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, 2019

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 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 28, 2019 was $76.4 million.

As of March 1, 2020, the registrant had 15,137,964 shares of voting common stock outstanding.

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Special Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K, or this annual report, and the documents incorporated by reference herein may contain "forward-looking statements" within the meaning of the federal securities laws made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth below under Part I, Item 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 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. We have omitted the ® and ™ designations, as applicable, for the trademarks used in this Annual Report on Form 10-K.

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.

Introduction

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

Our 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., as described more fully below.

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 good position to deliver on the next generation of nucleic medicines.

- We have deep expertise in the discovery and development of RNA medicines, including key experience in the production of RNA drug substance and nanoparticle-formulated drug product.
- We have a pipeline of seven drug candidates in late-stage discovery and early-stage development, two of which are wholly-owned and five of which involve partnered programs.
- We have developed and continue to develop LUNAR, a novel lipid-mediated delivery technology platform, which draws from a growing library of over 200 lipids that were designed at Arcturus and many of which are claimed in issued patents. Other lipids in this growing library are undergoing extensive research to test for desirable properties, and we continue to seek patent protection for newly designed lipids. Our lipid library is intended to enable safer and more efficient delivery than lipids commonly used in the industry.
- We have developed the STARR technology platform which combines self-replicating RNA with LUNAR into a single solution for partners.
- Our wholly-owned, LUNAR and nucleic acid technologies are covered by a patent portfolio of 182 patents and patent applications, issued in the United States, China, Europe, Japan and other countries.

We believe that we can use our proprietary technologies to develop RNA medicines in multiple therapeutic approaches: (1) mRNA, DNA, and replicon protein replacement for therapeutics and protein delivery for vaccines; (2) siRNA, microRNA, and antisense oligonucleotides – knockdown of genes overexpressed in disease; and (3) CRISPR, TALEN, zinc finger proteins, megaTALs and meganucleases – gene editing of errant genes.

Redomiciliation

In May 2019, shareholders of Arcturus Israel approved the Redomiciliation. In connection therewith, in February 2019, Arcturus Israel entered into a share exchange agreement (the "Exchange Agreement") with Arcturus Therapeutics Holdings Inc., a newly established Delaware corporation. In June 2019, pursuant to the terms of the Exchange Agreement, all issued ordinary shares and options to purchase ordinary shares of Arcturus Israel were exchanged on a one-for-one basis for newly issued shares of common stock and options to purchase common stock, respectively, of the Company, resulting in Arcturus Israel becoming a subsidiary of the Company.

In June 2019, Arcturus Israel's ordinary shares were delisted from trading on Nasdaq and the Company's shares commenced trading on Nasdaq under the symbol "ARCT." Arcturus Israel is now a wholly-owned subsidiary of the Company, which is the successor to Arcturus Israel. Proceedings to liquidate Arcturus Israel are now pending in Israeli court.

Recent Developments

On March 4, 2020, we were awarded a grant (the "Grant") from the Singapore Economic Development Board 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 million using the March 2, 2020 exchange rate) in grants to support the development of the vaccine. A portion of the Grant will be paid by the Economic Development Board in advance and the remainder of the Grant will be paid to us upon the achievement of certain milestones related to the progress of the development of the vaccine, as set forth in the award agreement. We have agreed to pay Duke -NUS Medical School a royalty based on annual net sales of the vaccine in markets or jurisdictions outside of Singapore.

In the first quarter of 2020, we submitted an Investigational New Drug ("IND") application for our LUNAR-OTC development program.

RNA Medicines, Markets and Arcturus' Technology

Rare Genetic Diseases

There is a significant unmet medical need in the field of rare genetic diseases. The World Health Organization estimates that approximately 10,000 diseases are caused by an error or mutation in a single gene, and over 95% of known rare genetic diseases lack a U.S. Food and Drug Administration ("FDA"), approved drug treatment. Moreover, these diseases affect approximately one in a hundred people at birth, and approximately 350 million people worldwide live with a rare genetic disease. Many of these diseases cause moderate to severe symptoms, significantly decreasing quality of life and life expectancy.

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 has the code, carried by a nucleic acid molecule called mRNA, informing the cell's machinery the pattern of building blocks for making 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).

siRNA therapies, which use double-stranded RNA compounds that activate machinery in the cell to destroy a target RNA in the body, are useful in treating diseases caused by viral infections, malfunctioning proteins or an excess of certain proteins that contribute to the severity of symptoms of a disease. siRNA compounds are designed to bind selectively to one mRNA and trigger machinery in the body to cause the cell to destroy the disease-causing mRNA. This mechanism, called RNA interference, can be used to prevent mutated genes from being translated into defective proteins that cause disease, and can stop viruses from replicating inside the body.

Naked RNA and some DNA molecules are quickly degraded by enzymes in the bloodstream and can cause a strong immune response. Therefore, nucleic acid medicines (mRNA, DNA and siRNA) developed for systemic use must use a vector or other targeting mechanism to deliver the nucleic acid medicine to target cells. Viral delivery vectors and lipid-mediated delivery systems are the two main delivery systems used in a large number of nucleic acid-based therapeutics in development.

Viral delivery vectors are very effective at delivering DNA to alter the genetic make-up of the patient's cells. However, they can cause liver damage and activate an immune response in human patients. Viral vectors may also cause accidental mutations in host DNA. Patients treated with viral vectors can also develop antibodies against these vectors that make the treatment less effective over time.

Lipid-mediated delivery systems are the most common non-viral vectors because they are biocompatible and do not cause insertional mutagenesis. They can also be manipulated to target specific cells in the body. In 2018, the first siRNA therapy using a lipid-mediated delivery system, Onpattro (patisiran), was approved by the FDA for the treatment of polyneuropathy associated with hereditary transthyretin amyloidosis.

Infectious Diseases

According to the National Foundation for Infectious Diseases, over 50,000 people die each year due to vaccine-preventable diseases in the United States alone. Viral infections can spread rapidly and become epidemic, as demonstrated by the outbreak of the H1N1 virus (Swine Flu), and most recently by the outbreak of the novel coronavirus ("Coronavirus") reported to have originated in Wuhan, China. The Coronavirus has resulted in thousands of deaths and tens of thousands of cases have been diagnosed worldwide.

Outbreaks of new infectious diseases create demand for a new and novel approaches to producing vaccines in a more cost effective and quicker manner. We believe that our STARR technology has potential to address this need. On March 4, 2020, we entered into a strategic partnership with the Singapore Economic Development Board and Duke-NUS Medical School to develop a potential vaccine for COVID-19. We continue to innovate to achieve a competitive advantage in LUNAR delivery of DNA-based and STARR-based vaccines. LUNAR lipid nanoparticles can be combined with STARR and have been shown to functionally deliver a replicon in rodents. Lead STARR constructs are currently being generated in order to evaluate their ability to generate an immune response to coronavirus (COVID-19).

Our Strategy

We aim to leverage our proprietary and licensed intellectual property relating to LUNAR and our nucleic acid technologies to develop a pipeline of mRNA therapeutics for rare genetic disorders and infectious diseases with significant unmet medical needs. In addition to our collaborations noted above, we are focused on balancing our portfolio with internally-owned and partnered programs to advance our preclinical candidates in a timely and cost-effective manner.

Our flagship program, LUNAR-OTC, is on track to enter first-in-human studies during 2020.

Our business strategy has four main areas of focus:

- *Drive existing collaborations to achieve first-in-human data for our LUNAR lipid-mediated delivery platform.* The value and promise of our proprietary LUNAR lipid-mediated delivery platform have been recognized by our current partners and have garnered continuing partner interest. This value is expected to increase substantially if preclinical data from our LUNAR formulated mRNA medicines is reproduced in our first human clinical studies. We continue to push our first mRNA therapeutic, LUNAR-OTC, toward the clinic. Our LUNAR-CF program is supported by our important collaboration with the Cystic Fibrosis Foundation, Inc. ("CFF").
- *Leverage our LUNAR lipid-mediated delivery platform to develop therapeutics for a broad range of additional rare liver and lung diseases.* We have demonstrated in preclinical models the utility of the LUNAR lipid-mediated delivery platform in two important liver cell types, stellate and hepatocyte, as well as bronchial cells in lungs. Our internal research teams and collaboration partners are currently focused on discovering our next wave of innovative mRNA medicines and other nucleic acid modalities, respectively, for patients with debilitating rare diseases.

- *Advance the new collaboration with the Singapore government and Duke-NUS Medical School utilizing our STARR and LUNAR technologies to develop LUNAR-COV19, a potential vaccine to address the Coronavirus outbreak.*
- *Develop a competitive advantage over other nucleic acid medicine companies by continuing to innovate in our core areas of research, including mRNA design and siRNA design, STARR technology, LUNAR lipid formulations and formulation production.* Our team has a wealth of research and development experience in the areas of siRNA and mRNA medicine design. We continue to research new and better ways to develop and produce these important potential nucleic acid medicines. In addition, our team has an advanced understanding of lipid-nanoparticle formulations, and is continually improving scalability and reproducibility of our LUNAR formulated nucleic acid drug candidates, which we believe will translate to better therapies for patients.

Our Competitive Strengths

We believe that our proprietary LUNAR lipid-mediated delivery and nucleic acid technologies (mRNA, DNA, siRNA, and STARR), extensive intellectual property portfolio and experienced research and development team will enable us to (i) advance our drug candidates and existing partnerships, and (ii) gain additional partners for our technology platform, thereby expanding future development and commercialization opportunities.

We believe that our competitive strengths include the following, among other areas:

- *LUNAR lipid-mediated delivery technology is potentially applicable to all nucleic acid medicines being developed today that require a formulation.* Preclinical studies have shown that LUNAR delivery technology is compatible with different types of nucleic acids therapeutics, including mRNA, STARR, siRNA, microRNA, antisense oligonucleotides and other oligonucleotide therapeutic approaches. We can combine our LUNAR technology with mRNAs that encode for a wide array of therapeutic proteins, including transmembrane proteins (such as transporters, GPCRs, and receptors), secreted proteins (such as hormones and antibodies), engineered nucleases (CRISPR and TALEN), engineered antigen receptors (CAR-T) and intracellular proteins (chaperones, enzymes, intrabodies). We also have preclinical data demonstrating proof-of-concept for LUNAR delivery of DNA-based and STARR-based vaccines and therapeutics. We believe that the potentially broad applicability of our LUNAR delivery technology is a distinct value driver.
- *In preclinical studies, LUNAR lipid-mediated delivery technology has been applied to different tissues and cell types via multiple routes of administration.* Most nucleic acid drugs that are marketed or in development are primarily active in liver cells called hepatocytes. Preclinical studies have shown that LUNAR can deliver nucleic acid therapies to the liver to hepatocytes and hepatic stellate cells via intravenous injection. If we are able to demonstrate in clinical studies our ability to deliver nucleic acid medicines to both of these cell types, this could provide us with a distinct advantage over other technologies that preferentially deliver to hepatocytes only, as stellate cells are key contributors to liver disease progression, including fibrosis and liver cancer. In preclinical studies, we have also demonstrated functional delivery of LUNAR-formulated mRNA to lung cells through nebulized inhalation. This is the foundation of our LUNAR-CF program and may pave the way for additional therapies to treat rare lung disorders. Additionally, we have observed in preclinical studies that LUNAR-formulated compounds can be modulated to deliver nucleic acid compounds to muscle cells via intramuscular injection, lung cells via intravenous administration and eye cells via subretinal and intravitrial routes of administration.
- *Ability to repeat dose.* Multiple preclinical studies in rodents and non-human primates have shown no reduction in efficacy upon repeat dosing of LUNAR formulated RNA medicines (siRNA or mRNA). We believe this indicates that LUNAR-delivered nucleic acids may not elicit antibody or cell-mediated immunity that can reduce potency upon repeat dosing.
- *Scalability of our technology.* Through our research and development activities, we have defined processes that allow for scalability of the production of nucleic acid therapeutics and the formulation of nucleic acid lipid delivery systems.

- *Biodegradability of Lipids.* Through an iterative process of rational design and *in vivo* evaluation, we have identified various structural motifs that favor fast esterase-catalyzed degradation and have leveraged our knowledge to generate a library of proprietary biodegradable lipids.
- *The STARR technology platform combines self-replicating RNA with LUNAR, a proprietary nanoparticle delivery system, into a potential single solution for partners*. We believe that when STARR technology is delivered into the cell it has the potential to generate a protective immune response or drive therapeutic protein expression to prevent against or treat a variety of diseases. A self-replicating RNA-based therapeutic vaccine has the potential to trigger rapid and immediate antigen expression within host cells and a stronger T-cell response. This combination potentially provides longer-lasting RNA, and hence more exposure of the immune system to the antigen, thus lowering dose requirements as compared to traditional RNA-based vaccines.
- *Experienced team.* Our team has extensive experience in the discovery and development of nucleic acid medicines and vaccines, as well as experience and know-how in lipid-mediated delivery technology. In early 2020, we added a new Chief Development Officer, Dr. Steven Hughes, who will manage our future global clinical development. Dr. Hughes brings over twenty years of clinical development experience in the fields of rare diseases, cardiovascular disease, and oncology. In early 2020 we expect to transition to becoming a clinical stage pharmaceutical company with our flagship ARCT-810 program, and Dr. Hughes will play a key role at this stage of our evolution.
- *Our intellectual property portfolio.* Our LUNAR and nucleic acid technologies are wholly-owned by us and covered by our patent portfolio of over 180 patents and patent applications in the United States, China, Europe, Japan and other countries. Our intellectual property portfolio serves as a barrier-to-entry for competitors. Unlike most other preclinical stage companies, our intellectual property portfolio is wholly-owned and not licensed-in, which should result in more favorable economic terms as we research, develop and commercialize our product candidates.
- *Ability to develop high barrier-to-entry products with rapid development of subsequent products with lower costs and risks.* The properties of our proprietary technologies, outlined above, allow us to develop high barrier-to-entry nucleic acid medicines. We expect that the versatility of our LUNAR, UNA, and STARR platforms as well as our growing expertise in the design and manufacture of RNA will allow us to develop subsequent product candidates relatively quickly with less risk and lower costs.

Arcturus Pipeline of mRNA Medicines

Name	Indication	Expected Regulatory Filing Date	Route of Administration	Target Organ	Target Cells	Prevalence Worldwide
LUNAR-OTC (ARCT-810)	Ornithine Transcarbamylase (OTC) Deficiency	IND Filed March 2020	Intravenous (i.v.)	Liver	Hepatocytes	> 10,000
LUNAR-CF	Cystic Fibrosis	2021	Nebulized Aerosol	Lung	Bronchial Epithelial Cells	> 70,000
LUNAR-COV19	Coronavirus COVID-19 Vaccine	2020+	Intramuscular (i.m.)	Muscle	Myocyte	Indeterminate
LUNAR-CV	Rare Cardiovascular Disease	Preclinical	Intravenous (i.v.)	Liver	Hepatocytes	Undisclosed
LUNAR-MD	Rare Metabolic Disease	Preclinical	Intravenous (i.v.)	Liver	Hepatocytes	Undisclosed

- **Pipeline programs focus on messenger RNA (mRNA) drug products for rare diseases**
- **LUNAR-OTC (ARCT-810, intravenous mRNA medicine): IND Filing Target Q1 2020**
- **LUNAR-CF is funded by the Cystic Fibrosis (CF) Foundation: IND Filing Target 2021**

We are using our proprietary technology to develop nucleic acid medicines to treat diseases with unmet medical needs, accelerated clinical paths and clear commercial opportunities. Our preclinical pipeline currently has seven active preclinical drug discovery and development programs. This includes wholly-owned programs as well as collaboration partnerships described below.

- The LUNAR-OTC development program is developing mRNA compounds to treat ornithine transcarbamylase (“OTC”) deficiency. We have achieved preclinical proof-of-concept for LUNAR-OTC in a mouse model of the disease and have completed our first toxicology studies that will allow us to initiate clinical studies. The toxicology studies will support our initial application of our IND application, which was submitted during the first quarter of 2020.
- The LUNAR-CF program is developing mRNA compounds to replace dysfunctional cystic fibrosis transmembrane conductance regulator (“CFTR”) protein in cystic fibrosis (“CF”) patients. This program is supported by the CFF. We have demonstrated proof of concept for LUNAR delivery into rodent epithelial airways, as well as functional restoration in the nasal epithelia of a CFTR-knock out mouse model. We currently intend to file an IND supported by the LUNAR-CF program in 2021.
- LUNAR-CV and LUNAR-MD are internal research programs focused on target validation of multiple pipeline LUNAR-mRNA program candidates. This program will guide the future selection of metabolic and/or cardiovascular development programs.

We currently have collaboration partnerships with Ultragenyx Pharmaceutical, Inc. (“Ultragenyx”); Millennium Pharmaceuticals, Inc. (“Takeda”), a wholly-owned subsidiary of Takeda Pharmaceutical Company Limited; Janssen Pharmaceuticals, Inc. (“Janssen”), an affiliate of Johnson & Johnson; CureVac AG (“CureVac”); the Singapore Economic Development Board and Duke-NUS Medical School, and other collaboration partners.

- We are partnering with Ultragenyx to develop up to twelve mRNA therapeutic candidates for certain rare disease targets. LUNAR-GSD3 is the first program under this partnership that has been publicly disclosed, and focuses on Glycogen Storage Disease Type 3, a disease caused by genetic mutations in the glycogen debranching enzyme, AGL, which leads to glycogen accumulation in liver and muscle.
- We are partnering with Takeda to develop a nucleic acid-based therapeutic candidate for the treatment of nonalcoholic steatohepatitis (“NASH”).
- We are partnering with Janssen to develop nucleic acid-based therapeutic candidates for the treatment of hepatitis B virus infection (“HBV”).
- We are partnering with the Singapore Economic Development Board and Duke-NUS Medical School to develop LUNAR-COV19, a potential vaccine to address the Coronavirus outbreak.
- We are also partnering with other collaboration partners, in addition to those described above.

Arcturus Platform: Enabling Genetic Medicines

Program	Partner	Indication	Arcturus Chemistry	Arcturus Delivery	Program Status
LUNAR-GSD3	ultragenyx	Glycogen Storage Disease Type III	mRNA	LUNAR Hepatocytes	Target IND 2020+
LUNAR-RARE	ultragenyx	Undisclosed Rare Disease	mRNA	LUNAR Hepatocytes	Preclinical
LUNAR-HBV	Johnson & Johnson	Hepatitis B	RNA	LUNAR Hepatocytes	Preclinical
LUNAR-NASH	Takeda	NASH	RNA	LUNAR Stellate Cells	Preclinical
LUNAR-RPL	Large Pharma	Infectious Disease Prophylactic Vaccines	SGI’s Replicon RNA	LUNAR	Preclinical
LUNAR-AH	Large Animal Health Pharma	Infectious Disease Prophylactic Vaccines	SGI’s Replicon RNA	LUNAR	Preclinical

- **Greater than $1 Billion in Potential Milestones & Royalties**
- **Enabling Different Types of RNA – Messenger RNA, Gene Editing RNA, Replicon RNA**
- **Multiple Cell Types Targeted**
- **LUNAR-GSD3 (UX053) partnered with Ultragenyx – IND Target 2020+**

Our LUNAR Platform Technology

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. However, mRNA therapies have yet to be successful in delivering an approved therapy to patients because of the technical hurdles facing this therapeutic approach. These hurdles include:

- 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.

An additional hurdle is that mRNA can be immunogenic. The first generation lipid nanoparticle technology used to deliver mRNA therapeutics are 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.

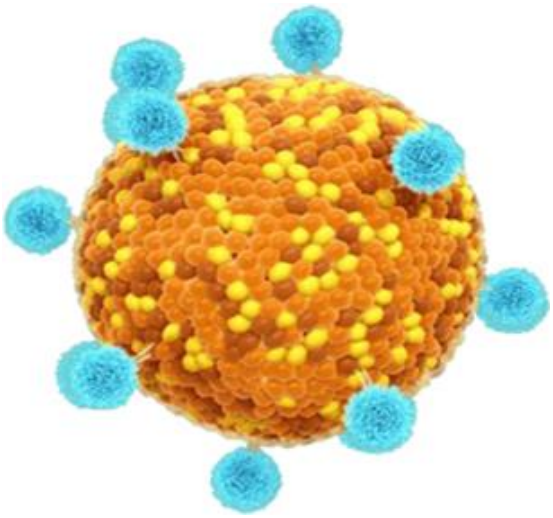
In addition to our LUNAR lipid-mediated delivery technology, we believe we have created innovative, proprietary advancements in producing mRNA medicines, including improvements that increase purity, scalability, efficiency in production times, and adaptability to different mRNA modification strategies. 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).

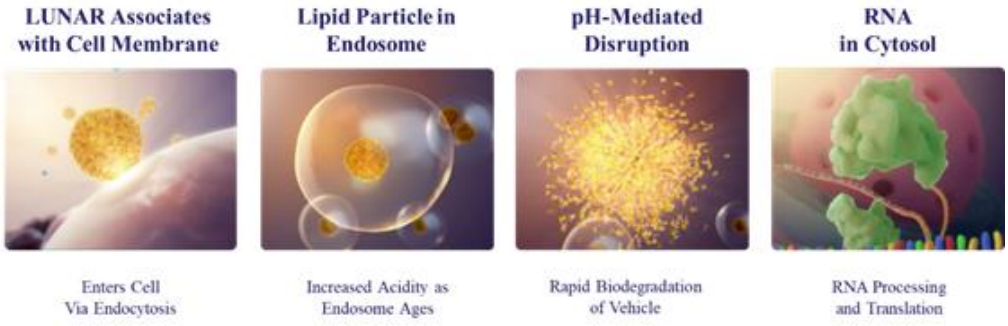
Graphic of LUNAR



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, used by competitors. 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.

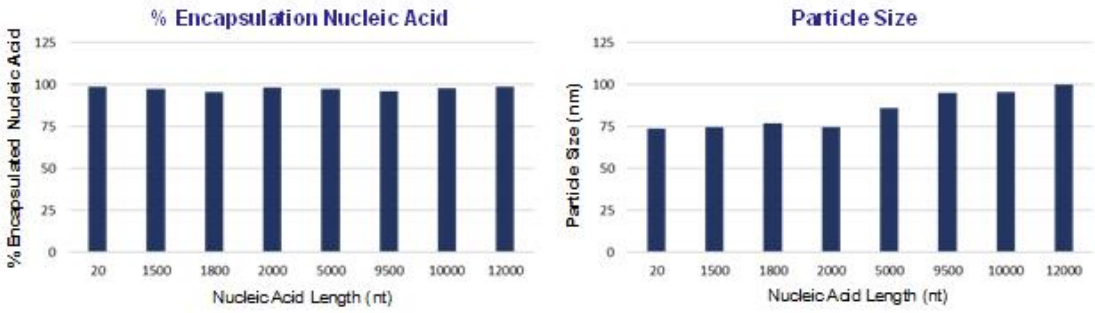
LUNAR-mediated delivery of a nucleic acid therapeutic into cells

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.



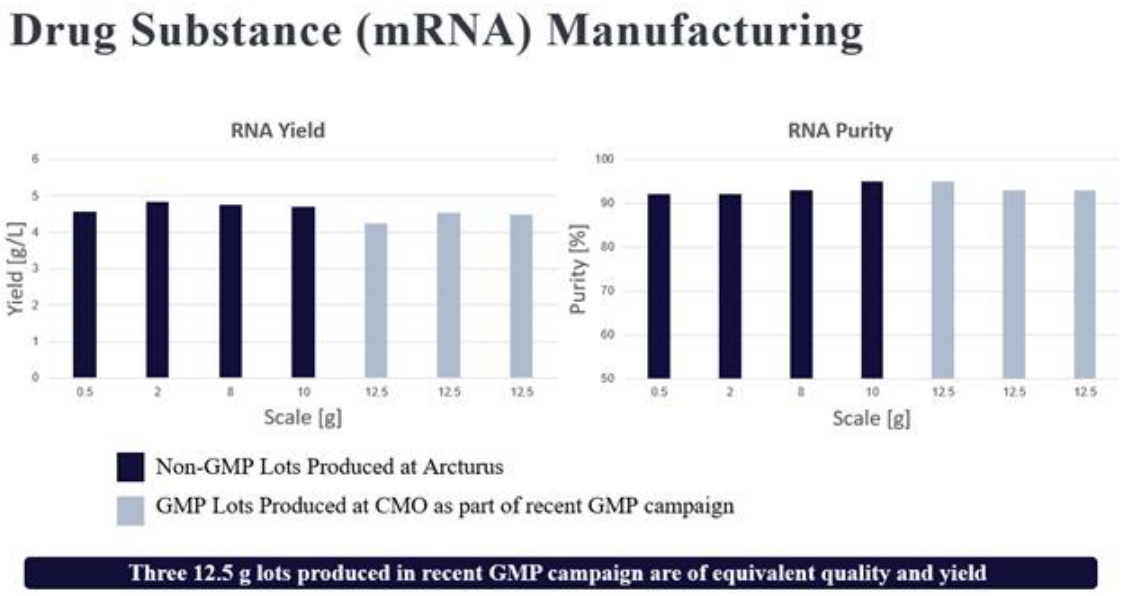
LUNAR compatibility with nucleic acids of various size

We have generated a growing library of over 150 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).

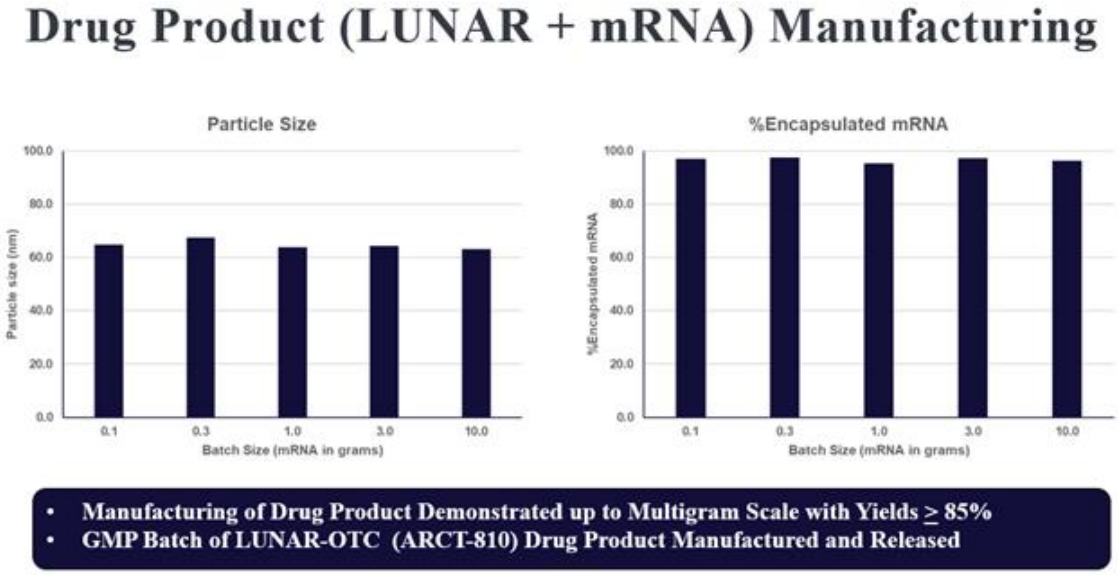


LUNAR Scalability and Reproducibility

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 12.5gram scales with equivalent yield and purity as shown in the figure below.



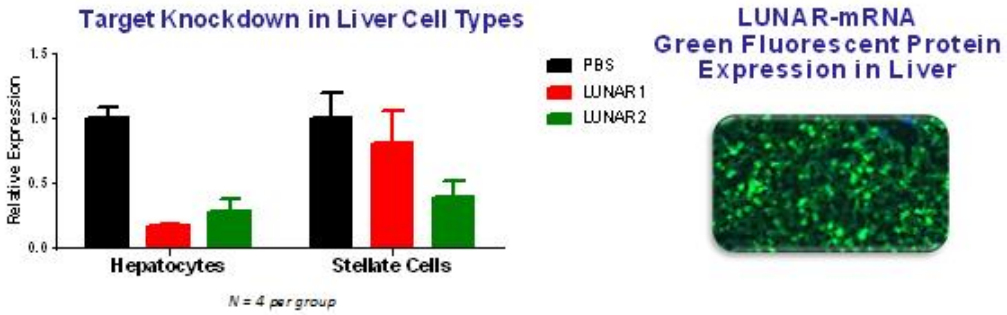
Additionally, we have demonstrated scalability of our LUNAR-mRNA platform from milligram to multigram scales. LUNAR-nRNA batches have been successfully produced at scales from 0.1 to 10grams while retaining key physicochemical attributes of particles. Examples of two such physicochemical properties, particle size and percent encapsulated mRNA across scales is shown in figure below.



LUNAR In Vivo Proof-of-Concept Data

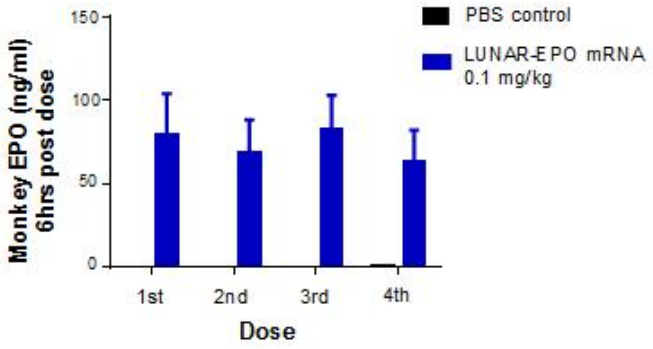
LUNAR formulations can be designed to target different cell types in the liver

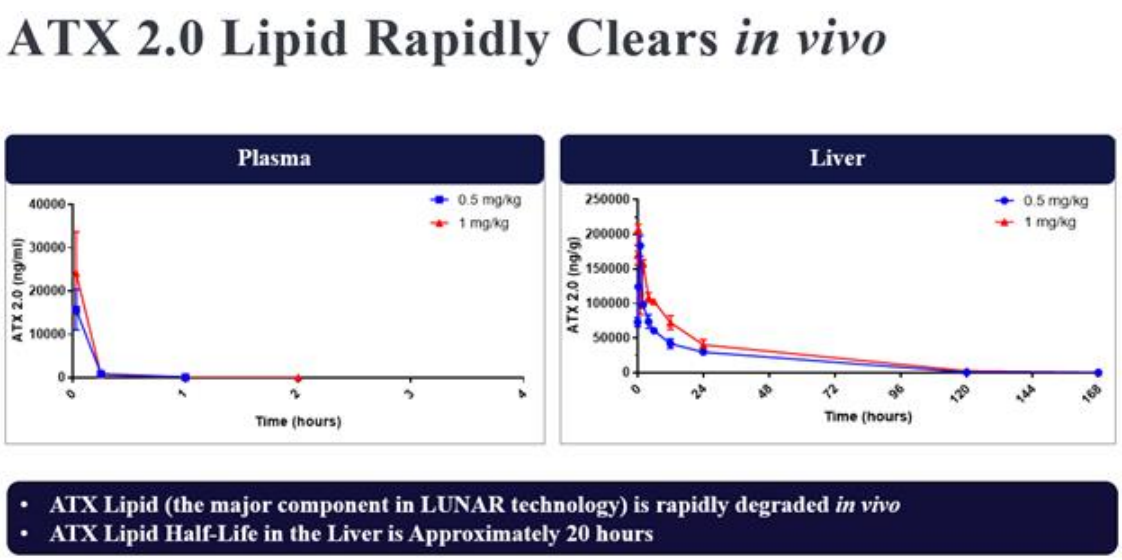
We have optimized LUNAR to deliver potential nucleic acid therapeutics preferentially to different cell types in the liver after intravenous (IV) delivery. When mice were treated with a single intravenous dose of two different LUNAR-siRNA formulations, significant target mRNA knockdown was observed in hepatocytes 72 hours post-treatment (figure below, left). Shown in green, the composition of a different LUNAR-siRNA formulation was modified to also achieve significant target mRNA knockdown in stellate cells, an important cell type for certain liver indications, such as NASH. The hepatocyte-targeting LUNAR (LUNAR 1, red bars) was also used to formulate a green fluorescent protein (GFP) mRNA and mice were treated with a single IV dose (figure below, right). Twenty-four hours later, GFP protein was seen throughout the liver, particularly in hepatocytes.



Repeat Dose Efficacy in Non-human Primates

To demonstrate efficacy of LUNAR-mRNA in a repeat-dose setting, we treated non-human primates once weekly for four weeks with LUNAR-formulated erythropoetin (EPO) mRNA (figure below). EPO protein expression levels were determined six hours following each treatment, and elevated serum EPO levels were maintained following each treatment.





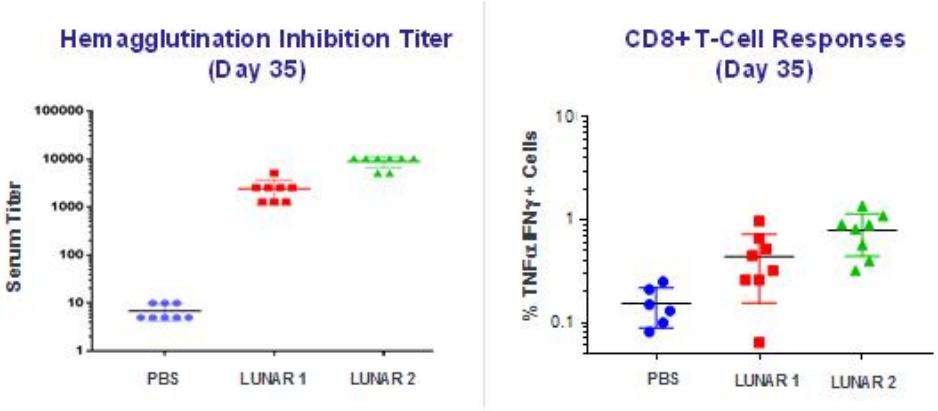
Biodegradability Translates to In Vivo Safety Profile

A key for RNA medicines is the safety profile. We have demonstrated that LUNAR delivery technology is well-tolerated in non-human primates at the following doses, which are proposed for human use:

- 8 weekly doses up to 10 mg/kg of LUNAR formulated non-coding siRNA
- 3 bi-weekly doses of LUNAR formulated mRNA at fold-multiples of the target therapeutic dose

Antigen-specific responses following IM delivery of LUNAR-mRNA in influenza vaccination mouse model

We have demonstrated in proof-of concept studies in mice the utility of LUNAR-formulated mRNA in oncology and infectious disease vaccine applications. Mice were treated at Day 0 (prime) and Day 21 (boost) via intramuscular delivery with 0.5 mg/kg LUNAR-encapsulated hemagglutinin mRNA (2 formulations; LUNAR 1 and LUNAR 2). At Day 35, serum titers were determined in a hemagglutination inhibition assay (figure below, left) and antigen-specific cytokine production was evaluated from CD8+ T-cells (figure below, right). With both formulations tested, titers between 10^3-10^4 were achieved and a significant increase in % of TNFα and IFNα expressing cells was observed.



Our Proprietary mRNA and Protein Design Technology

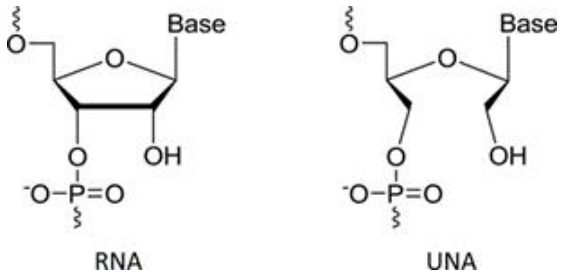
The mRNA programs in our pipeline are benefited by our in-house expertise in protein and mRNA design, which helps us address many of the known challenges that face the viability of mRNA therapeutics today. We have identified several design elements of mRNA compounds that provide improved translation (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 Unlocked Nucleic Acid (UNA) Oligomer Chemistry

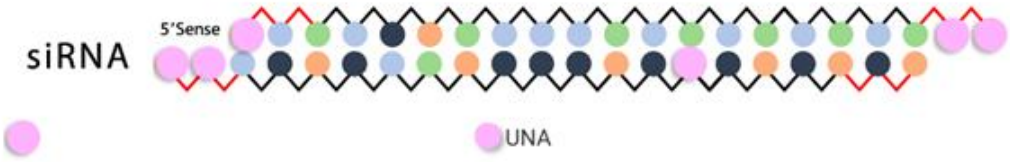
UNAs are RNA analogues in which the C2'-C3' bond of the ribose ring is absent (figure below). UNA chemistry technology can potentially be applied to multiple types of RNA medicines including mRNA, siRNA, microRNA and guide RNAs for gene editing. One or more UNAs can be positioned strategically along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

Internal Development Programs

We are developing mRNA therapeutic candidates to treat rare diseases with unmet medical needs through the following two internal development programs.

LUNAR-OTC (ARCT-810)

The LUNAR-OTC development program addresses OTC deficiency, a rare, genetic disease caused by mutations in the OTC gene that leads to dysfunctional or deficient OTC levels. OTC deficiency causes the body to accumulate ammonia levels which are neurotoxic and harmful to the liver. Currently, there are only treatments to remove excess ammonia and no disease-modifying treatments of the underlying genetic disorder are available. Our LUNAR-OTC development program uses our LUNAR platform to deliver normal OTC mRNA into hepatocytes, where OTC is produced and functions, to produce normal functioning OTC with potentially disease-modifying effects for patients.

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.

Overview of OTC Deficiency

OTC deficiency is caused by mutations in the OTC gene which lead to a non-functional or deficient OTC enzyme. 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 digested. 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. This 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. There is currently no cure 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 and ammonia scavengers to try and prevent patients from accumulating ammonia. These treatments do not address the underlying cause of disease.

LUNAR-OTC Proof-of-Concept

The in vivo efficacy and proof-of concept of an early prototype of LUNAR-OTC mRNA was evaluated in the OTC spf^{ash} mouse model of OTC deficiency. These hypomorphic mice possess a mutation in the OTC gene that results in 5-10% residual OTC activity allowing these animals to survive unless their urea cycle is challenged by an exogenous source of nitrogen such as ammonium chloride (NH_4Cl) or chronic exposure to a high protein diet (“HPD”) of 53% protein. In a survival study, OTC spf^{ash} mice were treated with a prototype LUNAR-OTC mRNA, and then exposed to a HPD. Animals received five weekly administrations of LUNAR-OTC mRNA and were monitored for HPD-induced mortality.

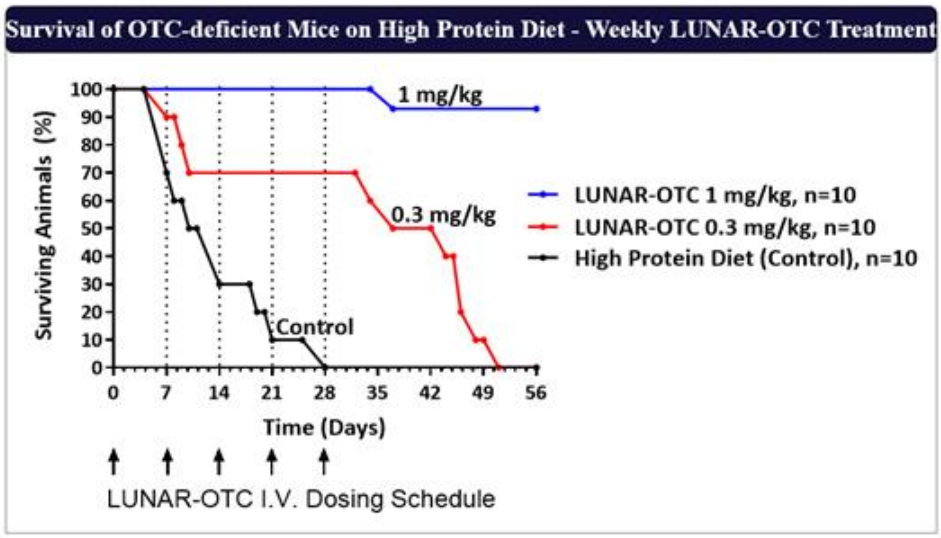


Figure A: Effects of a Prototype LUNAR-mRNA Treatments on Survival in an HPD Model in OTC spf^{ash} mice

Our LUNAR-OTC development program utilizes our current innovations in protein sequence optimization, mRNA coding region optimization and our proprietary untranslated regions that increase the efficiency of our mRNA therapeutic to translate into protein, the half-life of the OTC protein and also its localization into the mitochondria (a cellular structure) where the OTC protein resides and functions.

LUNAR-CF

The LUNAR-CF program addresses cystic fibrosis, a progressive lung disease caused by mutations in the CFTR gene. We use our LUNAR platform to deliver 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, regardless of what mutation type a patient has. The CFF has recognized the potential of the LUNAR-CF program and has partnered with us to develop this important therapy.

Overview of CF

According to the National Institutes of Health, CF is the most common rare disease in the world, with an estimated 30,000 diagnosed cases in the United States and 70,000 worldwide. Approximately 1,000 people are newly-diagnosed with CF each year. CF is caused by one of 2,000 known mutations in the CFTR gene, which scientists have grouped into several different classes based on the problems they cause in the production 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/bicarbonate into the airways, which generates an increase of sodium uptake by the cells, dehydrating the airways and causing accumulation of a thicker mucus layer. This thicker mucus layer has a strong impact on breathing quality and will decrease the clearance of air pathogens accumulated in the mucus, causing chronic infections, chronic coughing, severe inflammation, tissue scarring, and other serious complications not only related to the lung but to other epithelial 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 patients includes palliative treatments (such as antibiotics and mucolytics) to assist in clearing and reducing infection/inflammation of the airways, as well as the use of chest vests to mechanically move mucus. Many CF patients ultimately suffer from decreased lung function and require lung transplants.

There are currently no FDA-approved drugs that can treat all CF patients. 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 do not treat the underlying genetic cause of CF. Therefore, none of these modulator therapies are able to treat Class I mutations (which account for approximately 10% of CF cases worldwide), non-sense mutations, or non/low responders to CFTR modulator therapies. We are focusing our LUNAR-CF program on this group of patients, as it currently has the highest unmet need for CF therapies.

LUNAR-CF Proof-of-Concept

In preclinical studies in rodents, we have observed selective delivery of LUNAR-mRNA into ciliated epithelial cells in airways, the main cellular population affected in CF (A and B). In Figure A, immunostaining of TdTomato (dark staining) protein is evident in mouse airways treated intratracheally with LUNAR-mRNA. This data demonstrates delivery into large and small epithelial airways. Figure B shows TdTomato (red) expression co-localized (yellowish) with a specific marker for ciliated epithelial cells (green, FoxJ1) indicating selective delivery of LUNAR-mRNA into the CF-defected cell population. Dapi (blue) is used as a counterstaining for nuclei.

Figure A: LUNAR-mRNA targets rodent epithelial airways

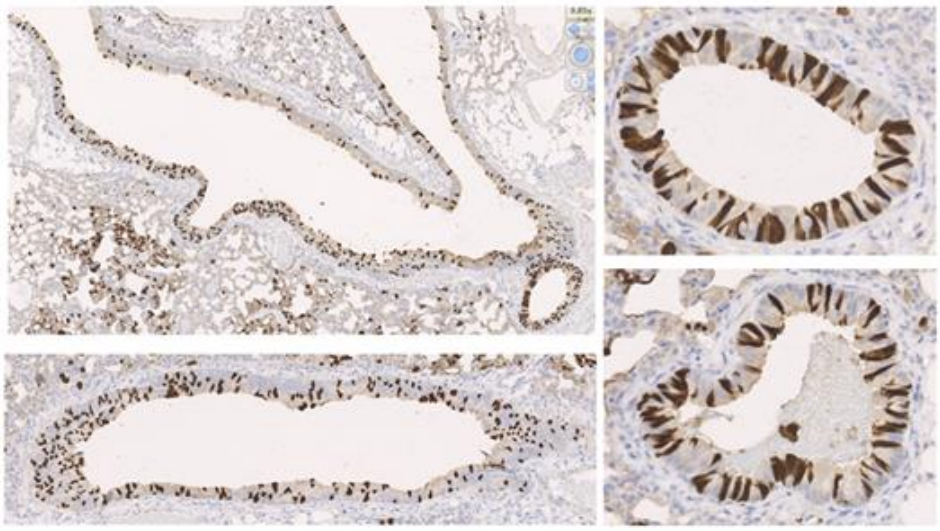
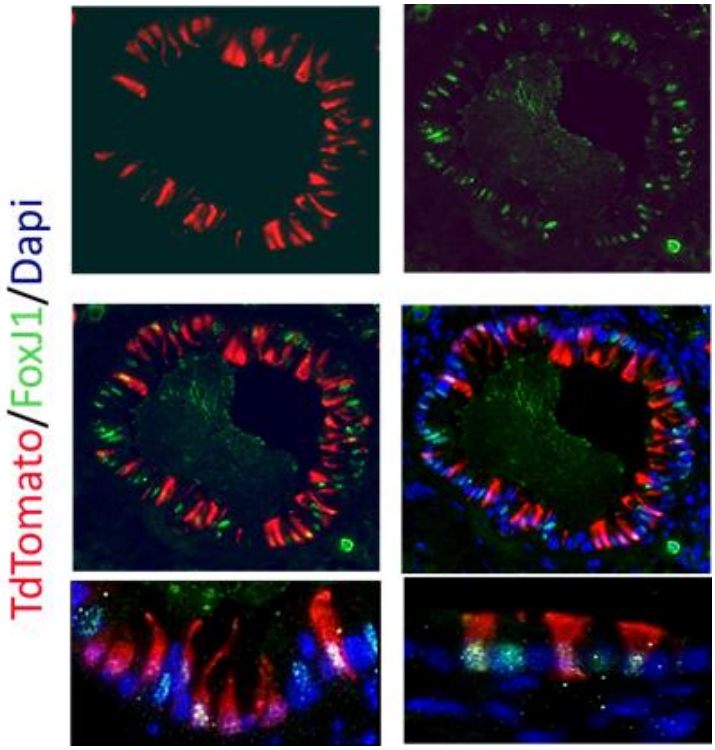
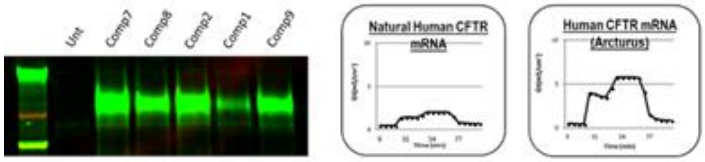


Figure B: Selective delivery of LUNAR-mRNA into rodent ciliated epithelial cells



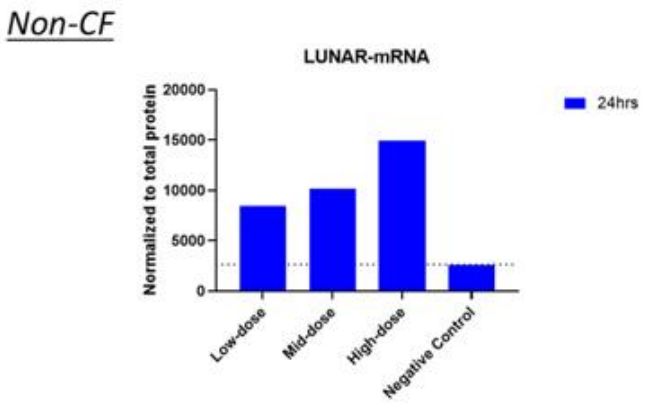
Cystic fibrosis bronchial epithelial ("CFBE") cells were transfected with codon optimized human CFTR ("hCFTR") mRNA leads and compared to the natural hCFTR sequence. The levels of protein expression observed from the codon optimized hCFTR sequences was significantly higher when compared to the natural sequence (figure C below, left). When our lead candidate hCFTR mRNA was transfected into FRT epithelial cells (a cell type used to measure conductance in CF research), a three-fold increase in transepithelial conductance was observed over the natural sequence (figure C below, right), indicating that the hCFTR protein produced from the mRNA is functional.

Figure C: Improved hCFTR mRNAs with higher protein levels and enhanced activity *in vivo*



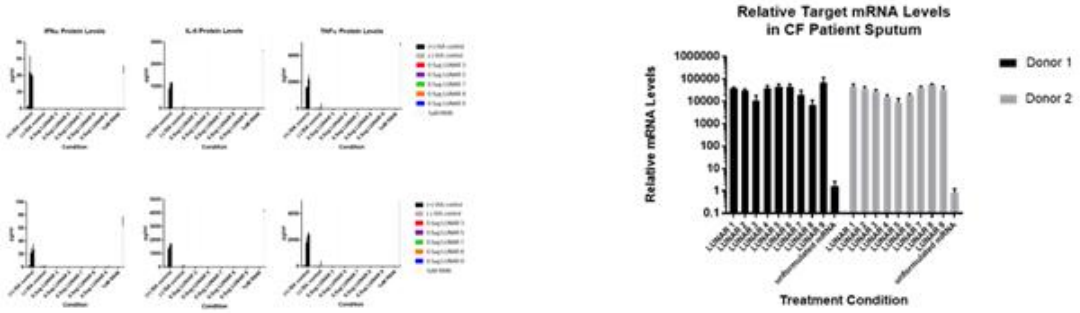
To evaluate the efficiency of delivery of LUNAR-mRNA to human lungs, we have developed an ex-vivo slice culture technique to treat human lungs with a LUNAR- mRNA encoding green fluorescent protein (LUNAR-eGFP mRNA). Effective delivery of the mRNA was demonstrated in these slice cultures of non-CF (Figure D).

Figure D: Slice culture of human lungs treated with LUNAR-mRNA



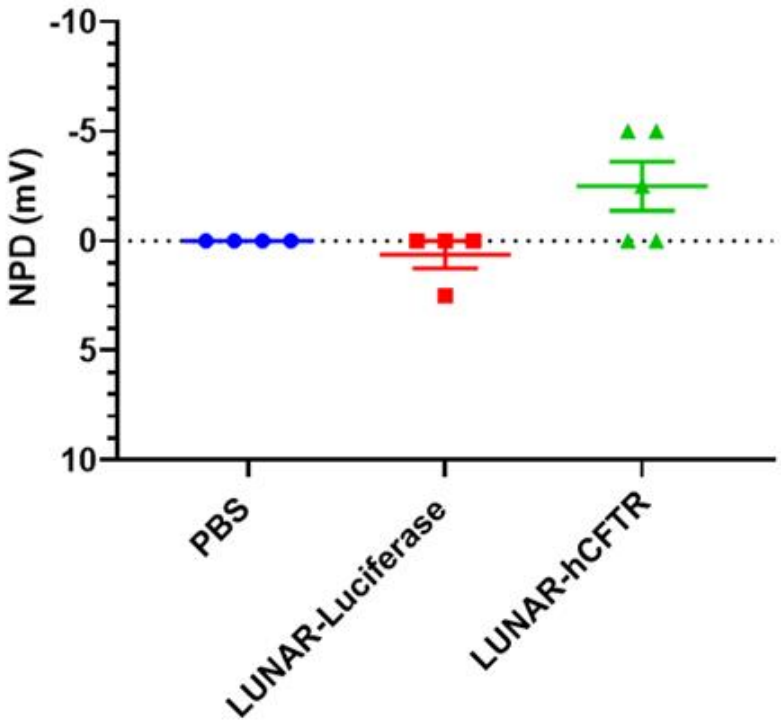
Our LUNAR-mRNA did not activate human peripheral blood mononuclear cells (PMCSs) *in vitro*. Very little to no immunostimulation of inflammatory cytokines, IFNα, IL-6, and TNFa, were observed when human peripheral blood mononuclear cells were exposed to a LUNAR-mRNA formulations in vitro. (Figure F, left panel). For a disease such as CF, where there is a thick mucus barrier, it is essential that a delivery platform like LUNAR shields and protects the mRNA from degradation in the mucus. When LUNAR-mRNA formulations were incubated with mucus derived from CF patients, no degradation of mRNA was observed after twenty-four hours, while all the non-LUNAR encapsulated mRNA was degraded, supporting that LUNAR shields and protects the mRNA in a mucus environment (Figure E right panel). This is a critical characteristic for any effective CF therapy based on RNA-therapeutics.

Figure E: LUNAR-mRNA properties in biological matrix



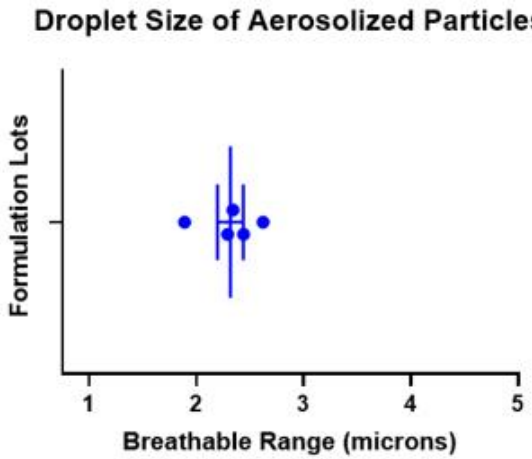
Restoration of functional hCFTR activity has been demonstrated in the CF knock out mouse model. Functional activity was determined by measuring the nasal potential difference in the nasal epithelium of this mouse model following intranasal instillation of LUNAR-hCFTR mRNA (Figure F). PBS and a LUNAR encapsulated negative control mRNA (encoding luciferase) are non-active, indicating that the current measure is hCFTR specific.

Figure F: LUNAR-hCFTR mRNA is functionally active *in vivo* in mouse model



We have developed optimal delivery conditions for an aerosolized lipid nanoparticle-based drug and have demonstrated that the physicochemical properties of the LUNAR formulations are maintained following aersolization. The LUNAR profiling shows the generation of a consistent and highly breathable droplet size (2-3 microns) optimal for lung delivery (Figure G).

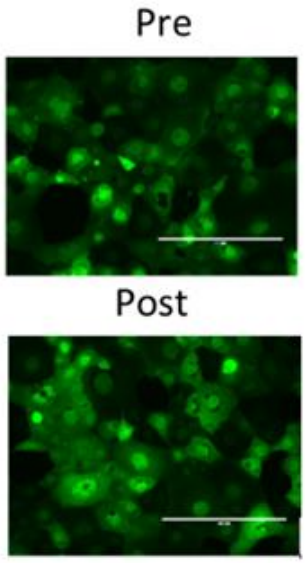
Figure G: A breathable droplet size was achieved with aerosolized LUNAR formulations



In addition to confirming that the physicochemical properties of the aerosolized LUNAR-mRNA are maintained, protein expression of LUNAR-eGFP mRNA formulations was evaluated pre-and post nebulization *in vitro.*

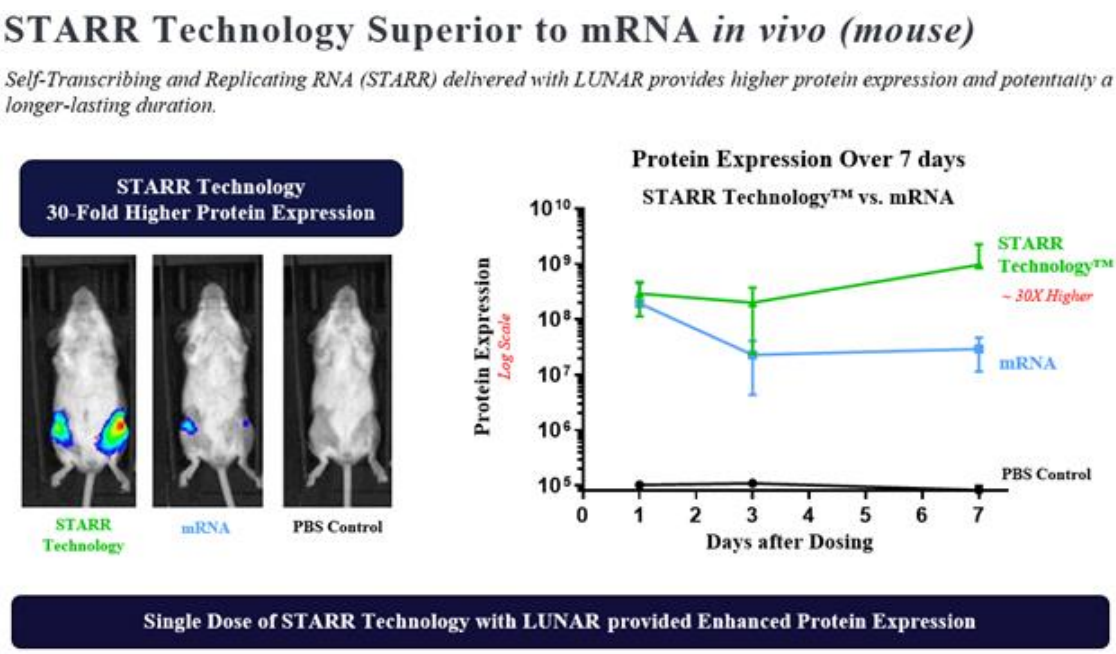
Pre-and post nebulized fractions of LUNAR-eGFP mRNA were transduced *in vitro* using CFBE cells; and, at six hours post-transduction, encoding green fluorescent protein ("eGFP") expression was observed using a fluorescent microscope. There was no material difference in the levels of eGFP expression from pre/post-nebulization fractions, demonstrating *in vitro* that the nebulization process affects neither the activity of the mRNA nor the integrity and stability of the LUNAR nanoparticle (Figure H).

Figure H: mRNA activity is preserved in aerosolized LUNAR-mRNA



STARR Proof-of-Concept

On November 7, 2019, we announced that we are expanding our platform to include STARR for human and vaccine applications. The STARR technology platform combines self-replicating RNA with LUNAR, a proprietary nanoparticle delivery system, into a single solution to produce proteins inside the human body. The versatility of the STARR technology comes from its ability upon delivery into the cell to generate a protective immune response or drive therapeutic protein expression to potentially prevent against or treat a variety of diseases. 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. This has the potential to enable us to simplify and increase the speed of vaccine production.



Collaboration Agreements

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 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 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.

Takeda Agreement

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 transfered 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.

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

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 suject 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.

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.

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 10, 2020, we are the sole owner of over 180 patents and pending patent applications including 29 U.S. patents, 26 pending U.S. patent applications, 6 pending international applications under Patent Cooperation Treaty ("PCT"), 56 foreign patents and 71 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 acid, 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 and use of our therapeutic candidates to treat target diseases including HBV and NASH. 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 10, 2020, we own 15 U.S. patents, 6 U.S. pending patent applications, 1 international patent application ("PCT"), 6 foreign granted patents, and 39 foreign pending patent applications covering the composition of matter, manufacture of lipid nanoparticles, and use of our LUNAR technology for nucleic acid delivery and drug delivery.
- UNA, mRNA and LNA – As of March 10, 2020, we own 14 U.S. patents, 14 U.S. pending patent applications, 4 PCT applications, 50 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.
- ARCT 810 Patents – As of March 10, 2020, we own 1 pending U.S. patent application and 1 PCT application specifically directed to the ARCT 810 drug substance, a specially designed mRNA encoding an OTC enzyme. We own 1 pending U.S. patent application directed to the ARCT-810 drug product candidate and methods of treating OTC deficiency. In addition, several of the mRNA and LUNAR platform patents and patent applications recite claims that cover key components of the ARCT 810 drug substance and drug product candidate. We anticipate that patents covering ARCT 810 will last until 2041, not including any patent term extensions.
- 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 1 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 10, 2020, we own 1 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.

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.

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.

Competition

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.

Companies currently developing mRNA therapeutics for prophylactic vaccines, cancer vaccines, or mRNA replacement therapy for rare genetic diseases include Moderna Therapeutics, Translate Bio, Ethris GmbH, CureVac GmbH, BioNTech, and eTheRNA. Translate Bio is developing mRNA replacement therapies for cystic fibrosis which are in early clinical development, and which directly compete with our LUNAR-CF program. Ethris is in preclinical development of ETH-CFTR, a mRNA replacement therapy for cystic fibrosis. A number of companies are developing viral vector or DNA-based approaches to gene delivery for rare liver diseases, including Ultragenyx Pharmaceutical, REGENXBIO, Inc., uniQure, Vivet Therapeutics, LogicBio Therapeutics, Touchlight Genetics

Ltd., Generation Bio, and Audentes Therapeutics. Ultragenyx is developing a gene therapy product for OTC deficiency which is in early clinical trials.

Companies developing siRNA therapeutics include Arbutus Biopharma, Arrowhead Pharmaceuticals, Inc, Quark Pharmaceuticals, Inc., Silence Therapeutics plc, Nitto Denko, Dicerna Pharmaceuticals, Inc., and Alnylam Pharmaceuticals, Inc. Antisense therapeutics are also in development by Ionis Pharmaceuticals, Roche Pharma, WAVE Life Sciences, Celgene Corporation, Akcea Therapeutics, Inc., Antisense Therapeutics, Ltd., ProQR, and Sarepta Therapeutics, Inc. Both Ionis Pharmaceuticals and ProQR are developing antisense therapies for cystic fibrosis which compete with our LUNAR-CF program.

In addition, to the companies mentioned above, several companies are developing non-nucleic acid therapies for OTC deficiency which are competitors to our LUNAR-OTC development program. For example, Synlogic's SYNB1020 product is treating urea cycle disorders, including OTC deficiency, by introducing engineered probiotic bacteria to the gut. Promethera's Heparesc product involves infusion of their HepaStem, liver-derived stem cells into urea cycle disorder patients to restore normal enzyme function. For cystic fibrosis, many companies are pursuing small molecule therapies designed to increase CFTR function, targeted to different patient populations, which could compete with our LUNAR-CF program. These include Vertex Pharmaceuticals, Proteostasis Therapeutics, Inc., Novartis and Galapagos.

The competitive landscape continues to expand and we expect that additional companies will initiate programs focused on the development of nucleic acid therapeutic products using the approaches described above as well as potentially new approaches that may result in the more rapid development of nucleic acid therapeutics or more effective technologies for nucleic acid drug development or delivery.

Manufacturing and Supply

To date, we have manufactured only limited quantities of drug substance for use in research activities. We have contracted with several third-party contract manufacturing organizations ("CMOs") for the supply of drug substance and finished product to meet our testing needs for preclinical toxicology and clinical testing. We expect to continue to rely on third-party CMOs for the supply of drug substance and drug product for our product candidates for at least the next several years, including to support the launch of our first commercial products.

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 FDA regulates drugs under the Federal Food, Drug and Cosmetic Act and implementing regulations. Drugs 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 may be marketed in the United States generally involves the following:

- completion of nonclinical laboratory tests, animal studies and formulation 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.
- Phase 3. Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for product labeling. Generally, two adequate and well-controlled Phase 3 clinical trials are required by the FDA 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. 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 drug safety and effectiveness and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized.

Post-approval requirements

Any drug 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 products 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. 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.

Employees

As of December 31, 2019, we had 88 employees, all of which were full-time or full-time equivalents. 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.

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 preclinical nucleic acid 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 preclinical 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 $26.0 million and $21.8 million for the years ended December 31, 2019 and 2018, respectively. As of December 31, 2019, we had an accumulated deficit of $71.7 million.

We have devoted most of our financial resources to research and development, including our preclinical 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 preclinical 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 preclinical 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.

Our auditor's report includes a going concern paragraph.

Our auditor's report on our financial statements for the year ended December 31, 2019 notes that based on our expected operating losses and negative cash flows, there is substantial doubt about our ability to continue as a going concern for a period of time in excess of twelve months after the date of this filing. Our products that are being developed have not generated significant revenue. As a result, we have suffered recurring losses and require significant cash resources to execute our business plans. These losses are expected to continue for an extended period of time. The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The financial statements do not include any adjustments relating to the recoverability and classification of asset amounts or the classification of liabilities that might be necessary should we be unable to continue as a going concern within one year after the date the financial statements are issued.

Historically, the major source of our cash has been from proceeds from various public and private offerings of common stock, debt issuances and through collaboration agreements. Management's plans to mitigate an expected shortfall of capital and to support future operations, include raising additional funds. The actual amount of cash that it will need to operate is subject to many factors.

We also recognize that we will need to raise additional capital in order to continue to execute our business plan in the future. There is no assurance that additional financing will be available when needed or that management will be able to obtain financing on terms acceptable to us or that we will become profitable and generate positive operating cash flow. If we are unable to raise sufficient additional funds, we will have to scale back our operations.

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. We do not anticipate generating revenues from sales of our products for the foreseeable future, if ever. Our ability to generate future revenues from product sales depends heavily on our success in:

- completing our research and preclinical 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.

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 preclinical 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, 2019, we had unrestricted cash and cash equivalents of $71.4 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 preclinical 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.

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 are exposed to interest rate risk, including under our existing loan agreements with our lender.

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, 2019, we had $15.0 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, 2019, under the Western Loan Agreement, would be approximately $90,000.

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 as well as covenants which include our (i) nomination of a clinical candidate, which we are in compliance with, and (ii) acceptance of an IND application by the FDA. 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

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 development. Specifically, 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 tests 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 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 nucleic acid 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 future 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 obtaining from the FDA, or comparable foreign regulatory authority, authorization to administer an investigational new drug product to humans through the submission or acceptance of an IND application;
- 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 sure that we will submit INDs on the expected timelines and we cannot be certain the submission on 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, will 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.

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. While we have not yet initiated clinical trials for any of our product candidates, it is likely that there will be side effects associated with their use. 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 the approval policies; 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. Our spending on research and development programs and product candidates for 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 preclinical 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 studies of product candidates. We currently rely and expect to continue to rely on third parties to conduct some aspects of our preclinical 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 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.

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.

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 March 10, 2020, we are the sole owner of over 180 patents and pending patent applications including 29 U.S. patents, 20 pending U.S. patent applications, 6 pending international applications under the PCT, 56 foreign patents and 71 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.

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.

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, 2019, we had 88 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 of $5,500 to $11,000 per false claim or statement ($11,665 to $23,331 per false claim or statement for penalties assessed after January 15, 2020 for violations occurring after November 2, 2015).
- 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 policy makers 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.

Since its passage, there have been judicial and Congressional challenges to certain aspects of the ACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the ACA. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been signed into law. On December 22, 2017, President Trump signed into law H.R. 1, "An Act to provide for reconciliation pursuant to titles II and V of the concurrent resolution on the budget for fiscal year 2018," informally titled the Tax Cuts and Jobs Act, which significantly revises the U.S. Internal Revenue Code of 1986, as amended (the "Code"). The Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." Additionally, on December 23, 2019, President Trump signed a spending bill that repealed the implementation of certain ACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Further, the Bipartisan Budget Act of 2018 (the "BBA"), among other things, amended the ACA, effective January 1, 2019, to increase from 50 percent to 70 percent 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." Additionally, in 2019, the United States Court of Appeals for the Fifth Circuit upheld a lower court decision finding the Affordable Care Act unconstitutional and eliminating the individual mandate. The U.S. Supreme Court declined to expedite this appeal, and thus will not issue a decision until late 2020 or early 2021. As a result, there is significant uncertainty regarding future healthcare reform and its impact on 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 2027 unless additional Congressional action is taken. 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

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, the Trump administration's budget proposal for fiscal year 2019 contained further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to

negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. While any proposed measures will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to 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.

General business conditions are vulnerable to the effects of epidemics, such as the coronavirus, which could materially disrupt business.

We are vulnerable to the general economic effects of epidemics and other public health crises, such as the novel strain of coronavirus reported to have surfaced in Wuhan, China in 2019. Due to the recent outbreak of the coronavirus, there has been a curtailment of global travel and business activities. If not resolved quickly, the impact of the epidemic could have a material adverse effect on our ability to coduct our researh and development efforts and impact our overall 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 wild fires, 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

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.

We are no longer an "emerging growth company" and are therefore subject to the auditor attestation requirement in the assessment of our internal controls over financial reporting and certain other increased disclosure and governance requirements.

At the end of fiscal year 2018, we lost our status as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012. As a result, we are no longer able to take advantage of certain exemptions from various reporting requirements. Therefore, we are now subject to certain requirements that apply to other public companies that did not previously apply to us, due to our previous status as an emerging growth company. These requirements include:

- compliance with the auditor attestation requirement in the assessment of our internal controls over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act;
- compliance with any new rules that may be adopted by the Public Company Accounting Oversight Board;
- compliance with any new or revised financial accounting standards applicable to public companies without an extended transition period;
- full disclosure regarding executive compensation required of larger public companies; and
- compliance with the requirement of holding a nonbinding advisory vote on executive compensation and obtaining shareholder approval of any golden parachute payments not previously approved.

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.

The recently enacted U.S. federal income tax reform bill could adversely affect our business and financial condition.

On December 22, 2017, President Trump signed into law the Tax Cuts and Jobs Act, which significantly revises the Code. The Tax Cuts and Jobs Act, among other things, contains significant changes to U.S. federal corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the Tax Cuts and Jobs Act is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will conform to the newly enacted federal tax law. The impact of the Tax Cuts and Jobs Act on holders of our common stock is also uncertain and could be adverse. We urge our shareholders to consult with their legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding 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, 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 at the completion of our merger with Alcobra, Ltd. in November 2017, 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.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

We have two properties located in San Diego, California. Our principal place of business is located at 10628 Science Center Drive, Suite 250, and consists of approximately 24,700 square feet of office space and laboratory space leased through March 2025. We have the right to extend this lease for an additional five-year term.

On February 1, 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 for a term of twelve months.

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. We are required to file a response to the SAC by March 20, 2020. We believe the allegations of Ms. Munoz in her complaint are without merit, and we intend to vigorously defend ourselves in the foregoing action. However, in light of the preliminary stage of the litigation, we are unable to provide any assurances as to the ultimate outcome of any of the lawsuit.

See *"Item 1. Redomiciliation"* regarding proceedings to liquidate Arcturus Israel pending is Israeli court.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

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

Holders of common stock

As of March 1, 2020, there were 23 holders of record of our common stock. As of such date, there were 15,137,964 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

In connection with the Third Amendment executed on June 18, 2019, Ultragenyx purchased 2.4 million shares of our common stock for $24.0 million in a private offering exempt from the registration requirements of the Securities Act pursuant to Regulation D.

Issuer and Affiliated Purchaser - Purchases of Equity Securities

We completed the sale of our intangible assets related to the ADAIR technology during fiscal year 2018. Pursuant to the asset purchase agreement for ADAIR, we received a 30% ownership interest in the common stock of a privately held company in consideration for the sale of the ADAIR technology. As of December 31, 2019, we hold a 19% ownership interest due to the issuance of common stock by the privately held company.

Item 6. Selected Financial Data.

The following tables set forth a summary of our historical financial data as of, and for the periods ended on, the dates indicated. We have derived the statement of operations data and balance sheet data from our audited financial statements (in thousands). You should read the selected financial data in conjunction with the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations," both of which are included elsewhere in this report.

	For the Year Ended December 31,				
	2019	2018	2017	2016	2015
Collaboration revenue	$ 20,789	$ 15,753	$ 12,998	$ 20,382	$ 6,138
Research and development, net	33,640	16,982	15,918	17,934	5,476
General and administrative	12,662	20,582	7,572	3,448	2,574
Net loss from operations	(25,513)	(21,811)	(10,492)	(1,000)	(1,912)
Net loss	(25,991)	(21,785)	(10,902)	(1,571)	(1,902)
Net loss per share, basic and diluted	$ (2.15)	$ (2.16)	$ (3.53)	$ (0.77)	$ (0.94)
Weighted-average shares outstanding, basic and diluted	12,069	10,069	3,087	2,032	2,016

	2019	2018	2017	2016	2015
Working capital	$ 52,966	$ 29,251	$ 39,662	$ 3,597	$ 1,208
Total assets	$ 82,143	$ 44,198	$ 52,024	$ 13,736	$ 14,947
Shareholders' equity (deficit)	$ 25,792	$ 13,642	$ 33,794	$ 1,577	$ (3,631)

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

We are an mRNA medicines company focused on significant opportunities within liver and respiratory rare diseases, and the development of infectious disease vaccines utilizing our STARR technology. In addition to our internal mRNA platform, our proprietary lipid nanoparticle delivery system, LUNAR, enables multiple nucleic acid medicines. The genetic medicines industry is constantly struggling to identify non-viral delivery solutions for large RNA molecules to different cell types. Our LUNAR delivery technology is lipid mediated – and non-viral. LUNAR is versatile, compatible with various types of RNA -- and has been shown to deliver large RNA to different cell types including liver hepatocytes, liver stellate cells, muscle cells (myocytes), and lung cells (including bronchial epithelial cells).

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, 2019, we had an accumulated deficit of $71.7 million.

Liquidity and Capital Resources

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

	Year Ended December 31,	
(Dollars in thousands)	**2019**	**2018**
Cash provided by (used in):		
Operating activities	$ (6,445)	$ (20,760)
Investing activities	(818)	22,134
Financing activities	41,907	10,204
Net increase in cash and restricted cash	$ 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 $6.4 million on a net loss of $26.0 million for the year ended December 31, 2019, compared to net cash used of $20.8 million on a net loss of $21.8 million for the year ended December 31, 2018. Adjustments for non-cash charges which includes share-based compensation and depreciation and amortization were $3.6 million and $2.2 million for the year ended December 31, 2019 and 2018, respectively. Changes in working capital resulted in adjustments to operating net cash inflows of $16.0 million for the year ended December 31, 2019, and net cash outflows of $1.2 million for the year December 31, 2018. The significant adjustments to operating net cash inflows for the year ended December 31, 2019 were primarily due to the Third Amendment to the collaboration agreement with Ultragenyx during the second quarter of 2019 along with increased accounts payable and accrued liabilities from LUNAR-OTC (ARCT-810), which expenses were incurred as discussed below.

Investing Activities

Net cash used in investing activities of $0.8 million for the year ended December 31, 2019 reflected the acquisition of property and equipment. Net cash provided by investing activities of $22.1 million for the year ended December 31, 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 $41.9 million for the year ended December 31, 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 the year ended December 31, 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 the first quarter of 2021, 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 to follow 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 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.

Going Concern and Management's Plans

Our products that are being developed have not generated significant revenue. As a result, we have suffered recurring losses and require significant cash resources to execute our business plans. These losses are expected to continue for an extended period of time. Based on our current planned operations and clinical development plans, and giving effect to our planned pace of research, our current overhead, personnel costs and obligations under our credit facility, and possible limited access to working capital, we believe there is substantial doubt that our current cash and cash equivalents balances will be sufficient to fund our operations for at least twelve months after the date the consolidated financial statements are filed. In drawing this conclusion we do not consider our ability to raise additional capital through equity, debt, collaborations or other funding arrangements with partners or through other sources of financing or to reduce the pace or scope of our activities. These conditions raise substantial doubt about our ability to continue as a going concern for a period of one year from the date of the issuance of our 2019 consolidated financial statements. The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The financial statements do not include any adjustments relating to the recoverability and classification of asset amounts or the classification of liabilities that might be necessary should we be unable to continue as a going concern within one year after the date the financial statements are issued.

Historically, our major sources of cash have comprised proceeds from collaboration partners, various public and private offerings of our common stock, option and warrant exercises, and interest income. From inception through December 2019, we raised approximately $210.4 million in gross proceeds from various public and private offerings of our common stock, debt issuances, collaboration agreements, and the merger with Alcobra Ltd.

As of December 31, 2019, we had approximately $71.5 million in cash, restricted cash and cash equivalents. Our plans to mitigate an expected shortfall of capital, to support future operations, include raising additional funds.

We also recognize we will need to raise additional capital in order to continue to execute our business plan in the future. There is no assurance that additional financing will be available when needed or that management will be able to obtain financing on terms acceptable to us or whether we will become profitable and generate positive operating cash flow. If we are unable to raise sufficient additional funds, we will have to scale back our operations.

Overview

Since our inception, we have funded our operations principally with proceeds from the sale of capital stock, convertible notes and revenues earned through collaborative agreements. At December 31, 2019, we had $71.4 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"). The Loan has a maturity date of October 1, 2022 and carries interest at the U.S. prime rate plus 1.25%. The loan has an interest-only period of 19 months, which could be extended by an additional 6 months if certain conditions are met, followed by an amortization period of 30 months, or 24 months if the interest-only period is extended. Upon maturity or prepayment, we will be required to pay a 3% fee, or a 2% fee if the U.S. Food and Drug Administration accepts certain Investigational New Drug applications prior to maturity.

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 amendment, the Bank agreed to make a term loan to us on October 30, 2019, in the amount of $15 million (the "Term Loan"). The resulting net increase in the indebtedness of us was $5 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 April 1, 2021, which is subject to extension to October 1, 2021 upon the occurrence of an equity or expansion event and the absence of an event of default, and thereafter shall make monthly payments of principal and interest during a 30-month amortization period.

The Term Loan also includes covenants which include our submission of a clinical candidate for IND application, made to the U.S. Food and Drug Administration by May 31, 2020 and obtaining acceptance by June 30, 2020.

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 the 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. There can be no assurances that additional financing will be secured or, if secured, will be on favorable terms. These conditions raise substantial doubt about the business, results of operations, financial condition and/or our ability to fund scheduled obligations on a timely basis or at all. The accompanying financial statements have been prepared assuming that we will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The consolidated financial statements do not reflect any adjustments related to the recoverability and classification of assets or the amounts and classification of liabilities that might be necessary if we are unable to continue as a going concern.

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 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,		2018 to 2019	
(Dollars in thousands)	2019	2018	$ change	% change
Collaboration revenue	$ 20,789	$ 15,753	$ 5,036	32.0%

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.

On February 11, 2019, we announced the termination of the obligations of CureVac for preclinical development, effective 180 days from February 5, 2019 and the re-assumption by us of the worldwide rights thereto. We reassumed 100% of the global rights of our flagship asset and clinical development candidate, a messenger RNA (mRNA) drug to treat ornithine transcarbamylase (OTC) deficiency.

Operating Expenses

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

	Year Ended December 31,		2018 to 2019	
(Dollars in thousands)	**2019**	**2018**	**$ change**	**% change**
Operating expenses:				
Research and development, net	$ 33,640	$ 16,982	$ 16,658	98.1%
General and administrative	12,662	20,582	$ (7,920)	-38.5%
Total	$ 46,302	$ 37,564	$ 8,738	23.3%

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

	Year Ended December 31,		2018 to 2019	
(Dollars in thousands)	**2019**	**2018**	**$ change**	**% change**
External pipeline development expenses:				
LUNAR-OTC (ARCT-810)	$ 15,616	$ 3,699	$ 11,917	*
LUNAR-CF, net	813	337	476	*
Discovery technologies	3,937	2,943	994	33.8%
External platform development expenses:				
Partnered discovery technologies	1,894	1,979	(85)	-4.3%
Total development expenses	$ 22,260	$ 8,958	$ 13,302	*
Personnel related expenses	$ 9,005	$ 6,533	$ 2,472	37.8%
Facilities and equipment expenses	2,375	1,491	884	59.3%
Total research and development expenses, net	$ 33,640	$ 16,982	$ 16,658	98.1%

* *Greater than 100%*

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, and laboratory supplies for research and development activities.

LUNAR-OTC (ARCT-810) expenses for the year ended December 31, 2019 increased by $11.9 million, from $3.7 million in 2018 to $15.6 million in 2019. The increase in LUNAR-OTC (ARCT-810) expenses was due primarily to preparation for an IND application, which was submitted during the first quarter of 2020.

Lunar-CF expenses for the year ended December 31, 2019 increased by $0.5 million, from $0.3 million in 2018 to $0.8 million in 2019. This amount was offset with funds awarded by the CFF. The increase in LUNAR-CF expenses 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 2021.

Discovery technologies represents our efforts to expand our product pipeline. Discovery technology expenses for the year ended December 31, 2019 increased by $1.0 million, or 33.8%, from $2.9 million in 2018 to $3.9 million in 2019. The increase in discovery technology expenses 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 for the year ended December 31, 2019 were $1.9 million, approximately the same as in 2018. We expect partnered discovery technologies expenses to fluctuate based on the needs of our collaboration partners.

Personnel related expenses for the year ended December 31, 2019 increased by $2.5 million, or 37.8% from $6.5 million in 2018 to $9.0 million in 2019. The increase in personnel related expenses was due primarily to increased headcount necessary to advance our external pipeline and platform efforts, and was offset by $0.9 million of funds received from the CFF. We expect personnel related expenses to increase in 2020 as we expand our headcount to execute our business plan.

Facilities and equipment expenses for the year ended December 31, 2019 increased by $0.9 million, or 59.3%, from $1.5 million in 2018 to $2.4 million in 2019. The increase in facilities and equipment expenses was due primarily to higher rent and related costs associated with our new 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 for the year ended December 31, 2019 decreased by $7.9 million, or 38.5%, from $20.5 million in 2018 to $12.6 million in 2019. The decrease in general and administrative expenses 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) an 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 with the prior year.

Finance income (expense), net

	Year Ended December 31,		2018 to 2019	
(Dollars in thousands)	**2019**	**2018**	**$ change**	**% change**
Finance income (expense), net:				
Interest income	$ 408	$ 514	$ (106)	-20.6%
Interest expense	(854)	(186)	$ (668)	*
Total	$ (446)	$ 328	$ (774)	*

* *Greater than 100%*

Interest income is generated on cash and cash equivalents. 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. 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, judgements and assumptions that we believe are reasonable, based upon information available to us. These judgements 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, 2019. 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 judgements:

Identifying the performance obligations contained in the agreement

Our assessment of what constitutes a separate performance obligation requires us to apply judgement. 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 judgements. 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 judgements 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").

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, 2019, 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, 2019.

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, 2019, 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, 2019, 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, 2019 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, 2019, 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, 2019, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2019 and 2018, the related consolidated statements of operations and comprehensive loss, changes in stockholders' equity, and cash flows, for each of the two years in the period ended December 31, 2019, and the related notes and our report dated March 16, 2020 expressed an unqualified opinion thereon that included an explanatory paragraph regarding the Company's ability to continue as a going concern.

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 16, 2020

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, 2019 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 2020 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2019. 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 2020 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2019. 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 2020 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2019. 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 2020 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2019. 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 2020 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2019. 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
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	Bylaws (incorporated by reference to Annex C 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).
4.1	Agreement and Plan of Merger and Reorganization, by and between Alcobra Ltd., Aleph MergerSub, Inc. and Arcturus Therapeutics, Inc., dated as of September 27, 2017. Incorporated by reference to Exhibit 99.2 to the Company's Report of Foreign Private Issuer on Form 6-K filed on September 28, 2017 (File No. 001-35932).
10.1*†	Form of Indemnification Agreement.
10.2†	2019 Omnibus Equity Incentive Plan. Incorporated by reference to Appendix A to the proxy statement filed on October 1, 2019 (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).
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).

Exhibit Number	Description
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).
10.23*	Lease Agreement, by and between Arcturus Therapeutics Holdings Inc. and ARE-SD Region No. 44, LLC dated February 1, 2020.
10.24**	Acceptance Letter, dated March 4, 2020, between Arcturus Therapeutics Holdings Inc. and the Economic Development Board of Singapore.
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.

Exhibit Number	Description
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, 2019 formatted in Extensible Business Reporting Language (XBRL):
	101.INS XBRL Instance Document
	101.SCH XBRL Taxonomy Extension Schema
	101.CAL XBRL Taxonomy Extension Calculation Linkbase
	101.DEF XBRL Taxonomy Extension Definition Linkbase
	101.LAB XBRL Taxonomy Extension Label Linkbase
	101.PRE XBRL Taxonomy Extension Presentation Linkbase

* 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 of 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 16, 2020

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 16, 2020
/s/ Dr. Padmanabh Chivukula **Dr. Padmanabh Chivukula**	Chief Scientific Officer, Chief Operating Officer and Secretary	March 16, 2020
/s/ Dr. Peter Farrell **Dr. Peter Farrell**	Chairman of the Board	March 16, 2020
/s/ Andrew Sassine **Andrew Sassine**	Director and Chief Financial Officer *(principal financial officer)*	March 16, 2020
/s/ Dr. Magda Marquet **Dr. Magda Marquet**	Director	March 16, 2020
/s/ James Barlow **James Barlow**	Director	March 16, 2020
/s/ Edward Holmes **Edward Holmes**	Director	March 16, 2020
/s/ Karah Parschauer **Karah Parschauer**	Director	March 16, 2020
/s/ Keith C. Kummerfeld **Keith C. Kummerfeld**	Vice President of Finance and Corporate Controller *(principal accounting officer)*	March 16, 2020

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, 2019 and 2018, the related consolidated statements of operations and comprehensive loss, changes in stockholders' equity, and cash flows, for each of the two years in the period ended December 31, 2019 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, 2019 and 2018, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2019, 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, 2019, 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 16, 2020 expressed an unqualified opinion thereon.

The Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has suffered recurring losses from operations, has negative cash flows from operations and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of these uncertainties.

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.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2018

San Diego, California
March 16, 2020

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

	As of December 31,	
	2019	**2018**
Assets		
Current assets:		
Cash and cash equivalents	$ 71,353	$ 36,709
Accounts receivable	2,179	4,481
Prepaid expenses and other current assets	758	638
Total current assets	74,290	41,828
Property and equipment, net	2,349	1,975
Operating lease right-of-use asset, net	5,134	—
Equity-method investment	263	288
Non-current restricted cash	107	107
Total assets	$ 82,143	$ 44,198
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 5,793	$ 2,398
Accrued liabilities	7,134	3,907
Deferred revenue	8,397	6,272
Total current liabilities	21,324	12,577
Deferred revenue, net of current portion	15,182	7,534
Long-term debt	14,995	9,911
Operating lease liability, net of current portion	4,850	—
Deferred rent	—	534
Total liabilities	56,351	30,556
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Common stock: $0.001 par value; 30,000 shares authorized; 15,138 issued and outstanding at December 31, 2019; NIS 0.07 par value; 30,000 shares authorized, 10,762 issued, 10,719 outstanding and 43 held in treasury at December 31, 2018;	15	214
Additional paid-in capital	97,445	58,302
Accumulated deficit	(71,668)	(44,874)
Total stockholders' equity	25,792	13,642
Total liabilities and stockholders' equity	$ 82,143	$ 44,198

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,	
	2019	2018
Collaboration revenue	$ 20,789	$ 15,753
Operating expenses:		
Research and development, net	33,640	16,982
General and administrative	12,662	20,582
Total operating expenses	46,302	37,564
Loss from operations	(25,513)	(21,811)
Loss from equity-method investment	(32)	(302)
Finance (expense) income, net	(446)	328
Net loss	(25,991)	(21,785)
Net loss per share, basic and diluted	$ (2.15)	$ (2.16)
Weighted-average shares outstanding, basic and diluted	12,069	10,069
Comprehensive loss:		
Net loss	$ (25,991)	$ (21,785)
Unrealized gain on short-term investments	—	3
Comprehensive loss	$ (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 restricted common stock and option, 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**

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,	
	2019	**2018**
OPERATING ACTIVITIES:		
Net loss	$ (25,991)	$ (21,785)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	684	582
Share-based compensation expense	1,982	1,259
Loss from equity-method investment	25	302
Other non-cash expenses	873	38
Changes in operating assets and liabilities:		
Accounts receivable	2,302	(4,001)
Prepaid expenses and other assets	(120)	421
Accounts payable	3,155	578
Accrued liabilities	1,675	1,687
Deferred revenue	8,970	159
Net cash used in operating activities	(6,445)	(20,760)
INVESTING ACTIVITIES:		
Acquisition of property and equipment	(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	(818)	22,134
FINANCING ACTIVITIES:		
Proceeds from long-term debt, net of lender fees	4,945	9,872
Proceeds from exercise of stock options	139	332
Proceeds from issuance of restricted common stock and option, net of issuance costs	15,545	—
Proceeds from issuance of common stock, net of issuance costs	21,278	—
Net cash provided by financing activities	41,907	10,204
NET INCREASE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	34,644	11,578
Cash, cash equivalents and restricted cash at beginning of year	36,816	25,238
Cash, cash equivalents and restricted cash at end of year	$ 71,460	$ 36,816

	Year Ended December 31,	
	2019	**2018**
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 691	$ 146
Non-cash investing activities		
Right-of-use asset obtained in exchange for lease liabilities	$ 5,868	$ —
Sale of intangible assets for equity method investment	$ —	$ 590
Purchase of property and equipment in accounts payable	$ 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 messenger RNA medicines company focused on significant opportunities within liver and respiratory rare diseases, and the development of infectious disease vaccines utilizing our Self-Transcribing and Replicating RNA ("STARR") technology. In addition to the Company's internal messenger RNA ("mRNA") platform, its proprietary lipid nanoparticle delivery system, LUNAR, enables multiple nucleic acid medicines.

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

Recent Developments

In May 2019, shareholders of Arcturus Therapeutics Ltd. ("Arcturus Israel") approved the Redomiciliation to the United States (the "Redomiciliation"). In connection therewith, in February 2019, Arcturus Israel entered into a share exchange agreement (the "Exchange Agreement") with Arcturus Therapeutics Holdings Inc., a newly established Delaware corporation. In June 2019, pursuant to the terms of the Exchange Agreement, all issued ordinary shares and options to purchase ordinary shares of Arcturus Israel were exchanged on a one-for-one basis for newly issued shares of common stock and options to purchase common stock, respectively, of the Company, resulting in Arcturus Israel becoming a subsidiary of the Company.

In June 2019, Arcturus Israel's ordinary shares were delisted from trading on Nasdaq and the Company's shares commenced trading on Nasdaq under the symbol "ARCT." Arcturus Israel is now a wholly-owned subsidiary of the Company, which is the successor to Arcturus Israel. Proceedings to liquidate Arcturus Israel are now pending in Israeli court.

On October 30, 2019, the Company amended its loan agreement with Western Alliance Bank (the "Bank"). See *"Note 7. Long-term debt with Western Alliance Bank"* for further information.

See *"Note 8 Stockholders' Equity – Registered Direct Offerings"* for further information on the Company's recent registered direct offerings.

See *"Note 14 Subsequent Events"* for further information on the Duke-NUS Medical School Agreement.

Going Concern

The Company's activities since inception have consisted principally of performing research and development 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.

The Company is a preclinical bioscience company that is dependent on obtaining external equity and debt financings to fund its operations. Historically, the Company's primary source of financing has been through the sale of its securities, through issuance of debt and through collaboration agreements. On June 18, 2019, the Company entered into a Third Amendment to the Research Collaboration and License Agreement with Ultragenyx Pharmaceutical Inc. ("Ultragenyx"), from which the Company received $24.0 million from Ultragenyx's purchase of common stock and a $6.0 million upfront payment. Furthermore, in separate offerings, the Company raised total net proceeds of $21.4 million during the third quarter of 2019 through the sale of equity securities. Research and development activities have required significant capital investment since the Company's inception.

The Company expects its operations to continue to require cash investment to pursue the Company's research and development activities, including preclinical studies, formulation development, clinical trials and related drug manufacturing. The Company has experienced net losses since its inception and as of December 31, 2019 has an accumulated deficit of $71.7 million. The Company expects to continue to incur additional losses for the foreseeable future, and the Company will need to raise additional debt or equity financing or enter into additional collaborations to fund its development. The ability of the Company to transition to profitability is dependent on identifying and developing successful mRNA drug candidates. In the near future, if the Company is not able to achieve planned milestones, incurs costs in excess of its forecasts, or does not meet covenant or other requirements of its debt (Note 7), it will need to reduce discretionary spending, discontinue the development of some or all of its products, which will delay part of its development programs, all of which would have a material adverse effect on the Company's ability to achieve its intended business objectives. There can be no assurances that additional financing will be secured or, if secured, will be on favorable terms. Management has prepared cash flow forecasts which indicate that based on the Company's expected operating losses and negative cash flows, there is substantial doubt about the Company's ability to continue as a going concern within twelve months after the date that the financial statements for the year ended December 31, 2019, are issued. The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The consolidated financial statements do not reflect any adjustments related to the recoverability and classification of assets or the amounts and classification of liabilities that might be necessary if the Company is unable to continue as a going concern.

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, 2019 and 2018, 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 (Note 4).

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, 2019 or 2018.

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 98% of the total accounts receivable balance at December 31, 2019 and one customer that comprised 96% of the total accounts receivable balance at December 31, 2018.

For the year ended December 31, 2019, the Company's top four customers collectively represented 91% of the Company's total revenue. For the year ended December 31, 2018, there were three customers that collectively represented 80% 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 a privately held company in consideration for the sale of the ADAIR technology. As this ownership interest is greater than 20% and one executive of the Company 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, 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. The was no income tax effect related to unrealized losses for the years ended December 31, 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.

Research and Development Costs, net

Research and development costs are expensed as incurred. These expenses result from the Company's independent research and development efforts as well as efforts associated with collaboration arrangements. Research and development costs include salaries and personnel-related costs, consulting fees, fees paid for contract research and manufacturing services, the costs of laboratory supplies, equipment and facilities and other external costs are shown net of any grants.

Share-Based Compensation

The Company recognizes share-based compensation for equity awards granted to employees, 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' share 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 fair value of share 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 shares, 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 share option activity and therefore estimates the expected term of share options granted using the simplified method, which represents the average of the contractual term of the share option and its weighted-average vesting period. The expected volatility of share 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 share options. The effect of forfeited awards is recorded when the forfeiture occurs.

Statement of cash flows

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

	As of December 31,	
(in thousands)	**2019**	**2018**
Cash and cash equivalents	$ 71,353	$ 36,709
Non-current Restricted cash	107	107
Total cash, cash equivalents and restricted cash shown in the statement of cash flows	$ 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, 2019 and 2018 are comprised of stock options.

No dividends were declared or paid during the reporting periods.

Recently Adopted Accounting Pronouncements

Revenue from Contracts with Customers

In May 2014, the Financial Accounting Standards Board (FASB) issued Topic 606, which supersedes nearly all existing revenue recognition guidance under GAAP. The FASB subsequently issued amendments to Topic 606 that have the same effective date and transition date.

The Company adopted this new guidance, effective January 1, 2019, using the modified retrospective transition method, in which the standard is applied as of the date of initial adoption. The Company recorded the cumulative effect of initially applying the standard as an adjustment to the opening balance of accumulated deficit. The adoption of the new revenue recognition guidance resulted in an increase of $0.8 million to deferred revenue and an increase of $0.8 million to accumulated deficit as of January 1, 2019. The change in revenue was due to a change in how the Company accounts for changes in the measure of progress and changes to the transaction price and for the recognition of revenue. Under Topic 605, the Company accounted for changes to the measure of progress and changes to the transaction price prospectively. Topic 606 requires companies to account for a change to the measure of progress or a change to the transaction price as a cumulative catch-up in the period of change. There were no other impacts upon the adoption of Topic 606. The Company will apply the standard to all new contracts initiated on or after the effective date.

Leases

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)* in order to increase transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet for those leases classified as operating leases under previous GAAP. ASU 2016-02 requires a lessee to recognize a liability for lease payments (the lease liability) and a right-of-use asset (representing its right to use the underlying asset for the lease term) on the balance sheet. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018 (including interim periods within those periods) using a modified retrospective approach.

In July 2018, the FASB issued ASU 2018-11, *Leases (Topic 842): Targeted Improvements*, which provides entities an optional transition method to apply the new guidance as of the adoption date, rather than as of the earliest period presented. In transition, entities may also elect a package of practical expedients that must be applied in its entirety to all leases commencing before the effective date, unless the lease was modified, to not reassess (a) the existence of a lease, (b) lease classification or (c) determination of initial direct costs, which effectively allows entities to carryforward accounting conclusions under previous U.S. GAAP.

The Company adopted ASU 2016-02, using the optional transition method and electing the package of practical expedients described above on January 1, 2019. Due to the adoption, the Company recognized a new lease liability on the Company’s consolidated balance sheet for its operating lease of office and lab space of $6.4 million on January 1, 2019, with a corresponding right-of-use asset of $5.9 million based on the present value of the remaining minimum lease payments. See Note 11 for further discussion.

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 I, II, and III 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, 2019 in the balances of contract assets, including receivables from collaborative partners, and contract liabilities, including deferred revenue.

(in thousands)	Contract Assets
BALANCE - December 31, 2018	$ 4,480
Additions for revenue recognized	17,523
Deductions for cash collections	(19,824)
BALANCE - December 31, 2019	$ 2,179

(in thousands)	Contract Liabilities
BALANCE - December 31, 2018	$ 13,806
Additions for advanced billings	30,134
Additions resulting from adoption of Topic 606	803
Deductions for promised goods/services provided in current period	(21,164)
BALANCE – December 31, 2019	$ 23,579

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

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

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

Collaboration Partner – Janssen

Janssen 2017 Agreement

In October 2017 the Company entered into a research collaboration and license agreement with Janssen (the "2017 Agreement"). 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 $56.5 million, as well as royalty payments on any future licensed product sales. The next milestone will be achieved upon demonstration 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 on annual net sales of licensed products in the low to mid-single digits range, 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 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 the 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, 2019, 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 33 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, 2019 and December 31, 2018 for Janssen was $5.9 million and $6.5 million, respectively. No transition adjustment was necessary upon adoption of Topic 606.

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 under 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 (as further described below) 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 this 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 internal and external development costs incurred pursuant to the Ultragenyx Agreement, and 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. Upon certain net annual commercial sales thresholds, 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 from $0.5 million to $1.5 million.

The current potential development, regulatory and commercial milestone payments for the existing development targets as of December 31, 2019 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, 2019, the Company 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 the option to purchase 0.6 million additional shares of common stock at $16 per share within two years of executing the amendment (Note 8).

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 are restricted for 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 the 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 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.

At December 31, 2019, the transaction price included the upfront consideration received, 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 milestone consideration is outside the control of the Company and contingent upon success in future clinical trials, approval from the Food and Drug Administration 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 will be 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 as of December 31, 2019 and December 31, 2018 from Ultragenyx was $12.7 million and $2.7 million, respectively.

Upon adoption of Topic 606, the Company reversed $0.8 million of previously recorded revenue related to Ultragenyx through an increase to deferred revenue and a decrease to beginning accumulated deficit. The adjustment was due to a change in the way the Company accounts for updates to the period over which revenue is recognized as well as accounting for adjustments to the transaction price. Under Topic 605, the Company accounted for these changes prospectively and under Topic 606 the Company accounts for the changes as a change in estimate recorded as a cumulative catch-up in the period in which the change occurred.

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 delivery technology (the LUNAR platform) (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 (which is 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 8 years (which was subsequently amended, as discussed below), the Agreement also includes an option to extend the term on an annual basis for up to 3 years and subject to payment by CureVac to Arcturus of a non-refundable annual extension fee. The agreement included potential milestone payments for selected targets from CureVac to the Company. The current potential milestone payment for the remaining targets as of December 31, 2019 is $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, 2019, the Company has not yet reached the clinical phase of the contract. Pursuant to a May 2018 amendment to the Development and Option Agreement (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 180 days from February 5, 2019 and the re-assumption by the Company of the worldwide rights thereto. As a result, Arcturus will reassume 100% of the global rights for its flagship asset, clinical development candidate ARCT-810, a messenger RNA (mRNA) drug to treat ornithine transcarbamylase deficiency.

On July 26, 2019, the Company entered into an amendment ("CureVac Amendment") to its Development and Option Agreement (as amended, the "Development and Option Agreement"), with CureVac, pursuant to which the Company and CureVac 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.

In connection with the CureVac Amendment, the Company and CureVac also entered into a Termination Agreement (the "Termination Agreement") terminating the Co-Development Agreement between the Company and CureVac dated as of January 1, 2018. The Termination Agreement is effective as of July 26, 2019. Pursuant to the Termination Agreement, CureVac agreed to make a settlement payment to Arcturus in the amount of $4.0 million. The payment was made in July 2019 and was recognized as revenue during the period in which the related expenses were incurred.

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 the 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.

At December 31, 2019, 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. During the year ended December 31, 2019, no adjustments were made to the transaction price.

The transaction price 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 amended forty-six-month contractual term as of December 31, 2019. As a result of CureVac Amendment, 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, 2019 and December 31, 2018 for CureVac was $3.2 million and $4.4 million, respectively. No adjustment was necessary upon adoption of Topic 606.

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, 2019, 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. Additionally, sublicensee consideration is fully constrained until the subsequent sublicence by SGI occurs. The Company recognized a sublicense revenue amount of $3.3 million for year ended December 31, 2019 as SGI sublicensed the technology to multiple parties.

Other Collaboration Agreements

The remaining revenue from smaller collaboration agreements relates to the agreements with Millennium Pharmaceuticals, Inc., a wholly owned subsidiary of Takeda Pharmaceutical Company Limited ("Takeda") and Providence Therapeutics, Inc. ("Providence"). Under the agreement with Takeda, the Company recognized $1.3 million related to amortization of an upfront payment during FY 2019 related to research and development activities. The current agreement was entered into on March 18, 2019 and is expected to be completed during the first half of 2020.

Under the agreement with Providence, the Company recognized revenue of $0.4 million from labor reimbursements and out-of-pocket cost reimbursements during FY 2019.

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, 2019 and 2018, 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, 2019 and December 31, 2018.

	December 31,	
(in thousands)	**2019**	**2018**
Accrued compensation	$ 1,608	$ 974
Cystic Fibrosis Foundation Liability (Note 11)	1,949	—
Refundable fees received	—	2,259
Current portion of operating lease liability	827	—
Other accrued research and development expenses	2,750	674
Total	$ 7,134	$ 3,907

NOTE 6. Property and Equipment, Net

Property and equipment, net consisted of the following:

	December 31,	
(in thousands)	**2019**	**2018**
Research equipment	$ 3,658	$ 2,711
Computers and software	271	200
Office equipment and furniture	561	527
Leasehold improvements	40	34
Total	$ 4,530	$ 3,472
Less accumulated depreciation and amortization	(2,181)	(1,497)
Property and equipment, net	$ 2,349	$ 1,975

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

NOTE 7. Debt

Long-term debt with Western Alliance Bank

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

The Loan is collateralized by all of the assets of the Company, 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 the Company's ability to dispose of assets, merge with or acquire other entities, incur indebtedness and make distributions to holders of the Company's capital stock. In addition, the Company is required to maintain at least 100% of its consolidated, unrestricted cash, or $15 million, whichever is lower, with the Bank.

On October 30, 2019, the Company 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 amendment, the Bank agreed to make a term loan to the Company on October 30, 2019, in the amount of $15 million (the "Term Loan"). The resulting net increase in the indebtedness of the Company 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. The Company shall make monthly payments of interest only until the interest-only end date of April 1, 2021, which is subject to extension to October 1, 2021 upon the occurrence of an equity or expansion event and the absence of an event of default, and thereafter shall make monthly payments of principal and interest during a 30-month amortization period.

The Company 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, the Company 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, provided that a prepayment fee is required to be paid by the Company upon prepayment. The prepayment fee ranges from 0.50% to 2.00% of the prepaid principal amount depending upon the date on which the prepayment is made. In connection with the Third Amendment, the Company guaranteed the obligations under the Loan Agreement and pledged substantially all of its assets as security under the Loan Agreement.

The Term Loan also includes covenants which includes the Company's submission of a clinical candidate for IND application made to the U.S. Food and Drug Administration by May 31, 2020 and have it accepted by June 30, 2020.

Upon maturity or prepayment, the Company will be required to pay a 3% fee, or a 2% fee if the U.S. Food and Drug Administration accepts certain Investigational New Drug ("IND") applications prior to maturity. Because acceptance of an IND is outside of the Company's control, management estimated that the Company will be liable for a fee of 3% of the principal balance, or $450,000 upon repayment or maturity, and such fee is accreted to the 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, 2019, 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, 2019:

Year Ending December 31,	
2020	$ —
2021	4,000,000
2022	6,000,000
2023	5,450,000
Total	15,450,000

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

NOTE 8. Stockholders' Equity

Common Stock

Registered Direct Offerings

In July and September of 2019, the Company entered into engagement letters with H.C. Wainwright & Co., LLC (the "Placement Agent") relating to registered direct offerings of common stock to certain institutional investors. Pursuant to each letter agreement, the Company agreed to pay the Placement Agent a cash fee of 6.0% of the gross proceeds from each offering and reimburse the cost of expenses.

In connection therewith, on August 1, 2019, August 2, 2019 and September 26, 2019, the Company and certain investors entered into securities purchase agreements relating to the issuance and sale of shares of common stock. The purchase price per share for each share offered in the offerings was $11.50. The aggregate gross proceeds of the offerings were $23.0 million for an aggregate of 1,995,653 shares of common stock.

The net proceeds to the Company from the offerings, after deducting Placement Agent fees and the Company's estimated offering expenses, were approximately $21.3 million.

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 is 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.

The Option to purchase additional shares of Common Stock may not be exercised if Ultragenyx's ownership of the Company's common stock would exceed 19.99% of the Company's total shares outstanding following such exercise. The option was recorded as a component of stockholders' equity within additional paid-in capital.

Pursuant to the terms of the Expanded Ultragenyx Agreement, 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 members of the board of directors (the "Board") are to be elected, the Company must nominate one director designated by Ultragenyx (the "Ultragenyx Designee"). Additionally, the Ultragenyx Designee has the contractual right to be appointed to all Board committees (subject to applicable Nasdaq rules). Ultragenyx also has the right to have a designee attend Board meetings as a non-voting observer.

In connection with the Expanded Ultragenyx Agreement, the Company and Ultragenyx entered into a Registration Rights Agreement (the "Registration Rights Agreement"). The Registration Rights Agreement required the Company to file a registration statement providing for the resale of the shares within 180 days of June 18, 2019 and provided Ultragenyx with certain "piggy-back" registration rights with respect to registration statements that the Company may file. The registration statement was filed by the Company on December 12, 2019.

Restricted Common Stock

In March 2013, the founders of the Company purchased 2,783,686 common stock of stock for $0.0068 per share. Of the shares purchased, 1,538,353 were subject to a repurchase option whereby the Company has an option for two months after date of termination of service to repurchase any or all of the unvested shares at the original purchase price per share. The repurchase option shall be deemed to be automatically exercised by the Company as of the end of the two-month period unless the Company notifies the purchaser that it does not intend to exercise its option. The shares will be vested (1) 25% after obtaining suitable siRNA license; (2) 25% after *in vivo* proof-of-concept achieved; (3) 25% after a regulatory agency new drug application (such as an IND application) is filed and accepted by the applicable regulatory agency; and (4) 25% after human biological proof-of-concept is achieved. The Company met the first two milestones during 2013 and 2014 leaving an unvested balance of 769,176 Common stock. In 2017, the common stock purchase agreements were amended to clarify vesting conditions and also to accelerate the vesting of 146,510 common stock resulting in a modification expense of $1,495,000 as of December 31, 2017. As of December 31, 2019 and 2018, there were 622,667 common stock unvested and subject to the repurchase option.

Net Loss per Share

Dilutive securities at December 31, 2019 and 2018 that were not included in the calculation of diluted net loss per share for the years ended December 31, 2019 and 2018 as they were anti-dilutive totaled 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 unvested restricted common stock of 622,667.

NOTE 9. Share-Based Compensation

In August 2018, the Company adopted the 2018 Omnibus Equity Incentive Plan ("2018 Plan"). Under the 2018 Plan, the Company is authorized to issue up to a maximum of 1,100,000 shares of common stock pursuant to the exercise of incentive stock options or other awards provided for therein. Outstanding options as shown in the table in this Note 9 represent a portion of authorized shares from the 2018 Plan along with previous option plans for all periods presented in the balance sheet. In June 2019, the Company adopted the 2019 Omnibus Equity Incentive Plan ("2019 Plan"), which was ratified by the shareholders at the Company's annual meeting on October 25, 2019. Under the 2019 Plan, the Company is authorized to issue up to a maximum of 2,600,000 shares of common stock pursuant to the exercise of incentive stock options or other awards provided for therein. In connection with the Redomiciliation, all outstanding options to purchase shares in Arcturus Israel were exchanged for an option to purchase the same number of shares of the Company's common stock under the 2019 Plan. Accordingly, as of December 31, 2019, a total of 927,457 shares remain available for future issuance under the 2019 Plan.

Share Options

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

	For the Year Ended December 31,	
	2019	2018
Expected life (in years)	5.92	6.07
Expected volatility	73.9%	73.3%
Expected dividend yield	—%	—%
Risk-free interest rate	1.82%	2.77%
Grant date weighted average fair value	$ 6.39	$ 5.38

The following table summarizes the Company's stock option activity for the year ended December 31, 2019:

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding – December 31, 2018	1,184,433	$ 7.41		
Granted	590,115	$ 7.81		
Exercised	(24,290)	$ 5.72		
Forfeited/cancelled	(101,182)	$ 8.01		
Outstanding – December 31, 2019	1,649,076	$ 7.54	8.59	$ 5,498
Exercisable – December 31, 2019	581,135	$ 7.03	7.68	$ 2,236
Exercisable and expected to vest – December 31, 2019	1,649,076	$ 7.54	8.59	$ 5,498

At December 31, 2019, the total unrecognized compensation cost of $5.8 million will be recognized over the weighted-average remaining service period of approximately 2.7 years. The fair value of the options vested during the years ended December 31, 2019 and 2018 was $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, 2019 and 2018 were:

(in thousands)	For the Year Ended December 31, 2019	2018
Research and development	$ 654	$ 566
General and administrative	1,328	693
Total	$ 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, 2019 and 2018 is as follows:

(In thousands)	For the Year Ended December 31, 2019	2018
United States	$ (25,922)	$ (21,604)
Foreign	(69)	(181)
Total loss before income taxes	$ (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 income tax expense for the years ended December 31, 2019 and 2018 is as follows (in millions):

	December 31,	
	2019	2018
Beginning balance of unrecognized tax benefits	$ 0.4	$ 0.4
Settlement of prior period tax positions	—	—
Increase for prior period tax positions	—	—
Increase for current period tax positions	—	—
Ending balance of unrecognized tax benefits	$ 0.4	$ 0.4

Included in the balance of unrecognized tax benefits at both December 31, 2019 and 2018 is $0.4 million 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 2018 and 2019 are under examination in Israel. The Company's tax years from 2013 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, 2019, there are unrecognized tax benefits of $0.2 million and $0.2 million for the United States and California, respectively. There was no tax related interest or penalties recognized for the years ended December 31, 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, 2019 and 2018:

	December 31,	
(in thousands)	2019	2018
Deferred tax assets:		
Net operating loss	$ 15,078	$ 8,399
Tax credits	28	35
Accrued liabilities	410	261
Deferred revenue	1,248	1,713
Lease liability	1,466	—
Depreciation and amortization	—	46
Share-based compensation	339	85
Total gross deferred tax assets	18,569	10,539
Deferred tax liabilities:		
Depreciation and amortization	(11)	—
Right-of-use asset	(1,326)	—
Valuation allowance	(17,232)	(10,539)
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, 2019, the Company had federal and state net operating losses ("NOL") carryforwards of approximately $59.0 million and $42.8 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 $43.2 million of net operating losses generated in 2018 and after. Federal net operating losses generated in 2018 and afterwards carryover indefinitely and may generally be used to offset up to 80% of future taxable income. The Company has foreign NOL carryforwards of approximately $89.3 million that do not expire and can be carried forward indefinitely. Due to the Company's recent Redomiciliation and planned liquidation of the Israel entity, it is more likely than not that the foreign NOL will not be realized. As a result, the Company has removed the foreign NOL carryforwards from its deferred tax asset schedule and recorded a corresponding decrease to its valuation allowance beginning January 1, 2018.

Excluded from the deferred tax assets for the net operating losses are pre-acquisition Alcobra Inc. and Alcobra Ltd. federal and foreign losses of $0.3 million and $20.5 million, respectively. The Company does not believe these losses will be available to use in the future due to limitations under IRC Section 382 and contemplated restructuring as well as restructuring and planned liquidation of Arcturus Therapeutics Ltd.

At December 31, 2019, the Company had federal and state research and development credit carryforwards of approximately $0.2 million and $0.2 million, respectively. The federal credit carryforwards begin to expire in 2033, and the state credits carry forward indefinitely.

The Company has also incurred research and development expenses of $33.6 million and $17.0 million for the years ended December 31, 2019 and 2018, respectively. The Company believes that a portion of these expenditures will yield additional federal and California tax credits; however, the potential credits under the tax laws have not yet been calculated.

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,	
	2019	2018
Federal statutory income tax rate	21.0%	21.0%
State income taxes, net of federal benefit	4.6%	5.3%
Foreign rate differential	0.3%	(1.3%)
Share-based compensation	(0.1%)	(0.2%)
Change in tax rate	(0.1%)	—%
Change in valuation allowance	(25.1%)	(20.7%)
Other	0.1%	(3.0%)
Permanent differences	(0.7%)	(1.1%)
Provision for income taxes	—%	—%

ASC Topic 606

The Company adopted Accounting Standards Codification ("ASC") Topic 606 - Revenue from Contracts with Customers (the new revenue guidance), on January 1, 2018. Under Topic 606, the Company recognizes revenue when its customers obtain control of promised goods or services, in an amount that reflects the consideration which the Company expects to be entitled in exchange for those goods or services. Upon adoption, no change in retained earnings was recorded related to income taxes as the Company maintains a full valuation allowance. An adjustment of $0.2 million was recorded as a deferred tax asset and a corresponding increase to the valuation allowance. See above for more information about the non-income tax impact of adoption of the new revenue guidance.

ASC Topic 842

The Company adopted Accounting Standards Codification ("ASC") Topic 842 - Leases, on January 1, 2019. Under Topic 842, the Company is required to recognize the assets and liabilities that arise from most operating leases on the balance sheet. Upon adoption, no change in retained earnings was recorded related to income taxes as the Company maintains a full valuation allowance. As of the implementation date, an adjustment of $1.7 million was recorded as a deferred tax liability and an adjustment of $1.7 million was recorded as a deferred tax asset. See above for more information about the non-income tax impact of adoption of the new leasing standard.

NOTE 11. Commitments and Contingencies

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 year ended December 31, 2019, the Company recognized $2.0 million of contra expense with $1.9 million remaining in accrued expenses.

Leases

In October 2017, the Company entered into a non-cancellable operating lease agreement for office space adjacent to its previously occupied headquarters. The commencement of the lease began in March 2018 and the lease extends for approximately 84 months from the commencement date with a remaining lease term through March 2025. Monthly rental payments are due under the lease and there are escalating rent payments during the term of the lease. The Company is also responsible for its proportional share of operating expenses of the building and common areas. In conjunction with the new lease, the Company received free rent for four months and received a tenant improvement allowance of $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.

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, 2019, the payments of the operating lease liability were as follows:

(in thousands)	Remaining Lease Payments
2020	$ 1,272
2021	1,310
2022	1,349
2023	1,390
2024	1,432
Thereafter	314
Total remaining lease payments	7,067
Less: imputed interest	(1,390)
Total operating lease liabilities	$ 5,677
Weighted-average remaining lease term	5.25 years
Weighted-average discount rate	8.4%

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

Note 12. Related Party Transactions

Ultragenyx

On June 17, 2019, Arcturus and Ultragenyx executed Amendment 3. In addition, as a result of the Expanded Ultragenyx Agreement, Ultragenyx owns 15.9% of the outstanding common stock of the Company as of December 31, 2019. For the year ended December 31, 2019, the Company has recognized revenue of $5.9 million and for the year ended December 31, 2018, the Company recognized revenue of $6.8 million. As of December 31, 2019 and 2018, the Company holds accounts receivable balances of negligible amounts.

Equity-Method Investment

As noted above at Note 2, 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 a privately held company in consideration for the sale of the ADAIR technology. The Company has no requirement to invest further in this private company. During the third quarter of 2019, the equity-method investee 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, partly offset by additional losses incurred by the equity-method investee and calculated on a lag, resulted in a net gain of a negligible amount for the year ended December 31, 2019. Subsequent to the equity-method investee issuing shares of its common stock, the Company’s ownership was reduced to 19%. As the Company continues to have the ability to exercise significant influence over the operating and financial policies of the investee, the Company will continue to account for the investment as an equity-method investment.

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 Company is required to file a response to the SAC by March 20, 2020. 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

On March 4, 2020, the Company was awarded a grant (the "Grant") from the Singapore Economic Development Board ("EDB") to support the co-development of a 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 March 4, 2020 exchange rate) in grants to support the development of the vaccine. A portion of the Grant will be paid by the EDB in advance and the remainder of the Grant will be paid to the Company upon the achievement of certain milestones related to the progress of the development of the vaccine, as set forth in the award agreement. The Company has agreed to pay Duke-NUS Medical School a royalty based on annual net sales of the vaccine in markets or jurisdictions outside of Singapore.

Exhibit 10.1

ARCTURUS THERAPEUTICS HOLDINGS INC.

INDEMNIFICATION AGREEMENT

This Indemnification Agreement ("**Agreement**") is made as of [__], by and between ARCTURUS THERAPEUTICS HOLDINGS INC., a Delaware corporation (the "**Company**"), and [__] ("**Indemnitee**"). This Agreement supersedes and replaces any and all previous Agreements between the Company and Indemnitee covering the subject matter of this Agreement.

WHEREAS, the Company and Indemnitee recognize the significant cost of directors' and officers' liability insurance and the general reductions in the coverage of such insurance;

WHEREAS, the Company and Indemnitee further recognize the substantial increase in corporate litigation in general, subjecting officers and directors to expensive litigation risks at the same time as the coverage of liability insurance has been severely limited;

WHEREAS, the Company desires to attract and retain the services of highly qualified individuals, such as Indemnitee, to serve as officers and directors of the Company and to indemnify its officers and directors so as to provide them with the maximum protection permitted by law;

WHEREAS, it is reasonable, prudent and necessary for the Company contractually to obligate itself to indemnify, and to advance expenses on behalf of, qualified individuals such as Indemnitee to the fullest extent permitted by applicable law so that they will serve or continue to serve the Company free from undue concern that they will not be so indemnified;

WHEREAS, this Agreement is a supplement to and in furtherance of the Bylaws and Certificate of Incorporation of the Company and any resolutions adopted pursuant thereto, and shall not be deemed to substitute therefor, nor to diminish or abrogate any rights of Indemnitee thereunder; and

WHEREAS, Indemnitee does not regard the protection available under the Bylaws and Certificate of Incorporation of the Company and insurance as adequate in the present circumstances, and may not be willing to serve as an officer or director without adequate protection, and the Company desires Indemnitee to serve in such capacity. Indemnitee is willing to serve, continue to serve and to take on additional service for or on behalf of the Company on the condition that he be so indemnified.

NOW, THEREFORE, in consideration for Indemnitee's services as an officer or director of the Company, the Company and Indemnitee hereby agree as follows:

1. Definitions.

(a) A "**Change in Control**" shall be deemed to occur upon the earliest to occur after the date of this Agreement of any of the following events:

(i) *Acquisition of Stock by Third Party*. Any Person (as defined below becomes the Beneficial Owner (as defined below), directly or indirectly, of securities of the Company representing fifteen percent (15%) or more of the combined voting power of the Company's then outstanding securities unless the change in relative Beneficial Ownership of the Company's securities by

any Person results solely from a reduction in the aggregate number of outstanding securities entitled to vote generally in the election of directors;

(ii) *Change in Board Composition*. During any period of two consecutive years (not including any period prior to the execution of this Agreement), individuals who at the beginning of such period constitute the Company's board of directors, and any new directors (other than a director designated by a person who has entered into an agreement with the Company to effect a transaction described in Sections 1(a)(i), 1(a)(iii) or 1(a)(iv)) whose election by the board of directors or nomination for election by the Company's stockholders was approved by a vote of at least two-thirds of the directors then still in office who either were directors at the beginning of the period or whose election or nomination for election was previously so approved, cease for any reason to constitute at least a majority of the members of the Company's board of directors;

(iii) *Corporate Transactions*. The effective date of a merger or consolidation of the Company with any other entity, other than a merger or consolidation which would result in the voting securities of the Company outstanding immediately prior to such merger or consolidation continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity) more than 50% of the combined voting power of the voting securities of the surviving entity outstanding immediately after such merger or consolidation and with the power to elect at least a majority of the board of directors or other governing body of such surviving entity;

(iv) *Liquidation*. The approval by the stockholders of the Company of a complete liquidation of the Company or an agreement for the sale or disposition by the Company of all or substantially all of the Company's assets; and

(v) *Other Events*. Any other event of a nature that would be required to be reported in response to Item 6(e) of Schedule 14A of Regulation 14A (or in response to any similar item on any similar schedule or form) promulgated under the Securities Exchange Act of 1934, as amended, whether or not the Company is then subject to such reporting requirement.

For purposes of this Section 1(a), the following terms shall have the following meanings:

(1) "**Person**" shall have the meaning as set forth in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended; *provided, however,* that "**Person**" shall exclude (i) the Company, (ii) any trustee or other fiduciary holding securities under an employee benefit plan of the Company, and (iii) any corporation owned, directly or indirectly, by the stockholders of the Company in substantially the same proportions as their ownership of stock of the Company.

(2) "**Beneficial Owner**" shall have the meaning given to such term in Rule 13d-3 under the Securities Exchange Act of 1934, as amended; *provided, however,* that "**Beneficial Owner**" shall exclude any Person otherwise becoming a Beneficial Owner by reason of (i) the stockholders of the Company approving a merger of the Company with another entity or (ii) the Company's board of directors approving a sale of securities by the Company to such Person.

(b) "**Corporate Status**" describes the status of a person who is or was a director, trustee, general partner, managing member, officer, employee, agent or fiduciary of the Company or any other Enterprise.

(c) "**DGCL**" means the General Corporation Law of the State of Delaware.

(d) "**Disinterested Director**" means a director of the Company who is not and was not a party to the Proceeding in respect of which indemnification is sought by Indemnitee.

(e) "**Enterprise**" means the Company and any other corporation, partnership, limited liability company, joint venture, trust, employee benefit plan or other enterprise of which Indemnitee is or was serving at the request of the Company as a director, trustee, general partner, managing member, officer, employee, agent or fiduciary.

(f) "**Expenses**" include all reasonable attorneys' fees, retainers, court costs, transcript costs, fees and costs of experts and other professionals, witness fees, travel expenses, duplicating costs, printing and binding costs, telephone charges, postage, delivery service fees, and federal, state, local or foreign taxes imposed on Indemnitee as a result of the actual or deemed receipt of any payments under this Agreement, ERISA excise taxes and penalties, and all other disbursements or expenses of the types customarily incurred in connection with prosecuting, defending, preparing to prosecute or defend, investigating, being or preparing to be a witness in, or otherwise participating in, a Proceeding. Expenses also include (i) Expenses incurred in connection with any appeal resulting from any Proceeding, including without limitation the premium, security for, and other costs relating to any cost bond, supersedeas bond or other appeal bond or their equivalent, and (ii) for purposes of Section 12(d), Expenses incurred by Indemnitee in connection with the interpretation, enforcement or defense of Indemnitee's rights under this Agreement or under any directors' and officers' liability insurance policies maintained by the Company. The parties agree that for the purposes of any advancement of Expenses for which Indemnitee has made written demand to the Company in accordance with this Agreement, all Expenses included in such demand that are certified by affidavit of Indemnitee's counsel as being reasonable shall be presumed conclusively to be reasonable. Expenses, however, shall not include amounts paid in settlement by Indemnitee or the amount of judgments or fines against Indemnitee.

(g) "**Independent Counsel**" means a law firm, or a partner or member of a law firm, that is experienced in matters of corporation law and neither presently is, nor in the past five years has been, retained to represent (i) the Company or Indemnitee in any matter material to either such party (other than as Independent Counsel with respect to matters concerning Indemnitee under this Agreement, or other indemnitees under similar indemnification agreements), or (ii) any other party to the Proceeding giving rise to a claim for indemnification hereunder. Notwithstanding the foregoing, the term "**Independent Counsel**" shall not include any person who, under the applicable standards of professional conduct then prevailing, would have a conflict of interest in representing either the Company or Indemnitee in an action to determine Indemnitee's rights under this Agreement. The Company agrees to pay the reasonable fees and expenses of the Independent Counsel referred to above and to fully indemnify such counsel against any and all Expenses, claims, liabilities and damages arising out of or relating to this Agreement or its engagement pursuant hereto.

(h) "**Proceeding**" means any threatened, pending or completed action, suit, claim, counterclaim, cross claim, arbitration, mediation, alternate dispute resolution mechanism, investigation, inquiry, administrative hearing or any other actual, threatened or completed proceeding, whether brought in the right of the Company or otherwise and whether of a civil, criminal, administrative, legislative or investigative (formal or informal) nature, including any appeal therefrom and including without limitation any such Proceeding pending as of the date of this Agreement, in which Indemnitee was, is or will be involved as a party, a potential party, a non-party witness or otherwise by reason of (i) the fact that Indemnitee is or was a director or officer of the Company, (ii) any action taken by Indemnitee or any action or inaction on Indemnitee's part while acting as a director or officer of the Company, or (iii) the fact that he or she is or was serving at the request of the Company as a director, trustee, general partner, managing member, officer, employee, agent or fiduciary of the Company or any other Enterprise, in each case whether or not serving in such capacity at the time any liability or Expense is incurred for which indemnification or

advancement of expenses can be provided under this Agreement. If the Indemnitee believes in good faith that a given situation may lead to or culminate in the institution of a Proceeding, this shall be considered a Proceeding under this paragraph.

(i) Reference to "**other enterprises**" shall include employee benefit plans; references to "**fines**" shall include any excise taxes assessed on a person with respect to any employee benefit plan; references to "**serving at the request of the Company**" shall include any service as a director, officer, employee or agent of the Company which imposes duties on, or involves services by, such director, officer, employee or agent with respect to an employee benefit plan, its participants or beneficiaries; and a person who acted in good faith and in a manner he or she reasonably believed to be in the best interests of the participants and beneficiaries of an employee benefit plan shall be deemed to have acted in a manner "**not opposed to the best interests of the Company**" as referred to in this Agreement.

2. **Indemnity in Third-Party Proceedings.** The Company shall indemnify Indemnitee in accordance with the provisions of this Section 2 if Indemnitee is, or is threatened to be made, a party to or a participant in any Proceeding, other than a Proceeding by or in the right of the Company to procure a judgment in its favor. Pursuant to this Section 2, Indemnitee shall be indemnified to the fullest extent permitted by applicable law against all Expenses, judgments, fines and amounts paid in settlement (including all interest, assessments and other charges paid or payable in connection with or in respect of such Expenses, judgments, fines and amounts paid in settlement) actually and reasonably incurred by Indemnitee or on his or her behalf in connection with such Proceeding or any claim, issue or matter therein, if Indemnitee acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the best interests of the Company and, with respect to any criminal action or proceeding, had no reasonable cause to believe that his or her conduct was unlawful. The parties hereto intend that this Agreement shall provide to the fullest extent permitted by law for indemnification in excess of that expressly permitted by statute, including, without limitation, any indemnification provided by the Certificate of Incorporation, the Bylaws, vote of its stockholders or disinterested directors or applicable law.

3. **Indemnity in Proceedings by or in the Right of the Company.** The Company shall indemnify Indemnitee in accordance with the provisions of this Section 3 if Indemnitee is, or is threatened to be made, a party to or a participant in any Proceeding by or in the right of the Company to procure a judgment in its favor. Pursuant to this Section 3, Indemnitee shall be indemnified to the fullest extent permitted by applicable law against all Expenses and, to the fullest extent permitted by law, amounts paid in settlement actually and reasonably incurred by Indemnitee or on Indemnitee's behalf in connection with such Proceeding or any claim, issue or matter therein, if Indemnitee acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the best interests of the Company. No indemnification shall be made under this Section 3 in respect of any claim, issue or matter as to which Indemnitee shall have been adjudged by a court of competent jurisdiction to be liable to the Company, unless and only to the extent that the Delaware Court of Chancery or any court in which the Proceeding was brought shall determine upon application that, despite the adjudication of liability but in view of all the circumstances of the case, Indemnitee is fairly and reasonably entitled to indemnification for such expenses as the Delaware Court of Chancery or such other court shall deem proper.

4. **Indemnification for Expenses of a Party Who is Wholly or Partly Successful.** Notwithstanding any other provisions of this Agreement, to the fullest extent permitted by applicable law and to the extent that Indemnitee is a party to or a participant in and is successful (on the merits or otherwise) in defense of any Proceeding or any claim, issue or matter therein, the Company shall indemnify Indemnitee against all Expenses actually and reasonably incurred by Indemnitee or on Indemnitee's behalf in connection therewith. To the extent permitted by applicable law, if Indemnitee is not wholly successful in such Proceeding but is successful, on the merits or otherwise, in defense of one or more but less than all claims, issues or matters in such Proceeding, the Company shall indemnify Indemnitee against all Expenses

actually and reasonably incurred by Indemnitee or on Indemnitee's behalf, to the fullest extent permitted by law, in connection with (a) each successfully resolved claim, issue or matter and (b) any claim, issue or matter related to any such successfully resolved claim, issuer or matter. For purposes of this section, the termination of any claim, issue or matter in such a Proceeding by dismissal, with or without prejudice, shall be deemed to be a successful result as to such claim, issue or matter.

5. **Indemnification for Expenses of a Witness.** Notwithstanding any other provisions of this Agreement, to the fullest extent permitted by applicable law and to the extent that Indemnitee is, by reason of his or her Corporate Status, a witness or otherwise asked to participate in any Proceeding to which Indemnitee is not a party, Indemnitee shall be indemnified to the extent permitted by applicable law against all Expenses actually and reasonably incurred by Indemnitee or on Indemnitee's behalf in connection therewith.

6. **Additional Indemnification.**

(a) Notwithstanding any limitation in Sections 2, 3 or 4, the Company shall indemnify Indemnitee to the fullest extent permitted by applicable law if Indemnitee is, or is threatened to be made, a party to or a participant in any Proceeding (including a Proceeding by or in the right of the Company to procure a judgment in its favor) against all Expenses, judgments, fines and amounts paid in settlement (including all interest, assessments and other charges paid or payable in connection with or in respect of such Expenses, judgments, fines and amounts paid in settlement) actually and reasonably incurred by Indemnitee or on his or her behalf in connection with the Proceeding or any claim, issue or matter therein.

(b) For purposes of Section 6(a), the meaning of the phrase "**to the fullest extent permitted by applicable law**" shall include, but not be limited to:

(i) the fullest extent permitted by the provision of the DGCL that authorizes or contemplates additional indemnification by agreement, or the corresponding provision of any amendment to or replacement of the DGCL; and

(ii) the fullest extent authorized or permitted by any amendments to or replacements of the DGCL adopted after the date of this Agreement that increase the extent to which a corporation may indemnify its officers and directors.

7. **Exclusions.** Notwithstanding any provision in this Agreement, the Company shall not be obligated under this Agreement to make any indemnity in connection with any Proceeding (or any part of any Proceeding):

(a) for which payment has actually been made to or on behalf of Indemnitee under any statute, insurance policy, indemnity provision, vote or otherwise, except with respect to any excess beyond the amount paid under any insurance policy or other indemnity provision;

(b) for an accounting or disgorgement of profits pursuant to Section 16(b) of the Securities Exchange Act of 1934, as amended, or similar provisions of federal, state or local statutory law or common law, if Indemnitee is held liable therefor (including pursuant to any settlement arrangements);

(c) for any reimbursement of the Company by Indemnitee of any bonus or other incentive-based or equity-based compensation or of any profits realized by Indemnitee from the sale of securities of the Company, as required in each case under the Securities Exchange Act of 1934, as amended (including any such reimbursements that arise from an accounting restatement of the Company pursuant to Section 304 of the Sarbanes-Oxley Act of 2002 (the "**Sarbanes-Oxley Act**"), or the payment to the

Company of profits arising from the purchase and sale by Indemnitee of securities in violation of Section 306 of the Sarbanes-Oxley Act), if Indemnitee is held liable therefor (including pursuant to any settlement arrangements);

(d) initiated by Indemnitee, including any Proceeding (or any part of any Proceeding) initiated by Indemnitee against the Company or its directors, officers, employees, agents or other indemnitees, unless (i) the Company's board of directors authorized the Proceeding (or the relevant part of the Proceeding) prior to its initiation, (ii) the Company provides the indemnification, in its sole discretion, pursuant to the powers vested in the Company under applicable law, (iii) otherwise authorized in Section 12(d) or (iv) otherwise required by applicable law; or

(e) if prohibited by applicable law.

8. **Advances of Expenses.** The Company shall advance, the Expenses incurred by Indemnitee in connection with any Proceeding (or any part of any Proceeding), and such advancement shall be made as soon as reasonably practicable, but in any event no later than 30 days, after the receipt by the Company of a written statement or statements requesting such advances from time to time, whether prior to or after final disposition of any Proceeding (which (a) shall include invoices received by Indemnitee in connection with such Expenses but, in the case of invoices in connection with legal services, any references to legal work performed or to expenditure made that would cause Indemnitee to waive any privilege accorded by applicable law shall not be included with the invoice, and (b) contain the affirmation required by Section 9(a)). Advances shall be unsecured and interest free and made without regard to Indemnitee's ability to repay such advances and without regard to Indemnitee's ultimate entitlement to indemnification under the other provisions of this Agreement. Indemnitee hereby undertakes to repay any advance to the extent that it is ultimately determined that Indemnitee is not entitled to be indemnified by the Company. No other form of undertaking shall be required other than the execution of this Agreement. This Section 8 shall not apply to the extent advancement is prohibited by law and shall not apply to any Proceeding for which indemnity is not permitted under this Agreement, but shall apply to any Proceeding referenced in Section 7(b) or 7(c) prior to a determination that Indemnitee is not entitled to be indemnified by the Company.

9. **Procedures for Notification and Defense of Claim.**

(a) Indemnitee shall notify the Company in writing of any matter with respect to which Indemnitee intends to seek indemnification or advancement of Expenses as soon as reasonably practicable following the receipt by Indemnitee of notice thereof. The written notification to the Company shall include, a description of the nature of the Proceeding and the facts underlying the Proceeding. The failure by Indemnitee to notify the Company will not relieve the Company from any liability which it may have to Indemnitee hereunder or otherwise than under this Agreement, and any delay in so notifying the Company shall not constitute a waiver by Indemnitee of any rights.

(b) If, at the time of the receipt of a notice of a Proceeding pursuant to the terms hereof, the Company has directors' and officers' liability insurance in effect, the Company shall give prompt notice of the commencement of the Proceeding to the insurers in accordance with the procedures set forth in the applicable policies. The Company shall thereafter take all necessary and desirable action to cause such insurers to pay, on behalf of Indemnitee, all amounts payable as a result of such Proceeding in accordance with the terms of such policies.

10. **Procedures upon Application for Indemnification**.

(a) To obtain indemnification, Indemnitee shall submit to the Company a written request, including therein or therewith such documentation and information as is reasonably available to

Indemnitee and as is reasonably necessary to determine whether and to what extent Indemnitee is entitled to indemnification following the final disposition of the Proceeding. The Company shall, as soon as reasonably practicable after receipt of such a request for indemnification, advise the board of directors that Indemnitee has requested indemnification. Any delay in providing the request will not relieve the Company from its obligations under this Agreement.

(b) Upon written request by Indemnitee for indemnification pursuant to Section 10(a), a determination, if required by applicable law, with respect to Indemnitee's entitlement thereto shall be made in the specific case (i) if a Change in Control shall have occurred, by Independent Counsel in a written opinion to the Company's board of directors, a copy of which shall be delivered to Indemnitee or (ii) if a Change in Control shall not have occurred, (A) by a majority vote of the Disinterested Directors, even though less than a quorum of the Company's board of directors, (B) by a committee of Disinterested Directors designated by a majority vote of the Disinterested Directors, even though less than a quorum of the Company's board of directors, (C) if there are no such Disinterested Directors or, if such Disinterested Directors so direct, by Independent Counsel in a written opinion to the Company's board of directors, a copy of which shall be delivered to Indemnitee or (D) if so directed by the Company's board of directors, by the stockholders of the Company. If it is determined that Indemnitee is entitled to indemnification, payment to Indemnitee shall be made within ten days after such determination. Indemnitee shall cooperate with the person, persons or entity making the determination with respect to Indemnitee's entitlement to indemnification, including providing to such person, persons or entity upon reasonable advance request any documentation or information that is not privileged or otherwise protected from disclosure and that is reasonably available to Indemnitee and reasonably necessary to such determination. Any costs or expenses (including attorneys' fees and disbursements) reasonably incurred by Indemnitee in so cooperating with the person, persons or entity making such determination shall be borne by the Company (irrespective of the determination as to Indemnitee's entitlement to indemnification) and the Company hereby indemnifies and agrees to hold Indemnitee harmless therefrom. The Company promptly will advise Indemnitee in writing with respect to any determination that Indemnitee is or is not entitled to indemnification, including a description of any reason or basis for which indemnification has been denied.

(c) In the event the determination of entitlement to indemnification is to be made by Independent Counsel pursuant to Section 10(b), the Independent Counsel shall be selected as provided in this Section 10(c). If a Change in Control shall not have occurred, the Independent Counsel shall be selected by the Company's board of directors, and the Company shall give written notice to Indemnitee advising him or her of the identity of the Independent Counsel so selected. If a Change in Control shall have occurred, the Independent Counsel shall be selected by Indemnitee (unless Indemnitee shall request that such selection be made by the Company's board of directors, in which event the preceding sentence shall apply), and Indemnitee shall give written notice to the Company advising it of the identity of the Independent Counsel so selected. In either event, Indemnitee or the Company, as the case may be, may, within ten days after such written notice of selection shall have been given, deliver to the Company or to Indemnitee, as the case may be, a written objection to such selection; *provided*, *however*, that such objection may be asserted only on the ground that the Independent Counsel so selected does not meet the requirements of "Independent Counsel" as defined in Section 1 of this Agreement, and the objection shall set forth with particularity the factual basis of such assertion. Absent a proper and timely objection, the person so selected shall act as Independent Counsel. If such written objection is so made and substantiated, the Independent Counsel so selected may not serve as Independent Counsel unless and until such objection is withdrawn or a court has determined that such objection is without merit. If, within 20 days after the later of (i) submission by Indemnitee of a written request for indemnification pursuant to Section 10(a) hereof and (ii) the final disposition of the Proceeding, the parties have not agreed upon an Independent Counsel, either the Company or Indemnitee may petition a court of competent jurisdiction for resolution of any objection which shall have been made by the Company or Indemnitee to the other's selection of Independent Counsel and for the appointment as Independent Counsel of a person selected by the court or by such other person as the court

shall designate, and the person with respect to whom all objections are so resolved or the person so appointed shall act as Independent Counsel under Section 10(b) hereof. Upon the due commencement of any judicial proceeding or arbitration pursuant to Section 12(a) of this Agreement, the Independent Counsel shall be discharged and relieved of any further responsibility in such capacity (subject to the applicable standards of professional conduct then prevailing).

(d) The Company agrees to pay the reasonable fees and expenses of any Independent Counsel and to fully indemnify such counsel against any and all Expenses, claims, liabilities and damages arising out of or relating to this Agreement or its engagement pursuant hereto.

11. **Presumptions and Effect of Certain Proceedings**.

(a) In making a determination with respect to entitlement to indemnification hereunder, the person, persons or entity making such determination shall, to the fullest extent not prohibited by law, presume that Indemnitee is entitled to indemnification under this Agreement if Indemnitee has submitted a request for indemnification in accordance with Section 10(a) of this Agreement, and the Company shall, to the fullest extent not prohibited by law, have the burden of proof to overcome that presumption in connection with the making by such person, persons or entity of any determination contrary to that presumption. Neither the failure of the Company (including by its directors or Independent Counsel) to have made a determination prior to the commencement of any action pursuant to this Agreement that indemnification is proper in the circumstances because Indemnitee has met the applicable standard of conduct, nor an actual determination by the Company (including by its directors or Independent Counsel) that Indemnitee has not met such applicable standard of conduct, shall be a defense to the action or create a presumption that Indemnitee has not met the applicable standard of conduct.

(b) Subject to Section 12(e), if the person, persons or entity empowered or selected under Section 10 of this Agreement to determine whether Indemnitee is entitled to indemnification shall not have made a determination within sixty (60) days after receipt by the Company of the request therefor, the requisite determination of entitlement to indemnification shall, to the fullest extent not prohibited by law, be deemed to have been made and Indemnitee shall be entitled to such indemnification, absent (i) a misstatement by Indemnitee of a material fact, or an omission of a material fact necessary to make Indemnitee's statement not materially misleading, in connection with the request for indemnification, or (ii) a prohibition of such indemnification under applicable law; provided, however, that such 60-day period may be extended for a reasonable time, not to exceed an additional thirty (30) days, if the person, persons or entity making the determination with respect to entitlement to indemnification in good faith requires such additional time for the obtaining or evaluating of documentation and/or information relating thereto; and provided, further, that the foregoing provisions of this Section 11(b) shall not apply (i) if the determination of entitlement to indemnification is to be made by the stockholders pursuant to Section 10(b) of this Agreement and if (A) within fifteen (15) days after receipt by the Company of the request for such determination the Board has resolved to submit such determination to the stockholders for their consideration at an annual meeting thereof to be held within seventy-five (75) days after such receipt and such determination is made thereat, or (B) a special meeting of stockholders is called within fifteen (15) days after such receipt for the purpose of making such determination, such meeting is held for such purpose within sixty (60) days after having been so called and such determination is made thereat, or (ii) if the determination of entitlement to indemnification is to be made by Independent Counsel pursuant to Section 10(b) of this Agreement.

(c) The termination of any Proceeding or of any claim, issue or matter therein, by judgment, order, settlement or conviction, or upon a plea of *nolo contendere* or its equivalent, shall not (except as otherwise expressly provided in this Agreement) of itself adversely affect the right of Indemnitee to indemnification or create a presumption that Indemnitee did not act in good faith and in a manner which

he or she reasonably believed to be in or not opposed to the best interests of the Company or, with respect to any criminal Proceeding, that Indemnitee had reasonable cause to believe that his or her conduct was unlawful.

(d) For purposes of any determination of good faith, Indemnitee shall be deemed to have acted in good faith to the extent Indemnitee relied in good faith on (i) the records or books of account of the Enterprise, including financial statements, (ii) information supplied to Indemnitee by the directors or officers of the Enterprise in the course of their duties, (iii) the advice of legal counsel for the Enterprise or its board of directors or counsel selected by any committee of the board of directors or (iv) information or records given or reports made to the Enterprise by an independent certified public accountant, an appraiser, investment banker or other expert selected with reasonable care by the Enterprise or its board of directors or any committee of the board of directors. The provisions of this Section 11(d) shall not be deemed to be exclusive or to limit in any way the other circumstances in which Indemnitee may be deemed to have met the applicable standard of conduct set forth in this Agreement.

(e) Neither the knowledge, actions nor failure to act of any other director, officer, trustee, partner, managing member, fiduciary, agent or employee of the Enterprise shall be imputed to Indemnitee for purposes of determining the right to indemnification under this Agreement.

12. **Remedies of Indemnitee**.

(a) Subject to Section 12(e), in the event that (i) a determination is made pursuant to Section 10 of this Agreement that Indemnitee is not entitled to indemnification under this Agreement, (ii) advancement of Expenses is not timely made pursuant to Section 8 or 12(d) of this Agreement, (iii) no determination of entitlement to indemnification shall have been made pursuant to Section 10 of this Agreement within 90 days after the later of the receipt by the Company of the request for indemnification or the final disposition of the Proceeding, (iv) payment of indemnification pursuant to this Agreement is not made (A) within ten days after a determination has been made that Indemnitee is entitled to indemnification or (B) with respect to indemnification pursuant to Sections 4, 5 and 12(d) of this Agreement, within 30 days after receipt by the Company of a written request therefor, or (v) the Company or any other person or entity takes or threatens to take any action to declare this Agreement void or unenforceable, or institutes any litigation or other action or proceeding designed to deny, or to recover from, Indemnitee the benefits provided or intended to be provided to Indemnitee hereunder, Indemnitee shall be entitled to an adjudication by a court of competent jurisdiction of his or her entitlement to such indemnification or advancement of Expenses. Indemnitee shall commence such proceeding seeking an adjudication within 180 days following the date on which Indemnitee first has the right to commence such proceeding pursuant to this Section 12(a); *provided, however,* that the foregoing clause shall not apply in respect of a proceeding brought by Indemnitee to enforce his or her rights under Section 4 of this Agreement. The Company shall not oppose Indemnitee's right to seek any such adjudication in accordance with this Agreement.

(b) Neither (i) the failure of the Company, its board of directors, any committee or subgroup of the board of directors, Independent Counsel or stockholders to have made a determination that indemnification of Indemnitee is proper in the circumstances because Indemnitee has met the applicable standard of conduct, nor (ii) an actual determination by the Company, its board of directors, any committee or subgroup of the board of directors, Independent Counsel or stockholders that Indemnitee has not met the applicable standard of conduct, shall be a defense to the action or create a presumption that Indemnitee has or has not met the applicable standard of conduct. In the event that a determination shall have been made pursuant to Section 10 of this Agreement that Indemnitee is not entitled to indemnification, any judicial proceeding commenced pursuant to this Section 12 shall be conducted in all respects as a *de novo* trial, on the merits, and Indemnitee shall not be prejudiced by reason of that adverse determination. In any judicial

proceeding commenced pursuant to this Section 12, the Company shall, to the fullest extent not prohibited by law, have the burden of proving Indemnitee is not entitled to indemnification or advancement of Expenses, as the case may be.

(c) To the fullest extent not prohibited by law, the Company shall be precluded from asserting in any judicial proceeding commenced pursuant to this Section 12 that the procedures and presumptions of this Agreement are not valid, binding and enforceable and shall stipulate in any such court that the Company is bound by all the provisions of this Agreement. If a determination shall have been made pursuant to Section 10 of this Agreement that Indemnitee is entitled to indemnification, the Company shall be bound by such determination in any judicial proceeding commenced pursuant to this Section 12, absent (i) a misstatement by Indemnitee of a material fact, or an omission of a material fact necessary to make Indemnitee's statements not materially misleading, in connection with the request for indemnification, or (ii) a prohibition of such indemnification under applicable law. It is the intent of the Company that, to the fullest extent permitted by law, the Indemnitee not be required to incur legal fees or other Expenses associated with the interpretation, enforcement or defense of Indemnitee's rights under this Agreement by litigation or otherwise because the cost and expense thereof would substantially detract from the benefits intended to be extended to the Indemnitee hereunder.

(d) To the extent not prohibited by law, the Company shall indemnify Indemnitee against all Expenses that are incurred by Indemnitee in connection with any action for indemnification or advancement of Expenses from the Company under this Agreement unless as a part of such action, the court of competent jurisdiction determines that each of the material assertions made by Indemnitee as a basis for such action were not made in good faith or were frivolous or to the extent Indemnitee is successful in such action, and, if requested by Indemnitee, shall (as soon as reasonably practicable, but in any event no later than 30 days, after receipt by the Company of a written request therefor) advance such Expenses to Indemnitee, subject to the provisions of Section 8.

(e) Notwithstanding anything in this Agreement to the contrary, no determination as to entitlement to indemnification shall be required to be made prior to the final disposition of the Proceeding.

13. **Contribution.** To the fullest extent permissible under applicable law, if the indemnification provided for in this Agreement is unavailable to Indemnitee, the Company, in lieu of indemnifying Indemnitee, shall contribute to the amounts incurred by Indemnitee, whether for Expenses, judgments, fines or amounts paid or to be paid in settlement, in connection with any claim relating to an indemnifiable event under this Agreement, in such proportion as is deemed fair and reasonable in light of all of the circumstances of such Proceeding in order to reflect (i) the relative benefits received by the Company and Indemnitee as a result of the events and transactions giving rise to such Proceeding; and (ii) the relative fault of Indemnitee and the Company (and its other directors, officers, employees and agents) in connection with such events and transactions.

14. **Non-exclusivity.** The rights of indemnification and to receive advancement of Expenses as provided by this Agreement shall not be deemed exclusive of any other rights to which Indemnitee may at any time be entitled under applicable law, the Company's certificate of incorporation or bylaws, any agreement, a vote of stockholders or a resolution of directors, or otherwise. To the extent that a change in Delaware law, whether by statute or judicial decision, permits greater indemnification or advancement of Expenses than would be afforded currently under the Company's certificate of incorporation and bylaws and this Agreement, it is the intent of the parties hereto that Indemnitee shall enjoy by this Agreement the greater benefits so afforded by such change. Except as expressly set forth herein, no right or remedy herein conferred is intended to be exclusive of any other right or remedy, and every other right and remedy shall be cumulative and in addition to every other right and remedy given hereunder or now or hereafter existing

at law or in equity or otherwise. Except as expressly set forth herein, the assertion or employment of any right or remedy hereunder, or otherwise, shall not prevent the concurrent assertion or employment of any other right or remedy.

15. **Primary Responsibility.** The Company acknowledges that Indemnitee has or may have certain rights to indemnification and advancement of expenses provided by other entities and/or organizations (collectively, the "**Secondary Indemnitors**"). The Company hereby agrees (i) that it is the indemnitor of first resort (i.e., its obligations to Indemnitee are primary and any obligation of the Secondary Indemnitors to advance Expenses or to provide indemnification for the same Expenses or liabilities incurred by Indemnitee in connection with a Proceeding are secondary), (ii) that it shall be required to advance the full amount of Expenses incurred by Indemnitee and shall be liable for the full amount of all Expenses, judgments, penalties, fines and amounts paid in settlement to the extent legally permitted and as required by the terms of this Agreement and the certificate of incorporation or bylaws of the Company (or any other agreement between the Company and Indemnitee), without regard to any rights Indemnitee may have against the Secondary Indemnitors, and (iii) that, to the extent not in contravention of any insurance policy or policies providing liability or other insurance for the Company or any director, trustee, general partner, managing member, officer, employee, agent or fiduciary of the Company or any other Enterprise, it irrevocably waives, relinquishes and releases the Secondary Indemnitors from any and all claims against the Secondary Indemnitors for contribution, subrogation or any other recovery of any kind in respect thereof. The Company further agrees that no advancement or payment by the Secondary Indemnitors on behalf of Indemnitee with respect to any claim for which indemnification is required under the terms of this Agreement shall affect the foregoing and the Secondary Indemnitors shall have a right of contribution and/or be subrogated to the extent of such advancement or payment to all of the rights of recovery of Indemnitee against the Company. The Company and Indemnitee agree that the Secondary Indemnitors are express third party beneficiaries of the terms of this Section 15.

16. **No Duplication of Payments.** The Company shall not be liable under this Agreement to make any payment of amounts otherwise indemnifiable hereunder (or for which advancement is provided hereunder) if and to the extent that Indemnitee has otherwise actually received payment for such amounts under any insurance policy, contract, agreement or otherwise.

17. **Insurance.** The Company shall, from time to time, make the good faith determination whether or not it is practicable for the Company to obtain and maintain a policy or policies of insurance with reputable insurance companies providing the officers and directors of the Company with coverage for losses from wrongful acts, or to ensure the Company's performance of its indemnification obligations under this Agreement. Among other considerations, the Company will weigh the costs of obtaining such insurance coverage against the protection afforded by such coverage. In all policies of director and officer liability insurance, Indemnitee shall be named as an insured in such a manner as to provide Indemnitee the same rights and benefits as are accorded to the most favorably insured of the Company's directors, if Indemnitee is a director; or of the Company's officers, if Indemnitee is not a director of the Company but is an officer. Notwithstanding the foregoing, the Company shall have no obligation to obtain or maintain such insurance if the Company determines in good faith that such insurance is not reasonably available, if the premium costs for such insurance are disproportionate to the amount of coverage provided, if the coverage provided by such insurance is limited by exclusions so as to provide an insufficient benefit, or if Indemnitee is covered by similar insurance maintained by a subsidiary or parent of the Company.

18. **Subrogation.** In the event of any payment under this Agreement, the Company shall be subrogated to the extent of such payment to all of the rights of recovery of Indemnitee, who shall execute all papers required and take all action necessary to secure such rights, including execution of such documents as are necessary to enable the Company to bring suit to enforce such rights.

19. **Services to the Company.** Indemnitee agrees to serve as a director or officer of the Company or, at the request of the Company, as a director, trustee, general partner, managing member, officer, employee, agent or fiduciary of another Enterprise, for so long as Indemnitee is duly elected or appointed or until Indemnitee tenders his or her resignation or is removed from such position. Indemnitee may at any time and for any reason resign from such position (subject to any other contractual obligation or any obligation imposed by operation of law), in which event the Company shall have no obligation under this Agreement to continue Indemnitee in such position.

This Agreement shall not be deemed an employment contract between the Company (or any of its subsidiaries or any Enterprise) and Indemnitee. Indemnitee specifically acknowledges that any employment with the Company (or any of its subsidiaries or any Enterprise) is at will, and Indemnitee may be discharged at any time for any reason, with or without cause, with or without notice, except as may be otherwise expressly provided in any executed, written employment contract between Indemnitee and the Company (or any of its subsidiaries or any Enterprise), any existing formal severance policies adopted by the Company's board of directors or, with respect to service as a director or officer of the Company, the Company's certificate of incorporation or bylaws or the DGCL. No such document shall be subject to any oral modification thereof. The foregoing notwithstanding, this Agreement shall continue in force after Indemnitee has ceased to serve as a director, as provided in Section 29 hereof.

20. **Successors.** This Agreement shall be binding upon and be enforceable by the parties hereto and their respective successors and assigns, including any direct or indirect successor by purchase, merger, consolidation or otherwise to all or substantially all of the business or assets of the Company, shall continue as to an Indemnitee who has ceased to be a director, officer, employee or agent of the Company or of any other Enterprise, and shall inure to the benefit of Indemnitee and his or her spouse, assigns, heirs, executors, administrators and other legal representatives. The Company shall require and cause any successor (whether direct or indirect by purchase, merger, consolidation or otherwise) to all or substantially all of the business or assets of the Company, by written agreement, expressly to assume and agree to perform this Agreement in the same manner and to the same extent that the Company would be required to perform if no such succession had taken place.

21. **Severability.** Nothing in this Agreement is intended to require or shall be construed as requiring the Company to do or fail to do any act in violation of applicable law. The Company's inability, pursuant to court order or other applicable law, to perform its obligations under this Agreement shall not constitute a breach of this Agreement. If any provision or provisions of this Agreement shall be held to be invalid, illegal or unenforceable for any reason whatsoever: (i) the validity, legality and enforceability of the remaining provisions of this Agreement (including without limitation, each portion of any section of this Agreement containing any such provision held to be invalid, illegal or unenforceable, that is not itself invalid, illegal or unenforceable) shall not in any way be affected or impaired thereby and shall remain enforceable to the fullest extent permitted by law; (ii) such provision or provisions shall be deemed reformed to the extent necessary to conform to applicable law and to give the maximum effect to the intent of the parties hereto; and (iii) to the fullest extent possible, the provisions of this Agreement (including, without limitation, each portion of any section of this Agreement containing any such provision held to be invalid, illegal or unenforceable, that is not itself invalid, illegal or unenforceable) shall be construed so as to give effect to the intent manifested thereby.

22. **Enforcement.** The Company expressly confirms and agrees that it has entered into this Agreement and assumed the obligations imposed on it hereby in order to induce Indemnitee to serve as a director or officer of the Company, and the Company acknowledges that Indemnitee is relying upon this Agreement in serving as a director or officer of the Company.

23. **Entire Agreement.** This Agreement constitutes the entire agreement between the parties hereto with respect to the subject matter hereof and supersedes all prior agreements and understandings, oral, written and implied, between the parties hereto with respect to the subject matter hereof; *provided*, *however*, that this Agreement is a supplement to and in furtherance of the Company's certificate of incorporation and bylaws and applicable law.

24. **Modification and Waiver.** No supplement, modification or amendment to this Agreement shall be binding unless executed in writing by the parties hereto. No amendment, alteration or repeal of this Agreement shall adversely affect any right of Indemnitee under this Agreement in respect of any action taken or omitted by such Indemnitee in his or her Corporate Status prior to such amendment, alteration or repeal. No waiver of any of the provisions of this Agreement shall constitute or be deemed a waiver of any other provision of this Agreement nor shall any waiver constitute a continuing waiver.

25. **Notices.** All notices and other communications required or permitted hereunder shall be in writing and shall be mailed by registered or certified mail, postage prepaid, sent by facsimile or electronic mail or otherwise delivered by hand, messenger or courier service addressed:

(a) if to Indemnitee, to Indemnitee's address, facsimile number or electronic mail address as shown on the signature page of this Agreement or in the Company's records, as may be updated in accordance with the provisions hereof; or

(b) if to the Company, to the attention of the Chief Executive Officer of the Company at 10628 Science Center Drive, Suite 250, San Diego, CA 92121, or at such other current address as the Company shall have furnished to Indemnitee, with a copy (which shall not constitute notice) to Jeffrey Baumel, Dentons US LLP, 1221 Avenue of the Americas, New York, NY 10020.

Each such notice or other communication shall for all purposes of this Agreement be treated as effective or having been given (i) if delivered by hand, messenger or courier service, when delivered (or if sent *via* a nationally-recognized overnight courier service, freight prepaid, specifying next-business-day delivery, one business day after deposit with the courier), or (ii) if sent *via* mail, at the earlier of its receipt or three days after the same has been deposited in a regularly-maintained receptacle for the deposit of the United States mail, addressed and mailed as aforesaid, or (iii) if sent *via* facsimile, upon confirmation of facsimile transfer or, if sent *via* electronic mail, upon confirmation of delivery when directed to the relevant electronic mail address, if sent during normal business hours of the recipient, or if not sent during normal business hours of the recipient, then on the recipient's next business day.

26. **Applicable Law and Consent to Jurisdiction.** This Agreement and the legal relations among the parties shall be governed by, and construed and enforced in accordance with, the laws of the State of Delaware, without regard to its conflict of laws rules. The Company and Indemnitee hereby irrevocably and unconditionally (i) agree that any action or proceeding arising out of or in connection with this Agreement shall be brought only in the Delaware Court of Chancery, and not in any other state or federal court in the United States of America or any court in any other country, (ii) consent to submit to the exclusive jurisdiction of the Delaware Court of Chancery for purposes of any action or proceeding arising out of or in connection with this Agreement, (iii) appoint, to the extent such party is not otherwise subject to service of process in the State of Delaware, The Corporation Trust Company, Wilmington, New Castle County, Delaware as its agent in the State of Delaware as such party's agent for acceptance of legal process in connection with any such action or proceeding against such party with the same legal force and validity as if served upon such party personally within the State of Delaware, (iv) waive any objection to the laying of venue of any such action or proceeding in the Delaware Court of Chancery, and (v) waive, and agree not to plead or to make, any claim that any such action or proceeding brought in the Delaware Court of Chancery has been brought in an improper or inconvenient forum.

27. **Counterparts.** This Agreement may be executed in one or more counterparts, each of which shall for all purposes be deemed to be an original but all of which together shall constitute one and the same Agreement. This Agreement may also be executed and delivered by facsimile signature and in counterparts, each of which shall for all purposes be deemed to be an original but all of which together shall constitute one and the same Agreement. Only one such counterpart signed by the party against whom enforceability is sought needs to be produced to evidence the existence of this Agreement.

28. **Captions.** The headings of the paragraphs of this Agreement are inserted for convenience only and shall not be deemed to constitute part of this Agreement or to affect the construction thereof.

29. **Duration of Agreement.** This Agreement shall continue until and terminate upon the later of: (a) ten (10) years after the date that Indemnitee shall have ceased to serve as a director of the Company or (b) one (1) year after the final termination of any Proceeding then pending in respect of which Indemnitee is granted rights of indemnification hereunder or advancement of Expenses hereunder and of any Proceeding commenced by Indemnitee pursuant to Section 12 of this Agreement relating thereto. The indemnification and advancement of Expenses rights provided by or granted pursuant to this Agreement shall be binding upon and be enforceable by the parties hereto and their respective successors and assigns (including any direct or indirect successor by purchase, merger, consolidation or otherwise to all or substantially all of the business or assets of the Company), shall continue as to an Indemnitee who has ceased to be a director, officer, employee or agent of the Company or of any other Enterprise, and shall inure to the benefit of Indemnitee and his or her spouse, assigns, heirs, devisees, executors and administrators and other legal representatives.

(*signature page follows*)

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the date first above written.

ARCTURUS THERAPEUTICS HOLDINGS INC.

By:
[__]
[__]

AGREED TO AND ACCEPTED:

[___]

FIRST AMENDMENT TO LEASE

THIS FIRST AMENDMENT TO LEASE (this "**First Amendment**") is made as of February 1, 2020, 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 now parties to that certain Lease dated as of October 4, 2017 (the "**Lease**"). Pursuant to the Lease, Tenant leases certain premises consisting of approximately 24,705 rentable square feet of space (the "**Premises**") in a building located at 10628 Science Center Drive, La Jolla, California ("**Building**"). The Premises are more particularly described in the Lease. Capitalized terms used herein without definition shall have the meanings defined for such terms in the Lease.

B. Landlord and Tenant desire, subject to the terms and conditions set forth below, to amend the Lease to, among other things, provide for Tenant to lease additional space on a temporary basis consisting of approximately 11,749 rentable square feet in that certain Building at the Project known as 10578 Science Center Drive, San Diego, California (the "**10578 Building**"), as shown on **Exhibit A** attached to this First Amendment.

NOW, THEREFORE, in consideration of the foregoing Recitals, which are incorporated herein by this reference, the mutual promises and conditions contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Landlord and Tenant hereby agree as follows:

1. **Temporary Premises**. Commencing on March 1, 2020 ("**Temporary Premises Commencement Date**"), and continuing until February 28, 2021 ("**Temporary Premises Term**"), Landlord shall lease to Tenant and Tenant shall lease from Landlord that portion of the 10578 Building, containing approximately 11,749 rentable square feet, as shown on **Exhibit A** attached to this First Amendment (the "**Temporary Premises**"). Tenant acknowledges and agrees that all of the terms and conditions of the Lease shall apply to the leasing of the Temporary Premises as if the Temporary Premises were the Premises, except that: (a) the term of the lease with respect to the Temporary Premises shall be as set forth in the first sentence of this Section 1; (b) commencing on the Temporary Premises Commencement Date, Tenant shall be required to pay Base Rent to Landlord on the first day of each month of the Temporary Premises Term in the amount of $60.00 per rentable square foot of the Temporary Premises per year on a triple net basis (which amount shall not be subject to adjustment during the Temporary Premises Term), (c) commencing on the Temporary Premises Commencement Date, Tenant shall pay Tenant's Share of Operating Expenses with respect to the 10578 Building with respect to the Temporary Premises (which shall be equal to 7.99%) and separately metered Utilities provided to the Temporary Premises, (d) commencing on the Temporary Premises Commencement Date, Tenant shall pay the Amenities Fee with respect to the Temporary Premises at the same rate that Tenant is then paying with respect to the Premises, as may be adjusted pursuant to Section 42(b) of the Lease, (e) Landlord shall not be required to make any improvements to the Temporary Premises and Tenant shall accept the Temporary Premises in its "as is" condition; (f) subject to the terms and conditions of Section 10 of the Lease, Tenant shall have the right during the Temporary Premises Term, in common with other tenants and occupants of the Project, to use 2.5 parking spaces per 1,000 rentable square feet of the Temporary Premises, which parking spaces shall be located in those areas designated for non-reserved parking, (g) Tenant shall have the exclusive use of 100% of the control area in the 10578 Building designated on **Exhibit C** attached to this First Amendment, which control area Landlord and Tenant acknowledge and agree is located within the Premises, (h) notwithstanding anything to the contrary contained in

Section 12 of the Lease, Tenant shall have no right to construct any Alterations or improvements in the Temporary Premises, and (i) interior signs on doors and the directory tablet of the 10578 Building shall be inscribed, painted or affixed for Tenant by Landlord at the sole cost and expense of Tenant, and shall be of a size, color and type acceptable to Landlord, but Tenant shall have no rights to monument signage or building signage in connection with the Temporary Premises. Tenant acknowledges that Tenant shall be responsible for obtaining all licenses required for Tenant's occupancy of the Temporary Premises including, without limitation, any Hazardous Materials-related licenses and for delivering a Surrender Plan as provided for in the Lease with respect to the Temporary Premises at the expiration or earlier termination of the Temporary Premises Term.

During the Temporary Premises Term, Tenant shall have the right to use the furniture, fixtures and equipment belonging to Landlord described on **Exhibit B** attached to this First Amendment and located within the Temporary Premises on the Temporary Premises Commencement Date ("**Landlord's Furniture**"). Tenant shall have no right to remove any of Landlord's Furniture from the Temporary Premises without Landlord's prior written consent and Landlord's Furniture shall be returned to Landlord at the expiration or earlier termination of the Term in substantially the same condition as received by Tenant, except for ordinary wear and tear and casualty. Landlord represents to Tenant that Landlord owns Landlord's Furniture reflected on **Exhibit B** as of date of this First Amendment free and clear of any third party liens or claims.

Landlord and Tenant acknowledge and agree that (x) Tenant occupied the Temporary Premises immediately preceding the Temporary Premises Commencement Date pursuant to a License Agreement between Landlord and Tenant dated of even date herewith (the "**License Agreement**"), (y) Tenant made certain Approved Alterations (as defined in the License Agreement) to the Temporary Premises while it occupied the Temporary Premises under the License Agreement, and (z) to the extent that the Approved Alterations were not completed by Tenant during the Term (as defined in the License Agreement) of the License Agreement, Tenant shall have the right to continue to construct and complete the Approved Alterations during the initial 30 days of the Temporary Premises Term. Tenant shall have the right to make additional Alterations in the Temporary Premises pursuant to and in accordance with the terms and conditions of Section 12 of the Lease; provided, however, that, prior to the expiration of the Temporary Premises Term, Tenant shall, at Tenant's sole cost and expense, remove the Approved Alterations and any and all additional Alterations constructed in the Temporary Premises during the Temporary Premises Term (or the Extended Temporary Premises Term (as defined below), and restore the Temporary Premises to its condition as of the Commencement Date (as defined in the License Agreement) of the License Agreement.

2. **Extension of Temporary Premises Term**. Notwithstanding anything to the contrary contained herein, so long as Tenant is not then in Default under the Lease, Tenant shall have the one time right to extend the Temporary Premises Term for a period of 12 months (the "**Extended Temporary Premises Term**"), to be exercised on or before December 1, 2020, on the same terms and conditions as set forth in this First Amendment, except that the Base Rent payable with respect to the Temporary Premises, as set forth in the first paragraph of Section 1 above, shall be increased by 3% commencing on the commencement date of the Extended Temporary Premises Term. Tenant shall have the right to terminate the Extended Temporary Premises Term prior to February 28, 2022, so long as Tenant delivers to Landlord a written notice of its election to exercise such termination right no less than 90 days in advance of such early termination and specifying the date of such early termination (the "**Early Temporary Premises Termination Date**"). If Tenant elects to exercise its early termination right pursuant to the immediately preceding sentence, Tenant shall vacate the Temporary Premises and deliver possession thereof to Landlord in the condition required by the terms of the Lease on or before the Early Temporary Premises Termination Date, and Tenant shall have no further obligations under the Lease with respect to the Temporary Premises after the Early Temporary Premises Termination Date, except for those accruing prior to the Early Temporary Premises Termination Date and those which, pursuant to the terms of the Lease, survive the expiration or early termination of the Lease.

3. **Hazardous Materials List**. Landlord and Tenant acknowledge and agree that Tenant delivered to Landlord a Hazardous Materials List, as required pursuant to Section 30(b) of the Lease, with respect to Tenant's use of the Temporary Premises, prior to the date of this First Amendment.

4. **Brokers**. Landlord and Tenant each represents and warrants that it has not dealt with any broker, agent or other person (collectively, "**Broker**") in connection with the transaction reflected in this First Amendment and that no Broker brought about this transaction, other than Cushman & Wakefield and CBRE. Landlord and Tenant each hereby agrees 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 First Amendment.

5. **OFAC**. Tenant and all beneficial owners of Tenant are currently (a) in compliance with and shall at all times during the Term of the 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.

6. **Miscellaneous**.

a. This First 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 First Amendment may be amended only by an agreement in writing, signed by the parties hereto.

b. This First Amendment is binding upon and shall inure to the benefit of the parties hereto, and their respective their respective successors and assigns.

c. This First Amendment may be executed in 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 First Amendment and all matters related thereto, with such electronic signatures having the same legal effect as original signatures.

d. Except as amended and/or modified by this First 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 First Amendment. In the event of any conflict between the provisions of this First Amendment and the provisions of the Lease the provisions of this First Amendment shall prevail. Whether or not specifically amended by this First 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 First Amendment.

[Signatures are on the next page]

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

TENANT:

ARCTURUS THERAPEUTICS, INC.,
a Delaware corporation

By:
Its:

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:
Its:

EXHIBIT 10.24

CERTAIN INFORMATION IDENTIFIED BY BRACKETED ASTERISKS ([* * *]) HAS BEEN OMITTED FROM THIS EXHIBIT BECAUSE IT IS BOTH NOT MATERIAL AND WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

SECTION 1: TERMS AND CONDITIONS SPECIFIC TO INNOVATION DEVELOPMENT SCHEME

1.1	Summary of Award	**Tranche 1** Period:21 Feb 2020 – 20 Feb 2021 **Maximum Grant Amount**: S$ 14,039,000 Cost CategorySupport RateCategory Sub-Cap(a)[* * *][* * *][* * *](b)[* * *][* * *][* * *](c)[* * *][* * *][* * *](d)[* * *][* * *][* * *]•[* * *][* * *][* * *](1)[* * *][* * *][* * *](g)[* * *][* * *][* * *](h)Other Costs[* * *][* * *]
1.2	Grant Amount	The amount claimable in each category is determined by the actual qualifying costs incurred in that category multiplied by the support rate for that category, and up to the respective category sub-cap. The total amount claimable under the Incentive is the maximum grant amount. Where the sum of the category sub-cap exceeds the maximum grant amount, the maximum grant amount shall prevail.
1.3	Qualifying Period	The qualifying period shall be from the start date of the 1st Tranche to the end date of the last Tranche. Only qualifying costs incurred during the qualifying period are claimable.

1.4	Qualifying Personnel	Qualifying personnel refers to the following: (a) Grantee's employees directly working on the Project but excludes employees undertaking support functions such as administration and finance. Both permanent employees and contract staff are qualifying personnel. (b) Undergraduate and post-graduate students from local Institutes of Higher Learning (11-ILs) and secondees from related parties of the Grantee or public research institutes, only if — i.They are directly working on the Project but excluding persons undertaking support functions such as administration and finance; ii.EDB is satisfied that their involvement has resulted in the building of local capability; and iii.The salaries of such persons are paid by the Grantee. “Locals” refers to qualifying personnel who are Singapore Citizens or Singapore Permanent Residents, while “Foreigners” refers to all other persons.
1.5	Manpower (Salary, COLA and Airfare)	The qualifying costs for this category refers to the following: (a) <u>Manpower — Salary</u> The qualifying costs for Manpower — Salary refers to basic salaries, annual wage supplement (AWS) and the corresponding employer's contribution to CPF on basic salaries and AWS, of the qualifying personnel. AWS is capped at 1 month per calendar year and is qualifying only if— i.It is a standard component in the personnel's salary package; iv.It is paid out during the Qualifying Period (regardless of the period for which the AWS is paid for work done); and v.The personnel is working on the Project at the point when the AWS is paid out. For qualifying personnel not exclusively working on the Project, only the pro-rated AWS based on the percentage of time spent working on the Project in the month of the AWS payout is claimable. The qualifying costs for basic salaries and the corresponding employer's CPF contribution shall be capped at S$20,000 per calendar month per qualifying personnel, while the qualifying costs for AWS and the corresponding employer's CPF contribution shall be capped at S$20,000 per calendar year per qualifying personnel. Other bonuses and allowances, and the corresponding CPF contributions, regardless of whether they are included under basic salaries for income tax purposes or any other purpose, are not qualifying costs. (b) <u>Manpower — Cost Of Living Allowance (COLA) & Airfare</u> The qualifying costs for COLA & Airfare refers to costs incurred for overseas trip(s) that is necessary for the Project, made by qualifying personnel, and shall be limited to accommodation, meals and local transportation (i.e. COLA), as well as airfare.

1.6	Training	The qualifying costs for Training refers to the following costs incurred for training that is necessary for the Project: (a) Fees for courses conducted by non-related parties for qualifying personnel who are Locals, only; or (b) Basic salaries and the corresponding employer's contribution to CPF, COLA and airfare of overseas trainers deployed to Singapore to train qualifying personnel within the Singapore operations. The qualifying costs for overseas trainer's basic salaries and the corresponding employer's contribution shall be capped at S$20,000 per calendar month per trainer. The qualifying costs for COLA are costs incurred for accommodation, meals and local transportation of the overseas trainer during the training in Singapore. AWS, other bonuses and allowances, and the corresponding CPF contributions, regardless of whether they are included under basic salaries for income tax purposes or any other purpose, are not qualifying. The Grantee may only claim either (a) or (b) for any one training programme.
1.7	Equipment	The qualifying costs for Equipment refers to the pro-rated purchase price of the equipment, principal repayments for equipment bought on hire purchase, or lease payments incurred for the period of use of the equipment for the Project during the Qualifying Period, and any direct costs attributed to bringing the equipment to working condition but excluding maintenance costs. For equipment that is leased or bought on hire purchase, any financing interest is not qualifying. The qualifying costs for Equipment shall be pro-rated based on the number of months the equipment is used for the Project during the Qualifying Period over the useful life of the equipment or 36 months, whichever is longer. Qualifying costs of equipment = $\frac{[\text{Cost incurred}] \times [\text{No. of months used for the Project}]}{\text{Equipment useful life or 36 months, whichever is longer}}$
1.8	Materials, Consumables and Technical Software	The qualifying costs for Materials and Consumables refers to the purchase price of materials and consumables used in the Project. The qualifying costs of Technical Software refers to the pro-rated purchase price, lease payments or licensing fees incurred for the period of use of the technical software for the Project during the Qualifying Period. For technical software that is leased, any financing interest is not qualifying. The qualifying costs for Technical Software shall be pro-rated based on the number of months the technical software is used for the Project during the Qualifying Period over the useful life of the technical software or 24 months, whichever is longer. Qualifying costs of technical software = $\frac{[\text{Cost incurred}] \times [\text{No. of months used for the Project}]}{\text{Technical Software useful life or 24 months, whichever is longer}}$
1.9	Professional Services	The qualifying costs for Professional Services refers to costs incurred for professional services performed in Singapore by Singapore-based service providers, whichmay include consultancy, subcontracting, testing and certification approval, that are necessary for the Project.

1.10	Intellectual Property Rights (IPR)	The qualifying costs for IPR refers to the pro-rated purchase price for technology acquisition, licensing fees or royalties payments incurred for the period of use of the IPR for the Project during the Qualifying Period. The qualifying costs for IPR shall be pro-rated based on the number of months the IPR is used for the Project during the Qualifying Period over the useful life of the IPR or 60 months, whichever is longer. Qualifying costs of IPR = $\frac{\text{[Cost incurred] x [No. of months used for the Project]}}{\text{IPR useful life or 60 months, whichever is longer}}$
1.11	Other Costs	The qualifying costs for Other Costs shall be in accordance to Details on Qualifying Cost, if any.
1.12	Non-Qualifying Costs	The following are non-qualifying costs: (a) Payments to a related party for the following: course fees, used equipment, used materials, used consumables, used technical software, professional services and intellectual property rights. For related party transactions other than those in the above non-qualifying list, the qualifying costs for each such transaction shall be only based on the actual costs incurred by the related party and excluding any mark-ups or administrative charges that may be imposed by the related party. This, however, does not absolve the Grantee from the requirement to carry out related party transactions at arm's length. (b) Alf cost items that are not used exclusively for the Project, unless the qualifying costs for that item is suitably pro-rated; (c) All rentals of business/operating premises or electricity/utility costs; (d) All construction costs; (e) All patent application and registration costs, and licensing costs incurred for the purpose of onward licensing acquired IPR to other parties; (f) All costs incurred in relation to the audit of claims or project milestones achievements; (g) All taxes, including but not limited to GST and withholding taxes; or (h) All cost items that have already been supported by another grant awarded by a Singapore government agency. For the avoidance of doubt, the above list of non-qualifying costs is not exhaustive. The Grantee shall not treat any cost item as qualifying unless it has been expressly provided as such in this Letter of Award.

1.13	Sale, Lease, Disposal or Transfer of Equipment or Technical Software or Intellectual Property Rights	The Grantee shall not sell, lease, dispose or otherwise transfer the equipment or technical software or intellectual property rights supported under the Incentive to another party during the Qualifying Period without first obtaining the written approval of EDB, which if so granted, shall be on such terms as EDB deems fit. In the event of a breach of the foregoing, or where any equipment or technical software or intellectual property rights whose acquisition has been supported under the Incentive otherwise ceases to be used for the Project during the Qualifying Period, any disbursements pertaining to the unutilized portion of the asset shall be offset against subsequent claim(s) or returned to EDB. Should the asset be subsequently re-activated for use for the Project during the Qualifying Period, the Grantee may submit the claim for the period of re-activated use.
1.14	Appendix	Please refer to the Appendix for additional terms and conditions not contained in Section 1, 3 and 4, if applicable.

SECTION 2: PROJECT MILESTONE CONDITIONS

2.1 Tranche 1 (21 Feb 2020 – 20 Feb 2021)

To qualify for tranche 1 of the Incentive, the Grantee shall fulfil all of the following as at the specified "Due Date" and maintain them until the specified "Maintain Till Date" at least the specified Quantum, where applicable:

ConditionQuantumDue DateMaintain Till Datei.[* * *]N.A.[* * *][* * *]ii.[* * *]N.A.[* * *][* * *]iii.[* * *]N.A.[* * *][* * *]iv.[* * *]N.A.[* * *][* * *]v.[* * *]N.A.[* * *][* * *]vi.[* * *]N.A.[* * *][* * *]vii.[* * *]N.A.[* * *][* * *]viii.[* * *]N.A.[* * *][* * *]

SECTION 3: TERMS AND CONDITIONS ON CLAIMS, DISBURSEMENTS AND PROGRESS UPDATES

Claims

1. Claims must be submitted using the prescribed Forms la and lb and be certified by a duly authorised signatory of the Grantee. Each claim should cover a period of at least 6 months. The amount of grant monies disbursed shall be based on the actual qualifying cost items incurred by the Grantee on the Project during the Qualifying Period.

2. **All claims must be externally audited by a Public Accountant/audit firm registered with the Accounting and Corporate Regulatory Authority**. The External Auditor's Statement, in accordance with the prescribed format in Annex 2, shall be submitted at least once every 12 months from the start of the claim period, and shall be accompanied by Forms la and lb as stamped by the external auditor (or stamped copies of Forms la and lb that were previously submitted) for the claims covered in the Statement. The Grantee shall make available to its auditor this Letter of Award and its accompanying annexes, including the Terms of Reference for External Auditors at Annex 2. In the event that the external auditor cannot issue an unqualified statement, EDB shall have direct access to the external auditor to obtain details with regard to the audit findings. For the avoidance of doubt, nothing in this paragraph prevents the Grantee from submitting unaudited claims in the interim.

3. The final audited claim shall be submitted to EDB with complete documentation (including the External Auditor's Statement on such part of the Qualifying Period as was not covered in the previous audit, if any) within 183 calendar days from the end of the Qualifying Period, or from completion or termination of the Project, whichever is earlier, unless otherwise approved by EDB.

Half-Yearly
Yearly and Final Claim
Claims Submissions

Form 1a – Fund Request
Form 1b – Breakdown of Fund Request
(download soft copy of the forms from EDB Portal or call EDB Finance hotline at Tel: +65 6832 6416)

Annex 2 – External Auditor’s Statement
Annex 1 – Direct Credit Authorisation (to submit together with the first fund request; resubmission is only necessary if there is change in bank details)

Requirements on Document Submissions for Claims

Disbursements

4. [* * *].

5. [* * *]

6. Disbursements for any qualifying equipment shall only be made after the equipment has been commissioned for the Project. In cases where the commissioning of equipment is not applicable, disbursements shall only be made after the qualifying equipment has been delivered.

7. [* * *].

8. [* * *].

Progress Updates

9. The Grantee shall submit the following:
   (a) An Annual Progress Update, in accordance with the prescribed format in Annex 3. This is to be submitted as and when notified by EDB.
   (b) A Final Progress Update, in accordance with the prescribed format in Annex 4. This is to be submitted within 183 calendar days from completion or termination of the Project, unless otherwise approved by EDB.

10. The submission by the Grantee and EDB's acceptance of the above progress updates shall not, in and of itself, constitute a waiver or variation of any of the terms and conditions of this Incentive, or a waiver of any breach thereof. If required by EDB, the Grantee must undertake to submit additional information and supporting documents to substantiate the information provided.

SECTION 4: ADDITIONAL TERMS AND CONDITIONS FOR GRANTS

Implementation of Project

1. The Grantee shall implement the Project as stated in the Application throughout the qualifying period.

Definitions

2. Where the term appears in this Letter of Award, cumulative fixed asset investment (FAI) refers to fixed assets (at cost), excluding land, as at the milestone date specified. Additional fixed asset investment (FAI) refers to additional fixed assets (at cost), excluding land, invested over the specified period. In each case, the calculation of FAI shall be net of disposal of assets. Where there is a requirement to "maintain" FAI, this means that any sale of the assets constituting the requisite FAI shall be compensated for by the incurring of replacement FAI.

3. Where the term appears in this Letter of Award, Total Business Expenditure (TBE) shall be ascribed the meaning attributed to it under Item D in Part II of the EDB Core Form. Unless otherwise specified in the Letter of Award, TBE refers to the expenditure incurred during the relevant twelve-month period immediately preceding the due date of the condition in question.

4. Where the terms appear in this Letter of Award, the terms: -

   (a) "Skilled Employees" shall refer to "Professionals", "Managers", "Associate Professionals and Technicians" and "Skilled Production Craftsmen", each as identified as the same in the EDB Supplementary Form;
   (b) "Research Scientists and Engineers (RSEs)" shall refer to scientists and engineers who are principally employed in a research capacity;
   (c) A person is "based in Singapore" if he/she is a tax resident of Singapore; and
   (d) "Singapore publicly-funded IHLs" refer to National University of Singapore (NUS), Nanyang Technological University (NTU), Singapore Management University (SMU), Singapore University of Technology and Design (SUTD), Singapore Institute of Technology (SIT), Singapore University of Social Sciences (SUSS), Institute of Technical Education (ITE), and all Polytechnics in Singapore.

Utilisation of grant monies

5. Virement from one qualifying cost category to another is not permitted unless first approved in writing by EDB.

6. Grant monies are not to be applied towards the payment of any form of taxes, including but not limited to GST and withholding taxes.

7. All Grant monies received shall be used solely for the implementation of the Project.

Submission of claims

8. EDB reserves the right to –
   (a) require the provision of any document or information for the purposes of verifying a claim; and
   (b) reject any claim not submitted in accordance with the prescribed procedures or in respect of which the Grantee is unable to provide justification to EDB's satisfaction.

Related Party Transactions

9. The Grantee is to carry out all related party transactions at arm's length. A related party, for the purposes of this clause, is determined with reference to Financial Reporting Standards 24.

Co-operation with EDB

10. The Grantee shall –
   (a) upon receipt of at least two weeks' notice in writing from EDB, and for the purpose of allowing EDB to determine whether the Grantee is complying with the terms and conditions of the Incentive, permit EDB officers or such other persons as EDB may nominate to inspect the premises where the Project is carried out, the Grantee's accounts on expenditures related to the Project and the Grantee's records on the progress of the Project, and such other information or documents as EDB may consider necessary. Any inspections shall be carried out at reasonable intervals. The Grantee shall, upon notification from EDB, reimburse EDB for reasonable costs incurred by EDB or its nominee in connection with any inspection carried out pursuant to this sub-clause;

   (b) if required by EDB, submit a report comparing its projections in the Application with the actual realised figures. The template for this report and the timeline for submission will be provided by EDB;

   (c) if required by EDB, submit an external auditor's report setting out its progress in meeting the terms and conditions of the Incentive. Where an external auditor's report is required, EDB may specify that this be submitted by a stipulated deadline and follows the Agreed-Upon Procedures Report Template ("AUP Template") as published on the website of the Institute of Singapore Chartered Accountants. In the event that the external auditor cannot issue an unqualified statement, EDB may elect to have direct access to the external auditor to gather details with regard to the external auditor's findings and the Grantee shall facilitate EDB's access in this regard, including but not limited to providing all necessary consents to enable the external auditor to resolve EDB's queries and/or concerns to EDB's satisfaction;

   (d) if required by EDB, submit a copy of its statutory filings (e.g. annual financial statements and audited accounts), together with the detailed profit and loss statement; and

   (e) provide information reasonably related to the Grant as well as other information required by EDB including responses to surveys or any other studies that may be carried out by EDB from time to time.

Effect of Incentive

11. The Grantee shall comply with the terms and conditions set out in the Letter of Award until the end of the Qualifying Period or the due date of the final condition(s) imposed under Section 2 of the Letter of Award, whichever is later. The Grantee shall notify EDB as soon as possible should it fail to fulfill or maintain any said term or condition.

12. Under no circumstances shall a failure to comply with the terms and conditions of the Grant permit the Grantee to unilaterally treat the Grant as having been terminated or revoked.

Termination and Default

13. Should the Grantee seek the withdrawal, termination, or revocation of the Grant, it shall make a request in writing to EDB and the Grant shall continue to have effect until such time as the request is approved and EDB notifies the Grantee of the revocation of the Grant.

14. In the event of any breach of any term or condition of the Grant, EDB shall give due consideration to a reassessment of the same. Notwithstanding the foregoing, EDB reserves the right to stop all disbursements, recover from the Grantee the total amount of Grant monies paid to the Grantee, and require payment by the Grantee of all costs and interest incurred by EDB in connection with such recovery.

15. In the event –

(a) the Project is terminated or aborted;
(b) the Grantee is likely to cease to exist as a distinct legal entity during the qualifying period; or
(c) where the Grantee is a foreign company with a branch registered in Singapore with the Accounting and Corporate Regulatory Authority, the Grantee's business operations or registration with the Accounting and Corporate Regulatory Authority is likely to cease during the Qualifying Period

then -

(i) the Grantee shall be obliged to inform EDB in writing of the same immediately, and in the case of sub-clauses (b) and (c), where the cessation of existence, cessation of business operations or cessation of registration is initiated by the Grantee, EDB shall be informed at least 183 calendar days before the intended date of cessation of existence, cessation of business operations or cessation of registration, as the case may be; and
(ii) such termination, abortion, cessation of existence, cessation of business operations or cessation of registration, as the case may be, shall constitute a breach of the terms and conditions of the Grant.

Confidentiality

16. The terms and conditions of the Grant shall be kept confidential by the Grantee and shall be disclosed to a director, officer or employee of the Grantee only to the extent that the disclosure is necessary for the said director's, officer's or employee's as the case may be, performance of his duties. Said information shall not be disclosed to any third parties, including but not limited to the general public and the press, except with the prior written approval of EDB. Notwithstanding the generality of the foregoing, the Grantee may release said information, on a strictly confidential and need to know basis, to auditors, tax consultants and legal advisors as may be necessary for the purposes of obtaining professional advice PROVIDED the Grantee ensures that such third parties are first informed of, and acknowledge in writing, the confidential nature of the disclosed information. The Grantee may also release

the said information to the Inland Revenue Authority of Singapore (IRAS) where the release is made pursuant to a statutory obligation owed to IRAS.

Disclaimers

17. The failure by EDB to insist upon strict performance of the terms and conditions of the Grant shall not constitute a waiver of any of EDB's rights therein, at law or in equity, or a waiver of EDB's right subsisting or future, to require the Grantee to comply with any other term or condition of the Grant.

18. Neither EDB nor the Grantee shall, by virtue of the Letter of Award, be deemed to be in a relationship of partnership, agency or employment with the other.

19. No waiver or variation of the terms and conditions of the Grant shall be valid unless such waiver or variation is notified or agreed upon in writing by a duly authorised representative of EDB of Director-level or higher.

20. No person, save EDB and the Grantee, shall have any right under any statutory provisions or applicable law to the extent their operation may be excluded, to enforce against EDB or the Grantee any of the terms or conditions of the Grant.

Others

21. The award of the Grant shall not absolve the Grantee from its obligation to comply with the requirements of any law for the time being in force that applies to its operations.

22. Save with the prior written approval of EDB, the Grantee may not seek or receive monies from any other incentives by the Government of Singapore or any of its agencies for funding of the Project.

23. EDB reserves the right to amend the terms and conditions of the Grant in the event of any errors on the part of EDB, including but not limited to typographical errors and accidental omissions. All other amendments to the terms and conditions in the Letter of Award shall be subject to mutual written consent.

24. The Letter of Award embodies the entire agreement between EDB and the Grantee in respect of the Grant and any prior or contemporaneous representations, either oral or written, are hereby superseded.

25. Headings or titles in this Letter of Award are for reference and convenience only and do not form part of this Letter of Award and shall not affect its interpretation.

Appendix to LOA

Section 1

Clauses 1.2, 1.5 and 1.9 of Section 1 shall be deleted in its entirety and replaced with the provision(s) set out in the third column of the following table.

1.2	Grant Amount	The amount claimable in each category is determined by the actual qualifying costs incurred in that category multiplied by the support rate for that category. Virement across all cost categories is allowable. The total amount claimable under the Incentive is the maximum grant amount.
1.5	Manpower (Salary, COLA and Airfare)	The qualifying costs for this category refers to the following: (a) Manpower – Salary The qualifying costs for Manpower – Salary refers to basic salaries and annual wage supplement (AWS), of the qualifying personnel. AWS is capped at 1 month per calendar year and is qualifying only if – i. It is a standard component in the personnel's salary package; ii. It is paid out during the Qualifying Period (regardless of the period for which the AWS is paid for work done); and iii. The personnel is working on the Project at the point when the AWS is paid out. For qualifying personnel not exclusively working on the Project, only the pro-rated AWS based on the percentage of time spent working on the Project in the month of the AWS payout is claimable. Other bonuses and allowances, regardless of whether they are included under basic salaries for income tax purposes or any other purpose, are not qualifying costs. (b) Manpower – Cost Of Living Allowance (COLA) & Airfare The qualifying costs for COLA & Airfare refers to costs incurred for overseas trip(s) that is necessary for the Project, made by qualifying personnel, and shall be limited to accommodation, meals and local transportation (i.e. COLA), as well as airfare.

1.9	Professional Services	The qualifying costs for Professional Services refers to costs incurred for professional services performed by service providers, which may include consultancy, subcontracting, testing and certification approval, that are necessary for the Project. Such costs may comprise of: 1.Costs incurred in Singapore for professional services by Singapore-based service providers; and 2.Costs incurred overseas for professional services by overseas-based non-related party providers.

Clause 1.15 shall be added with the provision(s) set out in the third column of the following table

1.15	Exchange Rate	The applicable USD/SGD exchange rate for all claims shall be USD1 : 1.39SGD.

Section 3

Clauses 2, 4, 5 and 7 of Section 3 shall be deleted in its entirety and replaced with the provision(s) set out below.

"2. **All claims must be externally audited by a Certified Public Accountant [1]**. The External Auditor's Statement, in accordance with the prescribed format in Annex 2, shall be submitted at least once every 12 months from the start of the claim period, and shall be accompanied by Forms 1a and 1b as stamped by the external auditor (or stamped copies of Forms 1a and 1b that were previously submitted) for the claims covered in the Statement. The Grantee shall make available to its auditor this Letter of Award and its accompanying annexes, including the Terms of Reference for External Auditors at Annex 2. In the event that the external auditor cannot issue an unqualified statement, EDB shall have direct access to the external auditor to obtain details with regard to the audit findings. For the avoidance of doubt, nothing in this paragraph prevents the Grantee from submitting unaudited claims in the interim."

"4. [* * *]
"5. [* * *]

"7. [* * *]

Clauses 8 of Section 3 shall not be applicable.

Section 4

Clause 5 of Section 4 shall not be applicable.

Clauses 10 (c) of Section 4 shall be deleted in its entirety and replaced with the provision(s) set out below.

"10. (c) if required by EDB, submit an external auditor's report setting out its progress in meeting the terms and conditions of the Incentive. Where an external auditor's report is required, EDB may specify that this be submitted by a stipulated deadline and follows the prescribed format in Annex 2. In the event that the external auditor cannot issue an unqualified statement, EDB may elect to have direct access to the external auditor to gather details with regard to the external auditor's findings and the Grantee shall facilitate EDB's access in this

regard, including but not limited to providing all necessary consents to enable the external auditor to resolve EDB's queries and/or concerns to EDB's satisfaction;

Clause 16 of Section 4 shall be deleted in its entirety and replaced with the provision(s) set out below.

"16. (a) The terms and conditions of the Grant shall be kept confidential by the Grantee and shall be disclosed to a director, officer or employee of the Grantee only to the extent that the disclosure is necessary for the said director's, officer's or employee's as the case may be, performance of his duties. Said information shall not be disclosed to any third parties, including but not limited to the general public and the press, except with the prior written approval of EDB. Notwithstanding the generality of the foregoing, the Grantee may release said information, on a strictly confidential and need to know basis, to auditors, tax consultants and legal advisors as may be necessary for the purposes of obtaining professional advice PROVIDED the Grantee ensures that such third parties are first informed of, and acknowledge in writing, the confidential nature of the disclosed information. The Grantee may also release the said information to the Inland Revenue Authority of Singapore (IRAS) where the release is made pursuant to a statutory obligation owed to IRAS. Furthermore, as a publicly traded company in the United States, Arcturus may disclose this Grant and the existence, terms and conditions of this Grant to the extent necessary, as reasonably determined by Grantee, to be in compliance with regulatory requirements with the U.S. Securities and Exchange Commission (SEC) and Food and Drug Administrations.

16. (b) Within the Incentive Period, to the extent that Grantee provides EDB with proprietary confidential information, which shall be marked as such if in written, electronic, or tangible form, or verbally indicated as such if communicated orally, EDB agrees to maintain such information in strict confidence, to use the confidential information only for the purposes articulated in this Letter of Award, and to not disclose the information except to those personnel of EDB who have a need to know the information, except as required by

(i) applicable law;

(ii) valid order of court or government authority; or

(iii) the Ministry of Trade and Industry of the Government of Singapore, the Ministry of Finance of the Government of Singapore, or the Inland Revenue Authority of

Singapore, for EDB's reporting, administrative or approval purposes, such information is not to be released to any external parties, the public or the press without the prior written approval of the Grantee."

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED 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, and
(3) Registration Statements (Form S-3 Nos. 333-232281 and 333-235475) of Arcturus Therapeutics Holdings Inc.;

of our reports dated March 16, 2020, 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, 2019.

/s/ Ernst & Young LLP

San Diego, California
March 16, 2020

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 16, 2020

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 16, 2020

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 16, 2020

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, 2019 (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 16, 2020

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, 2019 (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 16, 2020

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, 2019 (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 16, 2020

By: /s/ Keith C. Kummerfeld

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