side effects or have other properties impacting safety that could delay or prevent their regulatory approval or limit the scope of any approved label or market acceptance.

Even if we complete the necessary preclinical studies and clinical trials, we cannot predict whether or when we will obtain regulatory approval to commercialize a product candidate.

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.

We may fail to capitalize on programs or product candidates that may be more profitable or for which there is a greater likelihood of success than a particular program where we allocate resources.

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.

If certain third-party alliances are unsuccessful or are terminated, we may be unable to commercialize certain product candidates and we may be unable to generate revenues from our development programs.

Certain agreements with our alliance partners may impair or prevent entirely our ability to generate revenues from the development, manufacture and commercialization of certain product candidates.

We rely on third-party manufacturers to produce the supply of our product candidates, and we intend to rely on third parties to produce future clinical supplies of product candidates.

We rely on limited sources of supply for the drug substance of product candidates and any disruption in the chain of supply may cause a delay in developing and commercializing these product candidates.

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

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

Third-party claims of intellectual property infringement may prevent or delay our development and commercialization efforts.

We could lose license rights that are important to our business for failure to comply with such agreements under which we license intellectual property.

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.

If our alliance partners are unable or unwilling to perform in accordance with the terms of our agreements, our potential to generate future revenue from these programs would be significantly reduced

If we are unable to obtain regulatory approvals for a manufacturing facility for ARCT-021, our LUNAR-COV19 vaccine candidate, we may experience delays in product development, clinical trials, regulatory approval and commercial distribution.

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

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

If we are unable to establish 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.

If we obtain approval to commercialize any approved products outside of the United States, a variety of risks associated with international operations could materially adversely affect our business.

Coverage and adequate reimbursement may not be available for our product candidates, if approved.

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

RISKS RELATED TO OUR FINANCIAL CONDITION AND NEED FOR ADDITIONAL CAPITAL

We have a limited operating history, have incurred significant losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future.

We are a global clinical-stage 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 nucleic acid product platform, undertaking basic research around nucleic acid targets and conducting studies for our initial programs. We have not yet obtained regulatory approval for any product candidates. Consequently, any predictions about our future success or viability, or any evaluation of our business and prospects, may not be accurate.

We have incurred losses in each year since our inception. Our net losses were $72.1 million and $26.0 million for the years ended December 31, 2020 and 2019, respectively. As of December 31, 2020, we had an accumulated deficit of $143.8 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 clinical trials;
- seek marketing approvals for our product candidates that successfully complete clinical trials;
- ultimately 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 never generated any revenue from product sales, have generated only limited revenue since inception, and may never be profitable.

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:

- 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 third 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 the timing or amount of increased expenses and when we will be able to achieve or 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 one or more of the product candidates that we independently develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product. Even if we are able to generate revenues from the sale of any approved products, we may not become profitable and may need to obtain additional funding to continue operations.

The recent coronavirus outbreak has caused interruptions or delays of our business plan and may have a significant adverse effect on our business.

In December 2019, a strain of coronavirus, COVID-19, was reported to have surfaced in Wuhan, China, and on March 12, 2020, the World Health Organization declared COVID-19 to be a pandemic. In an effort to contain and mitigate the spread of COVID-19, many countries, including the United States, Canada and China, have imposed unprecedented restrictions on travel, quarantines, and other public health safety measures. The extent to which the pandemic may impact our business will depend on future developments, which are highly uncertain and cannot be predicted, but the development of clinical supply materials have been and will continue to be delayed and enrollment of patients in our study for ARCT-810 (LUNAR-OTC) and ARCT-021 (LUNAR-COV19 Vaccine) may be delayed or suspended, as hospitals and clinics in areas where we are conducting trials shift resources to cope with the COVID-19 pandemic and may limit access or close clinical facilities due to the COVID-19 pandemic. Additionally, if our trial participants are unable to travel to our clinical study sites as a result of quarantines or other restrictions resulting from the COVID-19 pandemic, we may experience higher drop-out rates or delays in our clinical studies.

Government-imposed quarantines and restrictions may also require us to temporarily suspend or terminate activity at our clinical sites. Furthermore, if we determine that our trial participants may suffer from exposure to COVID-19 as a result of their participation in our clinical trials, we may voluntarily terminate certain clinical sites as a safety measure until we reasonably believe that the likelihood of exposure has subsided. As a result, our expected development timelines for our product candidates may be negatively impacted. We cannot predict the ultimate continued impact of the COVID-19 pandemic as consequences of such an event are highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical studies or as a whole; however, the COVID-19 outbreak may materially disrupt or delay our business operations, further divert the attention and efforts of the medical community to coping with COVID-19, disrupt the marketplace in which we operate, and/or have a material adverse effect on our operations.

Notwithstanding the ongoing rollout of vaccines, it will still take a substantial amount of time to produce, distribute and administer the vaccines worldwide and, as a result, to achieve broad protection of the global population. It is also still unclear if the vaccines will enable adequate protection, as (i) some vaccinated individuals

may still become ill or transmit the virus, (ii) there are individuals who may 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 of the virus may have an impact on the efficacy of available vaccines.

Moreover, the various precautionary measures taken by many governmental authorities around the world in order to limit the spread of the coronavirus has had and may continue to have an adverse effect on the global markets and global economy generally, including on the availability and pricing of employees, resources, materials, manufacturing and delivery efforts and other aspects of the global economy. There have been business closures and a substantial reduction in economic activity in countries that have had significant outbreaks of COVID-19. Significant uncertainty remains as to the potential impact of the COVID-19 pandemic on the global economy as a whole. It is currently not possible to predict how long the pandemic will last or the time that it will take for economic activity to return to prior levels. The COVID-19 pandemic could materially disrupt our business and operations, interrupt our sources of supply, hamper our ability to raise additional funds or sell our securities, or continue to slow down the overall economy.

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

Developing pharmaceutical products, including conducting studies and clinical trials, is 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 or through clinical trials. We may 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, 2020, we had unrestricted cash and cash equivalents of $462.9 million. We cannot provide assurances that our plans will not change or that changed circumstances will not result in the depletion of our capital resources more rapidly than we currently anticipate. For example, our trials may encounter technical or other difficulties. Additionally, our strategic alliance partners may not elect to pursue the development and commercialization of any of our product candidates that are subject to their respective strategic alliance agreements with us. Any of these events may increase our development costs more than we expect. In order to support our long-term plans, we may need to raise additional capital or otherwise obtain funding through additional strategic alliances if we choose to initiate preclinical or clinical trials for new product candidates other than programs currently partnered. In any event, we will require additional capital to obtain regulatory approval for, and to commercialize, future product candidates.

A significant portion of our current cash balance of $462.9 million along with the $46.6 million from the Singapore Loan is expected to be utilized during fiscal year 2021 to fund (i) the Phase 2 trial and anticipated Phase 3 trial of our current LUNAR-COV19 vaccine candidate, (ii) the continued Phase 1 trial and anticipated Phase 2 trial of ARCT-810, our LUNAR-OTC candidate, (iii) advancing our new LUNAR-FLU program toward submission of an IND, and (iv) other programs and administrative costs.

The Phase 3 trial of our LUNAR-COV19 vaccine candidate is expected to be primarily or exclusively funded through our cash reserves. If we achieve EUA approval to market our LUNAR-COV19 vaccine candidate, we will need to raise additional funds through equity transactions, additional debt or prepayments from potential customers, among other options, to fund commercialization of LUNAR-COV19.

Any additional fundraising efforts may divert our management from our day-to-day activities, which may adversely affect our ability to develop and commercialize future product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. If we are unable to raise additional capital when required or on acceptable terms, we may be required to:

- significantly delay, scale back or discontinue the development or commercialization of any future product candidates;
- seek strategic alliances for research and development programs 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 product candidates that we otherwise would seek to develop or commercialize ourselves.

If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we will be prevented from pursuing development and commercialization efforts, which will have a material adverse effect on our business, operating results and prospects.

We will need to seek and secure significant funding through financings or from other sources to complete Phase 3 studies of ARCT-021, our LUNAR-COV19 vaccine candidate.

As of December 31, 2020, we had approximately $463.0 million in cash and cash equivalents. We expect that our existing cash and cash equivalents will be sufficient to fund our current operations through at least the next twelve months. If we have encouraging results from our current trial, we will need to seek additional funds sooner than planned, through public or private equity or debt financings, structured financings, government or other third-party funding, sales of assets, marketing and distribution arrangements, other collaborations and licensing arrangements, or a combination of these approaches. We will require additional capital to obtain regulatory approval for, and to commercialize ARCT-021.

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 Loan Agreement entered into on October 12, 2018 by our wholly-owned subsidiary, Arcturus Therapeutics, Inc., with Western Alliance Bank (the “Western Loan Agreement”). The Western Loan Agreement bears a variable interest rate of 1.25% above the prime rate published by the western edition of the Wall Street Journal. As of December 31, 2020, we had $15.1 million outstanding under the Western Loan Agreement. If we were to experience a 10% adverse change in the prime rate referenced above, the annual effect such change would have on our statement of operations, based on the amount we had outstanding as of December 31, 2020, under the Western Loan Agreement, would be approximately $26,000.

Additionally, on November 7, 2020, we entered into a Manufacturing Support Agreement with the EDB. Pursuant to the Manufacturing Support Agreement, the EDB agreed to make a term loan of up to S$62.1 million, subject to the satisfaction of customary deliveries, to support the manufacture of the LUNAR-COV19 vaccine candidate (the “Singapore Loan”). The Singapore Loan accrues interest at a rate of 4% per annum calculated on a daily basis. We elected to borrow the full amount available under the Support Agreement of S$62.1 million, or $46.6 million, as a result of applicable exchange rates, on January 29, 2021.

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

Agreements with our lenders, including with Western Alliance Bank, 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;
- 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 Western Loan 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 Western Loan 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 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.

RISKS RELATED TO THE DISCOVERY AND DEVELOPMENT OF PRODUCT CANDIDATES

We recently commenced a Phase 2 clinical trial for our COVID-19 vaccine candidate, ARCT-021. If we are unable to generate successful results, experience significant delays in doing so, or are unable to develop a vaccine that does not require a booster shot, we may be unable to market and sell a COVID-19 vaccine.

We recently commenced a Phase 2 trial of ARCT-021 and expect to commence a Phase 3 trial in the second quarter of 2021. We anticipate that the Phase 3 trial will continue through 2021, and we plan to continue to monitor subjects in the Phase 3 trial into 2022 (whether or not we receive emergency use authorization for ARCT-021 during 2021). We will need to identify additional funding sources to continue the Phase 3 trial. The data received to date, although providing sufficient information to allow us to proceed further is not complete enough to provide conclusive evidence with respect to safety and potential efficacy of ARCT-021. Our IND application to proceed with our Phase 2 clinical study was accepted by the HSA in December 2020, and by the FDA in January 2021. We are positioned to manufacture finished doses of ARCT-021 in the first quarter of 2021 for stockpiling purposes. Clinical trial results are inherently uncertain, and a significant portion of our success and business prospects depend on the progress of this program. Our failure to demonstrate safety or obtain positive clinical trial results, inability to meet the expected timeline for release of data for this trial, or failure to successfully develop a single-dose vaccine that does not require a booster shot could have an adverse effect on our business operations and financial condition. Furthermore, we will not have a detailed understanding of the efficacy of ARCT-021 until infection of a sufficient number of subjects in the placebo group of a Phase 3 clinical trial, enrollment for which may be delayed by rollout of competing vaccines for COVID-19, competing clinical trials and the refusal of certain countries' regulatory authorities to allow placebo-controlled trials for COVID-19 vaccine candidates. If our data is not positive or inconclusive, we may not be able to continue our studies or identify additional funding to continue the studies. No assurance can be given that the results of the trials will produce adequate results to allow us to commence or continue expected trials or that that adequate efficacy will be demonstrated such that ARCT-021 will be a viable commercial product.

There is significant competition in the development of a vaccine against COVID-19, and many of our competitors have substantially greater financial, scientific and other resources than us, and are further along in the development of their COVID-19 vaccine candidates.

A large number of vaccine manufacturers, academic institutions and other organizations currently have programs to develop COVID-19 vaccine candidates and may be further along in development of their vaccine candidates. While we are not aware of all of our competitors' efforts, there are reports that Johnson & Johnson/Janssen, Pfizer, GlaxoSmithKline, Moderna, Sanofi, Inovio, AstraZeneca and many other companies are all in various stages of developing vaccine candidates against COVID-19. In particular, Pfizer, Moderna and Johnson & Johnson have received emergency use authorization from the FDA for their COVID-19 vaccines and are already commercializing them and have vaccinated millions of people.

Despite funding provided to us to date, many of our competitors pursuing vaccine candidates 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 materially and adversely affected by our competitors commercialization of their vaccines before we complete development and seek approval for our vaccine candidate; if they develop and commercialize one or more COVID-19 vaccines that are safer, more effective, have fewer or less severe side effects, have broader market acceptance, are more convenient or are less expensive than any vaccine candidate that we may develop; or if we are unable to achieve a competitive advantage by successfully developing a single-dose vaccine that does not require a booster shot. 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 are relying on advance purchase commitments of ARCT-021, our LUNAR-COV19 vaccine candidate, from certain foreign governmental agencies.

Although we have previously raised capital to support the development and manufacture of our LUNAR-COV19 vaccine, we must also secure additional funding through contractual arrangements with third parties. We may be unable to enter into such arrangements on favorable terms, or at all, which would adversely affect our ability to develop, manufacture and distribute a potential vaccine.

Our ability to produce a successful vaccine may be curtailed by one or more government actions or interventions, which may be more likely during a global health crisis such as COVID-19.

Given the significant global impact of the COVID-19 pandemic, it is possible that one or more government entities may take actions that directly or indirectly have the effect of diminishing some of our rights or opportunities with respect to LUNAR-COV19 and the economic value of a COVID-19 vaccine to us could be limited. In the United States, the Defense Production Act of 1950, as amended (the "Defense Production Act") gives the U.S. government rights and authorities that may directly or indirectly diminish our own rights or opportunities with respect to LUNAR-COV19 and the economic value of a COVID-19 vaccine to us could be limited. Our third-party service providers may be impacted by government entities potentially invoking the Defense Production Act or other potential restrictions to all or a portion of services they might otherwise offer. Government entities imposing restrictions or limitations on our third-party service providers may require us to obtain alternative service sources for LUNAR-COV19. If we are unable to timely enter into alternative arrangements, or if such alternative arrangements are not available on satisfactory terms, we will experience delays in the development or production of LUNAR-COV19, increased expenses, and delays in potential distribution or commercialization of LUNAR-COV19, if approved.

Preclinical and clinical studies of our product candidates may not be successful. 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.

We have no products approved for commercial marketing and all of our product candidates are in preclinical or clinical development. Other than our LUNAR-COV19 vaccine candidate and LUNAR-OTC, none of our product candidates have ever been tested in a human subject. Our ability to achieve and sustain profitability depends on obtaining regulatory approvals for and, if approved, successfully commercializing our product candidates, either alone or with third parties. 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.

The approach we are taking to discover and develop drugs is novel and may never lead to marketable products.

We have concentrated our therapeutic product research and development efforts on nucleic acid technology, and our future success depends on the successful development of this technology and products based on our nucleic acid product platform. Except for Moderna (CX-024414), Onpattro (patisiran), which is marketed by Alnylam; Kynamro (mipomersen), which was marketed by Kastle Therapeutics; Vitravene (fomivirsen), which Novartis withdrew from the US market in 2006; and Spinraza (nusinersen), which is marketed by Biogen Inc., neither we, nor any other company, has to our knowledge received regulatory approval to market nucleic acid therapeutics. The scientific discoveries that form the basis for our efforts to discover and develop product candidates are relatively new. The scientific evidence to support the feasibility of developing product candidates based on these discoveries is both preliminary and limited. If we do not successfully develop and commercialize product candidates based upon our technological approach, we may not become profitable and the value of our common stock may decline.

Further, our focus solely on nucleic acid technology for developing drugs as opposed to multiple, more proven technologies for drug development increases the risks associated with the ownership of our common stock. 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 implement successfully an alternative product development strategy.

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 comparable 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.

Accordingly, we cannot be certain the submission of an IND will be accepted by the FDA.

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 do not know whether any clinical trials will begin as planned, need to be restructured or will 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 allow our competitors to bring products to market before we do, which would impair our ability to successfully commercialize our product candidates and may harm our business and results of operations. Any inability to 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 due to the development and rollout of competing vaccines for COVID-19 and due to the limited number of patients who have the diseases for which certain of our product candidates are being studied. In addition, the rollout of competing vaccines for COVID-19 may make it more difficult for us to achieve approval of certain clinical trial designs for our LUNAR-COV19 vaccine. Difficulty in enrolling patients, or in seeking approval for certain clinical trial designs, 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.

A number of preventative vaccines have recently been authorized for use in human populations by regulatory agencies in the U.S. and Europe and other countries. The rollout of these vaccines has resulted in slower than expected enrollment in the United States for the Phase 2 study of our LUNAR-COV19 vaccine candidate.

Because of the aggressive roll-out of COVID-19 vaccines, we may find it challenging to enroll sufficient subjects in our LUNAR-COV19 trials who have not otherwise received a vaccine. Additionally, competing COVID-19 vaccine clinical trials may make it more difficult to enroll subjects in our LUNAR-COV19 trial. We may also find it more difficult to identify subjects willing to participate in our studies. The regulatory authorities of certain countries have restricted placebo-controlled trials in studies for COVID-19 vaccine candidates. Such restrictions may make it more difficult to seek approval to proceed with certain clinical trial designs, and for the ultimate likelihood of approval of such candidates.

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 enroll an adequate number of patients in our studies for the foregoing or other reasons, the timeline for recruiting patients, conducting studies, and obtaining regulatory approval of potential products may 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.

Any of our product candidates may cause undesirable side effects or have other properties impacting safety that could delay or prevent their regulatory approval or limit the scope of any approved label or market acceptance.

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. Results of our trials could reveal a high and unacceptable severity and prevalence of side effects. In such an event, 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 business, financial condition, results of operations and prospects.

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, 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 cannot predict whether or when we will obtain regulatory approval to commercialize a product candidate and we cannot, therefore, predict the timing of any revenue from a future product.

Neither we nor our strategic alliance partners can commercialize a product until the appropriate regulatory authorities, such as the FDA, have reviewed and approved the product candidate. The 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;
- unfavorable or unclear results from our clinical trials or results that may not meet the level of statistical significance required by the FDA or comparable 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 our third-party manufacturers with which we contract for clinical and commercial supplies; or
- regulations 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.

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 REMS 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 ("AEs") 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 AEs 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 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. Currently, we have allocated significant resources to the testing and development of our LUNAR-COV19 and LUNAR-OTC vaccine candidates. Our spending on research and development programs and product candidates for COVID-19 or other specific indications may not yield any commercially viable products. 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 our 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.

RISKS RELATED TO OUR RELIANCE ON THIRD PARTIES

We depend upon our third-party alliances with partners and contract organizations for the development, manufacture and eventual commercialization of certain nucleic acid product candidates. If these third-party alliances are unsuccessful or are terminated, we may be unable to commercialize certain product candidates and we may be unable to generate revenues from our development programs.

We depend upon third party alliance partners for financial and scientific resources for the clinical development, manufacture and commercialization of certain of our nucleic acid product candidates. These alliances will likely provide us with limited control over the course of development of a nucleic acid product candidate, especially once a candidate has reached the stage of clinical development. For example, in our alliance with Ultragenyx, Ultragenyx has the option to obtain an exclusive worldwide license to develop, manufacture and commercialize product candidates upon the achievement of relevant endpoints in preclinical studies and clinical trials. However, Ultragenyx is not under any obligation to exercise these options to progress any of our nucleic acid product candidates. While Ultragenyx has development obligations with respect to programs that it may elect to pursue under our agreement, our ability to ultimately recognize revenue from this and future 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 successful 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 business strategies, 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 of milestones tied to such activities, thereby impacting our ability to fund our own activities;
- an alliance partner could develop a product that competes, either directly or indirectly, with an alliance product;
- 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 milestones, royalty payments or 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 nucleic acid development candidates or if they terminate the strategic alliance, then, depending on the event:

- 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 scarce resources to the development and commercialization of product candidates that were previously funded, or expected to be funded, by our alliance partners;
- we would bear all of 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 third-party partners; 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.

Certain agreements with our alliance partners may impair or prevent entirely our ability to generate revenues from the development, manufacture and commercialization of certain product candidates.

Under the Development and Option Agreement with CureVac, as amended (the "CureVac Agreement"), CureVac may be entitled to trigger an option to license certain of our product candidates. CureVac may identify certain of our development candidates as targets under the CureVac Agreement and exercise an option to enter into an exclusive or non-exclusive license agreement with us with respect to these identified targets, subject to the limitations given in the CureVac Agreement. The exercise of this option by CureVac may impair or prevent entirely our ability to generate revenues from the commercialization of these development candidates, as the licensing agreement may give CureVac the right to receive some or all of the revenues from the development, manufacture and/or commercialization of these development candidates. Our inability to realize the benefits from developing, manufacturing or marketing our development candidates with our alliance partners, including with CureVac, may have a material adverse impact on our business, financial condition and prospects.

We rely on third parties to conduct some aspects of our compound formulation, research and studies, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such formulation, research or testing.

We do not expect to 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 third parties to conduct some aspects of our preclinical and clinical studies and formulation development.

Any of these third parties may terminate their engagements with us at any time. If we need to enter into alternative arrangements, it would delay our product development activities. Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, for product candidates that we develop and commercialize on our own, we will 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 third parties 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.

We rely on third-party manufacturers to produce the supply of our preclinical and clinical product candidates, and we intend to rely on third parties to produce future clinical supplies of product candidates that we advance into clinical trials and commercial supplies of any approved product candidates.

Reliance on third-party manufacturers entails risks, including risks that 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 third parties under commercially reasonable terms;
- termination or nonrenewal of manufacturing agreements with third 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 third-party 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 FDA action, including injunction, recall, seizure or total or partial suspension of production.

We rely on limited sources of supply for the drug substance of product candidates and any disruption in the chain of supply may cause a delay in developing and commercializing these product candidates.

We have established manufacturing relationships with a limited number of suppliers to manufacture raw materials and the drug substance used to create our product candidates. The availability of such suppliers to manufacture raw materials for our product candidates may be limited. Further, each supplier may require licenses to manufacture such components if such processes are not owned by the supplier or in the public domain. Our ability to obtain the necessary drug substance of product candidates could be adversely impacted by the coronavirus outbreak. As part of any marketing approval, a manufacturer and its processes are required to be qualified by the FDA prior to commercialization. If supply from the approved vendor is interrupted, there could be a significant disruption in commercial supply. 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 pursue the development and commercialization of certain programs, we will lose control over the manufacturing of the product candidate subject to the agreement. Also, we will not be able to ensure that the product candidates will be manufactured under the correct conditions to permit the product candidates to be used in such clinical trials.

These factors could cause the delay of clinical trials, regulatory submissions, required approvals or commercialization of our product candidates, cause us to incur higher costs and prevent us from commercializing our products successfully. Furthermore, if our suppliers fail to deliver the required commercial quantities of active pharmaceutical ingredients on a timely basis and at commercially reasonable prices, and we are unable to secure one or more replacement suppliers capable of production in a timely manner at a substantially equivalent cost, our clinical trials may be delayed or we could lose potential revenue.

We currently have one supplier for two important components in our LUNAR-COV19 drug candidate, which supplier is located in China. Our dependence upon a single supplier located outside of the United States could place our commercialization efforts at risk.

Currently, we have one supplier for two important components in our LUNAR-COV19 drug candidate, which supplier is located in China. This supplier may only have a limited supply of such essential materials, may encounter unexpected delays, possible shutdowns, or other impediments to production, resulting in delays to our ability to manufacture and commercialize LUNAR-COV19.Further, our dependence upon a single supplier located outside of the United States could place our commercialization efforts at risk.

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

We intend to rely on third parties to conduct, supervise and monitor our clinical trials, and if those third parties perform in an unsatisfactory manner, it may harm our business.

We or our strategic alliance partners intend to rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials. While we will have agreements governing their activities, we and our strategic alliance partners have limited influence over their actual performance. We will control only certain aspects of our CROs' activities. Nevertheless, we or our strategic alliance partners will be responsible for ensuring that each of our clinical trials are conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CROs will not relieve us of our regulatory responsibilities.

We, our alliance partners and our CROs will be required to comply with the FDA's or other regulatory agency's GCPs, for conducting, recording and reporting the results of IND-enabling studies and clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of future clinical trial participants are protected. The FDA and non-U.S. regulatory agencies enforce these GCPs through periodic inspections of trial sponsors, principal investigators and clinical trial sites. If we or our future CROs fail to comply with applicable GCPs, 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 for the relevant jurisdiction. Upon inspection, the FDA or applicable non-U.S. regulatory agency may determine that our future clinical trials did not comply with GCPs. In addition, our future clinical trials will require a sufficiently large number of test subjects to evaluate the safety and effectiveness of a potential drug product. Accordingly, if our future 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 future CROs will not be our employees, and we will not be able to control whether or not they devote sufficient time and resources to our future 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 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, our financial results and 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 intend to rely on other third parties to store and distribute drug products for any clinical trials that we may conduct. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our product candidates or commercialization of our products, if approved, producing 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 future 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. As of February 15, 2021, we are the sole owner of over 209 patents and pending patent applications including 33 U.S. patents, 29 pending U.S. patent applications, 7 pending international applications under the PCT, 68 foreign patents and 72 pending foreign patent applications. The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or in-license may fail to result in patents with claims that cover the products in the United States or in other countries. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found; such prior art can invalidate a patent or prevent a patent from issuing based on a pending patent application. Even if patents do successfully issue, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed or invalidated. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims.

If the patent applications we hold or have in-licensed with respect to our programs or product candidates fail to issue 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. We cannot offer any assurances about which, if any, patents will issue or whether any issued patents will be found invalid and unenforceable or will be threatened by third parties. A patent may be challenged through one or more of several administrative proceedings including post-grant challenges, re-examination or opposition before the U.S. PTO or foreign patent offices. For example, re-examination of, or oppositions to, patents owned by or licensed to us have previously been initiated, and while we believe these concluded proceedings did not result in a commercially relevant impact on the individual patents, any successful challenge of patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any product candidates that we or our strategic alliance partners may develop.

Since patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we were the first to file any patent application related to a product candidate. Furthermore, in certain situations, if we and one or more third parties have filed patent applications in the United States and claiming the same subject matter, an administrative proceeding, known as an interference, can be initiated to determine which applicant is entitled to the patent on that subject matter. Such an interference proceeding provoked by third parties or brought by us may be necessary to determine the priority of inventions with respect to our patents or patent applications, or those of our alliance partners or licensors. An unfavorable outcome could require us to cease using the related technology or to require us 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.

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 of time 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 proprietary know-how that is not patentable, including processes for which patents are difficult to enforce and any other elements of our drug discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. 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, we cannot provide any assurances that all such agreements have been duly executed, that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. In addition, others may independently discover our trade secrets and proprietary information. For example, the FDA, as part of its Transparency Initiative, is currently considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA’s disclosure policies may change in the future, if at all.

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, results of operations and financial condition.

Third-party claims of intellectual property infringement may prevent or delay our development and commercialization efforts.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we and our strategic alliance partners are pursuing development candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire. Similarly, if any third-party patents were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy, the holders of any such patents may be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee 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 royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

If we fail to obtain licenses or comply with our obligations in these agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

We are a party to intellectual property license agreements that are important to our business and expect to enter into additional license agreements in the future. Our existing license agreements impose, and we expect that future license agreements will impose, various obligations on us, as described in "Other Material Agreements" and "Collaboration Agreements" under Part I, Item 1 and elsewhere in this annual report.

We may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates, and we have done so from time to time. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our future products, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties.

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 this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

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 third parties have an ownership interest in our patents. Litigation may be necessary to defend against these claims. There is no guarantee of success 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.

RISKS RELATED TO COMMERCIALIZATION OF PRODUCT CANDIDATES

The commercial success of our programs that are part of our strategic alliance agreements will depend in large part on the development and marketing efforts of our alliance partners. If our alliance partners are unable or unwilling to perform in accordance with the terms of our agreements, our potential to generate future revenue from these programs would be significantly reduced and our business would be materially and adversely harmed.

If or when our strategic alliance partners elect to further pursue the development and commercialization of any of the product candidates that are subject to a strategic alliance agreement, we will have limited influence and/or 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. If we terminate any of our strategic alliances or any program thereunder, we may have the right to assume the responsibility at our own expense for the development of the applicable product candidates. Assuming sole responsibility for further development will increase our expenditures, and may mean we will need to limit the size and scope of one or more of our programs, seek additional funding and/or choose to stop work altogether on one or more of the affected product candidates. This could result in a limited potential to generate future revenue from such product candidates and our business could be materially and adversely affected.

If we are unable to manufacture our vaccines in sufficient quantities, at sufficient yields or are unable to obtain regulatory approvals for a manufacturing facility for ARCT-021, our LUNAR-COV19 vaccine candidate, we may experience delays in product development, clinical trials, regulatory approval and commercial distribution.

Completion of our clinical trials and commercialization of our vaccine candidates require access to, or development of, facilities to manufacture our LUNAR-COV19 vaccine candidate at sufficient yields and at commercial-scale. We have limited experience manufacturing our vaccine candidates in the volumes that will be

necessary to support large-scale clinical trials or commercial sales. Efforts to establish these capabilities may not meet initial expectations as to scheduling, scale-up, reproducibility, yield, purity, cost, stability, potency or quality. In addition, other companies, many with substantial resources, may compete with us for access to materials needed to manufacture our vaccines.

Manufacturing our LUNAR-COV19 vaccine candidate involves a complicated process with which we have limited experience. We are dependent on third-party organizations to conduct a portion of our vaccine manufacturing activities. If third-party manufacturing organizations are unable to manufacture our vaccine candidates in clinical quantities or, when necessary, in commercial quantities and at sufficient yields, then we will need to identify and reach supply arrangements with additional third parties. Third-party manufacturers must also be inspected by the FDA as part of the FDA's review of our marketing application. Our LUNAR-COV19 vaccine candidate may be in competition with other products for access to these facilities and may be subject to delays in manufacture if third parties give other products higher priority. We may not be able to enter into any necessary additional third-party manufacturing arrangements on acceptable terms, or on a timely basis. In addition, we have to enter into technical transfer agreements and share our know-how with the third-party manufacturers, which can be time-consuming and may result in delays. Any delay in the manufacture or delivery of a vaccine could adversely affect our ability to sell the LUNAR-COV19 vaccine candidate, if approved.

Our reliance on third-party manufacturers may adversely affect our operations or result in unforeseen delays or other problems beyond our control. Because of contractual restraints and the limited number of third-party manufacturers with the expertise, required regulatory approvals and facilities to manufacture our bulk vaccines on a commercial scale, replacement of a manufacturer may be expensive and time-consuming and may cause interruptions in the production of our vaccine. A third-party manufacturer may also encounter difficulties in production. These problems may include:

- difficulties with production costs, scale up and yields;
- challenges in developing a lyophilized formula of, or validating a lyophilization process for, LUNAR-COV19;
- challenges in storage and cold chain distribution of LUNAR-COV19 (even with lyophilization);
- availability of raw materials and supplies;
- quality control and assurance;
- shortages of qualified personnel;
- compliance with strictly enforced federal, state and foreign regulations that vary in each country where products might be sold; and
- lack of capital funding.

As a result, any delay or interruption could have a material adverse effect on our business, financial condition, and results of operations.

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. Our competitors may have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing 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 or less costly than any product candidate that we may develop.

Other than our LUNAR-COV19 vaccine candidate and LUNAR-OTC, all of our programs are preclinical and targeted toward indications for which there are product candidates in clinical development. We will face competition

from other drugs currently approved or that may be approved in the future for the same therapeutic indications as our product candidates. For example, both Synlogic and Ultragenyx are currently conducting clinical trials with therapies to treat OTC deficiency. Currently approved therapies for these patients include the small molecule nitrogen scavengers sodium benzoate, sodium phenylacetate, and sodium phenylbutyrate, and glycerol phenylbutyrate (brand name Ravicti). Our ability to compete successfully will depend largely on our ability to leverage our experience in drug discovery and development to:

- discover and develop therapeutics that are superior to other products in the market;
- attract qualified scientific, product development and commercial personnel;
- obtain patent and/or other proprietary protection for our nucleic acid product platform and future product candidates;
- obtain required regulatory approvals; and
- successfully collaborate with pharmaceutical companies in the discovery, development and commercialization of new therapeutics.

The availability of our competitors' products could limit the demand, and the price we are able to charge, for any products that we may develop and commercialize. We will not achieve our business plan if the acceptance of any of these products is inhibited by price competition or the reluctance of physicians to switch from existing drug products to our products, or if physicians switch to other new drug products or choose to reserve our future products for use in limited circumstances. The inability to compete with existing or subsequently introduced drug products would have a material adverse impact on our business, financial condition and prospects.

Established pharmaceutical companies may invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make our product candidates less competitive. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA approval or discovering, developing and commercializing product candidates before we do, which would have a material adverse impact on our business.

The commercial success of our product candidates will depend upon the acceptance of these 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 AEs;
- limitations or warnings contained in the FDA-approved label for such products;
- availability of alternative treatments;
- pricing and cost-effectiveness;
- 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 third-party coverage and adequate reimbursement; and
- the willingness of patients to pay out-of-pocket in the absence of third-party coverage.

Unless other formulations are developed in the future, we expect our compounds to be formulated in an injectable 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 a product 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 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.

We currently do not have an organization for the sales, marketing and distribution of pharmaceutical products and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. 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 third parties to perform these services. With respect to certain of our current programs as well as future programs, we may rely completely on an alliance partner for sales and marketing. In addition, we intend to enter into strategic alliances with third 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 intend to 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 revenue 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.

If we obtain approval to commercialize any approved products outside of the United States, a variety of risks associated with international operations could materially adversely affect our business.

If we obtain approval to commercialize any approved products outside of the United States, we 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.

Coverage and adequate reimbursement may not be available for our product candidates, if approved, which could make it difficult for us to sell products 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 may 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 that we may develop and commercialize into our target markets. Obtaining formulary approval from hospitals and from 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 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. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the EU do not follow price structures of the U.S. and generally tend to be priced significantly lower.

RISKS RELATED TO OUR BUSINESS OPERATIONS AND INDUSTRY

Our future success depends on our ability to attract and retain key executives and to attract, retain and motivate qualified personnel.

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. There is currently a shortage of skilled executives in our industry, which is likely to continue. As a result, competition for skilled personnel is intense and the turnover rate can be high. 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.

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

As of December 31, 2020, we had 118 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.

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. Misconduct by employees could include intentional or nonintentional failures to comply with the regulations of the FDA and non-U.S. regulators, to provide accurate information to the FDA and non-U.S. 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. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements.

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. We have adopted a code of conduct, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in 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 any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, 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, and contractual damages. Even if we are ultimately successful in defending any such action, we could be required to divert financial and managerial resources in doing so and adverse publicity could result, all of which could harm our business.

Certain current and future relationships with customers and third-party payors as well as certain of our business operations may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such 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. 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 Affordable Care Act amended the Social Security Act to provide that the U.S. government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act penalties for which are described below.
- Federal civil and criminal false claims laws and civil monetary penalty laws, including the federal False Claims Act (“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 $11,665 to $23,331 per false claim or statement.
- 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.; and
- 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 European Union ("EU") has established its own data security and privacy legal framework, including but not limited to Directive 95/46/EC (the "Data Protection Directive"). The European General Data Protection Regulation ("GDPR") took effect on May 25, 2018, which contains new provisions specifically directed at the processing of health information, higher sanctions and extra-territoriality measures intended to bring non-EU companies under the regulation. We anticipate that over time we may expand our business operations to include additional operations in the EU, including potentially conducting preclinical and clinical trials. With such expansion, we would be subject to increased governmental regulation in the EU countries in which we might operate, including regulation due to the GDPR.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations or laws that apply to us, we may be subject to 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 Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 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.

There remain executive, legal and political challenges to certain aspects of the ACA. For example, in December 2017, Congress repealed the tax penalty for an individual's failure to maintain ACA-mandated health insurance as part of the Tax Cuts and Jobs Act of 2017 (the "Tax Act"), effective January 1, 2019. On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. On December 18, 2019, the U.S. Court of Appeals for the Fifth Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. On March 2, 2020, the U.S. Supreme Court granted the petitions for writs of certiorari to review the case and held oral arguments on November 10, 2020. Although the U.S. Supreme Court has not yet ruled on the constitutionality of the ACA, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare. It is unclear how the U.S. Supreme Court ruling, other such litigation, and the healthcare reform measures of the Biden administration will impact the ACA and our operations.

In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. On August 2, 2011, the Budget Control Act of 2011 among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of 2% per fiscal year, which started in April 2013, and, due to subsequent legislative amendments, will remain in effect through 2030 unless additional Congressional action is taken, except for a temporary suspension from May 1, 2020 through March 31, 2021 due to the COVID-19 pandemic. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, also reduced Medicare payments to several categories of healthcare providers. Additionally, the Bipartisan Budget Act of 2018, among other things, amended the ACA to increase from 50% to 70% the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole."

Further, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, Congress and the Biden administration may seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, to encourage importation from other countries and bulk purchasing.

We expect that healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and lower reimbursement, and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government-funded programs may result in a similar reduction in payments from private payors.

We cannot predict what healthcare reform initiatives may be adopted in the future. Further federal, state and foreign legislative and regulatory developments are likely, and we expect ongoing initiatives to increase pressure on drug pricing. Such reforms could have an adverse effect on anticipated revenues from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates.

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 future 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 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 product candidates, if approved for commercial sale.

We plan to obtain product liability insurance relating to the use of our therapeutics in future 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. 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 employees 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 criminal elements to attack computer systems are sophisticated, change frequently and may originate from less regulated and remote areas of the world. 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 are located in San Diego, California. We are vulnerable to natural disasters such as earthquakes 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.

RISKS RELATED TO OUR COMMON STOCK

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 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 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. 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**.**

We do not intend to pay dividends on our common stock so any returns 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.

GENERAL RISK FACTORS

The market price of our common stock may be highly volatile and investors may not be able to resell shares at or above the price at which they purchase the shares.

The trading price of our common stock is likely 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 IND or BLA for 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 develop and commercialize our product candidates;
- 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;
- 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. 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, 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 attestation, it could result in a loss of investor confidence in the accuracy, reliability, and completeness of our financial reports. We expect that the loss of "emerging growth company" status and compliance with these additional requirements will require management to expend additional time while also condensing the time frame available to comply with certain requirements, which may further increase our legal and financial compliance costs.

We may be at risk of securities class action litigation.

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 and product approvals. If we face such litigation, it could result in substantial costs, divert management's attention and resources, or have a material adverse effect on our business, operating results and prospects.

Sales of a substantial number 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 those common stock in the public market, the trading price of our common stock could decline. 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 are either subject to outstanding options or reserved for future issuance under our employee benefit plans are or may become eligible for sale in the public market to the extent permitted by the provisions of various 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 create downward pressure on the trading price of our common stock and 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, our shareholders may experience substantial dilution. Pursuant to our 2019 Omnibus Equity Incentive Plan, our management is authorized to grant options and other equity-based awards to our employees, directors and consultants. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time, 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.

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 cannot assure you that we would 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 are delisted from Nasdaq and are 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 2. Properties

We have three 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 2025. We have the right to extend this lease for an additional five-year term.

On February 16, 2020, we entered into a short-term lease for additional office and laboratory space located in close proximity to our main office at 10578 Science Center Drive, Suite 150. The additional space of approximately 11,750 square feet is leased through March 2025.

On February 26, 2021, we entered into a short-term lease for additional office and laboratory space located in close proximity to our main office at 10240 Science Center Drive, Suite 100. The additional space of approximately 4,312 square feet is leased for a term of twelve months. We have the right to extend this lease for an additional twelve months.

We believe that our properties are suitable for the conduct of our business.

Item 3. Legal Proceedings

On December 13, 2019, a former employee of the Company filed a complaint in San Diego County Superior Court, captioned Adonary Munoz v. Arcturus Therapeutics, Inc., et al, Case No. 37-2019-00066358-CU-PO-CTL. The lawsuit alleges sexual assault by an acquaintance of one of our employees and seeks to hold the Company liable on a number of causes of action. On January 17, 2020, a second amended complaint (“SAC”) was filed seeking $30 million in damages, including punitive damages and damages for emotional distress. The matter is scheduled for mediation on May 5, 2021. The Company believes the allegations of Ms. Munoz in her complaint are without merit, and intends to vigorously defend itself in the foregoing action. The Company is unable to estimate a potential loss or range of losses relating to this matter.

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

Holders of Common Stock

As of February 24, 2021, there were 18 holders of record of our common stock. As of such date, there were 26,280,275 shares of our common stock outstanding.

Dividends

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

Recent Sales of Unregistered Securities

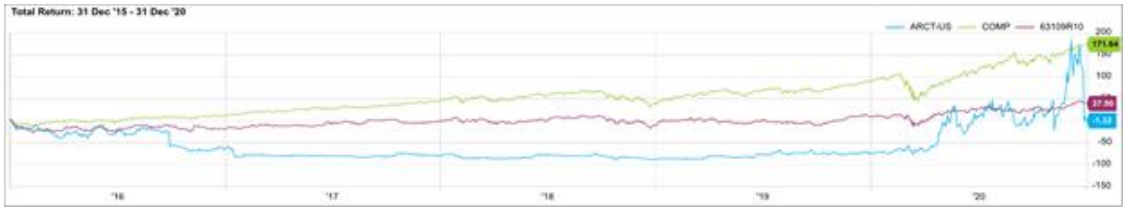
None.

Issuer and Affiliated Purchaser - Purchases of Equity Securities

During the fiscal year 2018, we completed the sale of our intangible assets related to the ADAIR technology. Pursuant to the asset purchase agreement for ADAIR, we received a 30% ownership interest in the common stock of Vallon Pharmaceuticals, Inc. ("Vallon") in consideration for the sale of the ADAIR technology. As of December 31, 2020, we held a 19% ownership interest due to the dilutive issuances of common stock by Vallon. Vallon completed an initial public offering and began trading on The Nasdaq Capital Market under the ticker "VLON" in February 2021. After this offering and other previous stock issuances of Vallon, Arcturus owns 843,750 shares of Vallon's total post-IPO 6,811,122 outstanding shares, or approximately 12%.

Five Year Performance Graph

The annual changes for the five-year period shown in the graph below are based on the assumption that $100 had been invested in Company common stock, the Nasdaq Composite Index, and the Nasdaq Biotechnology Index on December 31, 2015. With respect to "Market Information," our common stock is listed on Nasdaq under the trading symbol "ARCT".



Item 6. Selected Financial Data

The Company has elected to comply with Item 301 of Regulation S-K as amended effective February 10, 2021, and is omitting this disclosure in reliance thereon.

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.

Overview

Arcturus is a global clinical-stage messenger RNA medicines company focused on the development of infectious disease vaccines and significant opportunities within liver and respiratory rare diseases. In addition to our mRNA platform, our proprietary lipid nanoparticle delivery system, LUNAR, has the potential to enable multiple nucleic acid medicines, and our proprietary STARR technology has the potential to provide longer-lasting RNA and sustained protein expression.

Our key proprietary technology has the potential to address the major hurdles in RNA development, namely the effective and safe delivery of RNA therapeutics to disease-relevant target tissues. We believe that the versatility of our platform to target multiple tissues, its compatibility with various nucleic acid therapeutics, and our expertise in developing scalable manufacturing processes put us in a good position to deliver on the next generation of nucleic medicines.

In August 2020, we announced the dosing of all subjects in the first cohort of the Phase 1 clinical study of our LUNAR-COV19 vaccine candidate. The study was conducted with CTI Clinical Trial and Consulting Services, a global CRO, and in collaboration with Duke-NUS Medical School in Singapore. In December 2020, we announced that we received approval from the Singapore HSA to proceed with a Phase 2 clinical study of the LUNAR-COV19 vaccine candidate.

Additionally, in October 2020, we announced the completion of the first three dose escalation cohorts in our ongoing Phase 1 study of ARCT-810, our messenger RNA-based therapeutic candidate for OTC deficiency.

Our activities since inception have consisted principally of performing research and development 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, 2020, we had an accumulated deficit of $143.8 million.

Liquidity and Capital Resources

Overview

Since our inception, we have funded our operations principally with proceeds from the sale of capital stock and revenues earned through collaborative agreements. At December 31, 2020, we had $462.9 million in unrestricted cash and cash equivalents.

On October 12, 2018, we entered into a Loan and Security Agreement with Western Alliance Bank whereby we received gross proceeds of $10.0 million under a long-term debt agreement (the "Loan").

On October 30, 2019, we and the Bank entered into a Third Amendment (the "Third Amendment") to the Loan and Security Agreement dated as of October 12, 2018 (as amended, the "Loan Agreement").

Pursuant to the Third Amendment, the Bank agreed to make a term loan to us on October 30, 2019, in the amount of $15.0 million (the "Term Loan"). The resulting net increase in the indebtedness of us was $5.0 million. The Term Loan bears interest at a floating rate ranging from 1.25% to 2.75% above the prime rate. The amendment further provides that the Term Loan has a maturity date of October 30, 2023. We shall make monthly payments of interest only until the interest-only end date of October 1, 2021 and thereafter shall make monthly payments of principal and interest during a 24-month amortization period. Upon maturity or prepayment, we will be required to pay a 2% fee as a result of the FDA's approval to proceed with the Company's LUNAR-OTC (ARCT-810) program based on its IND submission.

On March 4, 2020, we were awarded a grant (the "Grant") from the Singapore EDB to support the co-development of a potential COVID-19 vaccine with the Duke-NUS Medical School. The Grant provides for up to S$14.0 million (approximately US$10.0 million using the exchange rate at the time the grant contract was entered into) in grants to support the development of the vaccine. We entered into an amendment to the Grant on September 24, 2020 to update certain delivery and milestone timelines. The Grant has been paid in full by the EDB as a result of the achievement of certain milestones related to the progress of the development of the vaccine, as set forth in the award agreement. The funds received have been recognized as contra research and development expense in proportion to the percentage covered by the EDB of the overall budget. We are liable for certain expenses during the program and are also subject to certain conditions, including (i) completing an external audit within 183 days of the conclusion of the claim period on February 20, 2021, or August 22, 2021, and (ii) delivering 10 grams of LUNAR-COV19 vaccine candidate suitable for use in a phase 3 trial in two shipments with a partial shipment by June 30, 2021 and a remaining shipment by September 30, 2021. Additionally, we are required to pay an agreed upon royalty rate to Duke-NUS on future net sales of the LUNAR-COV19 vaccine candidate in markets or jurisdictions outside of Singapore.

On October 2, 2020, we were awarded another grant from the Singapore EDB to support the further development of a potential COVID-19 vaccine. The grant provides for up to S$9.3 million (approximately US$6.7 million) to support the development of the vaccine candidate for costs incurred in Singapore subject to certain conditions including (i) completing an external audit within 183 days from March 31, 2021, or September 30, 2021, (ii) delivering 10 grams of LUNAR-COV19 vaccine candidate suitable for use in a phase 3 trial in two shipments with a partial shipment by June 30, 2021 and a remaining shipment by September 30, 2021 and (iii) creating an entity in Singapore which was completed during the fourth quarter of 2020. The grant will be paid in two installments upon the achievement of certain milestones related to the progress of the development of the vaccine candidate. We received the first installment of $3.6 million in the fourth quarter of 2020.

On November 7, 2020, we 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 of up to S$62.1 million, subject to the satisfaction of customary deliveries, to support the manufacture of the LUNAR-COV19 vaccine candidate (the "Singapore Loan"). The Singapore Loan and the related side letter includes certain loan covenants requiring (i) unused funds as of June 30, 2021 to be subsequently returned within thirty days, subject to the agreed upon extension of the reconciliation date, (ii) us to provide a quarterly reconciliation report within forty-five days of each financial quarter end, (iii) an external audit to be completed by September 26, 2021, (iv) us to deliver 10 grams of the LUNAR-COV19 vaccine candidate suitable for use in a phase 3 trial in two shipments with a partial shipment by June 30, 2021 and a remaining shipment by September 30, 2021, and (v) us to provide EDB with a right of first refusal on GMP manufacturing slots of the LUNAR-COV19 vaccine candidate up to an agreed-upon maximum amount. We elected to borrow the full amount available under the Support Agreement of S$62.1 million, or $46.6 million, as a result of applicable exchange rates, on January 29, 2021.

The Singapore Loan accrues interest at a rate of 4% per annum calculated on a daily basis. Subject to certain exceptions, the Singapore Loan is intended to be a limited recourse loan that will be repaid solely through a royalty payment of 10% of net sales proceeds of the LUNAR-COV19 vaccine candidate, up to the amount of the outstanding principal and interest under the Singapore Loan. However, all unpaid principal and interest under the Singapore Loan will be due and payable five years after the borrowing date, if net sales of the LUNAR-COV19 vaccine exceed a certain minimum threshold during this five year period or we obtain clearance to sell the vaccine in specified jurisdictions. Unpaid principal and interest under the Singapore Loan will also become due and payable upon an event of default under the Support Agreement. The first vaccine sales, including the amount of net sales, shall be reported to EDB within 10 days of delivery and quarterly reports of aggregate vaccine sales, including net sales proceeds shall be provided within 30 days after quarter end.

If any portion of the Singapore Loan is required to be forgiven pursuant to the terms of the Support Agreement, the EDB has the right to take ownership of certain raw materials and equipment that were purchased by us with proceeds of the Singapore Loan (the "Specified Assets"). We entered into a security agreement (the "Security Agreement") for the benefit of the EDB to provide that repayment of the Singapore Loan and related obligations are secured by a lien on the Specified Assets.

In connection with the entry into the Support Agreement, we entered into a consent agreement with Western Alliance Bank and an amendment to the Loan and Security Agreement, dated as of October 12, 2018, to exclude the Specified Assets from Western Alliance Bank's lien on certain assets of Arcturus.

A significant portion of our current cash balance of $462.9 million along with the $46.6 million from the Singapore Loan is expected to be utilized during fiscal year 2021 to fund (i) the Phase 2 trial and anticipated Phase 3 trial of our current LUNAR-COV19 vaccine candidate, (ii) the continued Phase 1 trial and anticipated Phase 2 trial of ARCT-810, our LUNAR-OTC candidate, (iii) advancing our new LUNAR-FLU program toward submission of an IND, (iv) and other programs and administrative costs.

The Phase 3 trial of our LUNAR-COV19 vaccine candidate is expected to be funded primarily or exclusively through our cash reserves. If we achieve EUA approval to market our LUNAR-COV19 vaccine candidate, we will need to raise additional funds through equity transactions, additional debt or prepayments from potential customers, among other options, to fund commercialization of LUNAR-COV19.

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. Our future capital requirements are difficult to forecast and will depend on many factors.

We expect to continue to incur additional losses for the foreseeable future, and we will need to raise additional debt or equity financing or enter into additional partnerships to fund development. The ability of our Company to transition to profitability is dependent on identifying and developing successful mRNA drug candidates. In the near future, if we are not able to achieve planned milestones, incur costs in excess of our forecasts, or do not meet covenant requirements of our debt, we will need to reduce discretionary spending, discontinue the development of some or all of our products, 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.

The following table shows a summary of our cash flows for the year ended December 31, 2020, 2019 and 2018 (in thousands):

	Year Ended December 31,		
(Dollars in thousands)	**2020**	**2019**	**2018**
Cash provided by (used in):			
Operating activities	$ (42,861)	$ (6,445)	$ (20,760)
Investing activities	(1,742)	(818)	22,134
Financing activities	436,145	41,907	10,204
Net increase in cash and restricted cash	$ 391,542	$ 34,644	$ 11,578

Operating Activities

Our primary use of cash is to fund operating expenses, which consist mainly of research and development and general and administrative expenditures. We have incurred significant expenses which have been partially offset by cash collected through our collaboration agreements. Cash collections under the collaboration agreements can vary from year to year depending on the terms of the agreement and work performed. These changes on cash flows primarily relate to the timing of cash receipts for upfront payments, reimbursable expenses and achievement of milestones under these collaborative agreements.

Net cash used in operating activities was $42.9 million on a net loss of $72.1 million for 2020, $6.4 million on a net loss of $26.0 million for 2019 and $20.8 million on a net loss of $21.8 million for 2018. Adjustments for non-cash charges which includes share-based compensation expense and depreciation and amortization were $8.1 million for 2020, $3.6 million for 2019 and $2.2 million for 2018. Changes in working capital resulted in adjustments to operating net cash inflows of $21.2 million for 2020, net cash inflows of $16.0 million for 2019, and net cash outflows of $1.2 million for 2018. The significant adjustments to operating net cash inflows for 2020 were primarily due to the supply agreement with Israeli MOH signed in the third quarter of 2020 along with increased accounts payable and accrued liabilities from LUNAR-COV19 (ARCT-021) and LUNAR-OTC (ARCT-810) clinical trial activities, which expenses were incurred as discussed below.

Investing Activities

Net cash used in investing activities of $1.7 million for 2020 and $0.8 million for 2019 reflected the acquisition of property and equipment. Net cash provided by investing activities of $22.1 million for 2018 reflected proceeds from the maturities of our short-term investments of $30.2 million, offset by purchases of short-term investments of $6.6 million, and cash used to purchase property and equipment of $1.5 million.

Financing Activities

Net cash provided by financing activities of $436.1 million for 2020 consisted of net proceeds from the issuance of common stock in three underwritten public offerings of $423.8 million, net proceeds of $9.6 million from the issuance of common stock to Ultragenyx upon exercise of its option and proceeds from the exercise of stock options of $2.7 million. Net cash provided by financing activities of $41.9 million for 2019 consisted of net proceeds from the issuance of common stock of $15.5 million to Ultragenyx, net proceeds from the issuance of common stock of $21.3 million related to public offerings, net proceeds from long-term debt of $4.9 million, and proceeds from the exercise of stock options of $0.1 million. Net cash provided by financing activities of $10.2 million for 2018 consisted of net proceeds from the exercise of stock options of $0.3 million and net proceeds from long-term debt of $9.9 million.

Funding Requirements

We anticipate that we will continue to generate annual net 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, continued funding from partners at anticipated levels and our payment obligations under our long-term credit facility referenced in Note 7 to our Consolidated Financial Statements continuing following the current maturity schedule. 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. 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 the following:

- the development of ARCT-021, our LUNAR-COV19 vaccine candidate;
- the achievement of milestones under our strategic alliance agreements;
- the terms and timing of any other strategic alliance, licensing and other arrangements that we may establish;
- 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.

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):

	Year Ended December 31,		
(Dollars in thousands)	**2020**	**2019**	**2018**
Collaboration revenue	$ 9,539	$ 20,789	$ 15,753

Collaboration revenue decreased by $11.3 million during the year ended December 31, 2020 as compared to the year ended December 31, 2019. The decrease in collaboration revenue primarily relates to (i) $5.6 million of decreased revenue from reduced reimbursements associated with the CureVac co-development agreement that terminated in the second quarter of 2019, (ii) a decrease in one-time sublicense revenue from Synthetic Genomics as we recognized sublicense revenue of $3.3 million during the second quarter of 2019, (iii) a reduction of $1.9 million in revenue recognized related to the Ultragenyx Agreement, as we recorded a large amount of upfront payment amortization upon the execution of the Ultragenyx Third Amendment during the second quarter of 2019 and also recognized fewer research and development expense reimbursements related to the Ultragenyx Agreement during 2020, and (iv) lower research and development expense reimbursements recognized in 2020 related to other collaboration agreements, including with Providence Therapeutics and Takeda. The decrease in collaboration revenue was partially offset by increased revenue recognition related to the Janssen agreement and other collaboration agreements.

Collaboration revenue increased by $5.0 million during the year ended December 31, 2019 as compared to the year ended December 31, 2018. The increase in revenue during the year was caused by a ramp up in activities on the Janssen collaboration agreement which led to an increase in revenue of $1.7 million. Additionally, an increase of $2.2 million was due to settling the terminated co-development program with CureVac (as discussed in the following paragraph) along with an increase in amortized revenue that was previously deferred. Lastly, there was an increase in revenue from Synthetic Genomics Inc. of $2.1 million due to recognizing revenue related to a sublicense payment during the year. These increases were primarily offset by negligible decreases from various programs and decreased revenue of $0.9 million associated with Ultragenyx as the collaboration agreement had less activity compared to the prior year.

Operating Expenses

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

	Year Ended December 31,		
(Dollars in thousands)	**2020**	**2019**	**2018**
Operating expenses:			
Research and development, net	$ 57,846	$ 33,640	$ 16,982
General and administrative	23,217	12,662	20,582
Total	$ 81,063	$ 46,302	$ 37,564

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

(Dollars in thousands)	Year Ended December 31, 2020	2019	2018
External pipeline development expenses:			
LUNAR-OTC (ARCT-810)	$ 13,008	$ 15,616	$ 3,699
LUNAR-CF (ARCT-032), net	4,405	813	337
LUNAR-COV19 (ARCT-021), net	20,896	—	—
Discovery technologies	1,748	3,937	2,943
External platform development expenses:			
Partnered discovery technologies	1,515	1,894	1,979
Total development expenses	$ 41,572	$ 22,260	$ 8,958
Personnel related expenses	$ 12,824	$ 9,005	$ 6,533
Facilities and equipment expenses	3,450	2,375	1,491
Total research and development expenses, net	$ 57,846	$ 33,640	$ 16,982

Research and Development Expenses, net

Our research and development expenses consist primarily of external manufacturing costs, in-vivo research studies performed by contract research organizations, clinical and regulatory consultants, personnel related expenses and laboratory supplies related to conducting research and development activities. Costs to acquire and manufacture pre-launch inventory, mRNA supply for preclinical studies and clinical trials are recognized and included in external pipeline development expenses for the specific program.

The IND for our LUNAR-OTC program was accepted by the FDA in April 2020. However, the ongoing pandemic has delayed patient enrollment, resulting in lower clinical costs. As a result, LUNAR-OTC expenses for the year ended December 31, 2020 decreased by $2.6 million as compared to the year ended December 31, 2019. LUNAR-OTC expenses for the year ended December 31, 2019 increased by $11.9 million as compared to the year ended December 31, 2018. The increase from 2018 to 2019 was due primarily to preparation for an IND application, which was submitted during the first quarter of 2020.

LUNAR-CF expenses were $4.4 million in the year ended December 31, 2020, $0.8 million in the year ended December 31, 2019 and $0.3 million in the year ended December 31, 2018. The increase in LUNAR-CF expenses from 2018 to 2019 and from 2019 to 2020 was due primarily to the amendment to the CFF Agreement executed in July 2019, and we expect that our development efforts and associated costs will increase over the next several years as the LUNAR-CF program moves toward expected IND submission in 2022. These amounts are net of funds awarded by the CFF.

In March 2020, we signed a contract for approximately $10.0 million (using the exchange rate at the time the grant contract was entered into) with the Singapore Economic Development Board that will fund a portion of the costs incurred in our LUNAR-COV19 program. In October 2020, we entered into an additional grant agreement for approximately $6.7 million (using the exchange rate at the time the grant contract was entered into). We expect that the program costs and pre-launch inventory costs will continue to increase as clinical trials progress and we advance program development. The research and development costs were $20.9 million for the year ended December 31, 2020. There were no comparable costs in 2019 or 2018.

Discovery technologies represents our efforts to expand our product pipeline. Discovery technology expenses were $1.7 million in the year ended December 31, 2020, $3.9 million in the year ended December 31, 2019 and $2.9 million in the year ended December 31, 2018. The decrease in discovery technology expenses from 2019 to 2020 was due to focusing our efforts on the advancement of our LUNAR-OTC and LUNAR-COV19 programs. The increase in discovery technology expenses from 2018 to 2019 was due to additional efforts to add new capabilities necessary to expand our future platform technology and discovery of our next programs. These efforts have resulted in new programs such as STARR technology.

Partnered discovery technologies expenses were $1.5 million in the year ended December 31, 2020, $1.9 million in the year ended December 31, 2019 and $2.0 million in the year ended December 31, 2018. The decrease

in partnered discovery technologies expenses from 2019 to 2020 was primarily caused by a decrease in activity relating to our collaboration with Takeda. We expect partnered discovery technologies expenses to fluctuate based on the needs of our collaboration partners.

Personnel related expenses, net of funds received from CFF and the Singapore EDB, were $12.8 million in the year ended December 31, 2020, $9.0 million in the year ended December 31, 2019 and $6.5 million in the year ended December 31, 2018. The increase in personnel related expenses from 2019 to 2020 was primarily due to (i) increased headcount related to the addition of our LUNAR-COV19 program and (ii) increased share-based compensation expense resulting from our increased stock price in 2020. The increase in personnel related expenses from 2018 to 2019 was due primarily to increased headcount necessary to advance our external pipeline and platform efforts. We expect personnel related expenses to increase in 2021 as we expand our headcount to execute our business plan.

Facilities and equipment expenses were $3.5 million in the year ended December 31, 2020, $2.4 million in the year ended December 31, 2019 and $1.5 million in the year ended December 31, 2018. The increase in facilities and equipment expenses from 2019 to 2020 was primarily due to the lease of a second building entered into in early 2020. The increase in facilities and equipment expenses from 2018 to 2019 was due primarily to higher rent and related costs associated with our headquarter lease.

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 $23.2 million in the year ended December 31, 2020, $12.7 million in the year ended December 31, 2019 and $20.6 million in the year ended December 31, 2018. The increase in general and administrative expenses from 2019 to 2020 was primarily caused by (i) a $5.9 million increase in personnel related expenses due to increased headcount and increased share-based compensation, (ii) a $1.6 million increase in facilities and insurance expenses due to the execution of a new lease agreement and (iii) a $2.3 million increase in professional fees due to a $2.4 million insurance settlement received in 2019 relating to the proxy matter that was recorded as contra-general and administrative expense. The decrease in general and administrative expenses from 2018 to 2019 was primarily due to (i) non-recurring proxy, legal and related costs incurred in 2018 of $7.3 million, which did not recur in 2019, and (ii) the insurance settlement of $2.4 million relating to the proxy matter that was recorded as contra-G&A expense when it was received in 2019, offset by increases in personnel costs of $1.1 million, public company related expenses of $0.4 million, and facilities and other costs of $0.3 million. Without the effect of the one-time proxy costs, general and administrative expenses would have been relatively consistent between 2018 and 2019. We expect general and administrative expenses to increase in 2021 as we expand our headcount, facilities and professional services to execute our business plan.

Finance income (expense), net

	Year Ended December 31,		
(Dollars in thousands)	**2020**	**2019**	**2018**
Finance income (expense), net:			
Interest income	$ 470	$ 408	$ 514
Interest expense	(831)	(854)	$ (186)
Total	$ (361)	$ (446)	$ 328

Interest income is generated on cash and cash equivalents. For the year ended December 31, 2020, the increase in interest income compared to the year ended December 31, 2019 resulted from increased interest on bank deposits due to higher cash balances, partially offset by lower interest rates earned. For the year ended December 31, 2019, the decrease in interest income compared to the year ended December 31, 2018 resulted from decreased investments.

Interest expense relates to the long-term debt with Western Alliance Bank. Interest expense was relatively flat for the year ended 2020 as compared to 2019. The increase in interest expense for the year ended 2019 as compared to 2018 was due to an entire year of interest incurred during 2019 versus one quarter of interest incurred during the fourth quarter of 2018.

Critical Accounting Policies and Estimates

We prepare our consolidated financial statements in conformity with accounting principles generally accepted in the United States ("U.S. GAAP"). As such, we make certain estimates, judgments and assumptions that we believe are reasonable, based upon information available to us. These judgments involve making estimates about the effect of matters that are inherently uncertain and may significantly impact our results of operations and financial condition. We describe our significant accounting policies more fully in Note 2 to our consolidated financial statements for the year ended December 31, 2020. In the following paragraphs, we describe the specific risks associated with these critical accounting policies and we caution that future events may not reflect exactly as one may expect, and that best estimates may require adjustment.

The following are our significant accounting policies which we believe are the most critical to aid in fully understanding and evaluating our reported financial results.

Revenue Recognition

Research and development revenue under collaborative agreements

We recognize R&D revenue from several collaboration agreements. Our collaboration agreements typically contain promised goods and services, including technology licenses or options to obtain technology licenses, R&D services, and manufacturing services. Upon entering into a collaboration agreement, we are required to make the following judgments:

Identifying the performance obligations contained in the agreement

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.

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 do not typically include any payments we may receive in the future in our initial transaction price 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

If we were to allocate the transaction price to more than one performance obligation, we would make estimates of the relative stand-alone selling price of each performance obligation, as it is not typical for us to sell our goods or services on a stand-alone basis. The estimate of the relative stand-alone selling price would require us to make significant judgments. To date, we have not entered into a collaboration agreement with more than one performance obligation.

The R&D revenue we recognize each period is comprised of several types of revenue, including amortization from upfront payments, milestone payments, option exclusivity fees 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 R&D 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 R&D services or the total length of time it will take us to complete our promised R&D 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").

Research and Development Expenses, Including Clinical Trial Accruals/Expenses

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

Clinical trial expenses are a significant component of research and development expenses, and we outsource a significant portion of these clinical trial activities to third parties. Third-party clinical trial expenses include investigator fees, site and patient costs, CRO costs, and costs for central laboratory testing and data management. The accrual for site and patient costs includes inputs such as estimates of patient enrollment, patient cycles incurred, clinical site activations, and other pass-through costs. These inputs are required to be estimated due to a lag in receiving the actual clinical information from third parties. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected on the balance sheets as prepaid assets or accrued expenses. These third-party agreements are generally cancelable, and related costs are recorded as research and development expenses as incurred. Non-refundable advance clinical payments for goods or services that will be used or rendered for future research and development activities are recorded as a prepaid asset and recognized as expense as the related goods are delivered or the related services are performed. When evaluating the adequacy of the accrued expenses, we analyze progress of the studies, including the phase or completion of events, invoices received and contracted costs. Significant 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 accrual estimates have not been materially different from our actual costs.

Off-balance sheet arrangements

None.

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 and term loan, we believe that we are not subject to any material market risk exposure. We do not have any foreign currency or other derivative financial instruments.

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

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our periodic and current reports that we file with the SEC is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated

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

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

Management's Report on Internal Control Over Financial Reporting

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

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

As of December 31, 2020, our management assessed the effectiveness of our internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework (2013). In adopting the 2013 Framework, management assessed the applicability of the principles within each component of internal control and determined whether or not they have been adequately addressed within the current system of internal control and adequately documented. Based on this assessment, management, under the supervision and with the participation of our Chief Executive Officer, Chief Financial Officer and Principal Accounting Officer, concluded that, as of December 31, 2020, our internal control over financial reporting was effective based on those criteria.

The effectiveness of our internal control over financial reporting as of December 31, 2020 has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in its report, which is included herein.

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 Arcturus Therapeutics Holdings Inc. and its Subsidiaries' internal control over financial reporting as of December 31, 2020, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), (the COSO criteria). In our opinion, Arcturus Therapeutics Holdings Inc. and its Subsidiaries (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2020, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2020 and 2019, the related consolidated statements of operations and comprehensive loss, changes in stockholders' equity, and cash flows, for each of the three years in the period ended December 31, 2020, and the related notes and our report dated March 1, 2021 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

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

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

/s/ Ernst & Young LLP

San Diego, California

March 1, 2021

Changes in Internal Control Over Financial Reporting.

An evaluation was also performed under the supervision and with the participation of our management, including our Chief Executive Officer, Chief Financial Officer and Principal Accounting Officer of any changes in our internal control over financial reporting that occurred during our last fiscal quarter and that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. There were no changes in our internal control over financial reporting identified in management's evaluation pursuant to Rules 13a-15(d) or 15d-15(d) of the Exchange Act during the quarter ended December 31, 2020 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Information required by this item will be contained in our Definitive Proxy Statement for our 2021 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2020. 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 2021 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2020. 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 2021 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2020. 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 2021 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2020. 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 2021 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2020. 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	Underwriting Agreement, dated December 7, 2020, by and among Arcturus Therapeutics Holdings Inc., Piper Sandler & Co., Guggenheim Securities, LLC and Wells Fargo Securities, LLC. Incorporated by reference to Exhibit 1.1 to Current Report on Form 8-K filed on December 8, 2020 (File No. 001-38942).
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**	Amended and Restated Amendment to Development and Option Agreement, dated as of September 28, 2018, by and between CureVac AG and Arcturus Therapeutics Inc. Incorporated by reference to Exhibit 99.2 to the Company's Report of Foreign Private Issuer on Form 6-K filed on October 1, 2018 (File No. 001-35932).
10.6**	Research Collaboration and License Agreement, by and between Arcturus Therapeutics, Inc. and Janssen Pharmaceuticals, Inc., dated October 18, 2017. Incorporated by reference to Exhibit 4.7 to Form 20-F filed on May 14, 2018 (File No. 001-35932).
10.7**	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).
10.8**	Research Agreement, by and between Arcturus Therapeutics, Inc. and Millennium Pharmaceuticals, Inc., a wholly-owned subsidiary of Takeda Pharmaceutical Company Limited, effective December 6, 2016, as amended December 21, 2017. Incorporated by reference to Exhibit 4.9 to Form 20-F filed on May 14, 2018 (File No. 001-35932).
10.9**	Research Collaboration and License Agreement, by and between Arcturus Therapeutics, Inc. and Ultragenyx Pharmaceutical Inc., entered into as of October 26, 2015, as amended October 17, 2017 and April 20, 2018. Incorporated by reference to Exhibit 4.10 to Form 20-F filed on May 14, 2018 (File No. 001-35932).

Exhibit Number	Description
10.10**	Third Amendment to Research Collaboration and License Agreement, by and between Arcturus Therapeutics, Inc. and Ultragenyx Pharmaceutical Inc., effective June 18, 2019. Incorporated by reference to Exhibit 10.2 to Form 8-K filed on June 20, 2019 (File No. 001- 38942).
10.11**	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).
10.12**	Amendment No. 2 to Letter Agreement, by and between Arcturus Therapeutics, Inc. and the Cystic Fibrosis Foundation, dated August 1, 2019. Incorporated by reference to Exhibit 10.16 to Form 10-Q filed on August 14, 2019.
10.13**	Development and Option Agreement, by and between Arcturus Therapeutics, Inc. and CureVac AG, dated January 1, 2018, as amended May 3, 2018. Incorporated by reference to Exhibit 4.12 to Form 20-F filed on May 14, 2018 (File No. 001-35932).
10.14**	Third Amendment to Development and Option Agreement, by and between Arcturus Therapeutics, Inc. and CureVac AG, dated July 26, 2019. Incorporated by reference to Exhibit 10.20 to Form 10-Q filed on August 14, 2019 (File No. 001-38942).
10.15**	Co-Development and Co-Commercialization Agreement, by and between Arcturus Therapeutics, Inc. and CureVac AG, dated January 1, 2018. Incorporated by reference to Exhibit 4.13 to Form 20-F filed on May 14, 2018 (File No. 001-35932).
10.16	Termination Agreement, by and between Arcturus Therapeutics, Inc. and CureVac AG, dated July 26, 2019. Incorporated by reference to Exhibit 10.21 to Form 10-Q filed on August 14, 2019 (File No. 001-38942).
10.17**	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).
10.18**	Patent Assignment and License Agreement, by and between Arcturus Therapeutics, Inc. and Marina Biotech, Inc., dated as of August 9, 2013. Incorporated by reference to Exhibit 4.15 to Form 20-F filed on May 14, 2018 (File No. 001-35932).
10.19	Share Exchange Agreement, dated as of February 11, 2019, by and between Arcturus Therapeutics Ltd. and Arcturus Therapeutics Holdings Inc. Incorporated by reference to Exhibit 10.13 to the Company's Annual Report on Form 10-K for the year ended December 31, 2018 filed on March 18, 2019 (File No. 001-35932).
10.20**	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).
10.21**	Research Collaboration Agreement, dated as of March 8, 2019 by and between Arcturus Therapeutics, Inc. and Millennium Pharmaceuticals, Inc., a wholly-owned subsidiary of Takeda Pharmaceutical Company Limited. Incorporated by reference to Exhibit 10.15 to the Company's Annual Report on Form 10-K for the year ended December 31, 2018 filed on March 18, 2019 (File No. 001-35932).
10.22	Lease Agreement, by and between Arcturus Therapeutics, Inc. and ARE-SD Region No. 44, LLC, dated October 4, 2017. Incorporated by reference to Exhibit 4.6 to Form 20-F filed on May 14, 2018 (File No. 001-35932).

Exhibit Number	Description
10.23	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).
10.24**	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).
10.25**	Supply Agreement, dated August 17, 2020, by and between Arcturus Therapeutics, Inc. and the Israeli Ministry of Health. Incorporated by reference to Exhibit 10.32 to Quarterly Report on Form 10-Q filed on November 9, 2020 (File No. 001-38942).
10.26**	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).
10.27	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).
10.28†	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).
10.29*	Second Amendment to Lease, by and between Arcturus Therapeutics, Inc. and ARE-SD Region No. 44, LLC, dated November 13, 2020.
10.30*	Third Amendment to Lease, by and between Arcturus Therapeutics, Inc. and ARE-SD Region No. 44, LLC, dated February 25, 2021.
23.1*	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 Officer pursuant to Rule 13a-14(a) or 15d-14(a) under the Securities Exchange Act of 1934, as amended.
31.3*	Certification by Principal Accounting Officer pursuant to Rule 13a-14(a) or 15d-14(a) under the Securities Exchange Act of 1934, as amended.
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.3*	Certification of Principal Accounting Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101*	The following financial statements and footnotes from the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2020 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

Exhibit Number	Description
	101.SCH Inline XBRL Taxonomy Extension Schema
	101.CAL Inline XBRL Taxonomy Extension Calculation Linkbase
	101.DEF Inline XBRL Taxonomy Extension Definition Linkbase
	101.LAB Inline XBRL Taxonomy Extension Label Linkbase
	101.PRE Inline XBRL Taxonomy Extension Presentation Linkbase
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 1, 2021

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 1, 2021
/s/ Dr. Peter Farrell **Dr. Peter Farrell**	Chairman of the Board	March 1, 2021
/s/ Andrew Sassine **Andrew Sassine**	Director and Chief Financial Officer *(principal financial officer)*	March 1, 2021
/s/ Dr. Magda Marquet **Dr. Magda Marquet**	Director	March 1, 2021
/s/ James Barlow **James Barlow**	Director	March 1, 2021
/s/ Edward Holmes **Edward Holmes**	Director	March 1, 2021
/s/ Karah Parschauer **Karah Parschauer**	Director	March 1, 2021
/s/ Keith C. Kummerfeld **Keith C. Kummerfeld**	Vice President of Finance and Corporate Controller *(principal accounting officer)*	March 1, 2021

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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 sheets of Arcturus Therapeutics Holdings Inc. and its Subsidiaries (the "Company") as of December 31, 2020 and 2019, the related consolidated statements of operations and comprehensive loss, changes in stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2020, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020, in conformity with U.S. generally accepted accounting principles.

We also have 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, 2020, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), and our report dated March 1, 2021 expressed an unqualified opinion thereon.

Adoption of ASU No. 2016-02

As discussed in Note 2 to the consolidated financial statements, the Company changed its method of accounting for lease arrangements in the year ended December 31, 2019 due to the adoption of Accounting Standards Update (ASU) No. 2016-02, *Leases*, and the related amendments.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

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

Accrued research and development expenses

Description of the Matter

At December 31, 2020, the Company incurred $57.8 million for research and development expenses and accrued $4.1 million for clinical trial expenses. As described in Note 2 to the consolidated financial statements, the Company records accruals for estimated costs of research and development activities, including contract services for clinical trials and related clinical manufacturing costs in connection with early discovery efforts. 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.

Auditing management’s accounting for accrued research and development expenses, for which the Company has either not been invoiced or has not received information on the actual costs incurred, was especially challenging as evaluating the progress or stage of completion of the activities under the Company’s research and development agreements is dependent upon information from internal clinical personnel and third party service providers and involves a high volume of data which is tracked in spreadsheets and other end user computing programs.

How We Addressed the Matter in Our Audit

We obtained an understanding, evaluated the design and tested the operating effectiveness of controls over the accounting for accrued research and development expenses. For example, we tested controls over management’s assessment and measurement of estimated accrued costs, including data inputs for study progress and remaining stages of completion under each study.

To test the Company’s accrued research and development expenses, we obtained supporting evidence of the research and development activities performed for significant clinical trials. We attended internal clinical trial and project status meetings with accounting and clinical project managers to inspect the status of significant research and development activities. To assess the appropriate measurement of accrued research and development costs, our audit procedures included, among others, obtaining and inspecting significant agreements and agreement amendments, evaluating the Company’s documentation of trial timelines, and testing a sample of transactions and comparing the costs against related invoices and contracts. We also tested a sample of subsequent payments to evaluate the completeness of the accrued expenses and compared the results to the current year accrual.

/s/ Ernst & Young, LLP

We have served as the Company's auditor since 2018.

San Diego, California

March 1, 2021

ARCTURUS THERAPEUTICS HOLDINGS INC. AND ITS SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
(in thousands, except par value information)

	As of December 31,	
	2020	2019
Assets		
Current assets:		
Cash and cash equivalents	$ 462,895	$ 71,353
Accounts receivable	2,125	2,179
Prepaid expenses and other current assets	2,769	758
Total current assets	467,789	74,290
Property and equipment, net	3,378	2,349
Operating lease right-of-use asset, net	5,182	5,134
Equity-method investment	—	263
Non-current restricted cash	107	107
Total assets	$ 476,456	$ 82,143
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 10,774	$ 5,793
Accrued liabilities	20,639	7,134
Deferred revenue	18,108	8,397
Total current liabilities	49,521	21,324
Deferred revenue, net of current portion	12,512	15,182
Long-term debt, net of current portion	13,845	14,995
Operating lease liability, net of current portion	4,025	4,850
Total liabilities	79,903	56,351
Stockholders' equity:		
Common stock: $0.001 par value; 60,000 shares authorized and 26,192 shares issued and outstanding at December 31, 2020; 30,000 shares authorized and 15,138 shares issued and outstanding at December 31, 2019	26	15
Additional paid-in capital	540,343	97,445
Accumulated deficit	(143,816)	(71,668)
Total stockholders' equity	396,553	25,792
Total liabilities and stockholders' equity	$ 476,456	$ 82,143

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

ARCTURUS THERAPEUTICS HOLDINGS INC. AND ITS SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except per share data)

	Year Ended December 31,		
	2020	2019	2018
Collaboration revenue	$ 9,539	$ 20,789	$ 15,753
Operating expenses:			
Research and development, net	57,846	33,640	16,982
General and administrative	23,217	12,662	20,582
Total operating expenses	81,063	46,302	37,564
Loss from operations	(71,524)	(25,513)	(21,811)
Loss from equity-method investment	(263)	(32)	(302)
Finance (expense) income, net	(361)	(446)	328
Net loss	(72,148)	(25,991)	(21,785)
Net loss per share, basic and diluted	$ (3.55)	$ (2.15)	$ (2.16)
Weighted-average shares outstanding, basic and diluted	20,305	12,069	10,069
Comprehensive loss:			
Net loss	$ (72,148)	$ (25,991)	$ (21,785)
Unrealized gain on short-term investments	—	—	3
Comprehensive loss	$ (72,148)	$ (25,991)	$ (21,782)

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

ARCTURUS THERAPEUTICS HOLDINGS INC. AND ITS SUBSIDIARIES
STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(in thousands)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
BALANCE - December 31, 2017	**10,699**	**$ 212**	**$ 56,674**	**$ (3)**	**$ (23,089)**	**$ 33,794**
Net loss	—	—	—	—	(21,785)	(21,785)
Unrealized gain on short-term investments	—	—	—	3	—	3
Share-based compensation	—	—	1,259	—	—	1,259
Issuance of common stock upon exercise of stock options	63	2	369	—	—	371
BALANCE – December 31, 2018	**10,762**	**214**	**58,302**	**—**	**(44,874)**	**13,642**
Net loss	—	—	—	—	(25,991)	(25,991)
Share-based compensation	—	—	1,982	—	—	1,982
Redomiciliation share exchange	(43)	(203)	203	—	—	—
Issuance of common stock to Ultragenyx, net of issuance costs	2,400	2	15,543	—	—	15,545
Issuance of common stock, net of issuance costs	1,995	2	21,276	—	—	21,278
Issuance of common stock upon exercise of stock options	24	—	139	—	—	139
Effect of adoption of ASU 2014-09	—	—	—	—	(803)	(803)
BALANCE – December 31, 2019	**15,138**	**15**	**97,445**	**—**	**(71,668)**	**25,792**
Net loss	—	—	—	—	(72,148)	(72,148)
Share-based compensation	—	—	6,764	—	—	6,764
Issuance of common stock to Ultragenyx on option exercise	600	1	9,599	—	—	9,600
Issuance of common stock, net of issuance costs	10,059	10	423,809	—	—	423,819
Issuance of common stock upon exercise of stock options	395	—	2,726	—	—	2,726
BALANCE – December 31, 2020	**26,192**	**$ 26**	**$ 540,343**	**$ —**	**$ (143,816)**	**$ 396,553**

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,		
	2020	**2019**	**2018**
OPERATING ACTIVITIES:			
Net loss	$ (72,148)	$ (25,991)	$ (21,785)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	882	684	582
Share-based compensation expense	6,764	1,982	1,259
Loss from equity-method investment	263	25	302
Other non-cash expenses	162	873	38
Changes in operating assets and liabilities:			
Accounts receivable	54	2,302	(4,001)
Prepaid expenses and other assets	(2,011)	(120)	421
Accounts payable	4,812	3,155	578
Accrued liabilities	11,320	1,675	1,687
Deferred revenue	7,041	8,970	159
Net cash used in operating activities	(42,861)	(6,445)	(20,760)
INVESTING ACTIVITIES:			
Acquisition of property and equipment	(1,742)	(818)	(1,478)
Purchases of short-term investments	—	—	(6,594)
Proceeds from maturities of short-term investments	—	—	30,206
Net cash (used in) provided by investing activities	(1,742)	(818)	22,134
FINANCING ACTIVITIES:			
Proceeds from long-term debt, net of lender fees	—	4,945	9,872
Proceeds from exercise of stock options	2,726	139	332
Proceeds from exercise of stock option by Ultragenyx and issuance of common stock and option, net of issuance costs, to Ultragenyx	9,600	15,545	—
Proceeds from issuance of common stock, net of issuance costs	423,819	21,278	—
Net cash provided by financing activities	436,145	41,907	10,204
NET INCREASE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	391,542	34,644	11,578
Cash, cash equivalents and restricted cash at beginning of year	71,460	36,816	25,238
Cash, cash equivalents and restricted cash at end of year	$ 463,002	$ 71,460	$ 36,816

	Year Ended December 31,		
	2020	**2019**	**2018**
Supplemental disclosure of cash flow information:			
Cash paid for interest	$ 751	$ 691	$ 146
Non-cash investing activities			
Right-of-use asset obtained in exchange for lease liabilities	$ 1,360	$ 5,868	$ —
Sale of intangible assets for equity-method investment	$ —	$ —	$ 590
Purchase of property and equipment in accounts payable	$ 169	$ 240	$ 30
Release of repurchase liability for restricted shares	$ —	$ —	$ 39

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

Note 1. Organization

Description of Business

Arcturus Therapeutics Holdings Inc. (the "Company") is a global clinical-stage messenger RNA medicines company focused on development of infectious disease vaccines and significant opportunities within liver and respiratory rare diseases. The Company became a clinical stage company during 2020 when it announced that its Investigational New Drug ("IND") application for ornithine transcarbamylase ("OTC") deficiency was deemed allowed to proceed by the U.S. Food and Drug Administration ("FDA"), and its Clinical Trial Application ("CTA") candidate LUNAR-COV19 was approved to proceed by the Singapore Health Sciences Authority.

The financial statements for periods prior to June 17, 2019, the effective date of the Redomiciliation, relate to Arcturus Therapeutics Ltd. and for the periods from and after June 17, 2019 relate to Arcturus Therapeutics Holdings Inc.

Recent Developments

See "*Note 3 Revenue – Other Agreements*" for further information on the agreement with and non-refundable payment of $12.5 million from the Israeli Ministry of Health.

See "*Note 7 Debt – Manufacturing Support Agreement*" for further information on the $46.6 million funded by the Singapore Economic Development Board in January 2021.

See "*Note 8 Stockholders' Equity – Underwritten Public Offerings of Common Stock*" for further information on the Company's recent public offerings with net proceeds of approximately $423.8 million.

Liquidity

The Company has incurred significant operating losses since its inception. As of December 31, 2020 and 2019, the Company had an accumulated deficit of $143.8 million and $71.7 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, 2020, the Company has funded its operations principally with the proceeds from the sale of capital stock and revenues earned through collaboration agreements. Through underwritten public offerings, the Company raised net proceeds of $423.8 million during fiscal year 2020, after deducting underwriting discounts, commissions, and offering expenses.

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 is the research and development of medical applications for the Company's nucleic acid-focused technology.

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 represents 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, 2020 and 2019, the Company had restricted cash of $107,000 in conjunction with property leases in San Diego, California, and such restriction is expected to be removed at the end of the lease term in 2025.

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, 2020 or 2019.

Concentration of Credit Risk and Significant Customers

Financial instruments, which potentially subject the Company to concentrations of credit risk, consist of cash and cash equivalents. The Company limits its exposure to credit loss by placing its cash and cash equivalents with high credit quality financial institutions in instruments with short maturities.

There was one customer that comprised 100% of the total accounts receivable balance at December 31, 2020 and one customer that comprised 98% of the total accounts receivable balance at December 31, 2019.

For the year ended December 31, 2020, the Company's top four customers collectively represented 94% of the Company's total revenue. For the year ended December 31, 2019, there were four customers that collectively represented 91% of the Company's total revenue.

Intangible Assets Held for Sale and Equity Method Investment

At the end of the second quarter of 2018, the Company completed the sale of its intangible assets related to the ADAIR technology. Pursuant to the asset purchase agreement for ADAIR, the Company received a 30% ownership interest in the common stock of Vallon Pharmaceuticals, Inc. ("Vallon"), which was then a privately held company, in consideration for the sale of the ADAIR technology. As the Company's Chief Executive Officer holds a seat on the investee's board of directors, the Company has the ability to exercise significant influence over the operating and financial policies of this investee; therefore, the Company accounts for this investment as an equity-method investment.

The Company accounts for its share of the earnings or losses of the investee with a reporting lag of three months, as the financial statements of the investee are not completed on a basis that is sufficient for the Company to apply the equity method on a current basis.

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, 2020, 2019 and 2018.

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. Other comprehensive loss represents unrealized losses on the Company's marketable securities. There was no income tax effect related to unrealized losses for the years ended December 31, 2020, 2019 or 2018.

Revenue Recognition

Effective January 1, 2019, the Company adopted *Accounting Standards Update ("ASU") 2014-09, Revenue from Contracts with Customers (Topic 606)* ("Topic 606"), using the modified retrospective transition method. Topic 606 provides a unified model to determine how revenue is recognized and the Company applied the standard

to collaborative research and technology agreements that were in progress as of the effective date, January 1, 2019. 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 collaborative research and development agreements include license fees, upfront payments, milestone payments, reimbursement for research and development activities, option exercise fees, and royalties on sales of commercialized products. Arrangements that include upfront payments are recorded as deferred revenue upon receipt or when due and may require deferral of revenue recognition to a future period until the Company performs obligations under these arrangements. 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.

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

Leases

In February 2016, the Financial Accounting Standards Board ("FASB") issued ASU 2016-02, Leases ("Topic 842"), which requires lessees to recognize most leases on the balance sheet as lease liabilities with corresponding right-of-use assets and to disclose key information about leasing arrangements. The Company adopted Topic 842 on its effective date in the first quarter of 2019 using a modified retrospective approach. The Company elected the available package of practical expedients upon adoption, which allowed it to carry forward historical assessments of whether existing agreements contained a lease and the classification of existing operating leases.

See *"Note 11, Commitments and Contingences"* 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), in process research and development expenses and license agreement expenses, net of any grants and prelaunch inventory. Payments made prior to the receipt of goods or services to be used in research and development are capitalized until the goods or services are received.

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

Share-Based Compensation

The Company recognizes share-based compensation for equity awards granted to employees, consultants, officers and directors as an expense on the statements of operations. 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 options 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. The expected volatility of stock options is based upon the historical volatility of a peer group of publicly traded companies. 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 awards is recorded when the forfeiture occurs.

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, 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.

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)	**2020**	**2019**	**2018**
Cash and cash equivalents	$ 462,895	$ 71,353	$ 36,709
Non-current Restricted cash	107	107	107
Total cash, cash equivalents and restricted cash shown in the statement of cash flows	$ 463,002	$ 71,460	$ 36,816

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 per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of shares of common stock outstanding for the period, without consideration for common stock equivalents. Diluted net loss per share is calculated by dividing the net loss by the weighted-average number of shares of common stock and dilutive common stock equivalents outstanding for the period determined using the treasury-stock method. Dilutive shares of common stock for the years ended December 31, 2020, 2019 and 2018 are comprised of stock options.

No dividends were declared or paid during the reporting periods.

Recently Issued Accounting Pronouncements

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes* (“ASU 2019-12”), which simplifies the accounting for income taxes by removing certain exceptions to the general principles in Topic 740 and amends existing guidance to improve consistent application of Topic 740. ASU 2019-12 is effective for fiscal years beginning after December 15, 2020, including interim periods within those fiscal years, with early adoption permitted in any interim period for which financial statements have not yet been made available for issuance. The Company is currently evaluating the effect ASU 2019-12 will have on its consolidated financial statements and related disclosures.

NOTE 3. Collaboration Revenue

The Company has entered into license agreements and collaborative research and development arrangements with pharmaceutical and biotechnology companies. Under these arrangements, the Company is entitled to receive license fees, upfront payments, milestone payments if and when certain research and development milestones or technology transfer 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.

The following table presents changes during the year ended December 31, 2020 in the balances of contract assets, including receivables from collaborative partners, and contract liabilities, including deferred revenue.

(in thousands)	Contract Assets
BALANCE - December 31, 2019	$ 2,179
Additions for revenue recognized from billings	4,030
Deductions for cash collections	(4,084)
BALANCE - December 31, 2020	$ 2,125

(in thousands)	Contract Liabilities
BALANCE - December 31, 2019	$ 23,579
Additions for advanced billings	16,579
Deductions for promised services provided in current period	(9,538)
BALANCE – December 31, 2020	$ 30,620

The following table summarizes the Company's collaboration revenues for the periods indicated (in thousands). Approximately $1.0 million, $7.0 million and $5.0 million of total collaboration revenue represents revenue derived from foreign countries for the years ended December 31, 2020, 2019 and 2018, respectively.

	For the Year Ended December 31,		
(Dollars in thousands)	2020	2019	2018
Collaboration Partner – Janssen	$ 2,964	$ 2,912	$ 1,232
Collaboration Partner – Ultragenyx	3,983	5,862	6,794
Collaboration Partner – CureVac	1,006	6,611	4,427
Collaboration Partner – SGI	256	3,518	1,402
Other	1,330	1,886	1,898
Total collaboration revenue	$ 9,539	$ 20,789	$ 15,753

The following paragraphs provide information on the nature and purpose of these collaboration arrangements.

Collaboration Partner – Janssen

In October 2017, the Company entered into a research collaboration and license agreement with Janssen (the "2017 Agreement") to collaborate on developing candidates for treating HBV with RNA therapeutics. The 2017 Agreement allocated discovery, development, funding obligations, and ownership of related intellectual property among the Company and Janssen Pharmaceuticals, Inc. ("Janssen"). The Company received an upfront payment of $7.7 million and may receive preclinical, development and sales milestone payments of up to $56.5 million, as well as royalty payments on any future licensed product sales. The next potential milestone to be achieved relates to demonstrating *in vivo* efficacy and safety. Janssen began reimbursing the Company for research costs during the first quarter of 2019 upon the completion of the first of three research periods. Janssen may also pay option exercise fees within the $1.0 million to $5.0 million range per target. Janssen will pay royalties as a low to mid-single digit percentage of net sales of licensed products, subject to reduction on a country-by-country and licensed-product-by-licensed-product basis and subject to certain events, such as expiration of program patents. In addition, the 2017 Agreement includes an exclusivity period.

In evaluating the 2017 Agreement in accordance with Accounting Standards Codification ("ASC") Topic 606, the Company concluded that the contract counterparty, Janssen, is a customer. The Company identified the following promised goods/services as of the inception of the 2017 Agreement: (i) research services, (ii) license to use Arcturus technology and (iii) participation in a joint research committee. The Company concluded that the promised goods/services are incapable of being distinct and consequently do not have any value on a standalone basis. Accordingly, they are determined to represent a single performance obligation. The Company concluded that Janssen's options to select additional collaboration targets and to license rights to selected targets are not priced at a discount and therefore do not represent performance obligations for which the transaction price would be allocated.

As of December 31, 2020, the remaining transaction price consisting of upfront consideration received and budgeted reimbursable out-of-pocket costs, is expected to be recognized using an input method over the remaining research period of 21 months. None of the development and commercialization milestones were included in the transaction price as they are outside the control of the Company and contingent upon success in future clinical trials and the collaborator's efforts. Any consideration related to sales-based royalties will be recognized when the related sales occur, provided that the reported sales are reliably measurable, and the Company has no remaining promised goods/services, as such sales were determined to relate predominantly to the license granted to Janssen and therefore have also been excluded from the transaction price.

Total deferred revenue as of December 31, 2020 and December 31, 2019 for Janssen was $5.9 million and $5.9 million, respectively.

Collaboration Partner – Ultragenyx

In October 2015 the Company entered into a research collaboration and license agreement with Ultragenyx (the "Ultragenyx Agreement"), whereby Arcturus granted to Ultragenyx a co-exclusive license to certain Arcturus technology, which is in effect only during the reserve target exclusivity term as discussed in the following paragraphs. This collaboration agreement was amended in 2017, 2018 and during the second quarter of 2019. During the initial phase of the collaboration, the Company will design and optimize therapeutics for certain rare disease targets. Ultragenyx has the option under the Ultragenyx Agreement to add additional rare disease targets during the collaborative development period. Additionally, during the collaborative development period, the Company will participate with Ultragenyx in a joint steering committee. The Ultragenyx Agreement also includes an initial exclusivity period with an option to extend such period.

As part of the Ultragenyx Agreement and related amendments, Ultragenyx has paid $27.9 million in upfront fees, exclusivity extension fees and additional consideration. Ultragenyx also reimburses the Company for all internal and external development costs incurred. Pursuant to the Ultragenyx Agreement, Ultragenyx is required to make additional payments upon exercise of the Ultragenyx expansion option or exclusivity extension (if any) and if Ultragenyx achieves certain, clinical, regulatory and sales milestones, then the Company is eligible to receive royalty payments. For each development target for which Ultragenyx exercises its option, Ultragenyx will pay the Company a one-time option exercise fee that increases based upon the number of development targets selected by Ultragenyx and ranges from $0.5 million to $1.5 million. During the fourth quarter of 2020, Ultragenyx exercised its option to move forward with Preclinical Candidate Designation for its development target, Glycogen Storage Disease III, and paid an option fee to the Company of $0.5 million which was partially recognized as revenue during the quarter through a cumulative catch-up to the transaction price.

The current potential development, regulatory and commercial milestone payments for the existing development targets as of December 31, 2020 are $138.0 million. Ultragenyx will pay royalties as a single-digit percentage of net sales on a product-by-product and country-by-country basis during the applicable royalty term. As of December 31, 2020, Ultragenyx has not yet reached the clinical phase of the contract.

On June 18, 2019, Arcturus and Ultragenyx amended the collaboration agreement for a third time ("Amendment 3"). As part of Amendment 3, the total number of targets was increased from 10 to 12, and reserve targets will be exclusively reserved for Ultragenyx with no fees for four years after execution of the amendment. An equity component was also added as part of Amendment 3 wherein Ultragenyx purchased 2.4 million shares of common stock at a premium price. Along with the equity purchase, Ultragenyx received an option to purchase 0.6 million additional shares of common stock at $16.0 per share. In May 2020, the option was exercised.

The consideration received from Ultragenyx as a result of Amendment 3 was equal to $30.0 million and was comprised of a $24.0 million common stock purchase and a $6.0 million upfront payment. Specifically for Amendment 3, management determined the transaction price to be $14.4 million. See further discussion below regarding determining the transaction price. Management determined the fair value of the premium received by using the opening stock price subsequent to execution of Amendment 3 and applying a lack of marketability discount, as the shares received by Ultragenyx were initially restricted for up to two years.

In evaluating the Ultragenyx Agreement in accordance with ASC Topic 606, the Company concluded that the contract counterparty, Ultragenyx, is a customer. The Company has identified the following promised goods/services as part of the initial agreement and subsequent amendments: (i) research services, (ii) license to use Arcturus technology, (iii) exclusivity and (iv) participation in a joint steering committee. The Company concluded that the promised goods/services are incapable of being distinct and consequently do not have any value on a

standalone basis. Accordingly, they are determined to represent a single performance obligation. The Company concluded that Ultragenyx's options to extend exclusivity and select additional collaboration targets and to license rights to selected targets are not priced at a discount and therefore do not represent performance obligations for which the transaction price would be allocated.

As of December 31, 2020, the transaction price included the upfront consideration received, option payments, exclusivity extension payments and additional consideration received pursuant to Amendment 3. The Company recognizes the reimbursement of labor and expenses as costs are incurred and none of the development and commercialization milestones were included in the transaction price, as all milestone amounts were fully constrained. As part of its evaluation of the constraint, the Company considered numerous factors, including that the consideration is outside the control of the Company and contingent upon success in future clinical trials, approval from the FDA and the collaborator's efforts. Any consideration related to sales-based royalties will be recognized when the related sales occur as they are constrained, provided that the reported sales are reliably measurable and the Company has no remaining promised goods/services, as such sales were determined to relate predominantly to the license granted to Ultragenyx and therefore have also been excluded from the transaction price.

Amendment 3 was deemed a contract modification and accounted for as part of the original Ultragenyx Agreement and the Company recorded a cumulative catch-up adjustment of $1.1 million on the modification date. The transaction price is recognized to revenue on a straight-line basis using an input method over the 4-year reserve target exclusivity period. The reserve target exclusivity period represents the timing over which promised goods/services will be provided. Total deferred revenue at December 31, 2020 and December 31, 2019 from Ultragenyx was $9.2 million and $12.7 million, respectively.

Collaboration Partner - CureVac

In January 2018, the Company entered into a Development and Option Agreement (the "Development and Option Agreement") with CureVac AG ("CureVac"). Under the terms of the Development and Option Agreement, the parties agreed to conduct joint preclinical development programs once CureVac makes a payment to pull down a target on the basis of which CureVac is granted options for taking a license on pre-agreed license terms to develop and commercialize certain products incorporating the Company's patents and know-how related to LUNAR delivery technology (the "Arcturus Delivery Technology"), and CureVac patents and know-how related to mRNA technology. Subject to certain restrictions, the parties will have an undivided one-half interest in the patents and know-how developed jointly by the parties during the course of the Development and Option Agreement. Pursuant to the terms of the Development and Option Agreement, CureVac will have a number of target options to co-develop from a reserved target list to enter into licenses under the Arcturus Delivery Technology with respect to the development, manufacture and commercialization of licensed products (which can include products identified for development by the Company, unless the Company is permitted by the terms of the Development and Option Agreement to place such products on a restricted list). A separate notice and fee will be required for each license agreement. If the target to which the license agreement relates is chosen by the parties for co-development under the Co-Development Agreement (as defined below and discussed in the following paragraph) the license agreement will terminate, as such programs will be covered under the Co-Development Agreement discussed below, and therefore CureVac will be given a credit for any exercise fees, milestone payments already paid and all other payments made in relation to the license agreement towards future such payments incurred with respect to future licenses under the Arcturus Delivery Technology.

Prior to expiration of the initial term of eight years (which was subsequently amended, as discussed below), the Development and Option Agreement also includes an option to extend the term on an annual basis for up to three years, subject to payment by CureVac to Arcturus of a non-refundable annual extension fee. The Development and Option Agreement includes potential milestone payments from CureVac to the Company for selected targets. The current potential milestone payments for the remaining targets as of December 31, 2020 are $14.0 million for rare disease targets and $23.0 million for non-rare disease targets. CureVac will pay royalties as a percentage of net sales on a product-by-product and country-by-country basis during the applicable royalty term in the low single-digit range. As of December 31, 2020, CureVac has not yet reached the clinical phase of the contract. Pursuant to a May 2018 amendment to the Development and Option Agreement (and as amended and restated on September 28, 2018), the Company increased the number of targets available to CureVac under the Development and Option Agreement and agreed upon the license forms to be executed upon selection of the targets by CureVac.

Concurrently with the Development and Option Agreement, the Company entered into a Co-Development and Co-Commercialization Agreement (the "Co-Development Agreement") which the Company considered a combined

contract with the Development and Option Agreement for purposes of revenue recognition. However, on February 11, 2019, the Company announced the termination of the obligations of CureVac for the preclinical development of ARCT-810, effective as of August 4, 2019, and the re-assumption by the Company of the worldwide rights thereto. As a result, Arcturus reassumed 100% global rights for clinical development candidate ARCT-810, a mRNA drug to treat OTC deficiency.

On July 26, 2019, the Company entered into an amendment ("CureVac Amendment") to its Development and Option Agreement with CureVac (as amended, the "Development and Option Agreement"), pursuant to which the Company and CureVac agreed to shorten the time period during which CureVac may select potential targets to be licensed from the Company from eight years to four years, and to reduce the overall number of maximum targets that may be reserved and licensed.

In connection with the July 2019 CureVac Amendment, the Company and CureVac also entered into a Termination Agreement (the "Termination Agreement") terminating the January 1, 2018 Co-Development Agreement between the Company and CureVac. Pursuant to the Termination Agreement, CureVac agreed to make a one-time payment to Arcturus in the amount of $4.0 million, which was made in July 2019.

In evaluating the CureVac Development and Option Agreement and Co-Development Agreement in accordance with ASC Topic 606, the Company concluded that the contract counterparty, CureVac, is a customer. The Company has identified the following promised goods/services as part of the initial agreement with CureVac and subsequent amendments: (i) research services, (ii) license to use Arcturus technology, (iii) exclusivity and (iv) participation in a joint steering committee. The Company concluded that the promised goods/services are incapable of being distinct and consequently do not have any value on a standalone basis. Accordingly, they are determined to represent a single performance obligation. The Company concluded that CureVac's options to extend the research term and options to select additional collaboration targets and to license rights to selected targets are not priced at a discount and therefore do not represent performance obligations for which the transaction price would be allocated.

As of December 31, 2020, the transaction price included the upfront consideration received. The Company recognizes the reimbursement of labor and expenses as costs are incurred and none of the development and commercialization milestones were included in the transaction price, as all milestone amounts were fully constrained. As part of its evaluation of the constraint, the Company considered numerous factors, including that receipt of the milestones is outside the control of the Company and contingent upon success in future clinical trials and the collaborator's efforts. Any consideration related to sales-based royalties will be recognized when the related sales occur as they are constrained, provided that the reported sales are reliably measurable and the Company has no remaining promised goods/services, as such sales were determined to relate predominantly to the license granted to CureVac and therefore have also been excluded from the transaction price. For the year ended December 31, 2020, no adjustments were made to the transaction price.

The upfront consideration of $5.0 million was recorded as deferred revenue in the Company's balance sheet upon receipt and is currently being recognized as revenue on a straight-line basis using an input method over the remaining 31 month contractual term as of December 31, 2020. As a result of Amendment 3, the Company recorded a cumulative catch up adjustment of $0.4 million on the modification date, July 26, 2019. Total deferred revenue as of December 31, 2020 and December 31, 2019 for CureVac was $2.3 million and $3.2 million, respectively.

Collaboration Partner – Synthetic Genomics

The Company entered into a Research and Exclusive License Agreement with Synthetic Genomics, Inc. ("SGI") during the fourth quarter of 2017. Under the agreement, the Company granted SGI an exclusive license certain of our technology to research, develop and sell products for diseases excluding all respiratory disease viruses other than influenza. Revenue related to this agreement is made up of labor reimbursements and sublicense revenue. The sublicense revenue is calculated as a percentage of all cash payments received by SGI from any sublicense for a LUNAR product, in the mid 10% to 20% range, less payments made to third parties to obtain the right to practice intellectual property used to develop or necessary to make, use, or sell all or part of licensed LUNAR product. Under certain circumstances, the Company will be owed a percentage ranging from 5% to 10% of amounts received by SGI should they enter into agreements. As part of the agreement, SGI paid an upfront fee of $0.2 million upon contract execution which is creditable against any payments to Arcturus. Therefore, the upfront fee was fully deferred upon the receipt of funds.

As of December 31, 2020, there is no consideration included in the transaction price as all forms of consideration included in the agreement are fully constrained. As it relates to FTE reimbursements, the Company

will recognize revenue as the services are performed and recognized $0.2 million and $1.2 million for the years ended December 31, 2019 and 2018, respectively. No FTE revenue was recognized by the Company for the year ended December 31, 2020. Additionally, sublicensee consideration is fully constrained until the subsequent sublicence by SGI occurs. The Company recognized a sublicense revenue amount of $0.3 million and $3.3 million for the years ended December 31, 2020 and 2019, respectively, as SGI sublicensed the technology to multiple parties.

Other Agreements

Other Collaboration Revenue

The remaining revenue from smaller collaboration agreements and material transaction agreements primarily relates to the agreement with Millennium Pharmaceuticals, Inc., a wholly owned subsidiary of Takeda Pharmaceutical Company Limited ("Takeda"). Under the agreement with Takeda, the Company recognized $1.0 million and $1.3 million of upfront payment amortization during the years ended December 31, 2020 and 2019, respectively, related to research and development activities. The current agreement was entered into on March 18, 2019 and is expected to be completed during fiscal year 2021.

Israeli Ministry of Health

On August 17, 2020, the Company entered into an agreement with the Israeli Ministry of Health ("MOH") to supply the Company's COVID-19 vaccine candidate to Israel (the "Israel Supply Agreement") subject to certain conditions, including applicable regulatory approvals. In October 2020, and in association with the Israel Supply Agreement, the Company received a non-refundable payment of $12.5 million from the MOH which is included in deferred revenue as of December 31, 2020. This payment of $12.5 million is associated with a specified clinical trial milestone and serves as an initial reserve payment for a specified number of doses of the LUNAR-COV19 vaccine candidate pursuant to the Israel Supply Agreement. As a result of the making of this payment, the MOH became bound to purchase an initial quantity of 500,000 reserved vaccine doses, as set forth in and subject to the terms and conditions of the Israel Supply Agreement.

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, and accrued liabilities 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.

As of December 31, 2020 and 2019, all assets measured at fair value on a recurring basis consisted of cash equivalents, money market funds, 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. Balance Sheet Details

Accrued liabilities consisted of the following as of December 31, 2020 and 2019.

(in thousands)	December 31, 2020	December 31, 2019
Accrued compensation	$ 2,097	$ 1,608
Cystic Fibrosis Foundation liability	6,585	1,949
Singapore Economic Development Board liability	1,761	—
Current portion of operating lease liability	1,630	827
Current portion of long-term debt	1,250	—
Clinical accruals	4,067	—
Other accrued research and development expenses	3,249	2,750
Total	$ 20,639	$ 7,134

NOTE 6. Property and Equipment, Net

Property and equipment, net consisted of the following:

(in thousands)	December 31, 2020	December 31, 2019
Research equipment	$ 5,539	$ 3,658
Computers and software	284	271
Office equipment and furniture	574	561
Leasehold improvements	44	40
Total	$ 6,441	$ 4,530
Less accumulated depreciation and amortization	(3,063)	(2,181)
Property and equipment, net	$ 3,378	$ 2,349

Depreciation and amortization expense was $882,000, $684,000 and $582,000 for the years ended December 31, 2020, 2019 and 2018, respectively.

NOTE 7. Debt

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 of up to S$62.1 million to the Company, subject to the satisfaction of customary deliveries, to support the manufacture of the LUNAR-COV19 vaccine candidate (the "Singapore Loan"). The Singapore Loan and the related side letter includes certain loan covenants requiring (i) unused funds as of June 30, 2021 to be subsequently returned within thirty days, subject to the agreed upon extension of the reconciliation date, (ii) the Company to provide a quarterly reconciliation report within forty-five days of each financial quarter end, (iii) an external audit to be completed by September 26, 2021, (iv) the Company to deliver 10 grams of LUNAR-COV19 vaccine candidate suitable for use in a phase 3 trial in two shipments with a partial shipment by June 30, 2021 and a remaining shipment by September 30, 2021, (v) and the Company to provide EDB with a right of first refusal on GMP manufacturing slots of the LUNAR-COV19 vaccine candidate up to an agreed-upon maximum amount. The Company elected to borrow the full amount available under the Support Agreement of S$62.1 million, or $46.6 million as a result of applicable exchange rates, on January 29, 2021.

The Singapore Loan accrues interest at a rate of 4% per anum calculated on a daily basis. Subject to certain exceptions, the Singapore Loan is intended to be a limited recourse loan that will be repaid solely through a royalty payment of 10% of net sales proceeds of the LUNAR-COV19 vaccine candidate, up to the amount of the outstanding principal and interest under the Singapore Loan. However, all unpaid principal and interest under the Singapore Loan will be due and payable five years after draw date, if net sales of the LUNAR-COV19 vaccine exceed a certain minimum threshold during this five year period or the Company obtains clearance to sell the vaccine in specified jurisdictions. Unpaid principal and interest under the Singapore Loan will also become due and payable upon an event of default under the Support Agreement. The first vaccine sales, including the amount of net sales, shall be reported to EDB within 10 days of delivery and quarterly reports of aggregate vaccine sales, including net sales proceeds shall be provided within 30 days after quarter end

If, any portion of the Singapore Loan is required to be forgiven pursuant to the terms of the Support Agreement, the EDB has the right to take ownership of certain raw materials and equipment that were purchased by the Company with proceeds of the Singapore Loan (the "Specified Assets"). The Company entered into a security agreement (the "Security Agreement") for the benefit of the EDB to provide that repayment of the Singapore Loan and related obligations are secured by a lien on the Specified Assets.

In connection with the entry into the Support Agreement, the Company entered into a consent agreement with Western Alliance Bank (the "Bank") and an amendment to the Loan and Security Agreement, dated as of October 12, 2018, between Western Alliance Bank and the Company (the "Loan"), to exclude the Specified Assets from Western Alliance Bank's lien on certain assets of the Company.

Long-term debt with Western Alliance Bank

On October 12, 2018, Arcturus Therapeutics, Inc. entered into the Loan with the Bank, whereby it received $10.0 million.

The Loan is collateralized by all of the assets of Arcturus Therapeutics, Inc., excluding intellectual property, which is subject to a negative pledge. The Loan contains customary conditions of borrowing, events of default and covenants, including covenants that restrict Arcturus Therapeutics, Inc.'s ability to dispose of assets, merge with or acquire other entities, incur indebtedness and make distributions to holders of its capital stock. In addition, Arcturus Therapeutics, Inc. is required to maintain at least 100% of its consolidated, unrestricted cash, or $15.0 million, whichever is lower, with the Bank.

On October 30, 2019, Arcturus Therapeutics, Inc. and the Bank entered into a Third Amendment (the "Third Amendment") to the Loan (as amended, the "Loan Agreement").

Pursuant to the amendment, the Bank agreed to make a term loan to Arcturus Therapeutics, Inc. on October 30, 2019, in the amount of $15.0 million (the "Term Loan"). The resulting net increase in the indebtedness of Arcturus Therapeutics, Inc. was $5.0 million. The Term Loan bears interest at a floating rate ranging from 1.25% to 2.75% above the prime rate. The amendment further provides that the Term Loan has a maturity date of October 30, 2023. Arcturus Therapeutics, Inc. will make monthly payments of interest only until October 1, 2021.

Arcturus Therapeutics, Inc. paid a loan origination fee of $54,000 which was recorded as a debt discount along with the remaining loan origination fee from the Loan and is being accreted over the term of the Term Loan. In addition, Arcturus Therapeutics, Inc. is required to pay a fee of $525,000 upon certain change of control events.

The Term Loan may be prepaid in full at any time, subject to a prepayment fee ranging from 0.50% to 2.00% of the prepaid principal amount depending upon the date of the prepayment.

Upon maturity or prepayment (as previously discussed), Arcturus Therapeutics, Inc. will be required to pay a 2% fee as a result of the FDA's approval to proceed with the Company's LUNAR-OTC program based on its IND submission. Such fee is accreted to the long-term debt balance using the effective interest method over the term of the Loan Agreement.

Should an event of default occur, including the occurrence of a material adverse effect, the Company could be liable for immediate repayment of all obligations under the Loan Agreement. As of December 31, 2020, the Company was in compliance with all covenants under the Loan Agreement.

Principal payments, including the final payment due at repayment, on the long-term debt are as follows as of December 31, 2020:

Year Ending December 31,		
2021	$	1,250,000
2022		7,500,000
2023		6,550,000
Total	$	15,300,000

The Company recognized interest expense related to its long-term debt of $0.9 million, $0.9 million and $0.2 million during the years ended December 31, 2020, 2019 and 2018, respectively.

NOTE 8. Stockholders' Equity

Common Stock

On November 25, 2020, the Company amended its Certificate of Incorporation to increase the number of shares of common stock it is authorized to issue from 30,000,000 shares to 60,000,000 shares.

Underwritten Public Offering of Common Stock

During fiscal year 2020, the Company completed three underwritten public offerings totaling 10,058,820 shares of common stock (including the underwriters' overallotment options) at prices per share of $17.00, $53.00 and $110.00, which resulted in gross proceeds of approximately $452.1 million. After deducting offering costs of $28.3 million, the Company received net proceeds of approximately $423.8 million from the offerings.

Equity Purchase Agreement

On June 18, 2019, the Company entered into an Equity Purchase Agreement (the "Expanded Ultragenyx Agreement") with Ultragenyx. Pursuant to the terms of the Expanded Ultragenyx Agreement, the Company sold an aggregate of 2,400,000 shares of common stock, par value $0.001 per share ("Common Stock") at a price of $10.00 per share to Ultragenyx on June 19, 2019. Ultragenyx was restricted from selling the shares of common stock for two years subsequent to the issuance date. Pursuant to the Expanded Ultragenyx Agreement, the Company also granted Ultragenyx a two-year option (the "Option") to purchase up to 600,000 additional shares of Common Stock at a price of $16.00 per share. In May 2020, Ultragenyx exercised its option to purchase 600,000 shares of the Company's common stock at $16.00 per share, and the Company received proceeds of $9.6 million as a result of the option exercise.

Net Loss per Share

Dilutive securities that were not included in the calculation of diluted net loss per share for the years ended December 31, 2020, 2019 and 2018 as they were anti-dilutive totaled 1,157,175, 138,377 and 94,000, respectively.

For the years ended December 31, 2019 and 2018, the calculation of the weighted-average number of shares outstanding excludes 622,667 unvested restricted common shares held by founders of the Company. As the remaining milestones under the founder share agreements were achieved during the year ended 2020, these restricted common shares completely vested equally during the second and third quarters of 2020

NOTE 9. Share-Based Compensation

In June 2020, the stockholders of the Company approved an increase to the number of shares authorized for use in making awards under the 2019 Omnibus Equity Incentive Plan (the "2019 Plan") by 2,400,000 shares to 5,000,000. Accordingly, as of December 31, 2020, a total of 1,257,159 shares remain available for future issuance under the 2019 Plan, subject to the terms of the 2019 Plan.

Employee Stock Purchase Plan

In June 2020, the stockholders of the Company approved the 2020 Employee Stock Purchase Plan ("2020 Plan") which provides for 600,000 shares of Company common stock reserved for future issuance. The first accumulation period under the 2020 Plan commenced on August 17, 2020.

Under the 2020 Plan, eligible employees may purchase shares of the Company's common stock at a discount annually, subject to a maximum of $25,000 per year. The discounted purchase price is equal to the lower of 85% of (i) the market value per share of the common stock on the first day of the accumulation period or (ii) the market value per share of common stock on the purchase date. Share-based compensation expense recognized under the ESPP was $0.1 million for 2020.

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,		
	2020	2019	2018
Expected life (in years)	6.04	5.92	6.07
Expected volatility	72.4%	73.9%	73.3%
Expected dividend yield	—%	—%	—%
Risk-free interest rate	0.74%	1.82%	2.77%
Grant date weighted average fair value	$ 42.33	$ 6.39	$ 5.38

The following table summarizes the Company's stock option activity for the year ended December 31, 2020:

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding – December 31, 2019	1,649,076	$ 7.54		
Granted	2,175,184	$ 66.91		
Exercised	(394,661)	$ 6.82		
Forfeited/cancelled	(104,886)	$ 21.37		
Outstanding – December 31, 2020	3,324,713	$ 46.03	9.02	$ 59,449
Exercisable – December 31, 2020	718,301	$ 10.11	7.95	$ 23,975
Exercisable and expected to vest – December 31, 2020	3,324,713	$ 46.03	9.02	$ 59,449

At December 31, 2020, the total unrecognized compensation cost of $89.8 million will be recognized over the weighted-average remaining service period of approximately 3.2 years. The fair value of the options vested during the years ended December 31, 2020, 2019 and 2018 was $4.2 million, $1.9 million and $1.0 million, respectively.

Share-based compensation expenses included in the Company's statements of operations and comprehensive loss for the years ended December 31, 2020, 2019 and 2018 were:

	For the Year Ended December 31,		
(in thousands)	2020	2019	2018
Research and development	$ 2,670	$ 654	$ 566
General and administrative	4,094	1,328	693
Total	$ 6,764	$ 1,982	$ 1,259

NOTE 10. Income Taxes

A reconciliation of loss before income taxes for domestic and foreign locations for the years ended December 31, 2020, 2019 and 2018 is as follows:

	For the Year Ended December 31,		
(In thousands)	**2020**	**2019**	**2018**
United States	$ (72,148)	$ (25,922)	$ (21,604)
Foreign	—	(69)	(181)
Total loss before income taxes	$ (72,148)	$ (25,991)	$ (21,785)

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 for the years ended December 31, 2020 and 2019 is as follows (in millions):

	December 31,	
	2020	**2019**
Beginning balance of unrecognized tax benefits	$ 0.4	$ 0.4
Settlement of prior period tax positions	—	—
Increase for prior period tax positions	0.3	—
Increase for current period tax positions	0.8	—
Ending balance of unrecognized tax benefits	$ 1.5	$ 0.4

Included in the balance of unrecognized tax benefits at December 31, 2020 and 2019 is $1.5 million and $0.4 million, respectively, that could impact the Company's effective tax rate, if recognized, subject to a valuation allowance. None of the unrecognized tax benefits currently impact the Company's effective tax rate due to the full valuation allowance the Company has recorded against its deferred tax assets.

The Company is subject to taxation and files income tax returns in the United States, California and Israel. The Company's tax years from 2014 to date are subject to examination by the Israeli, 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. As of December 31, 2020 and 2019, there are unrecognized tax benefits of $1.5 million and $0.4 million, respectively, for both the United States and California. There was no tax related interest or penalties recognized for the years ended December 31, 2020, 2019 and 2018.

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

The significant components of deferred income taxes at December 31, 2020 and 2019:

(in thousands)	December 31, 2020	December 31, 2019
Deferred tax assets:		
Net operating loss	$ 33,896	$ 15,078
Tax credits	6,278	28
Accrued liabilities	535	410
Deferred revenue	3,230	1,248
Lease liability	1,274	1,466
Share-based compensation	1,338	339
Total gross deferred tax assets	46,551	18,569
Deferred tax liabilities:		
Depreciation and amortization	(69)	(11)
Right-of-use asset	(1,168)	(1,326)
Valuation allowance	(45,314)	(17,232)
Net deferred tax asset	$ —	$ —

The Company has established a valuation allowance against net deferred tax assets due to the uncertainty that such assets will be realized. The Company periodically evaluates the recoverability of the deferred tax assets. At such time as it is determined that it is more likely than not that deferred tax assets will be realizable, the valuation allowance will be reduced.

At December 31, 2020, the Company had federal and state net operating losses (“NOL”) carryforwards of approximately $125.8 million and $111.2 million, respectively. The federal NOL carryforwards begin to expire in 2034, and the state NOL carryforwards begin to expire in 2034. The federal net operating loss carryover includes $110.0 million of net operating losses generated in 2018 and after, which do not expire. The Company had foreign NOL carryforwards of approximately $89.0 million in the previous year which have been removed from the deferred tax assets in the current year as a result of the Company’s recent Redomiciliation.

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act (“CARES Act”) was enacted and signed into law in response to coronavirus disease 2019 (“COVID-19”). The CARES Act, among other things, included several significant provisions that impacted corporate taxpayers’ accounting for income taxes. Prior to the enactment of the CARES Act, the 2017 Tax Cuts and Jobs Act generally eliminated the ability to carryback net operating losses (“NOLs”), and permitted the NOLs arising in tax years beginning after December 31, 2017 to be carried forward indefinitely, limited to 80% of the taxpayer’s income. The CARES Act amended the NOL rules, suspending the 80% limitation on the utilization of NOLs generated after December 31, 2017 and before January 1, 2021. Additionally, the CARES Act allows corporate NOLs arising in taxable years beginning after December 31, 2017 and before January 1, 2021, to be carried back to each of the five taxable years preceding the taxable year of the loss. Also, the CARES Act allows companies to defer making certain payroll tax payments until future years. With the enactment of the CARES Act, the company does not expect a financial statement impact from income taxes.

At December 31, 2020, the Company had federal and state research and development credit carryforwards of approximately $2.3 million and $1.9 million, respectively. The federal credit carryforwards begin to expire in 2033, and the state credits carry forward indefinitely. Additionally, the Company has an Orphan Drug Credit of $3.9 million as of December 31, 2020 which will begin to expire in 2039 unless previously utilized.

Pursuant to Internal Revenue Code of 1986, as amended (the “Code”) 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 not completed a Code Section 382 analysis regarding the limitation of net operating loss carryforwards and other tax attributes. There is a risk that changes in ownership have occurred since Company’s formation. If a change in ownership were to have occurred, the NOL carryforwards and other tax attributes could be limited or restricted. If limited, the related asset would be removed from the deferred tax asset schedule with a corresponding reduction in the valuation allowance. Due to the existence of the valuation allowance, limitations

created by future ownership changes, if any, related to the Company's operations in the U.S. will not impact the Company's effective tax rate.

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,		
	2020	2019	2018
Federal statutory income tax rate	21.0%	21.0%	21.0%
State income taxes, net of federal benefit	6.8%	4.6%	5.3%
Foreign rate differential	—%	0.3%	(1.3%)
Share-based compensation	5.5%	(0.1%)	(0.2%)
Research and development credits	8.7%	—%	—%
Uncertain tax position	(1.5%)	—%	—%
Change in tax rate	(1.5%)	(0.1%)	—%
Foreign net operating losses	28.5%	—%	—%
Change in valuation allowance	(67.4%)	(25.1%)	(20.7%)
Other	(0.1%)	0.1%	(3.0%)
Permanent differences	—%	(0.7%)	(1.1%)
Provision for income taxes	—%	—%	—%

NOTE 11. Commitments and Contingencies

COVID-19 Vaccine Development

On March 4, 2020, the Company was awarded a grant (the "Grant") from the Singapore EDB to support the co-development of a potential COVID-19 vaccine with the Duke-NUS Medical School. The Grant provides for up to S$14.0 million (approximately US$10.0 million using the exchange rate at the time the grant contract was entered into) in grants to support the development of the vaccine. The Company entered into an amendment to the Grant on September 24, 2020 to update certain delivery and milestone timelines. The Grant has been paid in full by the EDB as a result of the achievement of certain milestones related to the progress of the development of the vaccine, as set forth in the award agreement. The funds received have been recognized as contra research and development expense in proportion to the percentage covered by the EDB of the overall budget. The Company is liable for certain expenses during the program and is also subject to certain conditions including the completion of an external audit within 183 days of the conclusion of the claim period on February 20, 2021, or August 22, 2021, and delivery of 10 grams of LUNAR-COV19 vaccine candidate suitable for use in a phase 3 trial in two shipments with a partial shipment by June 30, 2021 and a remaining shipment by September 30, 2021. Additionally, the Company is required to pay an agreed upon royalty rate to Duke-NUS on future net sales of the LUNAR-COV19 vaccine candidate in markets or jurisdictions outside of Singapore. For the year ended December 31, 2020, the Company recognized $8.7 million of contra expense, with $1.3 million remaining in accrued expenses.

On October 2, 2020, the Company was awarded another grant from the Singapore EDB to support the further development of a potential COVID-19 vaccine. The grant provides for up to S$9.3 million (approximately US$6.7 million) to support the development of the vaccine candidate for costs incurred in Singapore subject to certain conditions including (i) completing an external audit within 183 days from March 31, 2021, or September 30, 2021, (ii) delivering 10 grams of LUNAR-COV19 vaccine candidate suitable for use in a phase 3 trial in two shipments with a partial shipment by June 30, 2021 and a remaining shipment by September 30, 2021 and (iii) creating an entity in Singapore which was completed during the fourth quarter of 2020. The grant will be paid in two installments upon the achievement of certain milestones related to the progress of the development of the vaccine candidate. The Company received the first installment of $3.6 million in the fourth quarter of 2020. The funds received have been recognized as contra research and development expense as costs are incurred. For the year ended December 31, 2020, the Company recognized $3.1 million of contra expense, with $0.5 million remaining in accrued expenses.

Cystic Fibrosis Foundation Therapeutics Funding agreement

On August 1, 2019, the Company amended its Development Program Letter Agreement, dated May 16, 2017 and as amended July 13, 2018, with the Cystic Fibrosis Foundation ("CFF"). Pursuant to the amendment, (i) CFF will increase the amount it will award to advance LUNAR-CF to $15.0 million from approximately $3.2 million, (ii) the Company will provide $5.0 million in matching funds for remaining budgeted costs, (iii) the related disbursement schedule from CFF to Arcturus will be modified such that (a) $4.0 million will be disbursed upon execution of the CFF Amendment, (b) $2.0 million will be disbursed within 30 days of the first day of each of January, April, July and October 2020 upon Arcturus invoicing CFF to meet project goals, and (c) the last payment of $3.0 million less the prior award previously paid out, equaling approximately $2.3 million, will be disbursed upon Arcturus Sub invoicing CFF to meet good manufacturing practices and opening an Investigational New Drug ("IND") application. The funds received from CFF will be recognized as contra research and development expense in proportion to the percentage covered by CFF of the overall budget. For the years ended December 31, 2020 and 2019, the Company recognized $3.4 million and $2.0 million of contra expense with $6.6 million and $1.9 million remaining in accrued expenses, respectively.

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 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 $74,000. The lease may be extended for one five-year period at the then current market rate with annual escalations; however, the Company deemed the extension option not reasonably certain to be exercised and therefore excluded the option from the lease terms. The Company entered into an irrevocable standby letter of credit with the landlord for a security deposit of $96,000 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 non-cancellable operating lease agreement for office space near its current headquarters. The lease extends for 13 months from the commencement date. In conjunction with the new lease, the Company received free rent for one month. The lease may be extended for one twelve-month period, and in November 2020 the Company deemed the extension option reasonably certain to be exercised and included the option in the lease terms beginning in December 2020. In February 2021, the Company opted to extend the lease through March 2025 to coincide with the Company's other lease term.

In February 2021, the Company entered into a third non-cancellable operating lease agreement for office space near its current headquarters. The lease extends for 12 months from the commencement date with monthly base rent of approximately $11,000.

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, 2020, the payments of the operating lease liability were as follows:

(in thousands)	Remaining Lease Payments
2021	$ 2,033
2022	1,470
2023	1,390
2024	1,432
Thereafter	314
Total remaining lease payments	6,639
Less: imputed interest	(984)
Total operating lease liabilities(1)	$ 5,655
Weighted-average remaining lease term	3.87 years
Weighted-average discount rate	8.4%

(1) Amount does not include the lease agreement and lease ammendment which were executed subsequent to December 31, 2020.

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 $1.9 million, $1.2 million and $1.1 million for the years ended December 31, 2020, 2019 and 2018, respectively.

Note 12. Related Party Transactions

Ultragenyx

On June 17, 2019, Arcturus and Ultragenyx executed Amendment 3 to the Ultragenyx Agreement. Pursuant to the amended Ultragenyx Agreement, the Company also granted Ultragenyx a two-year option to purchase up to 600,000 additional shares of common stock at a price of $16.00 per share. Ultragenyx exercised the option in May 2020, and as a result, owns 8.4% of the outstanding common stock of the Company as of December 31, 2020. For the years ended December 31, 2020, 2019 and 2018, the Company has recognized revenue of $4.0 million, $5.9 million and $6.8 million, respectively, related to the Ultragenyx Agreement. As of December 31, 2020 and 2019, the Company holds accounts receivable balances of negligible amounts related to the Ultragenyx Agreement.

Equity-Method Investment

As noted above at Note 2, in June 2018, the Company completed the sale of its intangible asset related to the ADAIR technology. Pursuant to the asset purchase agreement for ADAIR, the Company received a 30% ownership interest in the common stock of Vallon Pharmaceuticals, Inc. (“Vallon”) in consideration for the sale of the ADAIR technology. The Company has no requirement to invest further in Vallon. During the third quarter of 2019, Vallon issued shares of its common stock at a share price greater than the initial investment which resulted in the Company recording a gain in its equity-method investment. The gain has been offset by additional losses incurred by Vallon. Vallon completed an initial public offering and began trading on The Nasdaq Stock Market under the ticker “VLON” in February 2021. Immediately after this offering, Arcturus owned 843,750 shares of Vallon, or approximately 12%.

Note 13. Litigation

On December 13, 2019, a former employee of the Company filed a complaint in San Diego County Superior Court, captioned Adonary Munoz v. Arcturus Therapeutics, Inc., et al, Case No. 37-2019-00066358-CU-PO-CTL. The lawsuit alleges sexual assault by an acquaintance of one of our employees and seeks to hold the Company liable on a number of causes of action. On January 17, 2020, a second amended complaint (“SAC”) was filed seeking $30 million in damages, including punitive damages and damages for emotional distress. The matter is scheduled for mediation on May 5, 2021. The Company believes the allegations of Ms. Munoz in her complaint are without merit,

and intends to vigorously defend itself in the foregoing action. However, in light of the preliminary stage of the litigation, the Company is unable to estimate a potential loss or range of losses relating to this matter.

Note 14. Subsequent Events

Alexion Pharmaceuticals License Agreement

On February 17, 2021, the Company entered into an exclusive license agreement with Alexion Pharmaceuticals, Inc. ("Alexion") pursuant to which Alexion granted to the Company an exclusive, worldwide license to exploit certain specified Alexion patent applications. In accordance with the terms of the license agreement, and in exchange for the license, the Company issued 74,713 shares of its common stock to Alexion on February 19, 2021 at a price of $66.92 per share. The price was determined based on the volume weighted average closing price of the Company's common stock on The NASDAQ Global Market for the thirty trading days ending on February 17, 2021.

Alexandria Lease Extension

See *"Note 8, Commitments and Contingences"* for discussion of the lease extension.

Note 15. Selected Quarterly Financial Data (Unaudited)

A summary of our quarterly results is as follows:

(in thousands, except per share data)	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Year Ended December 31, 2020:				
Collaboration revenue	$ 2,646	$ 2,322	$ 2,333	$ 2,238
Research and development expenses, net	7,917	7,944	17,699	24,286
General and administrative expenses	4,191	4,420	5,572	9,034
Loss from operations	(9,462)	(10,042)	(20,938)	(31,082)
Net loss	(9,777)	(10,263)	(21,004)	(31,104)
Net loss per share, basic and diluted	$ (0.67)	$ (0.55)	$ (0.92)	$ (1.25)
Weighted average shares outstanding, basic and diluted	14,521	18,794	22,938	24,886
Year Ended December 31, 2019:				
Collaboration revenue	$ 4,350	$ 10,153	$ 3,318	$ 2,968
Research and development expenses, net	7,324	7,269	7,053	11,994
General and administrative expenses	3,534	3,456	3,881	1,791
Loss from operations	(6,508)	(572)	(7,616)	(10,817)
Net loss	(6,884)	(685)	(7,433)	(10,989)
Net loss per share, basic and diluted	$ (0.68)	$ (0.07)	$ (0.56)	$ (0.76)
Weighted average shares outstanding, basic and diluted	10,095	10,412	13,201	14,505

Common Stock

As of February 24, 2021, there were 26,205,562 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 Delaware General Corporation Law, or 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,

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.

SECOND AMENDMENT TO LEASE

THIS SECOND AMENDMENT TO LEASE (the "**Amendment**") is made this _____, 2020 (the "**Effective Date**"), by and between **ARE-SD REGION NO. 44, LLC**, a Delaware limited liability company ("**Landlord**"), and **ARCTURUS THERAPEUTICS, INC.**, a Delaware corporation ("**Tenant**").

RECITALS

A. Landlord and Tenant are parties to a certain Lease Agreement dated as of October 4, 2017, as amended by a First Amendment to Lease dated January 31, 2020 (as so amended, the "**Lease**"), wherein, in addition to Premises located at 10628 Science Center Drive, La Jolla, California, Landlord leased to Tenant certain premises on a temporary basis (the "**Temporary Premises**") located at 10578 Science Center Drive, La Jolla, California as more particularly described therein.

B. The term of the Lease with respect to the Temporary Premises expires on February 28, 2021 (the "**Termination Date**"). Tenant desires to extend the term of Lease as it affects the Temporary Premises for a period of twelve (12) months, and Landlord is willing to extend the term of the Lease on the terms herein set forth.

AGREEMENT

NOW, THEREFORE, the parties hereto agree that the Lease is amended as follows:

1. **Extension; Rent**.

(a) Notwithstanding anything to the contrary contained in the Lease, the term of the Lease as it affects the Temporary Premises shall expire, unless terminated earlier pursuant to the Lease, on February 28, 2022 (the "**Amended Termination Date**").

(b) Tenant shall continue to pay, through the Amended Termination Date, all amounts due and owing under the Lease including, without limitation, Base Rent and Operating Expenses as provided under the Lease. Commencing on March 1, 2021 (the "**Adjustment Date**"), Base Rent shall be increased by multiplying the Base Rent payable immediately before such Adjustment Date by 3% and adding the resulting amount to the Base Rent payable immediately before such Adjustment Date.

(c) Tenant shall voluntarily surrender the Temporary Premises on or before the Amended Termination Date. Tenant agrees to cooperate reasonably with Landlord in all matters, as applicable, relating to (i) surrendering the Temporary Premises in accordance with the surrender requirements and in the condition required pursuant to the Lease, and (ii) all other matters related to restoring the Temporary Premises to the condition required under the Lease.

(d) Any and all rights of Tenant to extend the term of the Lease with respect to the Temporary Premises beyond the Amended Termination Date are hereby revoked, and Tenant shall have no further rights to extend the term of the Lease with respect to the Temporary Premises after the Amended Termination Date. Nothing herein shall excuse Tenant from its obligations under the Lease prior to the Amended Termination Date.

(e) The parties agree and acknowledge that Tenant's right to terminate the Temporary Premises on the Early Temporary Premises Termination Date is hereby revoked and of no further force or effect.

2. **OFAC.** Tenant and all beneficial owners of Tenant are currently (a) in compliance with and shall at all times during the Term of this Lease remain in compliance with the regulations of the Office of Foreign Assets Control **("OFAC")** of the U.S. Department of Treasury and any statute, executive order, or regulation relating thereto (collectively, the **"OFAC Rules"),** (b) not listed on, and shall not during the term of the Lease be listed on, the Specially Designated Nationals and Blocked Persons List, Foreign Sanctions Evaders List, or the Sectoral Sanctions Identification List, which are all maintained by OFAC and/or on any other similar list maintained by OFAC or other governmental authority pursuant to any authorizing statute, executive order, or regulation, and (c) not a person or entity with whom a U.S. person is prohibited from conducting business under the OFAC Rules.

3. **Miscellaneous**.

(a) Capitalized terms used herein but not defined herein shall have the respective meanings ascribed to such terms in the Lease.

(b) This Amendment is the entire agreement between the parties with respect to the subject matter hereof and supersedes all prior and contemporaneous oral and written agreements and discussions. This Amendment may be amended only by an agreement in writing, signed by the parties hereto.

(c) Except as amended and/or modified by this Amendment, the Lease is hereby ratified and confirmed and all other terms of the Lease shall remain in full force and effect, unaltered and unchanged by this Amendment. In the event of any conflict between the provisions of this Amendment and the provisions of the Lease, the provisions of this Amendment shall prevail. Whether or not specifically amended by this Amendment, all of the terms and provisions of the Lease are hereby amended to the extent necessary to give effect to the purpose and intent of this Amendment.

(d) This Amendment is binding upon and shall inure to the benefit of the parties hereto, their respective agents, employees, representatives, officers, directors, divisions, subsidiaries, affiliates, assigns, heirs, successors in interest and shareholders.

(e) Landlord and Tenant each represent and warrant that it has not dealt with any broker, agent or other person (collectively, "**Broker**") in connection with this transaction other than Cushman & Wakefield and CBRE, and that no Broker brought about this transaction other than Cushman & Wakefield and CBRE. Landlord and Tenant each hereby agree to indemnify and hold the other harmless from and against any claims by any Broker, other than Cushman & Wakefield and CBRE, claiming a

commission or other form of compensation by virtue of having dealt with Tenant or Landlord, as applicable, with regard to this leasing transaction.

(f) This Amendment may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Counterparts may be delivered via facsimile, electronic mail (including pdf or any electronic signature process complying with the U.S. federal ESIGN Act of 2000) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes. Electronic signatures shall be deemed original signatures for purposes of this Amendment and all matters related thereto, with such electronic signatures having the same legal effect as original signatures.

(g) For purposes of Section 1938 of the California Civil Code, as of the date of this Amendment, the Building has not been inspected by a certified access specialist.

(Signatures on Next Page)

IN WITNESS WHEREOF, the parties hereto have executed this Amendment as of the day and year first above written.

TENANT:

ARCTURUS THERAPEUTICS, INC.,
a Delaware corporation

By: _____
Its: _____

☐ I hereby certify that the signature, name, and title above are my signature, name and title.

LANDLORD:

ARE-SD REGION NO. 44, LLC,
a Delaware limited liability company

By: ALEXANDRIA REAL ESTATE EQUITIES, L.P.,
a Delaware limited partnership,
managing member

By: ARE-QRS CORP.,
a Maryland corporation,
general partner

By: _____

THIRD AMENDMENT TO LEASE

THIS THIRD AMENDMENT TO LEASE (the **"Amendment")** is made this February 25, 2021 (the **"Effective Date"),** by and between **ARE-SD REGION NO. 44, LLC,** a Delaware limited liability company **("Landlord"),** and **ARCTURUS THERAPEUTICS, INC.,** a Delaware corporation **("Tenant").**

RECITALS

A. Landlord and Tenant are parties to a ce1tain Lease Agreement dated as of October 4, 2017, as amended by a First Amendment to Lease dated January 31, 2020, and a Second Amendment to Lease dated November 13, 2020 (as so amended, the **"Lease"),** wherein , in addition to Premises located at 10628 Science Center Drive, La Jolla, California, Landlord leased to Tenant ce1tain premises on a temporary basis (the **"Temporary Premises")** located at 10578 Science Center D1ive, La Jolla, California as more particularly described therein.

B. The term of the Lease with respect to the Temporary Premises expires on February 28, 2022 (the **"Termination Date").** Tenant desires to extend the term of Lease as it affects the Temporary Premises for a period of thi1ty-seven months, and Landlord is willing to extend the term of the Lease on the terns herein set forth.

AGREEMENT

NOW, THEREFORE, the parties hereto agree that the Lease is amended as follows:

1. Extension; Rent.

(a) Notwithstanding anything to the contrary contained in the Lease, the tern.1 of the Lease as it affects the Tempora1y Premises shall expire, unless terminated earlier pursuant to the Lease, on March 31, 2025 (the **"Amended Termination Date").**

(b) Tenant shall continue to pay, through the Amended Termination Date, all amounts due and owing under the Lease including, without limitation , Base Rent and Operating Expenses as provided under the Lease. Commencing on March 1, 2022, Tenant shall pay Base Rent with respect to theTempora1y Premises in the amount of $5.50 per rentable square foot of the Temporary Premises per month . Base Rent with respect to the Temporary Premises shall be increased on March 1, 2023 and on each March pt thereafter (each, an **"Adjustment Date"),** by multiplying the Base Rent payable immediately before such Adjustment Date by 3% and adding the resulting amount to the Base Rent payable in1llle diately before such Adjustment Date.

(c) Notwithstanding anything to the contrary contained herein, so long as Tenant is not in Default under the Lease, Tenant shall not be required to pay Base Rent for the months of March 2022, and Ap1il 2022 (collectively, **"Abatement Months").** Tenant shall continue to pay Tenant's Share of Operating Expenses as required under the Lease during the Abatement Months.

(d) Tenant shall voluntarily surrender the Tempora1y Premises on or before the Amended Termination Date. Tenant agrees to cooperate reasonably with Landlord in all matters , as applicable, relating to (i) surrendering the Tempora1y Premises in accordance with the surrender requirements and in the condition required pursuant to the Lease, and (ii) all other matters related to restoring the Temporary Premises to the condition required under the Lease.

(e) Any and all rights of Tenant to extend the term of the Lease with respect to the Temporary Premises beyond the Amended Termination Date are hereby revoked, and Tenant shall have no further rights to extend the term of the Lease with respect to the Temporary Premises after the Amended Termination Date. Nothing herein shall excuse Tenant from its obligations under the Lease prior to the Amended Termination Date.

2. **OFAC.** Tenant and all beneficial owners of Tenant are currently (a) in compliance with and shall at all times during the Term of this Lease remain in compliance with the regulations of the Office of Foreign Assets Control **("OFAC")** of the U.S. Department of Treasury and any statute, executive order, or regulation relating thereto (collectively, the **"OFAC Rules"),** (b) not listed on, and shall not during the term of the Lease be listed on, the Specially Designated Nationals and Blocked Persons List, Foreign Sanctions Evaders List, or the Sectoral Sanctions Identification List, which are all maintained by OFAC and/or on any other similar list maintained by OFAC or other governmental authority pursuant to any authorizing statute, executive order, or regulation, and (c) not a person or entity with whom a U.S. personis prohibited from conducting business under the OFAC Rules.

3. **Miscellaneous.**

(a) Capitalized terms used herein but not defined herein shall have the respective meanings ascribed to such terms in the Lease.

(b) This Amendment is the entire agreement between the parties with respect to the subject matter hereof and supersedes all prior and contemporaneous oral and written agreements and discussions. This Amendment may be amended only by an agreement in writing, signed by the parties hereto.

(c) Except as amended and/or modified by this Amendment, the Lease is hereby ratified and confirmed and all other terms of the Lease shall remain in full force and effect, unaltered and unchanged by this Amendment. In the event of any conflict between the provisions of this Amendment and the provisions of the Lease, the provisions of this Amendment shall prevail. Whether or not specifically amended by this Amendment, all of the terms and provisions of the Lease are hereby amended to the extent necessary to give effect to the purpose and intent of this Amendment.

(d) This Amendment is binding upon and shall inure to the benefit of the parties hereto, their respective agents, employees, representatives, officers, directors, divisions, subsidiaries, affiliates, assigns, heirs, successors in interest and shareholders.

(e) Landlord and Tenant each represent and warrant that it has not dealt with any broker, agent or other person (collectively, **"Broker")** in connection with this transaction other than Cushman & Wakefield and CBRE, and that no Broker brought about this transaction other than Cushman & Wakefield and CBRE. Landlord and Tenant each hereby agree to indemnify and hold the other harmless from and against any claims by any Broker, other than Cushman & Wakefield and CBRE, claiming a

commission or other form of compensation by virtue of having dealt with Tenant or Landlord, as applicable, with regard to this leasing transaction.

(f) This Amendment may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Counterparts may be delivered via facsimile, electronic mail (including pdf or any electronic signature process complying with the U.S. federal ESIGN Act of 2000) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes. Electronic signatures shall be deemed original signatures for purposes of this Amendment and all matters related thereto, with such electronic signatures having the same legal effect as original signatures.

(g) For purposes of Section 1938 of the California Civil Code, as of the date of this Amendment, the Building has not been inspected by a certified access specialist.

(Signatures on Next Page)

IN WITNESS WHEREOF, the parties hereto have executed this Amendment as of the day and year first above written.

TENANT:

ARCTURUS THERAPEUTICS, INC.,
a Delaware corporation

By: /s/ Joseph E. Payne
Its: President & CEO

I hereby certify that the signature, name, and title above are my signature, name and title.

LANDLORD:

ARE-SD REGION NO. 44, LLC,
a Delaware limited liability company

By: ALEXANDRIA REAL ESTATE EQUITIES, L.P.,
a Delaware limited partnership,
managing member

By: ARE-QRS CORP.,
a Maryland corporation,
general partner

By: **/s/** Gary Dean, EVP Legal

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. 333-240397) pertaining to the Arcturus Therapeutics Holdings Inc. Amended and Restated 2019 Omnibus Equity Incentive Plan, and
(4) Registration Statements (Form S-3 Nos. 333-232281, 333-235475, 333-237703, 333-238139, 333-235475 and 333-251175) of Arcturus Therapeutics Holdings Inc.;

of our reports dated March 1, 2021, with respect to the consolidated financial statements of Arcturus Therapeutics Holdings Inc., and the effectiveness of internal control over financial reporting of Arcturus Therapeutics Holdings Inc. included in this Annual Report (Form 10-K) for the year ended December 31, 2020.

/s/ Ernst & Young LLP

San Diego, California
March 1, 2021

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 1, 2021

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 1, 2021

By: /s/ Andrew Sassine

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

Exhibit 31.3

CERTIFICATION PURSUANT TO
RULES 13a-14(a)

I, Keith C. Kummerfeld, 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 1, 2021

By: /s/ Keith C. Kummerfeld

Keith C. Kummerfeld
Vice President of Finance and Corporate Controller
(principal 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, 2020 (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 1, 2021

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, 2020 (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 1, 2021

By: /s/ Andrew Sassine

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

Exhibit 32.3

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, 2020 (the "Report"), I, Keith C. Kummerfeld, Vice President of Finance and Corporate Controller 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 1, 2021

By: /s/ Keith C. Kummerfeld

Keith C. Kummerfeld
Vice President of Finance and Corporate Controller
(principal accounting officer)