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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2020

Or

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

For the transition period from to

Commission file number 001-37990

LEAP THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware State or other jurisdiction of incorporation or organization	**27-4412575** (I.R.S. Employer Identification No.)
47 Thorndike Street, Suite B1-1 **Cambridge, MA** (Address of principal executive offices)	**02141** (Zip Code)

Registrant's telephone number, including area code **(617) 714-0360**

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	LPTX	Nasdaq Global Market

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 Section 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, a smaller reporting company, or an emerging growth company. See definitions of "large accelerated filer," "accelerated filer", "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

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

The aggregate market value of the voting and non-voting common stock held by non-affiliates of the registrant, computed based on the closing price for such stock as reported on the Nasdaq Global Market on June 30, 2020, the last business day of the registrant's most recently completed second quarter, was approximately: $108.6 million.

As of March 9, 2021 there were 59,657,742 outstanding shares of the registrant's common stock, par value $0.001 per share, which is the only outstanding capital stock of the registrant.

DOCUMENTS INCORPORATED BY REFERENCE:

Portions of the registrant's definitive proxy statement for its 2021 Annual Meeting of Stockholders, which is expected to be filed with the Securities and Exchange Commission not later than 120 days after the end of the registrant's fiscal year ended December 31, 2020, are incorporated by reference into Part III, Items 10-14 of this Annual Report on Form 10-K. With the exception of the portions of the registrant's definitive proxy statement for its 2021 Annual Meeting of Stockholders that are expressly incorporated by reference into this Annual Report on Form 10-K, such proxy statement shall not be deemed filed as part of this Annual Report on Form 10-K.

TABLE OF CONTENTS

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA

This Annual Report on Form 10-K (this "Annual Report") contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which reflect our current views with respect to, among other things, our operations and financial performance. In some cases, you can identify forward-looking statements by terminology such as "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "will" or the negative of such terms or other comparable terminology. Forward-looking statements appear in a number of places throughout this Annual Report and include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, that the initiation, conduct, and completion of clinical trials, laboratory operations, manufacturing campaigns, and other studies may be delayed, adversely affected, or impacted by COVID-19 related issues; our ability and plan to develop and commercialize DKN-01; status, timing and results of preclinical studies and clinical trials; the potential benefits of DKN-01; the timing of our development programs and seeking regulatory approval of DKN-01; our ability to obtain and maintain regulatory approval; our estimates of expenses and future revenues and profitability; our estimates regarding our capital requirements and our needs for additional financing; our estimates of the size of the potential markets for DKN-01; the benefits to be derived from our agreement with BeiGene, Ltd. ("BeiGene") and any other collaborations, license agreements, or other acquisition efforts, including those relating to the development and commercialization of DKN-01; sources of revenues and anticipated revenues, including contributions from our agreement with BeiGene any other collaborations or license agreements for the development and commercialization of products; our ability to create an effective sales and marketing infrastructure if we elect to market and sell DKN-01 directly; the rate and degree of market acceptance of DKN-01; the timing and amount of reimbursement for DKN-01; the success of other competing therapies that may become available; the manufacturing capacity for DKN-01; our intellectual property position; our ability to maintain and protect our intellectual property rights; our results of operations, financial condition, liquidity, prospects, and growth and strategies; the industry in which we operate; and the trends that may affect the industry or us.

By their nature, forward-looking statements involve risks and uncertainties because they relate to events, competitive dynamics and industry change, and depend on economic circumstances that may or may not occur in the future or may occur on longer or shorter timelines than anticipated. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Annual Report, we caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this Annual Report. In addition, even if our results of operations, financial condition and liquidity, and events in the industry in which we operate are consistent with the forward-looking statements contained in this Annual Report, they may not be predictive of results or developments in future periods. You should carefully read this Annual Report and the documents that we have filed as exhibits to this Annual Report completely.

You should refer to Item 1A. Risk Factors in this Annual Report for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Annual Report will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified timeframe, or at all. Any forward-looking statement that we make in this Annual Report speaks only as of the date of such statement, and, except to the extent required by applicable law, we undertake no obligation to update such statements to reflect events or circumstances after the date of this Annual Report or to reflect the occurrence of unanticipated events. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Annual Report. Comparisons of results for current and any prior periods are not intended to express any future trends or indications of future performance, unless expressed as such, and should only be viewed as historical data.

DKN-01 and TRX518 are investigational drugs undergoing clinical development and have not been approved by the U.S. Food and Drug Administration (the "FDA"), nor been submitted to the FDA for approval. DKN-01 and TRX518 have not been, and may never be, approved by any regulatory agency or marketed anywhere in the world. Statements contained in this Annual Report should not be deemed to be promotional.

We obtained the industry, market and competitive position data in this Annual Report from our own internal estimates and research as well as from industry and general publications and research surveys and studies conducted by third parties. Industry publications and surveys generally state that the information contained therein has been obtained from sources believed to be reliable. We believe this data is accurate in all material respects as of the date of this Annual Report.

INTRODUCTORY COMMENT

References to Leap

Throughout this Annual Report on Form 10-K, the "Company," "Leap," "Leap Therapeutics," "we," "us," and "our," except where the context requires otherwise, refer to Leap Therapeutics, Inc. and its consolidated subsidiaries, and "our board of directors" refers to the board of directors of Leap Therapeutics, Inc.

PART I

Item 1. BUSINESS

Corporate Information

We were incorporated in the state of Delaware on January 3, 2011. During 2015, HealthCare Pharmaceuticals Pty Ltd ("HCP Australia") was formed and is our wholly owned subsidiary.

On December 10, 2015, we entered into a merger agreement with GITR Inc. ("GITR"), an entity under common control, whereby a wholly owned subsidiary was merged with GITR and the surviving name of the wholly owned subsidiary was GITR Inc.

On August 29, 2016, we entered into a merger agreement with Macrocure Ltd. ("Macrocure"), a publicly held, clinical-stage biotechnology company based in Petach Tikva, Israel. In connection with the merger, we applied to be listed on the Nasdaq Global Market. Nasdaq approved the listing, and trading in our common stock commencing on January 24, 2017, under the trading symbol "LPTX." On February 1, 2017, Macrocure's name was changed to Leap Therapeutics Ltd. In 2020, Leap Therapeutics Ltd. was dissolved.

The mailing address of Leap's principal executive office is 47 Thorndike Street, Suite B1-1, Cambridge, MA 02141. Leap's telephone number is 617-714-0360. Leap's website address is *www.leaptx.com* (the information contained therein or linked thereto shall not be considered incorporated by reference in this Form 10-K).

Overview

We are a biopharmaceutical company developing novel therapies designed to treat patients with cancer by inhibiting fundamental tumor-promoting pathways and by harnessing the immune system to attack cancer cells. Our strategy is to identify, acquire, and develop molecules that will rapidly translate into high impact therapeutics that generate durable clinical benefit and enhanced patient outcomes. Our lead clinical stage program is DKN-01, a monoclonal antibody that inhibits Dickkopf-related protein 1, or DKK1. DKK1 is a protein that regulates the Wnt signaling pathways and enables tumor cells to proliferate and spread, as well as suppresses the immune system from attacking the tumor. When DKN-01 binds to DKK1, an anti-tumor effect can be generated. DKN-01-based therapies have generated responses and clinical benefit in several patient populations. We are currently studying DKN-01 in multiple ongoing clinical trials in patients with esophagogastric cancer, hepatobiliary cancer, gynecologic cancers, or prostate cancer. In January 2020, we entered into an Option and License Agreement with BeiGene, Ltd., or BeiGene, which granted BeiGene the right to develop and commercialize DKN-01 in Asia (excluding Japan), Australia, and New Zealand. We intend to apply our extensive experience identifying and developing transformational products to aggressively develop DKN-01 and build a pipeline of programs that have the potential to change the practice of cancer medicine.

Market

Cancer is the general name for a group of more than 100 diseases in which cells grow and divide out of control. Over 14 million people in the United States have cancer. The National Cancer Institute, or NCI, estimated that approximately 1.7 million people developed cancer and that nearly 610,000 people died of cancer in 2018. While progress has been made from the War on Cancer to the Human Genome Project, and despite advances in early detection and new cancer cell targeted treatments, cancer generally remains an incurable disease.

Esophagogastric Cancer (EGC)

Esophageal cancer, or EC, and gastric cancer, or GC, are malignancies of the digestive tract. The American Cancer Society, or ACS, estimates that there are about 18,000 new patients diagnosed in the United States with EC and 28,000 new patients with GC each year. The World Cancer Research Fund estimates that there are over 450,000 EC patients and 950,000 GC patients diagnosed each year worldwide, with a majority of the prevalence in Eastern Asia. EC patients have difficulty swallowing and often have pain while swallowing. Substantial weight loss can result from reduced appetite, poor nutrition and having an active cancer. Pain may be severe, occur almost daily, and be worsened by swallowing any form of food. The disruption of normal swallowing can lead to aspiration of food content, nausea, vomiting and an increased risk of pneumonia. The tumor itself may be irritable and bleed, which can either cause spitting up with blood or blood in the bowels. Compression of local structures in the esophagus occurs in advanced disease, leading to problems such as upper airway obstruction. Many people diagnosed with EGC have late-stage disease, because people usually do not have significant symptoms until the tumor is fairly large. In advanced stages, the cancer frequently spreads into the liver or lungs. EC and GC patients have few treatment options, and patients have a 5-year survival rate of 18.8% and 30.6%, respectively. The frequently-used therapies in patients who have not had many previous courses of treatment have low objective response rates, defined as patients with a greater than 30% reduction in tumor volume as determined by the Response Evaluation Criteria in Solid Tumors v1.1, known as RECIST. Published data has demonstrated that paclitaxel monotherapy generated a response rate of 6.7% in second-line EC patients and 16% in second-line GC patients. Studies have also demonstrated that PD-1 antibody monotherapy generated a response rate of 9% in GC patients who have tumors that are not microsatellite instability high.

Gynecologic Cancers

There are numerous forms of gynecologic cancers, but two of the most prevalent types are cancers of the uterus or ovaries. According to the NCI, there are more than 61,000 patients diagnosed with uterine cancer and 22,000 patients diagnosed with ovarian cancer each year in the United States. There are currently very few treatment options for these patients, typically consisting of chemotherapy, local radiation therapy, and hormonal agents, and poor treatment outcomes. Patients with endometrioid cancers have a high frequency of mutations in a protein known as beta-catenin, with alterations estimated at approximately 30% of cases according to The Cancer Genome Atlas. These b-catenin mutations are often driver mutations leading to rapid disease progression and poor outcomes. Recently the combination of lenvatinib and pembrolizumab was approved under accelerated approval for second line non-MSI-H or mismatch repair deficient endometrial carcinoma based on response rate and durability of response.

Prostate Cancer

Prostate cancer is one of the most common types of cancer in men. There are several types of prostate cancer, but the vast majority are adenocarcinomas that arise from the gland cells that produce prostate fluid as part of the male reproductive system. According to the American Cancer Society, about 175,000 cases are diagnosed each year in the United States. Treatment options include the surgical removal of the prostate, radiation, as well as hormonal agents; many of which can result in poor side effects, such as urinary incontinence and erectile dysfunction. Most prostate cancer tumors eventually become resistant to hormonal treatments. As this stage, which is referred to as metastatic castration-resistant prostate cancer, or mCRPC, chemotherapies, usually taxanes, offer the next line of treatment offering objective response rates of 30% or less. After progressing through taxanes, the next line of treatment consists of cabazitaxel or Radium-223, both of which are associated with significant toxicity. Androgen-receptor negative, non-neuroendocrine, or double negative, mCRPC is a particularly difficult-to-treat subtype that comes with a worsened prognosis. Research has shown that, in this double negative subtype, DKK1 is specifically upregulated and patients with higher DKK1 levels have a loss of certain immune system cells that could target the cancer.

Cancer Therapies and New Targets

Older, established cancer therapies, or chemotherapies, target rapidly dividing cells. While chemotherapies can attack and kill cancer cells, these drugs also attack and destroy rapidly dividing non-cancer normal cells and, unfortunately, are associated with unwanted side effects. Even though outcomes can often be improved by giving a cancer patient two or more chemotherapies in combination, physicians and patients desire new drugs with greater efficacy and fewer side effects. Recently, a revolution in the understanding of cancer biology has generated compelling new anti-cancer targets that are based on fundamental mechanisms used by cancer cells to grow, spread, and survive, which are:

- cell signaling pathways that promote tumor growth, and

- evading detection and avoiding destruction by the immune system.

Cancer Cell Signaling

Cancer cells often hijack proteins that are involved in cell signaling pathways, the complex communication system that governs basic cellular functions and activities, such as cell division, cell movement, cell responses to specific stimuli, and even cell death. By blocking signals that tell cancer cells to grow and divide uncontrollably, to generate new blood vessels, a process referred to as angiogenesis, or to spread to other parts of the body, a process referred to as metastasis, a new generation of cancer therapies is seeking to help stop cancer progression, which could lead to cancer cell death. By focusing on cellular signaling pathways and molecules that are used by cancer cells, these targeted cancer therapies may be more effective than other types of treatment, including chemotherapy, and less harmful to normal cells. Several small molecule and monoclonal antibodies that target cell signaling pathways have been approved by the FDA as cancer therapies for specific patient populations.

Cancer Immunotherapy

The immune system has evolved a dynamic ability to identify and attack cells which pose a danger to the body. Often these dangerous cells are foreign, or non-self, cells, but a person’s own cells can become a danger, such as with cancer. Ideally, the immune system identifies cancer cells as dangerous and removes them before they can grow into tumors. However, cancer cells can evade or suppress the body’s natural immune response by secreting anti-inflammatory molecules and by using receptors on the cell membrane of either immune system cells or cancer cells known as immune checkpoints. Cancer therapies known as checkpoint inhibitors, such as nivolumab, pembrolizumab, atezolizumab, and tislelizumab, are designed to block checkpoint receptors, such as Programmed Cell Death protein-1, or PD-1, or its ligand, PD-L1, and prevent the cancer cell from evading the natural immune response, thus enabling the immune system to mount an attack on the tumor. While there are several FDA-approved checkpoint inhibitors, there is a consensus in the scientific and medical communities that there remains room for improvement in response rate and efficacy. In many cases, the lack of efficacy has been attributed to an insufficient immune response.

Our Approach

Our approach to treating cancer patients seeks to enhance the effectiveness of approved chemotherapies and immune checkpoint inhibitors by:

- altering cell signaling pathways that promote tumor growth and spreading;
- stimulating the immune cells that could attack the tumor; and
- inhibiting immune suppression that would prevent an attack on the tumor.

Altering cell signaling. An important set of signaling pathways in cancer cells are known as the canonical and non-canonical Wnt pathways and the PI3 kinase—AKT pathway. DKK1 serves as one of the inhibitors of the canonical Wnt signaling pathway, modulates the non-canonical Wnt signaling pathways, and directly activates the PI3 kinase—AKT pathway. Changes in these pathways can lead to the expression of several cancer-causing genes and factors associated with cell growth, angiogenesis, and metastasis. We believe that a monoclonal antibody that reduces free DKK1 could shift signaling to healthier levels, thereby resulting in a direct anti-tumor effect as well as a local anti-angiogenic effect in the diseased tissue. These mechanisms could enhance or complement the anti-tumor mechanisms used by chemotherapies or other therapies targeted at different cell signaling pathways.

Enhancing anti-tumor immune cells. A potential way to enhance an immune response against a tumor is by activating tumor-attacking immune cells, such as natural killer cells, or NK cells, or T lymphocytes, or T cells. This strategy is expected to overcome mechanisms that would prevent these immune cells from attacking a tumor. Preclinical data has shown that DKK1 suppresses the activity of NK cells in the tumor microenvironment and that inhibition of DKK1 can enhance NK cell activity. Antibodies that enhance the immune system have the potential to be combined with chemotherapy or checkpoint inhibitors to generate a more robust anti-tumor immune response.

Inhibiting immune suppression. The human immune system has the ability to recognize and protect its own cells and tissues. Certain kinds of white blood cells, such as T regulatory cells and myeloid-derived suppressor cells, serve to prevent other cells from attacking the body. In the case of cancer, these cells may fail to recognize the danger posed by the tumor and suppress the activity of potentially tumor-fighting white blood cells. In addition, cancer cells promote these suppressor cells by producing anti-inflammatory molecules, such as DKK1. We believe that monoclonal antibodies that reduce the levels of anti-inflammatory molecules, such as DKK1, in the tumor microenvironment could result in the inhibition of immune suppressor cells and create a pro-inflammatory environment to enhance the immune system activity against the tumor.

By targeting novel pathways and immune cell types, our therapies are designed to combine with existing drugs and have the potential to significantly increase the survival and quality of life of cancer patients.

Our Product and Clinical Studies

DKN-01

DKK1 is a cell secreted protein that research has found plays a crucial role in embryonic development. DKK1 binds to specific cell surface receptors and affects the signaling of key cellular pathways, known as the canonical and non-canonical Wnt signaling pathways. DKK1 serves as one of the inhibitors of the canonical Wnt signaling pathway and modulates the non-canonical Wnt signaling pathways. DKK1 is also a modulator of CKAP4/PI3K/AKT signaling. Changes in these pathways can lead to the expression of several cancer-causing genes and factors associated with cell growth, angiogenesis, and metastasis. DKK1 also has a role in suppressing the immune system from effectively targeting and clearing the cancer.

Published data indicates that DKK1 expression levels are significantly higher in many cancers, including esophagogastric cancer, or EGC, biliary tract cancer, and non-small cell lung cancer(NSCLC). In addition, elevated DKK1 expression is associated with worse overall survival for patients with EGC, biliary tract cancer, NSCLC, and other cancers. Researchers have shown that when the DKK1 protein is added in certain animal models, the cancer grows larger.

Recent publications have also demonstrated a role for DKK1 in maintaining an environment around a tumor that suppresses the immune system’s ability to clear the tumor and to prevent metastasis. DKK1 has been shown to activate the suppressive effects of myeloid-derived suppressor cells, or MDSC, a type of white blood cell that can potently block other immune system cells. Other published data has shown that metastatic tumor cells with stem cell-like features avoid the immune system by overexpressing DKK1 and secreting it out of the cell. Secreted DKK1 can then down-regulate certain molecules on tumor cells known as natural killer cell activating ligands, or NK cell ligands, that would activate the immune system, causing these cancer cells to remain invisible to NK cells and evade the immune system. Through these multiple activities, research has shown that DKK1 helps protect the cancer cells from being targeted by the immune system.

Preclinical studies that we and others have conducted demonstrated that using an anti-DKK1 antibody can lead to clinical benefits in xenograft cancer models. The anti-DKK1 antibody is believed to shift cell signaling to healthy levels, thereby resulting in a direct anti-tumor effect as well as a local anti-angiogenic effect in the diseased tissue. In these models, researchers demonstrated that an anti-DKK1 antibody allowed the immune system to recognize and attack the cancer cells. We believe that the more selective and local the activity is to the tumor, the more likely a drug will be safe and well tolerated and a potential combination partner to other anti-cancer drugs.

DKN-01 is a high affinity, neutralizing monoclonal antibody targeting DKK1. We have shown that DKN-01 reduces free DKK1 levels and has demonstrated an anti-tumor effect in preclinical models.

On June 11, 2020, the FDA granted orphan drug designation to DKN-01 for the treatment of gastric and gastroesophageal junction cancer. In addition, on September 24, 2020 the FDA granted Fast Track designation to DKN-01 in combination with BeiGene’s tislelizumab for the treatment of patients with gastric and gastroesophageal junction adenocarcinoma whose tumors express high DKK1, following disease progression on or after prior fluoropyrimidine- and platinum- containing chemotherapy and if appropriate, human epidermal receptor growth factor (HER2)/neu-targeted therapy.

First-in-human study

Our first-in-human study of DKN-01 was a single ascending dose Phase 1 trial in patients with low bone density. DKN-01 was administered by intravenous infusion at doses from 7 mg to 300 mg and as a subcutaneous injection at a dose of 44 mg. Eight subjects were treated per cohort, five of whom received DKN-01 and three of whom received placebo, for a total of 48 subjects in six cohorts. There were no clinically significant safety signals observed with increasing doses of DKN-01, and all reported adverse events were mild in severity.

P100—Advanced Solid Tumors or Multiple Myeloma Study

We conducted study P100, a two-part dose-finding Phase 1 study, to establish the safety, maximum tolerated dose, and antitumor activity of DKN-01 as a monotherapy for patients with advanced malignancies. Other endpoints were progression free survival, or PFS, overall response rate, or ORR, and overall survival, or OS. Part A of the study was a dose escalation designed to evaluate increasing doses of DKN-01 between 75 mg and 600 mg administered weekly or biweekly in a 28 day cycle. Part B of the study was an expansion cohort designed to evaluate the activity of DKN-01 as a single agent in patients with advanced NSCLC. For Part B, DKN-01 was administered to refractory NSCLC patients at 300 mg on days 1 and 15 of each 28 day cycle.

We enrolled thirty-two patients in Parts A and B, twenty-four of whom were patients with NSCLC. DKN-01 was well tolerated with no dose limiting toxicities, or DLTs, or serious adverse events, or SAEs, that were deemed by the physician to be related to DKN-01 treatment or treatment-emergent adverse events, or TEAEs, which lead to study discontinuation. All of the treatment-related adverse events were Grade 1 or Grade 2, the two lowest severity levels. TEAEs were generally those typically observed in cancer patients; and the most frequently reported treatment-related TEAEs were fatigue (25%) and nausea (9.4%).

DKN-01 as a single agent demonstrated clinical activity in patients with refractory NSCLC, with a clinical benefit rate of 45.9%, including one NSCLC patient (4.2%) with more than a 30% reduction in the size of their tumor, referred to as a partial response or PR. In the Part B group of NSCLC patients who were dosed at a level of 300 mg every two weeks, the clinical benefit rate was 47.4%, including the patient with the PR (5.3%). Median PFS in the evaluable Part B NSCLC patients was 2.2 months and median OS was 6.6 months.

P102—Esophagogastric Cancer (EGC)

We conducted study P102, a multi-part Phase 1/2 study of DKN-01 as a monotherapy and in combination with paclitaxel or KEYTRUDA® (pembrolizumab) in advanced EGC patients, all of whom have had previous treatment with standard therapies. Many of these subjects have had multiple lines of prior therapy and/or rapidly growing tumors, representing a difficult to treat population. The study is intended to establish the safety and activity of DKN-01 as a monotherapy and in combination with paclitaxel or pembrolizumab and has the secondary endpoints of ORR, PFS, and OS.

Monotherapy

Two DKN-01 monotherapy patients in the sub-study experienced PRs by central imaging analysis. A patient who had previously been treated with prior immunotherapies, including an anti-PD-L1 antibody and an inhibitor of indoleamine-2,3-dioxygenase (IDO), achieved a PR and was on therapy for over one year, and an additional esophageal cancer patient experienced a single agent PR. Six additional patients of the twenty evaluable for central imaging assessment were determined to have had a best response of stable disease(SD).

Paclitaxel Combination

In total fifty-eight patients were treated with DKN-01 in combination with paclitaxel chemotherapy, with fifty-two patients evaluable for response. Across all lines of prior therapy and tumor types, DKN-01 plus paclitaxel generated a 25.0% ORR, 13.4 weeks PFS, and 27.9 weeks OS. The combination of DKN-01 plus paclitaxel generated a 46.7% ORR, 19.6 weeks PFS, and 61.1 weeks OS in fifteen evaluable patients as a second-line therapy.

One of our goals is to identify biomarkers or genetic alterations that could define a patient population more likely to respond to treatment with DKN-01. In this study, four patients evaluated with genetic testing on pre-treatment biopsies were found to have activating/stabilizing mutations of beta-catenin, which is a molecule in the Wnt signaling pathway implicated in oncogenesis, metastasis, and immune suppression. Of these four patients, two achieved PRs and one had prolonged SD. One patient had a response exceeding 2.5 years, of which over 1.5 years was on DKN-01 monotherapy with continued tumor reduction.

Pembrolizumab Combination

Sixty-three patients were treated with DKN-01 plus pembrolizumab combination therapy. Fifty-three patients had not received prior PD-1/PD-L1 therapy, and ten patients were refractory to PD-1/PD-L1 therapy. All of the patients enrolled had tumors that were microsatellite stable or unknown. Patients in the study were heavily pretreated having had received one to five prior lines of therapy, with nearly 64% having received a prior taxane regimen, 37% having received prior ramucirumab, and 24% having received prior trastuzumab. The combination therapy was well tolerated with no new safety signals.

The combination of DKN-01 and pembrolizumab in gastroesophageal junction and gastric cancer patients demonstrated improved outcomes in patients whose tumors expressed high levels of DKK1 as measured by in situ hybridization RNAscope, or DKK1-high, and who had not previously been treated with PD-1/PD-L1 therapy. DKK1-high patients experienced over 22 weeks median PFS and nearly 32 weeks OS, with a 50% ORR and an 80% disease control rate, or DCR, in ten evaluable patients. Patients whose tumors expressed low levels of DKK1, or DKK1-low, experienced nearly 6 weeks median PFS and just over 17 weeks OS, with a 20% DCR in fifteen evaluable patients.

By independent central imaging review, two out of six DKK1-high PD-1/PD-L1 naïve esophageal cancer patients experienced a PR. Both of these responses lasted over 200 days. Of the ten PD-1/PD-L1 naïve esophageal cancer patients who had received more than one prior line of therapy, there was a 40% DCR in the five DKK1-high patients compared to a 0% DCR for the five DKK1-low patients.

The DKK1-high anti-PD-1/PD-L1 refractory patients treated with DKN-01 plus pembrolizumab experienced a significantly longer PFS of 12.8 weeks and OS of 46 weeks compared to the DKK1-low patients who experienced a PFS of 6 weeks and OS of 16 weeks. Among the six GEJ/GC patients who were refractory to PD-1/PD-L1 therapy, three DKK1-high patients had a best response of SD, whereas the three patients with DKK1-low tumors had progressive disease (PD).

PD-L1 Combined Positive Scores, or CPS, did not predict efficacy on the combination of DKN-01 plus pembrolizumab. In multi-variate analysis, DKK1-high status correlated with longer PFS independent of PD-L1 CPS scores. One-third of patients in the study were DKK1-high.

P205—Tislelizumab Combination in GC/GEJ

As part of the collaboration with BeiGene, we are studying the combination of DKN-01 and BeiGene's anti-PD-1 antibody, tislelizumab. We are evaluating approximately forty patients with second-line gastric cancer or gastroesophageal junction cancer whose tumors are DKK1-high per prospective analysis. In addition, we are evaluating the combination of DKN-01 with tislelizumab and capecitabine and oxaliplatin in approximately twenty patients with first-line GC/GEJ. We initiated this clinical trial in the third quarter of 2020 and expect to present initial data in the second half of 2021.

P204—Gynecologic Malignancies

We conducted study P204, a Phase 2 basket study of DKN-01 as a monotherapy and in combination with paclitaxel in patients with advanced epithelial endometrioid cancer (EEC), epithelial ovarian cancer (EOC), and carcinosarcoma. The study consisted of six dosing groups and enrolled 111 patients. The primary objective in each independent study group was to determine the ORR. Secondary objectives were to determine additional measurements of efficacy, such as OS and PFS, and to evaluate the safety of the study treatment regimen. The study was designed to enroll at least 50% of patients whose tumors have predefined activating mutations or signaling alterations in the Wnt pathway.

Twenty-nine EEC patients, who had previously received one to ten lines of therapy, enrolled on DKN-01 monotherapy. In the cohort of twenty evaluable monotherapy EEC patients with identified Wnt signaling mutations, patients had higher response rates and demonstrated longer PFS as compared to patients without Wnt signaling mutations. One patient (5%) has an ongoing complete response, one patient (5%) had a PR, eight patients (40%) had a best response of SD, and 10 patients (50%) had PD, representing an ORR of 10% and a DCR of 50%. In the group of six patients without any Wnt signaling alterations, one patient (16.7%) had a best response of SD and five patients (83.3%) had PD. The patients with a Wnt signaling alteration experienced PFS of 1.9 months and OS of 15.1 months, compared to the patients without a Wnt signaling alteration who experienced PFS of 1.8 months and OS of 8.4 months. The nine patients with a Wnt activating mutation experienced PFS of 5.5 months and had not reached a median OS, compared to the 20 patients without a Wnt activating mutation who experienced PFS of 1.8 months and OS of 12.2 months.

Tumoral DKK1 expression data was available for 19 EEC patients treated with DKN-01 monotherapy. In the group of seven patients with DKK1-high tumors, one patient (14.3%) had a PR, three patients (42.9%) had SD, and 3 patients (42.9%) had PD, representing an ORR of 14.3% and a DCR of 57.1%. In the group of 12 patients with DKK1-low tumors, one patient (8.3%) had SD and 11 patients (91.7%) had PD. The DKK1-high patients experienced PFS of 3.0 months, compared to the DKK1-low patients who experienced PFS of 1.8 months.

Additional data from this study is expected to be presented in March 2021.

P103—Biliary Tract Cancer

We have conducted study P103, a two-part Phase 1/2 study of DKN-01 in combination with gemcitabine and cisplatin in patients with advanced biliary tract cancer. The study enrolled fifty-one patients. Seven patients received one of two dose levels (150 mg or 300 mg) of DKN-01 in combination with gemcitabine and cisplatin during Part A, with forty-four additional patients treated at the 300 mg dose level of DKN-01 in the Part B expansion cohort. Forty-two patients were chemotherapy treatment-naïve, and nine patients had received 1-2 prior therapies. The primary objective of this study was to evaluate the safety, pharmacokinetics, and efficacy of DKN-01 in combination with gemcitabine and cisplatin.

DKN-01 in combination with gemcitabine and cisplatin was well tolerated with no new emerging safety trends. Forty-seven patients overall were treated at the 300 mg DKN-01 dose level, and their median OS was 53.7 weeks (12.4 months). Median PFS was 37.7 weeks (8.7 months). Ten patients (21.3%) had a PR and thirty-one patients (66.0%) experienced a best response of SD, representing a DCR of 87.2%. Two patients (4.3%) had progressive disease, and four patients (8.5%) were non-evaluable for response. The one-year probability of overall survival was 0.51, and the six-month probability of progression free survival was 0.58. The median number of cycles of DKN-01 was seven (range of 1 to 23), and the median duration on study was 331 days.

Investigator-Initiated and Collaborative Group Studies

As part of our strategy to advance the development of DKN-01 in a cost-effective manner and on a global basis, we work with key opinion leaders and groups to initiate and conduct clinical trials in targeted patient populations and in combination with other therapies. We currently have established relationships for four investigator-initiated studies (ISTs):

Prostate Cancer: We have an IST led by David R. Wise, M.D., Ph.D. of the Perlmutter Cancer Center at NYU Langone Health evaluating DKN-01 in advanced metastatic castration-resistant prostate cancer patients whose tumors are DKK1-positive or have Wnt activating mutations.

Hepatocellular Cancer: Our DIAL-1 IST is evaluating DKN-01 as a monotherapy and in combination with sorafenib in patients with hepatocellular carcinoma, a type of liver cancer that has a high percentage of patients with Wnt pathway alterations. The study is led by principal investigators Markus Moehler, M.D., Ph.D, Professor of Gastrointestinal Oncology, and Jens Marquardt, M.D., Lichtenberg Professor for Molecular Hepatocarcinogenesis, Johannes-Gutenberg University in Mainz, Germany.

Biliary Tract Cancer: We have an IST at Massachusetts General Hospital evaluating DKN-01 in combination with Bristol-Myers Squibb's OPDIVO® (nivolumab) in previously treated patients with advanced biliary tract cancer that enrolled 13 patients who had progressed after one or more lines of systemic therapy for advanced biliary tract cancer. Bristol-Myers Squibb is providing nivolumab drug supply and partial funding for the study.

Esophagogastric Cancer: The Royal Marsden Hospital in the United Kingdom is conducting the WAKING study that is evaluating DKN-01 in combination with Roche's Tecentriq® (atezolizumab) in patients with microsatellite stable esophagogastric cancer. Roche is providing atezolizumab drug supply and funding the study as part of its imCORE network.

Intellectual Property

We strive to protect and enhance the proprietary technology, inventions and improvements that are commercially important to our business, including seeking, maintaining and defending patent rights. We also rely on confidential know-how that may be important to the development of our business. We protect our confidential know-how as trade secrets and through confidentiality agreements and invention assignment agreements with our employees, consultants, scientific advisors and others. We additionally expect to rely on regulatory protection afforded through data exclusivity as well as patent term extensions, where available.

Our commercial success may depend in part on our ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to our business; to defend and enforce our patents; to preserve the confidentiality of our know-how and trade secrets; and to operate without infringing the valid and enforceable patents and proprietary rights of third parties.

Our ability to prevent third parties from making, using, selling, offering to sell or importing competing products to ours, including a competitor to DKN-01, depends on the validity, enforceability and/or scope of our patents. We have several patents and patent applications relating to DKN-01 and its therapeutic uses, and possess substantial know-how relating to the development and commercialization of DKN-01. We cannot be sure that any of our pending patent applications or future patent filings will lead to the issuance of new patents, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will be adequate to protect our market.

We plan on pursuing in-licensing opportunities to develop, strengthen and maintain our proprietary position in our field. We expect to use trademark protection for our products as they are marketed.

Patents

We exclusively license from Eli Lilly and Company, or Lilly, rights under 23 issued patents and 4 pending patent applications, all of which belong to the same patent family. The patents and applications in this patent family are directed to the composition of matter and use of DKN-01, and include (i) one issued U.S. Patent, (ii) issued patents in the following jurisdictions: Argentina, Australia, Canada, China, Eurasia, Europe, Gulf Cooperation Council, India, Israel, Japan, Lebanon, Macao, Mexico, New Zealand, Pakistan, Singapore, South Africa, Taiwan, Ukraine, Hong Kong and South Korea and (iii) pending applications in the following jurisdictions: Brazil, Europe, Venezuela and Thailand. The base 20-year term for patents in this family would expire in 2030. The U.S. patent will expire 87 days after the base term due to patent term adjustment. Patent term extensions for delays in marketing approval may also extend the terms of patents in this family.

We own pending applications directed to the use of a biomarker in patients receiving DKN-01 therapy in the following jurisdictions: Australia, Brazil, Canada, China, Europe, Hong Kong, India, Israel, Japan, Korea, Mexico, New Zealand, Russia, Singapore and the United States. Any patents that may issue in the United States based on the pending U.S. Application will expire in 2037, absent any terminal disclaimer, patent term adjustment due to administrative delays by the USPTO or patent term extension under the Hatch-Waxman Act, and provided that all required maintenance fee payments are timely paid. Any patents that may issue in foreign jurisdictions will likewise expire in 2037, provided that all required annuities are timely paid. We also own two pending international patent applications filed under the Patent Cooperation Treaty (PCT) directed to the treatment of cancer using DKN-01 in specific subpopulations of patients. The PCT is an international patent law treaty that provides a unified procedure for filing a single initial patent application to seek patent protection for an invention simultaneously in each of the member states. Although a PCT application is not itself examined and cannot issue as a patent, it allows the applicant to seek protection in any of the member states through national-phase applications. In the first PCT application, the patient subpopulation is defined by its DKK-1 expression level. In the second PCT application, the patient subpopulation is defined as harboring a specific genetic mutation. Any patents than may issue in the United States based on the pending PCT applications will expire in 2040, absent any terminal disclaimers, patent term adjustment due to administrative delays at the USPTO or patent term extension under the Hatch-Waxman Act, and provided that all required maintenance fee payments are timely paid. Any patents that may issue in foreign jurisdictions will likewise expire in 2040, provided that all required annuities are timely paid.

We have historically been developing a second pipeline product, TRX518, which is a monoclonal antibody that targets the glucocorticoid TNF-family receptor, or GITR. We discontinued the active development of TRX518 in November 2019. We own 67 patents and 5 pending patent applications relating to TRX518 and uses thereof. The patents and applications primarily fall into two families. The base 20-year term for U.S. patents in the first family would expire in 2026 and in the second family would expire in 2028 provided that all required maintenance fee payments are timely paid and no terminal disclaimers are filed. Patent term extensions for delays in marketing approval may also extend the terms of patents in these two families. The various patent applications and patents covering TRX518 include claims directed to compositions of matter (antibodies and antigen-binding fragments), pharmaceutical compositions, methods for inducing or enhancing an immune response, methods of treating a subject having a cancerous tumor, combination therapies, and uses of antibodies and antigen-binding fragments. Patent applications and patents claiming these subject matters have been filed and/or granted in the following jurisdictions: the United States, Australia, Canada, Europe (Austria, Belgium, Denmark, Finland, France, Germany, Ireland, Italy, the Netherlands, Portugal, Spain, Sweden, Switzerland, and the United Kingdom), Hong Kong, India and Japan.

Patent Term

The base term of a U.S. patent is 20 years from the filing date of the earliest-filed non-provisional patent application to which the patent is entitled to priority. The term of a U.S. patent can be lengthened by patent term adjustment, which compensates the owner of the patent for administrative delays at the United States Patent and Trademark Office (USPTO). In some cases, the term of a U.S. patent is shortened by a terminal disclaimer that reduces its term to that of an earlier-expiring U.S. patent.

The term of a U.S. patent may be eligible for patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Act or Hatch-Waxman Amendment, to account for at least some of the time a product is under development and regulatory review after the patent is granted. With regard to a product for which FDA approval is the first permitted marketing of the active ingredient, the Hatch-Waxman Act allows for extension of protection of one U.S. patent that includes at least one claim covering the composition of matter of an FDA-approved product, an FDA-approved method of treatment using the product, and/or a method of manufacturing the FDA-approved product. The extended protection cannot exceed the shorter of five years beyond the non-extended expiration of the patent or 14 years from the date of the FDA approval of the product. Some foreign jurisdictions, including Europe, have patent extension provisions (e.g., supplementary protection certificates), which allow for extension of the protection of a patent that covers a drug approved by the applicable foreign regulatory agency. In the future, if and when DKN-01 receives FDA approval, we expect to apply for patent term extension to extend the protection of one of our U.S. patents covering DKN-01, its use, or a method of manufacturing this product. We also may pursue extensions in foreign jurisdictions where applicable.

Lilly License Agreement

On January 3, 2011, we entered into a license agreement with Lilly (the “Lilly Agreement”), pursuant to which Lilly granted us an exclusive license for certain intellectual property rights relating to pharmaceutically active compounds that may be useful in the treatment of bone healing, cancer and, potentially, other medical conditions. The license includes a right to sublicense, under certain Lilly intellectual property rights to further develop and commercialize, on a worldwide basis, pharmaceutical products containing such licensed compounds.

Pursuant to the Lilly Agreement, we granted to Lilly 657,614 shares of common stock and agreed to pay Lilly a royalty in the low single digits of net sales of a particular product in the territory during the applicable royalty term, with certain adjustments to be made to the royalty rate in connection with third person intellectual property, sales of competing products, and sales of biosimilar or generic products. We have not yet paid any royalties to Lilly pursuant to this agreement.

The royalty term, with respect to each country in which a product is sold, on a country-by-country and product-by-product basis, begins on first commercial sale of the product in the country and the later of (i) the tenth anniversary of the first date of commercial sale of the product in the country, (ii) expiration of the last-to-expire issued patent included within the patents licensed under the Lilly Agreement having a valid claim covering the sale of the product, and (iii) the expiration of any data exclusivity period for the product in the country.

The term of the Lilly Agreement began on January 3, 2011 and, unless earlier terminated pursuant to the termination provisions described below, will continue on a country-by-country basis until we have no remaining royalty or other payment obligations in a specific country. Upon expiration in a given country, the licenses granted with respect to such country shall become fully paid up, perpetual and irrevocable.

Either party may terminate the Lilly Agreement with immediate effect if the other party enters into bankruptcy or takes similar action. We may terminate the Lilly Agreement (i) at any time without cause upon ninety (90) days written notice to Lilly or (ii) upon material breach of the Lilly Agreement by Lilly upon ninety (90) days written notice to Lilly, unless Lilly cures such breach or violation during such ninety (90) day period. Lilly may terminate the agreement (i) upon our material breach of the Lilly Agreement upon ninety (90) days written notice to us, unless we cure such breach or violation during such ninety day period or (ii) if we challenge, or materially assist any third person to challenge, the validity or enforceability of the licensed intellectual property that is the subject of the Lilly Agreement upon thirty (30) days written notice to us, unless we cure such breach or violation during such thirty (30) day period.

If Lilly terminates the Lilly Agreement or if we terminate the Lilly Agreement without cause, (i) all rights under the licensed intellectual property rights will terminate and immediately and automatically revert to Lilly, (ii) any sublicense will be assigned by us to Lilly so that such sublicense becomes a direct license between Lilly and such sublicensee, (iii) subject to certain limitations, we will be required to grant to Lilly an irrevocable, non-exclusive, perpetual, fully paid up license under all patent rights developed or acquired by us during the term of the Lilly Agreement that relate to the Lilly licensed intellectual property, (iv) subject to certain limitations, we will be required to grant to Lilly an irrevocable, non-exclusive, perpetual, fully paid up license to the results of data from all preclinical and clinical studies of any compound or product covered by the Lilly Agreement, (v) subject to certain limitations, we will be required to take all steps necessary to permit Lilly to commence marketing product covered by the Lilly Agreement, and (vi) we will be required to assign or re-assign to Lilly all Lilly patents covered by the Lilly Agreement and that were assigned by Lilly to us. If we terminate the Lilly Agreement for material breach by Lilly or Lilly’s bankruptcy, the licenses will remain in full force and effect and we will remain liable for the payment of all royalty obligations under the Lilly Agreement. However, in this case, we may offset against such royalties any damages that we are entitled to for breach of the Lilly Agreement by Lilly.

The Lilly Agreement also contains certain standard representations and warranties and certain standard confidentiality and indemnification provisions.

Lonza License Agreement

On May 28, 2015, we entered into a license agreement with Lonza Sales AG (the “Lonza Agreement”), pursuant to which Lonza granted us a world-wide, non-exclusive license for certain intellectual property rights relating to a gene expression system, solutions of nutrients used in mammalian cell culture and related know-how and patent rights to use, test, develop, manufacture, market, sell offer for sale, distribute, import and export DKN-01. Such license includes a right to sublicense to (i) a competing contract manufacturer solely for the purpose of such manufacturer producing DKN-01 and (ii) our affiliates and strategic partners solely for undertaking commercial activities.

In exchange for the license and sublicense described above, we agreed to pay to Lonza a low single-digit royalty calculated as a percentage of net sales on DKN-01. In addition, in connection with DKN-01 manufactured by Lonza, or a strategic partner of Lonza, we agreed to pay (i) an annual payment to Lonza beginning on the date of initiation of phase 1 clinical trials for DKN-01 and (ii) an increased annual payment to Lonza beginning on the date of initiation of phase 2 clinical trials for DKN-01, for so long as Lonza, or a strategic partner of Lonza, manufactures DKN-01. In connection with DKN-01 manufactured by any other party, we agreed to pay (i) an annual amount to Lonza per sublicense beginning on the commencement date of such sublicense and continuing for so long as the sublicense exists and (ii) a low single-digit royalty calculated as a percentage of net sales of DKN-01. All royalty amounts are subject to certain adjustments if, on a country-by-country basis, the manufacture and/or sale of DKN-01 are not protected by a valid claim. All royalty obligations will expire on a country-by-country basis upon the later of (i) the expiration, revocation or complete rejection of all valid claims covering product in such country or (ii) ten (10) years from first commercial sale of DKN-01 in such country.

The Lonza Agreement will remain in force in each country of the world until either the expiration of the last valid patent claim or for so long as the know-how is identified and remains secret and substantial, whichever is later. Upon expiration of the Lonza Agreement with respect to DKN-01 in a particular country, the licenses granted under the Lonza Agreement with respect to DKN-01 in that country will become fully paid and royalty free.

Either party may terminate the Lonza Agreement (i) if the other party commits a breach of the Lonza Agreement and such breach is not cured within forty-five (45) days of receiving notice of the breach (or thirty (30) days in the case of payment defaults) or (ii) if the other party is unable to pay its debts and enters into compulsory or voluntary liquidation or enters into a bankruptcy or takes other similar action. We may terminate the Lonza Agreement by giving sixty (60) days written notice to Lonza. Lonza may, at its option, immediately terminate any or all of the licenses granted under the Lonza Agreement if we knowingly oppose any patent application within the patent rights granted or dispute the validity of any patent within under the Lonza Agreement or assist any third party to do so. Termination of the Lonza Agreement will terminate all licenses granted under the Lonza Agreement.

The Lonza Agreement also contains certain standard confidentiality and indemnification provisions.

Competition

The biotechnology and pharmaceutical industries are characterized by continuing technological advancement and significant competition. While we believe that our product candidates, technology, knowledge, experience and scientific resources provide us with competitive advantages, we face competition from major pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions, among others. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. Key product features that would affect our ability to effectively compete with other therapeutics include the efficacy, safety and convenience of our products and the ease of use and effectiveness of any companion diagnostics. The level of generic competition and the availability of reimbursement from government and other third-party payors will also significantly affect the pricing and competitiveness of our products. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

Many of the companies against which we may compete 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. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. For example, Novartis, Merck, Amgen, and Pfizer are all currently developing or have previously been developing anti-DKK1 monoclonal antibodies. 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.

Manufacturing and Distribution

We do not have, and we do not currently plan to acquire or develop, the facilities or capabilities to manufacture clinical trial material for use in human clinical trials or finished drug product for commercialization. We depend on third-party contract manufacturers, or CMOs, for the production of clinical trial material for our studies. Our bulk drug substance, or DS, is produced at our CMO, Patheon Biologics, which is required to comply with the FDA's Current Good Manufacturing Practice, or cGMP, regulations. Our finished drug product is produced at a contract fill/finisher provider, which is also required to comply with cGMP regulations. We have personnel with significant technical, manufacturing, analytical, quality and project management experience to oversee our third-party CMOs and to manage manufacturing and quality data and information for regulatory compliance purposes.

We must manufacture drug product for clinical trial use in compliance with cGMP regulations. The cGMP regulations include requirements relating to organization of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports, and returned or salvaged products. Our third-party CMOs are also subject to periodic inspections of facilities by the FDA and other authorities, including procedures and operations used in the testing and manufacture of our products to assess our compliance with applicable regulations. Failure to comply with statutory and regulatory requirements subjects a manufacturer to possible legal or regulatory action, including warning letters, the seizure or recall of products, injunctions, consent decrees placing significant restrictions on or suspending manufacturing operations and civil and criminal penalties. These actions could have a material impact on the availability of our products. CMOs often encounter difficulties involving production yields, quality control and quality assurance, as well as shortages of qualified personnel.

We have not yet established a sales, marketing or product distribution infrastructure because our lead candidates are still in clinical development. We eventually may, however, choose to build (or obtain through strategic acquisition) our own sales and marketing team to commercialize some or all of our products if they receive FDA approval and if it is in our long-term interests. We have entered into an Option and License Agreement with BeiGene pursuant to which BeiGene has the right to manufacture and commercialize DKN-01 in Asia (excluding Japan), Australia, and New Zealand. We may choose to enter into distribution agreements with strategic partners with their own robust distribution channels for the United States, Europe, Japan, and other non-BeiGene territories.

Government Regulation and Product Approval

Government authorities in the United States, at the federal, state, and local level, and in other countries, extensively regulate, among other things, the research, development, testing, approval, manufacture, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, post-approval monitoring and reporting, marketing, import, and export of biopharmaceutical products such as those we are developing. In addition, manufacturers of biopharmaceutical products participating in Medicaid and Medicare are required to comply with mandatory price reporting, discount, and rebate requirements. The processes for obtaining regulatory approvals in the United States and in foreign countries, along with subsequent compliance with applicable statutes and regulations, require the expenditure of substantial time and financial resources. The following is a summary of the primary government regulations applicable to our business.

FDA Regulation

In the United States, the FDA regulates biologics under the Federal Food, Drug, and Cosmetic Act, or FDCA, the Public Health Services Act, or PHSA, and their implementing regulations. Any product we may develop must be cleared by the FDA before it is marketed in the United States. The process required by the FDA before product candidates may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests, animal studies, and formulation studies in compliance with the FDA's Good Laboratory Practice, or GLP, regulations;

- submission to the FDA of an Investigational New Drug application, or IND, which must become effective before human clinical trials may begin;
- approval by an Institutional Review Board, or IRB, for each clinical site, or centrally, before each trial may be initiated;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed product candidates for its intended use, performed in accordance with GCPs;
- development of manufacturing processes to ensure the product candidate’s identity, strength, quality, and purity;
- submission to the FDA of a Biologics License Application, or BLA;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the products are produced to assess compliance with cGMPs, and to assure that the facilities, methods, and controls are adequate to preserve the therapeutic’s identity, strength, quality, and purity, as well as satisfactory completion of an FDA inspection of selected clinical sites and selected clinical investigators to determine GCP compliance; and
- FDA review and approval of the BLA to permit commercial marketing for particular indications for use.

Preclinical Studies and IND Submission

The testing and approval process of product candidates requires substantial time, effort, and financial resources. Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity, and novelty of the product or disease. Preclinical studies include laboratory evaluation of chemistry, pharmacology, toxicity, and product formulation, as well as animal studies to assess potential safety and efficacy. Such studies must generally be conducted in accordance with the FDA’s GLPs. Prior to commencing the first clinical trial with a product candidate, an IND sponsor must submit the results of the preclinical tests and preclinical literature, together with manufacturing information, analytical data, any available clinical data or literature, and proposed clinical study protocols among other things, to the FDA as part of an IND.

An IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, notifies the applicant of safety concerns or questions related to one or more proposed clinical trials and places the trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Clinical holds also may be imposed by the FDA at any time before or during trials due to safety concerns or non-compliance. As a result, submission of an IND may not result in FDA authorization to commence a clinical trial. A separate submission to an existing IND must also be made for each successive clinical trial conducted during product development.

Clinical Trials

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with federal regulations and GCP requirements, which include the requirements that all research subjects provide their informed consent in writing for their participation in any clinical trial, as well as review and approval of the study by an IRB. Investigators must also provide certain information to the clinical trial sponsors to allow the sponsors to make certain financial disclosures to the FDA. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, the trial procedures, the parameters to be used in monitoring safety, the effectiveness criteria to be evaluated, and a statistical analysis plan. A protocol for each clinical trial, and any subsequent protocol amendments, must be submitted to the FDA as part of the IND. In addition, an IRB at each study site participating in the clinical trial or a central IRB must review and approve the plan for any clinical trial, informed consent forms, and communications to study subjects before a study commences at that site. An IRB considers, among other things, whether the risks to individuals participating in the trials are minimized and are reasonable in relation to anticipated benefits and whether the planned human subject protections are adequate. The IRB must continue to oversee the clinical trial while it is being conducted. Once an IND is in effect, each new clinical protocol and any amendments to the protocol must be submitted to the IND for FDA review, and to the IRB for approval. Progress reports detailing the results of the clinical trials must also be submitted at least annually to the FDA and the IRB and more frequently if serious adverse events or other significant safety information is found.

The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements or if the trial poses an unexpected serious harm to subjects, or may impose other conditions. We may also discontinue clinical trials as a result of risks to subjects, a lack of favorable results, or changing business priorities.

Information about certain clinical trials, including a description of the study and study results, must be submitted within specific timeframes to the National Institutes of Health, or NIH, for public dissemination on their clinicaltrials.gov website.

Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group regularly reviews accumulated data and advises the study sponsor regarding the continuing safety of trial subjects, potential trial subjects, and the continuing validity and scientific merit of the clinical trial. The data safety monitoring board receives special access to unblinded data during the clinical trial and may advise the sponsor to halt the clinical trial if it determines there is an unacceptable safety risk for subjects or on other grounds, such as no demonstration of efficacy.

The manufacture of investigational biologics for the conduct of human clinical trials is subject to cGMP requirements. Investigational biologics and active ingredients imported into the United States are also subject to regulation by the FDA relating to their labeling and distribution. Further, the export of investigational products outside of the United States is subject to regulatory requirements of the receiving country as well as U.S. export requirements under the FDCA.

In general, for purposes of BLA approval, human clinical trials are typically conducted in three sequential phases, which may overlap or be combined.

- *Phase 1* — Studies are initially conducted in healthy human volunteers or subjects with the target disease or condition and test the product candidate for safety, dosage tolerance, target engagement, mechanism of action, absorption, metabolism, distribution, and excretion. If possible, Phase 1 trials may also be used to gain an initial indication of product effectiveness.
- *Phase 2* — Controlled studies are conducted in limited subject populations with a specified disease or condition to evaluate preliminary efficacy, identify optimal dosages, dosage tolerance and schedule, possible adverse effects and safety risks, and expanded evidence of safety.
- *Phase 3* — These adequate and well-controlled clinical trials are undertaken in expanded subject populations, generally at geographically dispersed clinical trial sites, to generate enough data to provide statistically significant evidence of clinical efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product, and to provide adequate information for the labeling of the product. Typically, two Phase 3 trials are required by the FDA for product approval.

The FDA may also require, or companies may conduct, additional clinical trials for the same indication after a product is approved. These so-called Phase 4 studies may be made a condition to be satisfied after approval. The results of Phase 4 studies can confirm the effectiveness of a product candidate and can provide important safety information.

Phase 1, Phase 2, and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. Regulatory authorities, an IRB, or the sponsor may suspend or discontinue a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk, the clinical trial is not being conducted in accordance with the FDA's or the IRB's requirements, the product has been associated with unexpected serious harm to the subjects, or based on evolving business objectives or competitive climate.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product candidate 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 product candidate and, among other things, must develop methods for testing the identity, strength, quality, potency, and purity of the final product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

During the development of a new therapeutic, a sponsor may be able to request a Special Protocol Assessment, or SPA, the purpose of which is to reach agreement with the FDA on the Phase 3 clinical trial protocol design and analysis that will form the primary basis of product approval and an efficacy claim as well as preclinical carcinogenicity trials and stability studies. An SPA may only be modified with the agreement of the FDA and the trial sponsor, or if the director of the FDA reviewing division determines that a substantial scientific issue essential to determining the safety or efficacy of the product was identified after the testing began. An SPA is intended to provide assurance that, in the case of clinical trials, if the agreed upon clinical trial protocol is followed, the clinical trial endpoints are achieved, and there is a favorable risk-benefit profile, the data may serve as the primary basis for an efficacy claim in support of a BLA. However, SPA agreements are not a guarantee of an approval of a product candidate or any permissible claims about the product candidate. In particular, SPAs are not binding on the FDA if, among other reasons, previously unrecognized public health concerns arise during the performance of the clinical trial, other new scientific concerns regarding the product candidate’s safety or efficacy arise, or if the sponsoring company fails to comply with the agreed upon clinical trial protocol.

BLA Submission, Review by the FDA, and Marketing Approval

Assuming successful completion of the required clinical and preclinical testing, the results of product development, including chemistry, manufacture, and controls, non-clinical studies, and clinical trial results, including negative or ambiguous results as well as positive findings, are all submitted to the FDA, along with the proposed labeling, as part of a BLA requesting approval to market the product for one or more indications. In most cases, the submission of a BLA is subject to a substantial application user fee. These user fees must be paid at the time of the first submission of the application, even if the application is being submitted on a rolling basis. Fee waivers or reductions are available in certain circumstances. One basis for a waiver of the application user fee is if the applicant employs fewer than 500 employees, including employees of affiliates, the applicant does not have an approved marketing application for a product that has been introduced or delivered for introduction into interstate commerce, and the applicant, including its affiliates, is submitting its first marketing application. Product candidates that are designated as orphan drugs, which are further described below, are also not subject to application user fees unless the application includes an indication other than the orphan indication.

In addition, under the Pediatric Research Equity Act, or PREA, a BLA or supplement to a BLA for a new active ingredient, indication, dosage form, dosage regimen, or route of administration, must contain data that are adequate to assess the safety and effectiveness of the product 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, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements.

The FDA also may require submission of a risk evaluation and mitigation strategy, or REMS, to ensure that the benefits of the biologic outweigh the risks. The REMS plan could include medication guides, physician communication plans, and elements to assure safe use, such as restricted distribution methods, patient registries, or other risk minimization tools. An assessment of the REMS must also be conducted at set intervals. Following product approval, a REMS may also be required by the FDA if new safety information is discovered and the FDA determines that a REMS is necessary to ensure that the benefits of the biologic outweigh the risks.

Once the FDA receives an application, it has 60 days to review the BLA to determine if it is substantially complete to permit a substantive review, before it accepts the application for filing. The FDA may request additional information rather than accept a BLA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review.

Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act, or PDUFA, the FDA has set the review goal of completing its review of 90% of all applications within ten months from the 60-day filing date for its initial review of an initial BLA. Such deadlines are referred to as the PDUFA date. The PDUFA date is only a goal, thus, the FDA does not always meet its PDUFA dates. The review process and the PDUFA date may also be extended if the FDA requests or the sponsor otherwise provides substantial additional information or clarification regarding the submission.

The FDA may also refer certain applications to an advisory committee. An advisory committee is typically a panel that includes clinicians and other experts, which reviews, evaluate, and make 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.

The FDA reviews applications to determine, among other things, whether a product is safe, pure and potent and whether the manufacturing methods and controls are adequate to assure and preserve the product’s identity, strength, quality, safety, potency, and purity. Before approving a BLA, the FDA typically will inspect the facility or facilities where the product is manufactured, referred to as a Pre-Approval Inspection. The FDA will not approve an application unless it determines that the manufacturing processes and facilities, including contract manufacturers and subcontractors, are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will inspect one or more clinical trial sites to assure compliance with GCPs.

The approval process is lengthy and difficult, and the FDA may refuse to approve a BLA if the applicable regulatory criteria are not satisfied or may require additional clinical data or other data and information. Even if such data and information are submitted, the FDA may ultimately decide that the 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 an applicant interprets the same data.

After evaluating the BLA and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter, or, in some cases, a Complete Response Letter, or CRL. If a CRL is issued, the applicant may either: resubmit the BLA, addressing all of the deficiencies identified in the letter; withdraw the application; or request an opportunity for a hearing. A CRL indicates that the review cycle of the application is complete, and the application is not ready for approval and describes all of the specific deficiencies that the FDA identified in the BLA. A CRL generally contains a statement of specific conditions that must be met in order to secure final approval of the BLA and may require additional clinical or preclinical testing in order for the FDA to reconsider the application. The deficiencies identified may be minor, for example, requiring labeling changes; or major, for example, requiring additional clinical trials. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA’s satisfaction, the FDA may issue an approval letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications.

Even if the FDA approves a product, it may limit the approved indications for use of the product, require that contraindications, warnings, or precautions be included in the product labeling, including a boxed warning, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess a product’s safety and efficacy after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms under a REMS which can materially affect the potential market and profitability of the product. The FDA may also not approve label statements that are necessary for successful commercialization and marketing.

After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes, and additional labeling claims, are subject to further testing requirements and FDA review and approval. The FDA may also withdraw the product approval if compliance with the pre- and post-marketing regulatory standards are not maintained or if problems occur after the product reaches the marketplace. Further, should new safety information arise, additional testing, product labeling, or FDA notification may be required.

Biosimilars, Orphan Drugs, and Exclusivity

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, creates an abbreviated approval pathway for biological products shown to be highly similar to or interchangeable with an FDA-licensed reference biological product. Biosimilarity sufficient to reference a prior FDA-approved product requires a high similarity to the reference product notwithstanding minor differences in clinically inactive components, and no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency. Biosimilarity must be shown through analytical studies, animal studies, and at least one clinical trial, absent a waiver by the FDA. There must be no difference between the reference product and a biosimilar product in conditions of use, route of administration, dosage form, and strength. A biosimilar product may be deemed interchangeable with a prior approved product if it meets the higher hurdle of demonstrating that it can be expected to produce the same clinical results as the reference product and, for products administered multiple times, the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. Complexities associated with the larger, and often more complex, structures of biological products, as well as the process by which such products are manufactured, pose significant hurdles to implementation which are still being evaluated by the FDA.

A reference biologic is granted 12 years of exclusivity from the time of first licensure of the reference product, and no application for a biosimilar can be submitted for four years from the date of licensure of the reference product. However, certain changes and supplements to an approved BLA, and subsequent applications filed by the same sponsor, manufacturer, licensor, predecessor in interest, or other related entity do not qualify for the twelve-year exclusivity period.

The Orphan Drug Act provides incentives for the development of products intended to treat rare diseases or conditions, which generally are diseases or conditions affecting less than 200,000 individuals annually in the United States, or affecting more than 200,000 in the United States and for which there is no reasonable expectation that the cost of developing and making the product available in the United States will be recovered from United States sales. Additionally, sponsors must present a plausible hypothesis for clinical superiority to obtain orphan designation if there is a product already approved by the FDA that is intended for the same indication and that is considered by the FDA to be the same as the already approved product. This hypothesis must be demonstrated to obtain orphan exclusivity. If granted, prior to product approval, Orphan Designation entitles a party to financial incentives such as opportunities for grant funding towards clinical study costs, tax advantages, and user-fee waivers. In addition, if a product receives FDA approval for the indication for which it has orphan designation, the product is generally entitled to orphan exclusivity, which means the FDA may not approve any other application to market the same product for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity.

Special FDA Expedited Review and Approval Programs

The FDA has various programs, including Fast Track designation, priority review, and breakthrough designation, that are intended to expedite or simplify the process for the development and FDA review of certain products that are intended for the treatment of serious or life threatening diseases or conditions, and demonstrate the potential to address unmet medical needs or present a significant improvement over existing therapy. The purpose of these programs is to provide important new therapeutics to patients earlier than under standard FDA review procedures.

To be eligible for a Fast Track designation, the FDA must determine, based on the request of a sponsor, that a product is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address an unmet medical need. The FDA will determine that a product will fill an unmet medical need if the product will provide a therapy where none exists or provide a therapy that may be potentially superior to existing therapies based on efficacy, safety, or public health factors. If Fast Track designation is obtained, sponsors may be eligible for more frequent development meetings and correspondence with the FDA. In addition, the FDA may initiate reviews of certain sections of an application before the application is complete. This “rolling review” is available if the applicant provides and the FDA approves a schedule for the remaining information. In some cases, a Fast Track product may be eligible for accelerated approval or priority review. On September 24, 2020 the FDA granted Fast Track designation to DKN-01 for the treatment of patients with gastric and gastroesophageal junction adenocarcinoma whose tumors express high DKK1, following disease progression on or after prior fluoropyrimidine- and platinum- containing chemotherapy and if appropriate, human epidermal receptor growth factor (HER2)/neu-targeted therapy.

The FDA may give a priority review designation to products that are intended to treat serious conditions and, if approved, would provide significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions. A priority review means that the goal for the FDA is to review an application within six months, rather than the standard review of ten months under current PDUFA guidelines, of the 60-day filing date.

Drug or biological products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval, which means the FDA may approve the product based upon a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. A drug or biologic candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, will allow the FDA to withdraw the drug or biologic from the market on an expedited basis. All promotional materials for drug or biologic candidates approved under accelerated regulations are subject to prior review by the FDA.

Moreover, under the provisions of the Food and Drug Administration Safety and Innovation Act, or FDASIA, enacted in 2012, a sponsor can request designation of a product candidate as a “breakthrough therapy”. A breakthrough therapy is defined as a product that is intended, alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Products designated as breakthrough therapies are eligible for the Fast Track designation features as described above, intensive guidance on an efficient development program beginning as early as Phase 1 trials, and a commitment from the FDA to involve senior managers and experienced review staff in a proactive collaborative, cross-disciplinary review.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Post-approval Requirements

Any products manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements related to manufacturing, recordkeeping, and reporting, including adverse experience reporting, shortage reporting, and periodic reporting, product sampling and distribution, advertising, marketing, promotion, certain electronic records and signatures, and post-approval obligations imposed as a condition of approval, such as Phase 4 clinical trials, REMS, and surveillance to assess safety and effectiveness after commercialization.

After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data. In addition, manufacturers and other entities involved in the manufacture and distribution of approved therapeutics are required to register their establishments with the FDA and certain state agencies, list their products, and are subject to periodic announced and unannounced inspections by the FDA and these state agencies for compliance with cGMP and other requirements, which impose certain procedural and documentation requirements upon a company and its third-party manufacturers. Manufacturers must continue to expend time, money, and effort in the areas of production and quality-control to maintain compliance with cGMPs. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered.

Changes to the manufacturing process are strictly regulated and often require prior FDA approval or notification before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and specifications, and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

Moreover, the enacted Drug Quality and Security Act, or DQSA, imposes obligations on manufacturers of biopharmaceutical products related to product tracking and tracing. Among the requirements of this legislation, manufacturers are required to provide certain information regarding the products to individuals and entities to which product ownership is transferred, will be required to label products with a product identifier, and are required to keep certain records regarding the product. The transfer of information to subsequent product owners by manufacturers will eventually be required to be done electronically. Manufacturers must also verify that purchasers of the manufacturers’ products are appropriately licensed. Further, under this legislation, manufacturers will have product investigation, quarantine, disposition, and notification responsibilities related to counterfeit, diverted, stolen, and intentionally adulterated products that would result in serious adverse health consequences of death to humans, as well as products that are the subject of fraudulent transactions or which are otherwise unfit for distribution such that they would be reasonably likely to result in serious health consequences or death. Similar requirements additionally are and will be imposed through this legislation on other companies within the biopharmaceutical product supply chain, such as distributors and dispensers.

Adverse event reporting and the submission of periodic reports, including annual reports and deviation reports, are required following FDA approval of a BLA. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in significant regulatory actions. Such actions may include refusal to approve pending applications, license suspension or revocation, withdrawal of an approval, imposition of a clinical hold or termination of clinical trials, warning letters, untitled letters, cyber letters, modification of promotional materials or labeling, provision of corrective information, imposition of post-market requirements including the need for additional testing, imposition of distribution or other restrictions under a REMS, product recalls, product seizures or detentions, refusal to allow imports or exports, total or partial suspension of production or distribution, FDA debarment, injunctions, fines, consent decrees, corporate integrity agreements, debarment from receiving government contracts, and new orders under existing contracts, exclusion from participation in federal and state healthcare programs, restitution, disgorgement, or civil or criminal penalties, including fines and imprisonment, and result in adverse publicity, among other adverse consequences.

Other Regulation

In addition to any FDA restrictions on marketing and promotion of drugs and devices, other federal and state laws restrict our business practice including, without limitation, anti-kickback and false claims laws, data privacy and security laws, as well as transparency laws regarding payment or other items of value provided to healthcare providers. Future legislative proposals to reform healthcare may also impact us.

We are also governed by other federal, state and local laws of general applicability, such as laws regulating working conditions, employment practices, as well as environmental protection.

Research and Development Expenses

Our total research and development expenses were $20.4 million and $24.4 million, during the years ended December 31, 2020 and 2019, respectively. See Part II — Item 7 — “Management’s Discussion and Analysis of Financial Condition and Results of Operations” of this Annual Report on Form 10-K for additional detail regarding our research and development activities.

Employees

As of December 31, 2020, we had 30 full-time employees, including 20 in research and development and ten in general and administrative roles. None of our employees are represented by a labor union or subject to a collective bargaining agreement. We have not experienced a work stoppage and consider our relations with our employees to be good.

Web Availability

We make available free of charge through our website, www.leaptx.com, our Annual Report on Form 10-K, other reports that we file with the Securities and Exchange Commission and any amendments to the reports filed or furnished pursuant to Sections 13(a) and 15(d) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), as well as certain of our corporate governance policies, including the charters for the audit, compensation and nominating and governance committees of our board of directors and our code of ethics and corporate governance guidelines. We make these reports available as soon as reasonably practicable after they are filed with or furnished to the SEC. The information contained on, or that can be accessed through our website is not a part of or incorporated by reference into this Annual Report on Form 10-K. We will also provide to any person without charge, upon request, a copy of any of the foregoing materials. Any such request must be made in writing to us at: Leap Therapeutics, Inc. c/o Investor Relations, 47 Thorndike Street, Suite B1, Cambridge, MA 02141.

Item 1A. Risk Factors.

The following risk factors and other information included in this Annual Report on Form 10-K should be carefully considered. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we presently deem less significant may also impair our business operations. Please see the "Special Note Regarding Forward-Looking Statements and Industry Data" at the beginning of this Annual Report on Form 10-K for a discussion of some of the forward-looking statements that are qualified by these risk factors. If any of the following risks occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected.

Risks Related to Leap's Financial Position and Capital Needs

We have incurred significant losses since our inception and anticipate that we will continue to incur losses in the future.

We are a clinical-stage biopharmaceutical company with a limited operating history on which to base your investment decision. Investment in our biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that our lead product candidate, DKN-01, or any other products will fail to gain regulatory approval or become commercially viable. We do not currently have any products approved by regulatory authorities for marketing and have not generated any revenue from product sales. We have incurred significant research, development and other expenses related to our ongoing operations.

As a result, we have not been profitable to date and have incurred losses in every reporting period since our inception in 2011. For the year ended December 31, 2020, we reported a net loss of $27.5 million, and had an accumulated deficit of $223.0 million at December 31, 2020.

We expect to continue to incur significant expenses and operating losses for the foreseeable future. We anticipate these losses to increase as we continue the research and development of, and seek regulatory approvals for DKN-01, and as we potentially begin to commercialize DKN-01, if it receives regulatory approval. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenues. If DKN-01 fails in clinical trials or does not gain regulatory approval, or if approved, fails to achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods.

The timing of the milestone and royalty payments we may be entitled to receive from BeiGene, Ltd. is uncertain and could adversely affect our cash flows and results of operations.

In January 2020, we entered into an option and license agreement, or the BeiGene Agreement, with BeiGene, Ltd., or BeiGene, pursuant to which we granted BeiGene the option to develop and commercialize DKN-01 in Asia (excluding Japan), Australia and New Zealand (the "BeiGene Territory"). We may be entitled to receive additional payments upon the exercise of BeiGene's option and the achievement of certain milestones and royalties upon BeiGene's sales of DKN-01. The receipt of these payments is inherently uncertain. There can be no assurance that we will receive any future milestone or royalty payments from BeiGene.

We currently have no source of product revenue and may never become profitable.

We have not generated any product revenues, and we have no commercial products. Our ability to generate revenue from product sales and achieve profitability will depend upon our ability to successfully gain regulatory approval and commercialize DKN-01 or other product candidates that we may in-license or acquire in the future. Even if we are able to successfully achieve regulatory approval, we do not know when we will generate revenue from product sales, if at all. Our ability to generate revenue from product sales from any product candidates also depends on a number of additional factors, including but not limited to, our ability to:

- initiate and successfully complete development activities, including enrollment of study participants and completion of the necessary clinical trials;
- complete and submit new drug applications, or NDAs, or biologics license applications, or BLAs, to the FDA and obtain regulatory approval for indications for which there is a commercial market;
- complete and submit applications to, and obtain regulatory approval from, foreign regulatory authorities;
- make or have made commercial quantities of our products at acceptable cost levels;
- develop a commercial organization capable of manufacturing, sales, marketing and distribution for any products we intend to sell ourselves in the markets in which we choose to commercialize on our own; and
- obtain adequate pricing, coverage and reimbursement from third parties, including government and private payors.

In addition, because of the numerous risks and uncertainties associated with product development, including that DKN-01 may not advance through development or achieve the endpoints of applicable clinical trials, we are unable to predict the timing or amount of increased expenses, or when or if we will be able to achieve or maintain profitability.

We will require additional capital to fund our operations and if we fail to obtain necessary financing, we may be unable to complete the development and potential commercialization of DKN-01 or acquire other products.

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts to advance the clinical development of DKN-01 and launch and commercialize our product candidates, if we receive regulatory approval. We will require additional capital for further development and potential commercialization. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.

We believe that our cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months from the date of this filing. We have based this estimate on assumptions that may prove to be wrong, and we could deploy our available capital resources sooner than we currently expect. Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to the:

- initiation, progress, timing, costs and results of pre-clinical studies and clinical trials for our product candidates;
- costs and timing of additional clinical trial and commercial manufacturing activities;
- clinical development plans we establish for DKN-01 and any other future product candidates;
- number and characteristics of any new product candidates that we in-license and develop;
- outcome, timing and cost of regulatory review by the FDA and comparable foreign regulatory authorities, including the potential for the FDA or comparable foreign regulatory authorities to require that we perform more studies than those that we currently expect;
- costs of filing, prosecuting, defending and enforcing any patent claims and maintaining and enforcing other intellectual property rights;
- effect of competing product candidates and market developments; and
- costs and timing of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval.

If we are unable to fund our operations or otherwise capitalize on our business opportunities due to a lack of capital, our ability to become profitable will be compromised.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our product candidates.

Until we can generate substantial revenue from product sales, if ever, we expect to seek additional capital through a combination of private and public equity offerings, debt financings, strategic collaborations and alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of existing stockholders will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of existing stockholders. If we are unable to raise additional funds through equity or debt financing when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts or grant rights to develop and market our product candidates that we would otherwise prefer to develop and market ourselves. If we raise additional funds through strategic collaborations and alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates in particular countries, or grant licenses on terms that are not favorable to us.

Risks Related to Our Business and Industry

The ongoing outbreak of the Coronavirus could have a material adverse impact on our business and operations, including on our development of our lead product candidate, DKN-01.

As a result of the continuing novel Coronavirus outbreak, or COVID-19, we may experience disruptions that could severely affect our business, including our plans to clinically develop DKN-01, our lead product candidate. For example, our employees are all currently working remotely from our office and unable to work and collaborate physically in person. In addition, widespread business interruptions resulting from the novel Coronavirus may adversely affect our ability to initiate, conduct, and complete critical clinical trials and laboratory operations relating to DKN-01. Specifically, temporary closures or prioritization of COVID-19 related work at certain laboratories, offices, or hospitals at which our nonclinical studies and clinical trials for DKN-01 are conducted, or restrictions on the ability of our employees, clinicians, patients enrolled in our trials, or patients who we would like to recruit to enroll in our trials to travel to or enter into certain facilities due to COVID-19 could adversely affect our operations and our ability to conduct nonclinical studies and clinical trials for DKN-01. Further, governmental health protocols and mandates have restricted the ability of many businesses to operate normally. These measures may have a material adverse impact on the third parties with whom we collaborate, including our clinical trial sites, contract research organizations, contract manufacturing organizations, laboratory service providers, or BeiGene., and on their ability to devote sufficient time and resources to us. This could negatively affect our ability to advance DKN-01 and cause delays and increased expenses in our projected development timelines and cost.

We are continuing to monitor and assess the real and potential effects of the COVID-19 pandemic on our business, including with respect to our development of DKN-01. However, the ultimate extent to which the novel Coronavirus impacts our business will depend upon future developments which are highly uncertain and cannot be accurately predicted at this time, such as the ultimate geographic spread of the virus, the severity of the disease, the duration of the current outbreak or subsequent outbreaks, travel restrictions, actions to contain the outbreak or mitigate its impact, and the effectiveness of other actions taken in the United States and other countries to treat the disease.

The failure to maintain the BeiGene Agreement or the failure of BeiGene to perform its obligations under the BeiGene Agreement could negatively impact our business.

Pursuant to the terms of the BeiGene Agreement, we granted to BeiGene the right to an exclusive license to develop, manufacture and commercialize DKN-01 in the BeiGene Territory. We have limited control over the amount and timing of resources that BeiGene will dedicate to these efforts or BeiGene’s decision whether and when to exercise its option. We are subject to a number of other risks associated with our dependence on the BeiGene Agreement with respect to DKN-01 in the BeiGene Territory, including:

- BeiGene may not comply with applicable regulatory guidelines with respect to developing, manufacturing or commercializing DKN-01, which could adversely impact sales or future development of DKN-01 in the BeiGene Territory or elsewhere;

- We and BeiGene could disagree as to future development plans and BeiGene may delay, fail to commence or stop future clinical trials or other development;
- There may be disputes between us and BeiGene, including disagreements regarding the BeiGene Agreement, that may result in (1) the delay of or failure to achieve developmental, regulatory and commercial objectives that would result in milestone or royalty payments, (2) the delay or termination of any future development or commercialization of sitravatinib in the BeiGene Territory, and/or (3) costly litigation or arbitration that diverts our management's attention and resources;
- Business combinations or significant changes in BeiGene's business strategy may adversely affect BeiGene's ability or willingness to exercise its option or perform its obligations under the BeiGene Agreement; and
- BeiGene may not properly defend our intellectual property rights, or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property rights or expose us to potential litigation.

The BeiGene Agreement is also subject to BeiGene's right to terminate without cause upon advance notice to us. If the agreement is terminated early, we may not be able to find another collaborator for the further development and commercialization of DKN-01 in the BeiGene Territory on acceptable terms, or at all, and we may be unable to pursue continued development and commercialization of DKN-01 in the BeiGene Territory on our own.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process.

The results of preclinical studies, preliminary study results, and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials or the ultimately completed trials. For instance, while we have early clinical trial results for our clinical studies of DKN-01 in esophagogastric cancer and gynecologic cancer, additional clinical trials are still ongoing and will be needed for the registration of DKN-01. Moreover, these results may not be representative of the ultimate study population. The ultimate study results of our ongoing or future trials may be different than the ones we have seen to date. Additionally, the clinical trials conducted to date were relatively small, open-label, uncontrolled studies. Preliminary and final results from such studies may not be representative of study results that are found in larger, controlled, blinded, and longer term studies.

Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. Preclinical studies may also reveal unfavorable product candidate characteristics, including safety concerns. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, the impact of an active comparator arm, differences in the size and type of patient populations, changes in and adherence to clinical trial protocols, changes in medical prescribing practices, and the rate of dropout among clinical trial participants.

Our future clinical trial results may not be successful. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials, notwithstanding promising results in earlier trials. Moreover, should there be a flaw in a clinical trial, it may not become apparent until the clinical trial is well advanced. Further, because we currently plan to develop our product candidates for use in combination with other oncology products, the design, implementation, and interpretation of the clinical trials necessary for marketing approval may be more complex than if we were developing our product candidates alone.

We may also experience numerous unforeseen events during, or as a result of, clinical trials that could delay or adversely affect our existing or future development programs, including:

- we may have delays in identifying and adding new investigators or clinical trial sites, we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites and our third-party clinical research organizations, or CROs, or we may experience a withdrawal of clinical trial sites;

- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment may be slower than we anticipate or participants may drop out at a higher rate than we anticipate;
- clinical trials of our product candidates may produce negative or inconclusive results, or our studies may fail to reach the necessary level of statistical significance, and we may decide to conduct additional clinical trials or abandon product development programs;
- we may not be able to demonstrate that a product candidate provides an advantage over current standards of care or current or future competitive therapies in development;
- the cost of clinical trials of our product candidates may be greater than we anticipate or we may have insufficient funds for a clinical trial;
- the supply or quality of the clinical trial material of our product candidates may be insufficient or inadequate to conduct clinical trials; and
- there may be changes to the therapies which we are administering in combination with our product candidates or changes to standards of care, which require that we change our study design, or otherwise halt, discontinue or delay our clinical studies.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, especially for an early-stage company such as ours. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we may not be able to commercialize our product candidates as expected, and our ability to generate revenue could be materially impaired.

Because we are at the early stages of the clinical and regulatory development of our product candidates, the time required to obtain approval for them from the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of such regulatory authorities.

In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate’s clinical development and may vary among jurisdictions. Any such change may require us to amend our clinical trial protocols, conduct additional studies that require regulatory or institutional review board, or IRB, approval, or otherwise cause delays in the approval or rejection of an application. We have not obtained regulatory approval for any product candidate and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval. Moreover, we have only completed early studies and enrolled limited numbers of patients for DKN-01. DKN-01 will require additional preclinical and clinical development, as well as additional manufacturing development before we will be able to submit a marketing application to the FDA. Moreover, should the FDA determine that a companion diagnostic device is required for use of our product candidates or should we decide to pursue the development of a companion diagnostic device for the use of our product candidates, further development work would be required for such a device, including, possibly the approval of an Investigational Device Exemption for the study of such a device from the FDA, compliance with the FDA’s device regulations, and either FDA clearance or approval of the device for commercial use. Such development would potentially take additional time and be subject to the risk of FDA non-approval or clearance of the diagnostic. Any delay in obtaining or failure to obtain required approvals could materially adversely affect our ability or the ability of any of our future collaborators to generate revenue from the particular product candidate, which could result in significant harm to our financial position and adversely impact our stock price.

Our product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, marketing, promotion, sale, and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by the European Medicines Agency, or EMA, and similar regulatory authorities outside the United States and Europe. Failure to obtain marketing approval for a product candidate will prevent us from commercializing that product candidate. We have no experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on CROs and consultants to assist us in this process. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate’s safety, purity, and potency for that indication. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities and clinical trial sites by, the relevant regulatory authorities.

We may also experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including:

- regulators or IRBs may not authorize us or our investigators to commence a clinical trial or to conduct a clinical trial at a prospective trial site, we may fail to reach an agreement with regulators or IRBs regarding the scope, design, or implementation of our clinical trials or regulators or IRBs may require that we modify or amend our clinical trial protocols;
- our third-party contractors may fail to comply with regulatory requirements, standard operating procedures or clinical trial protocols, or fail to meet their contractual obligations to us in a timely manner, or at all, or we may be required to engage in additional clinical trial site monitoring or manufacturing activities;
- we, relevant regulators, or IRBs may require the suspension or termination of clinical research for various reasons, including noncompliance with regulatory requirements or a finding that participants are being exposed to unacceptable health risks, undesirable side effects, or other unexpected characteristics of a product candidate, or due to findings of undesirable effects caused by a chemically or mechanistically similar therapeutic or therapeutic candidate;
- changes in or the enactment of additional statutes or regulations;
- there may be changes in marketing approval or regulatory review policies during the development period rendering our data insufficient to obtain marketing approval;
- we may decide, or regulators may require us, to conduct additional clinical trials, analyses, reports, data, or preclinical trials, or we may abandon product development programs;
- there may be regulatory questions or disagreements regarding interpretations of data and results, or new information may emerge regarding our product candidates, the FDA or comparable foreign regulatory authorities may disagree with our study design or our interpretation of data from preclinical studies and clinical trials or find that a product candidate’s benefits do not outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our intended indications;
- the FDA or comparable foreign regulatory authorities may fail to approve or subsequently find fault with our manufacturing processes or our manufacturing facilities for clinical and future commercial supplies;
- the data collected from clinical trials of our product candidates or any additional product candidate may not be sufficient to cause the FDA or comparable foreign regulatory authorities to support the submission of a BLA, or other comparable submission in foreign jurisdictions or to obtain regulatory approval in the United States or elsewhere; and
- the FDA or comparable foreign regulatory authorities may take longer than we anticipate to make a decision on our product candidates.

Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. The number and types of preclinical studies and clinical trials that will be required for regulatory approval also varies depending on the product candidate, the disease or condition that the product candidate is designed to address, and the regulations applicable to any particular product candidate.

Approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate’s clinical development and may vary among jurisdictions, which may cause delays or limitations in the approval of or the decision not to approve an application. It is possible that neither of our product candidates nor any product candidates we may seek to develop in the future will ever obtain the appropriate regulatory approvals necessary for us or any future collaborators to commence product sales.

Finally, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications or uses than we request, may require significant safety warnings, including black box warnings, contraindications, and precautions, may grant approval contingent on the performance of costly post-marketing clinical trials, surveillance, or other requirements, including risk evaluation and mitigation strategies, or REMS, to monitor the safety or efficacy of the product, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of these scenarios could compromise the commercial prospects for our product candidates.

If we experience delays in obtaining approval, if we fail to obtain approval of a product candidate or if the label for a product candidate does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate, the commercial prospects for such product candidate may be harmed and our ability to generate revenues from that product candidate could be materially impaired.

If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of clinical data and necessary regulatory approvals could be delayed or prevented.

We may not be able to initiate or continue conducting clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. Some of our competitors have ongoing clinical trials for product candidates that treat the same indications or use the same mechanism of action as our product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates. Patient enrollment is affected by other factors including:

- the size and nature of the patient population;
- the severity of the disease under investigation;
- the eligibility criteria for, and design of, the clinical trial in question, including factors such as frequency of required assessments, length of the study and ongoing monitoring requirements;
- the perceived risks and benefits of the product candidate under study, including the potential advantages or disadvantages of the product candidate being studied in relation to other available therapies;
- competition in recruiting and enrolling patients in clinical trials;
- efforts to facilitate timely enrollment in clinical trials;
- the patient referral practices of physicians;
- effectiveness of publicity created by clinical trial sites regarding the trial;
- patients' ability to comply with the specific instructions related to the trial protocol, proper documentation, and use of the biologic product;
- our inability to obtain or maintain patient informed consents;
- the risk that enrolled patients will drop out before completion or not return for post-treatment follow-up;
- the ability to monitor patients adequately during and after treatment; and
- the proximity and availability of clinical trial sites for prospective patients.

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether.

Enrollment delays in our clinical trials may result in increased development costs for our product candidates, or our inability to complete the development of our product candidates, which could materially impair our ability to generate revenues, limit our ability to obtain additional financing and cause the value of our company to decline.

The FDA may determine that any of our current or future product candidates have undesirable side effects that could delay or prevent their regulatory approval or commercialization.

Undesirable side effects caused by our product candidates could cause us, IRBs, and other reviewing entities 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 comparable foreign authorities. For example, if concerns are raised regarding the safety of a new therapeutic as a result of undesirable side effects identified during clinical or preclinical testing of a product candidate, the FDA may order us to cease further development, decline to approve that product candidate or issue a letter requesting additional data or information prior to making a final decision regarding whether or not to approve it. FDA requests for additional data or information can result in substantial delays in the approval of a new biologic.

If any of our product candidates is associated with serious adverse events or undesirable side effects or has properties that are unexpected, we may need to abandon development or limit development of that product candidate to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. The therapeutic-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may significantly harm our business, financial condition, results of operations, and prospects.

Risks Related to the Development and Commercialization of Our Product Candidates

The therapeutic safety and efficacy of DKN-01 is unproven, and we may not be able to successfully develop and commercialize DKN-01.

DKN-01 is a novel monoclonal antibody and its potential benefit as a therapeutic cancer drug is unproven. Our ability to generate revenues from the sale of product, which we do not expect will occur in the short term, if ever, will depend on successful development and commercialization after approval, if achieved, which is subject to many potential risks. DKN-01 may interact with human biological systems in unforeseen, ineffective or harmful ways. If DKN-01 is associated with undesirable side effects or has characteristics that are unexpected, we may need to abandon its development or limit development to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Many compounds that initially showed promise in early stage testing for treating cancer have later been found to be ineffective in later stage studies or cause side effects that prevented further development of the compound. As a result of these and other risks described herein that are inherent in the development of novel therapeutic agents, we may never successfully develop, enter into or maintain third party licensing or collaboration transactions with respect to, or successfully commercialize DKN-01, in which case we will not achieve profitability and the value of our stock may decline.

Our future success is dependent primarily on the regulatory approval and commercialization of DKN-01, which is currently undergoing early stage clinical trials.

We do not have any products that have gained regulatory approval. Currently, our most advanced clinical-stage product candidate is DKN-01. As a result, our business is substantially dependent on our ability to obtain regulatory approval for, and, if approved, to successfully commercialize DKN-01 in a timely manner. We cannot commercialize the product in the U.S. without first obtaining regulatory approval from the FDA; similarly, we cannot commercialize the product outside of the U.S. without first obtaining regulatory approval from comparable foreign regulatory authorities. Before obtaining regulatory approvals for the commercial sale of the product for a target indication, we must demonstrate, with substantial evidence gathered in preclinical studies and well-controlled clinical trials, that the product is safe and effective for use for that target indication and that the manufacturing facilities, processes and controls are adequate. Even if DKN-01 were to successfully obtain approval from the FDA and comparable foreign regulatory authorities, any approval might contain significant limitations, such as use restrictions for specified age groups, warnings, precautions or contraindications, or may be subject to burdensome post-approval study or risk management requirements. If we are unable to obtain regulatory approval in one or more jurisdictions, or any approval contains significant limitations, we may not be able to obtain sufficient funding or generate sufficient revenue to continue the development of any other product candidate that we may discover, in-license, develop or acquire in the future. If we are unable to successfully commercialize our products, we may not be able to earn sufficient revenues to continue our business.

We face substantial competition, which may result in others discovering, developing or commercializing products before, or more successfully than, we do.

The development and commercialization of new drug products is highly competitive, especially in the oncology space in which we operate. We face competition with respect to DKN-01, and will likely face competition with respect to any other product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of cancer. Some of these competitive products and therapies are based on scientific approaches that are the same as or similar to our approach for DKN-01, and others are based on entirely different approaches. For example, there are several companies developing product candidates that target the same cancer pathways that we are targeting or that are testing product candidates in the same cancer indications that we are testing. For example, Novartis AG, or Novartis, Merck & Co., or Merck, Pfizer, Inc., and Amgen, Inc. have previously been developing anti-DKK1 monoclonal antibodies.

More established companies may have a competitive advantage over us due to their greater size, cash flows and institutional experience. Compared to us, many of our competitors may have significantly greater financial, technical and human resources. As a result of these factors, our competitors may obtain regulatory approval of their products before we are able to, which may limit our ability to develop or commercialize DKN-01. Our competitors may also develop drugs that are safer, more effective, more widely used and/or cheaper than ours, and may also be more successful than us in manufacturing and marketing their products. These appreciable advantages could render DKN-01 non-competitive before we can recover the expenses of development and commercialization.

We may acquire other assets, form collaborations or make investments in other companies or technologies, that could harm our operating results, dilute our stockholders' ownership, increase our debt or cause us to incur significant expense.

As part of our business strategy, we may pursue acquisitions of assets, including preclinical or clinical stage product candidates, or enter into strategic alliances and collaborations to expand our existing programs and operations, such as we did with the BeiGene Agreement. We may not maintain or complete these transactions on a cost-effective basis, or at all, and we may not realize the anticipated benefits of any such transaction, any of which could have a detrimental effect on our financial condition, results of operations and cash flows. We may not be able to find suitable acquisition candidates, and if we make any acquisitions, we may not be able to integrate these acquisitions successfully into our existing business and we may incur additional debt or assume unknown or contingent liabilities in connection therewith. Any integration of an acquired company or assets may also disrupt our ongoing operations, require the hiring of additional personnel and the implementation of additional internal systems and infrastructure, and require management resources that would otherwise be focused on developing our existing business. We may not be able to find or maintain suitable strategic alliance or collaboration partners or identify other investment opportunities, and we may experience losses related to any such investments.

To finance any acquisitions or collaborations, we may choose to issue debt or shares of our common stock as consideration. Any such issuance of shares would dilute the ownership of our stockholders. If the price of our common stock is low or volatile, we may not be able to acquire other assets or companies or fund a transaction using our stock as consideration. Alternatively, it may be necessary for us to raise additional funds for acquisitions through public or private financings. Additional funds may not be available on terms that are favorable to us, or at all.

Risks Related to Our Dependence on Third Parties

We expect to rely on BeiGene to perform its obligations under the BeiGene Agreement and to develop and commercialize DKN-01 in the BeiGene Territory.

Pursuant to the terms of the BeiGene Agreement, we granted to BeiGene the right to an exclusive license to develop, manufacture and commercialize DKN-01 in the BeiGene Territory. We expect to rely on BeiGene with respect to DKN-01 in the BeiGene Territory, and will have limited influence over their performance. The failure of BeiGene to exercise the option or to successfully carry out its contractual development and commercialization responsibilities could substantially harm our business, because we have no development or commercialization experience or personnel in the BeiGene Territory. We cannot assure you that BeiGene will execute its option or successfully develop or commercialize DKN-01. If BeiGene were to terminate the BeiGene Agreement, then that could delay our DKN-01 development activities and adversely affect our business.

We rely, and expect to continue to rely, on third parties to conduct, supervise, and monitor our preclinical studies and clinical trials. If these third parties do not carry out their contractual duties or do not perform satisfactorily, including failing to meet deadlines for the completion of such trials or failing to comply with regulatory requirements, our business could be substantially harmed.

We rely on CROs to conduct, supervise, and monitor our preclinical and clinical trials for our product candidates. We expect to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions, and clinical investigators, to conduct our preclinical studies and clinical trials. While we have agreements governing their activities, we have limited influence over their actual performance and control only certain aspects of their activities. The failure of these third parties to successfully carry out their contractual duties or meet expected deadlines could substantially harm our business, because we may be delayed in completing or unable to complete the clinical trials required to support future approval of our product candidates, and we may not obtain marketing approval for or commercialize our product candidates in timely manner or at all. Moreover, these agreements might terminate for a variety of reasons, including a failure to perform by such third parties. If we need to enter into alternative arrangements, our product development activities could be delayed, which could adversely affect our business.

Our reliance on these third parties for development activities reduces our control over these activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with applicable protocols, legal, regulatory, and scientific standards, and our reliance on CROs does not relieve us of our regulatory responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and applicable protocols for that trial and for ensuring that our preclinical trials are conducted in accordance with Good Laboratory Practice Standards, or GLPs, as appropriate. Moreover, the FDA and comparable foreign regulatory authorities require us to comply with Good Clinical Practices, commonly referred to as GCPs, for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity, and confidentiality of trial participants are protected. Regulatory authorities enforce these requirements through periodic inspections of trial sponsors, clinical investigators, and trial sites. If we or any of our CROs fail to comply with applicable GCPs or other regulatory requirements, we or our CROs may be subject to enforcement or other legal actions, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays could occur, which could compromise our ability to meet our desired development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects, and results of operations.

If the contract manufacturers upon whom we rely fail to produce our product candidates or components in the volumes that we require on a timely basis, or to comply with stringent regulations applicable to biopharmaceutical manufacturers, we may face delays in the development and commercialization of, or be unable to meet demand for, our product candidates and may lose potential revenues.

We do not manufacture any of our product candidates, and we do not currently plan to develop any capacity to do so. We utilize third-party contract manufacturing organizations, or CMOs, to manufacture the clinical trial material of DKN-01 and expect to do so for commercial products, if approved. We do not have any long-term commitments from our CMOs for clinical trial material or guaranteed prices for our product candidates. Any delays in obtaining adequate supplies with respect to our product candidates will delay the development or commercialization of our product candidates.

Our product candidates compete with other products and product candidates for access to contract manufacturing facilities. There are a limited number of CMOs that operate under cGMP regulations and that are both capable of manufacturing for us and willing to do so. If our existing CMOs, or any new third party CMOs that we engage in the future to manufacture our product candidates for our clinical trials, should cease to continue to do so for any reason, we likely would experience delays in obtaining sufficient quantities of our product candidates for us to advance our clinical trials while we identify and qualify replacement suppliers. We may not succeed in our efforts to establish sufficient manufacturing relationships or other alternative arrangements to meet our needs for any of our existing or future product candidates. If for any reason we are unable to obtain adequate supplies of our product candidates, it will be more difficult for us to conduct clinical trials, develop our product candidates and operate our business.

Any problems or delays we experience in preparing for commercial-scale manufacturing of a product candidate or component may result in a delay in FDA approval of the product candidate or may impair our ability to manufacture commercial quantities or such quantities at an acceptable cost, which could result in the delay, prevention, or impairment of clinical development and commercialization of our product candidates and could adversely affect our business.

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of therapeutics often encounter difficulties in production, particularly in scaling up initial production, including difficulties with production costs and yields, quality control, (including stability of the product candidate and quality assurance testing), shortages of qualified personnel, and compliance with strictly enforced federal, state, and foreign regulations. Our CMOs may not perform as agreed or may have a failure of a manufacturing campaign. Any changes or deviations in a manufacturing process may result in the failure of the product to meet the necessary specifications. If our CMOs were to encounter any of these difficulties, our ability to provide product candidates to patients in our clinical trials and for commercial use, if approved, could be jeopardized. Reliance on third-party CMOs entails exposure to risks to which we would not be subject if we manufactured the product candidate ourselves, including:

- reduced day-to-day control over the manufacturing process for our product candidates as a result of using third-party CMOs for all aspects of manufacturing activities;
- reduced control over the protection of our trade secrets and know-how from misappropriation or inadvertent disclosure;
- termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that may be costly or damaging to us or result in delays in the development or commercialization of our product candidates; and
- disruptions to the operations of our third-party CMOs caused by conditions unrelated to our business or operations, which could result in disruptions in the development or commercialization of our product candidates.

In addition, all CMOs of our product candidates and therapeutic substances must comply with cGMP requirements enforced by the FDA that are applicable to both finished product and their active components used both for clinical and commercial supply, through its facilities inspection program. Our CMOs must be approved by the FDA pursuant to inspections that will be conducted after we submit our marketing applications to the agency. Our CMOs will also be subject to continuing FDA and other regulatory authority inspections should we receive marketing approval. Further, we, in cooperation with our CMOs, must supply all necessary chemistry, manufacturing, and control documentation in support of a BLA on a timely basis. The cGMP requirements include quality control, quality assurance, and the maintenance of records and documentation. Manufacturers of our product candidates and therapeutic substances may be unable to comply with our specifications, these cGMP requirements and with other FDA, state, and foreign regulatory requirements. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of product candidates that may not be detectable in final product testing. If our CMOs cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or other regulatory authorities, they may not be able to secure or maintain regulatory approval for their manufacturing facilities. Any such deviations may also require remedial measures that may be costly and/or time-consuming for us or a third party to implement and that may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business.

While we are ultimately responsible for the manufacture of our product candidates and therapeutic substances, other than through our contractual arrangements, we have little control over our CMOs' compliance with these regulations and standards. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which could significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. A failure to comply with these requirements may also result in regulatory enforcement actions against our CMOs or us, including fines and civil and criminal penalties. If the safety of any quantities supplied is compromised due to our CMOs' failure to adhere to applicable laws or for other reasons, we may not be able to obtain regulatory approval for or successfully commercialize our product candidates.

Any failure or refusal to supply sufficient quantities of our product candidates could delay, prevent or impair our clinical development or commercialization efforts. Any change in our CMOs could be costly because the commercial terms of any new arrangements could be less favorable than our existing arrangements and because the expenses relating to the transfer of necessary technology and processes could be significant, as there are significant regulatory requirements which must be met prior to receiving FDA approval for the transfer of a manufacturing process for a therapeutic antibody product to a new manufacturing facility.

We also rely on third parties to store and distribute our product candidates for the clinical trials that we conduct. Any performance failure on the part of our distributors could delay clinical development of our product candidates, which could produce additional losses.

Risks Related to Legal and Compliance Matters

If we fail to comply with federal and state healthcare laws, including fraud and abuse and health and other information privacy and security laws, we could face substantial penalties and our business, financial condition, results of operations, and prospects could be adversely affected.

As a biopharmaceutical company, we are subject to many federal and state healthcare laws. If we or our operations are found to be in violation of any federal or state healthcare law, or any other governmental regulations that apply to us, we may be subject to penalties, including civil, criminal, or administrative penalties, damages, fines, disgorgement, debarment from government contracts and/or refusal of orders under existing contracts, exclusion from participation in U.S. federal or state health care programs, corporate integrity agreements, or the curtailment or restructuring of our operations, any of which could materially adversely affect our ability to operate our business and our financial results. If any of the physicians or other healthcare providers or entities with whom we expect to do business, including our collaborators, is found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including but not limited to, exclusions from participation in government healthcare programs, which could also materially adversely affect our business.

Although an effective compliance program can mitigate the risks of investigation and prosecution for violations of these laws, these risks cannot be entirely eliminated. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security, and fraud laws may prove to be costly. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

Risks Related to Our Intellectual Property

If we are unable to protect our intellectual property rights or if our intellectual property rights are inadequate to protect our technology and product candidates, our competitive position could be harmed.

Our commercial success will depend in large part on our ability to obtain and maintain patent and other intellectual property protection in the U.S. and other countries with respect to our proprietary technology and products. We rely on patent, trade secret, copyright and trademark laws, and confidentiality, licensing and other agreements with employees and third parties, all of which offer only limited protection. We have sought and continue to seek to protect our proprietary position by filing and prosecuting patent applications in the U.S. and abroad related to our novel technologies and products that are important to our business.

The patent positions of biotechnology and pharmaceutical companies generally are highly uncertain, involve complex legal and factual questions and have in recent years been the subject of much litigation. As a result, the scope, validity, enforceability and commercial value of our patents, including those patent rights licensed to us by third parties, are highly uncertain. The steps we or our licensors have taken to protect our proprietary rights may not be adequate to preclude misappropriation of our proprietary information or infringement of our intellectual property rights, both inside and outside the U.S. Further, the examination process may require us or our licensors to narrow the claims for our pending patent applications and those of our licensors, which may limit the scope of patent protection that may be obtained if these applications issue. The rights already granted under any of our currently issued patents or those licensed to us and those that may be granted under future issued patents may not provide us with the proprietary protection or competitive advantages we are seeking. If we or our licensors are unable to obtain and maintain patent protection for our technology and products, or if the scope of the patent protection obtained is not sufficient, our competitors could develop and commercialize technology and products similar or superior to ours, and our ability to successfully commercialize our technology and products may be adversely affected. It is also possible that we or our licensors will fail to identify patentable aspects of inventions made in the course of our development and commercialization activities before it is too late to obtain patent protection for them.

With respect to patent rights, we do not know whether any of our pending patent applications will result in the issuance of patents that protect our technology or products, or if any of our or our licensors' issued patents will effectively prevent others from commercializing competitive technologies and products. Patents in the field of therapeutic monoclonal antibodies are frequently limited in scope based on the sequence of amino acids that form particular parts of the antibody. A portion of our intellectual property portfolio is limited by amino acid sequences found in our product candidates. Other competing companies may have therapeutic antibodies to the same target as our product candidates, but have a different amino acid sequence and, as a result, may not be determined to infringe our patents which are limited by amino acid sequence(s). Even for those patents which are defined by the target of a therapeutic antibody and not limited by an amino acid sequence, we cannot be certain that we will be able to successfully enforce those patents against our competitors with antibodies to these targets.

Our pending applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, issued patents that we own or have licensed from third parties may be challenged in the courts, administrative agencies or patent offices in the U.S. and abroad. Such challenges may result in the loss of patent protection, the narrowing of claims in such patents or the invalidity or unenforceability of such patents, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection for our technology and products. Protecting against the unauthorized use of our or our licensors' patented technology, trademarks and other intellectual property rights is expensive, difficult and may in some cases not be possible. In some cases, it may be difficult or impossible to detect third-party infringement or misappropriation of our intellectual property rights, even in relation to issued patent claims, and proving any such infringement may be even more difficult.

Risks Related to our Common Stock

Our share price may be volatile, which could subject us to securities class action litigation and our stockholders could incur substantial losses.

The market price of shares of our common stock could be subject to wide fluctuations in response to many risk factors listed in this section, and others beyond our control, including:

- the results of clinical trials or development activities of our programs, or any future programs we may acquire;
- actual or anticipated fluctuations in our financial condition and operating results;
- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;
- issuance of new or updated research or reports by securities analysts;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- additions or departures of key management or other personnel;
- disputes or other developments related to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
- announcement or expectation of additional debt or equity financing efforts;
- sales of our common stock by us, our insiders or our other stockholders; and
- general economic and market conditions.

These and other market and industry factors may cause the market price and demand for our common stock to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from readily selling their shares of common stock and may otherwise negatively affect the liquidity of our common stock. In addition, the stock market in general, and Nasdaq and emerging growth companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. In the past, when the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. If in the future any of our stockholders brought a lawsuit against us, we could incur significant legal expenses, settlement costs or damage awards that are not covered by, or exceed the limits of, our available directors' and officers' liability insurance, which could adversely impact our financial condition, results of operations or cash flows. Such a lawsuit could also divert the time and attention of our management.

We are an "emerging growth company" and a "smaller reporting company" and we intend to take advantage of reduced disclosure and governance requirements applicable to emerging growth companies and smaller reporting companies, which could result in our common stock being less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act, and we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock, our stock price may be more volatile and it may be difficult for us to raise additional capital as and when we need it. If we are unable to raise additional capital as and when we need it, our financial condition and results of operations may be materially and adversely affected.

We may take advantage of these reporting exemptions until we are no longer an emerging growth company, which in certain circumstances could be for up to five years. We will remain an "emerging growth company" until the earliest of (a) the last day of the first fiscal year in which our annual gross revenues exceed $1.07 billion, (b) the date that we become a "large accelerated filer" as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended, or the Exchange Act, which would occur if the market value of our shares that are held by non-affiliates exceeds $700 million as of the last business day of our most recently completed second fiscal quarter, (c) the date on which we have issued more than $1.0 billion in nonconvertible debt during the preceding three-year period and (d) the last day of our 2022 fiscal year containing the fifth anniversary of the date on which shares of our common stock became publicly traded in the U.S.

Even after we no longer qualify as an emerging growth company, we may still continue to qualify as a "smaller reporting company" which would allow us to take advantage of many of the same exemptions from the disclosure requirements described above, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, and being subject to reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statement. We will also be exempt from providing selected and supplemental financial information.

Our business is subject to changing regulations for corporate governance and public disclosure that has increased both our costs and the risk of noncompliance.

Each year we are required to evaluate our internal controls systems in order to allow management to report on our internal controls as required by Section 404 of the Sarbanes-Oxley Act. As a result, we continue to incur additional expenses and divert our management's time to comply with these regulations. We currently do not have an internal audit group, and we will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. If we are not able to comply with the requirements of Section 404 in a timely manner, or if we or our independent registered public accounting firm identify deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our common stock could decline and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities, which would require additional financial and management resources.

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

Sales of a substantial number of shares of our common stock in the public market, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. Our management is authorized to grant stock options and other equity-based awards to our employees, directors and consultants under our equity incentive plans. Grants under our equity incentive plans may also cause our stockholders to experience additional dilution, which could cause our stock price to fall. We are unable to predict the effect that sales may have on the prevailing market price of our common stock. Most of our outstanding shares of common stock, as well as a substantial number of our shares of common stock underlying outstanding warrants, are eligible for sale in the public market, subject in some cases to the volume limitations and manner of sale requirements of Rule 144 under the Securities Act. Sales of common stock by our stockholders could have a material adverse effect on the trading price of our common stock.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future. There is no guarantee that shares of our common stock will appreciate in value or even maintain the price at which you purchased them.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 2. Properties.

We have leased our principal offices in Cambridge, Massachusetts covering approximately 7,667 square feet of space. We assumed this lease effective January 1, 2017, from HealthCare Ventures LLC pursuant to an Assignment and Assumption Agreement, dated as of January 1, 2017. In November 2018, we extended the lease through April 30, 2022.

Item 3. Legal Proceedings.

From time to time we may become involved in legal proceedings or be subject to claims that arise in the ordinary course of business. As of the date of this report, and other than as described in the following paragraph, we are not currently a party to any material legal proceedings.

A patent covering the TRX518 antibody and its uses in methods of inducing or enhancing an immune response in a subject was granted in 2013 to the Company by the European Patent Office (EPO). Three notices of opposition to this patent were filed: two by major pharmaceutical companies and a third by an individual, possibly on behalf of a major pharmaceutical company. At the conclusion of the opposition proceedings before the Opposition Division of the EPO, the Opposition Division issued a decision indicating that our patent was maintained with modified claims that differ from the claims as originally granted. These narrowed claims cover the TRX518 antibody and uses of the TRX518 antibody in methods of inducing or enhancing an immune response in a subject. We have filed an appeal of the decision of the Opposition Division seeking to obtain broader claims that more closely reflect the claims as granted in the patent. A hearing before the EPO Boards of Appeal took place on September 16, 2020, which resulted in the Boards of Appeal dismissing the appeal and maintaining the Decision of the Opposition Division. A written Decision by the Boards of Appeal was issued on September 25, 2020.

In 2016, a patent covering the use of the TRX518 antibody in combination with a chemotherapeutic agent for treating cancer was granted to us by the EPO. In March 2017, notices of opposition to this patent were filed at the EPO by ten different entities, including several major pharmaceutical companies. Oral proceedings at the EPO took place on December 4 and 5, 2018. At the conclusion of the oral proceedings, the Opposition Division decided that the patent should be revoked in its entirety on the ground that the claims as granted contained added matter. Subsequently, the Opposition Division issued an interlocutory decision restating its conclusion that the claims as granted contained added matter and revoking the patent. We have filed an appeal of the decision of the Opposition Division seeking to obtain a reversal of the Opposition Division’s decision on added matter. The EPO Board of Appeal has not yet scheduled the appeal hearing.

In December 2019, a patent covering the use of the TRX518 antibody in combination with the chemotherapeutic agent, gemcitabine, for treating a colon tumor or adenocarcinoma of the colon, was granted to us by the EPO. A Notice of Opposition was filed against the patent by a single opponent, Sanofi, on September 25, 2020. The EPO issued a Communication on October 9, 2020 setting a deadline of February 9, 2021 for the Patentee to file a response to the Notice of Opposition. We filed a timely reply to the opponent’s Notice of Opposition on February 9, 2021. Oral proceedings at the EPO have not yet been scheduled.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Market Information

Our common stock, par value $0.001 per share, has been publicly traded on the Nasdaq Global Market under the symbol "LPTX" since January 24, 2017. Prior to that time, there was no market for our common stock.

Holders of Record

As of March 9, 2021, there were approximately 26 holders of record of our common stock. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividends

We have never declared or paid cash dividends on our common stock, and we do not expect to pay any cash dividends on our common stock in the foreseeable future. We currently intend to retain our future earnings, if any, to fund the development and growth of our business. Payment of future dividends, if any, on our common stock will be at the discretion of our board of directors after taking into account various factors, including our financial condition, operating results, anticipated cash needs, and plans for expansion.

Recent Sales of Unregistered Securities

Set forth below is information regarding securities issued and options granted by us during the last three fiscal years that were not registered under the Securities Act of 1933, as amended, or the Securities Act. Also included is the consideration, if any, received by us for any such shares, options and warrants and information relating to the section of the Securities Act, or rule of the SEC, under which exemption from registration was claimed.

January 2020 Private Placement

On January 3, 2020, the Company entered into a Securities Purchase Agreement with investors, providing for a private placement transaction exempt from the Securities Act, pursuant to which the Company issued and sold 1,421,801 shares of its Series A Preferred Stock, at a purchase price of $10.54 per share, 1,137,442 shares of its Series B Preferred Stock at a purchase price of $10.55 per share, and one (1) share of the Company's Special Voting Stock entitling the purchaser of Series A Preferred Stock to elect one member of the Company's board of directors (the "January 2020 Private Placement").

On March 5, 2020, the Company's stockholders approved the conversion of the Series A Preferred Stock into a pre-funded warrant to purchase 14,413,902 shares of common stock at an exercise price of $0.001 (the "March 2020 Pre-funded Warrants") and the conversion of the Series B Preferred Stock into 11,531,133 shares of common stock. Each investor also received a warrant to purchase an equal number of shares of common stock at an exercise price of $2.11 per share (the "Coverage Warrants"). The March 2020 Pre-funded Warrants and the Coverage Warrants expire on March 5, 2027 and qualify for equity classification.

The securities issued and sold in connection with the January 2020 Private Placement were offered pursuant to Section 4(a)(2) of the Securities Act and Rule 506(b) of Regulation D as promulgated by the SEC under the Securities Act. Each purchaser was either (i) an "accredited investor" as defined in Rule 501(a)(1), (a)(2), (a)(3), (a)(7) or (a)(8) under the Securities Act or (ii) a "qualified institutional buyer" as defined in Rule 144A(a) under the Securities Act and acquired the securities for investment purposes only and not with a view to, or for sale in connection with, any distribution thereof. The securities were not issued through any general solicitation or advertisement.

Purchases of Equity Securities

We did not purchase any of our registered equity securities during the period covered by this Annual Report on Form 10-K.

Item 6. Selected Financial Data.

Not applicable.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors. We discuss factors that we believe could cause or contribute to these differences below and elsewhere in this report, including those set forth under Item 1A. "Risk Factors" and under "Cautionary Note Regarding Forward-Looking Statements" in this Annual Report.

Overview

We are a biopharmaceutical company developing novel therapies designed to treat patients with cancer by inhibiting fundamental tumor-promoting pathways and by harnessing the immune system to attack cancer cells. Our strategy is to identify, acquire, and develop molecules that will rapidly translate into high impact therapeutics that generate durable clinical benefit and enhanced patient outcomes.

Our lead clinical stage program is DKN-01, a monoclonal antibody that inhibits Dickkopf-related protein 1, or DKK1. DKK1 is a protein that regulates the Wnt signaling pathways and enables tumor cells to proliferate and spread, as well as suppresses the immune system from attacking the tumor. When DKN-01 binds to DKK1, an anti-tumor effect can be generated. DKN-01-based therapies have generated responses and clinical benefit in several patient populations. We are currently studying DKN-01 in multiple ongoing clinical trials in patients with esophagogastric cancer, hepatobiliary cancer, gynecologic cancers, or prostate cancer. We entered into an exclusive option and license agreement (the "BeiGene Agreement") with BeiGene, Ltd., or BeiGene, which granted BeiGene the right to develop and commercialize DKN-01 in Asia (excluding Japan), Australia, and New Zealand.

We intend to apply our extensive experience identifying and developing transformational products to aggressively develop these antibodies and build a pipeline of programs that has the potential to change the practice of cancer medicine.

We have devoted substantially all of our resources to development efforts relating to our product candidates, including manufacturing and conducting clinical trials of our product candidates, providing general and administrative support for these operations and protecting our intellectual property. We do not have any products approved for sale and have not generated any revenue from product sales. We have funded our operations primarily through proceeds from our sales of common stock and preferred stock and proceeds from the issuance of notes payable.

We have incurred net losses in each year since our inception in 2011. Our net loss was $27.5 million for the year ended December 31, 2020 and $32.9 million for the year ended December 31, 2019. As of December 31, 2020, we had an accumulated deficit of approximately $223.0 million. Our net losses have resulted primarily from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations. We expect to continue to incur significant expenses and have operating losses for at least the next several years as we:

- continue the development of our product candidate, DKN-01;
- seek to obtain regulatory approvals for DKN-01;

- outsource the manufacturing of DKN-01 for clinical trials and any indications for which we receive regulatory approval;
- contract with third parties for the sales, marketing and distribution of DKN-01 for any indications for which we receive regulatory approval;
- maintain, expand and protect our intellectual property portfolio;
- continue our research and development efforts;
- add operational, financial and management information systems and personnel, including personnel to support our product development efforts; and
- operate as a public company.

We do not expect to generate revenue from product sales unless and until we successfully complete development and obtain marketing approval for one or more of our product candidates, which we expect will take a number of years and is subject to significant uncertainty. Accordingly, we will need to raise additional capital prior to the commercialization of DKN-01 or any other product candidate. Until such time, if ever, as we can generate substantial revenue from product sales, we expect to finance our operating activities through a combination of equity offerings, debt financings, government or other third-party funding, commercialization, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements, such as the BeiGene Agreement. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements as and when needed would have a negative impact on our financial condition and our ability to develop our product candidates.

As of December 31, 2020, we had cash and cash equivalents of $52.1 million. We believe that our cash and cash equivalents as of December 31, 2020 will enable us to fund our operating expenses and capital expenditure requirements for at least 12 months from issuance of the financial statements included in this Annual Report on Form 10-K. See "—Liquidity and Capital Resources."

Financial Overview

Research and Development Expenses

Our research and development activities have included conducting nonclinical studies and clinical trials, manufacturing development efforts and activities related to regulatory filings for DKN-01 and TRX518. We recognize research and development expenses as they are incurred. Our research and development expenses consist primarily of:

- salaries and related overhead expenses for personnel in research and development functions, including costs related to stock-based compensation;
- fees paid to consultants and CROs for our nonclinical and clinical trials, and other related clinical trial fees, including but not limited to laboratory work, clinical trial database management, clinical trial material management and statistical compilation and analysis;
- costs related to acquiring and manufacturing clinical trial materials; and
- costs related to compliance with regulatory requirements.

We plan to increase our research and development expenses for the foreseeable future as we continue the development of DKN-01 and any other product candidates, subject to the availability of additional funding.

Our direct research and development expenses are tracked on a program-by-program basis and consist primarily of internal and external costs, such as employee costs, including salaries and stock-based compensation, other internal costs, fees paid to consultants, central laboratories, contractors and CROs in connection with our clinical and preclinical trial development activities. We use internal resources to manage our clinical and preclinical trial development activities and perform data analysis for such activities.

We participate, through our subsidiary in Australia, in the Australian government's R&D Incentive program, such that a percentage of our eligible research and development expenses are reimbursed by the Australian government as a refundable tax offset and such incentives are reflected as other income. This percentage was 43.5% for both the years ended December 31, 2020 and 2019.

The table below summarizes our research and development expenses incurred by development program and the R&D incentive income for the years ended December 31, 2020 and 2019:

	Year Ended December 31,	
	2020	2019
	(in thousands)	
Direct research and development by program:		
DKN-01 program	$17,956	$16,130
TRX518 program	2,467	8,236
Total research and development expenses	$20,423	$24,366
Australian research and development incentives	$ 231	$ 132

The successful development of our clinical product candidates is highly uncertain. At this time, we cannot reasonably estimate the nature, timing or costs of the efforts that will be necessary to complete the remainder of the development of any of our product candidates or the period, if any, in which material net cash inflows from these product candidates may commence. This is due to the numerous risks and uncertainties associated with developing drugs, including the uncertainty of:

- the scope, rate of progress and expense of our ongoing, as well as any additional, clinical trials and other research and development activities;
- future clinical trial results; and
- the timing and receipt of any regulatory approvals.

A change in the outcome of any of these variables with respect to the development of a product candidate could result in a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials beyond those that we currently anticipate will be required for the completion of clinical development of a product candidate, or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related costs, including stock-based compensation, for personnel in executive, finance and administrative functions. General and administrative expenses also include direct and allocated facility-related costs as well as professional fees for legal, patent, consulting, accounting and audit services.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our continued research activities and development of our product candidates. We also anticipate that we will incur increased accounting, audit, legal, regulatory, compliance, director and officer insurance costs as well as investor and public relations expenses associated with being a public company.

Interest income

Interest income consists primarily of interest income earned on cash and cash equivalents. During the years ended December 31, 2020 and 2019, interest income was $0.1 million and $0.3 million, respectively.

Research and development incentive income

Research and development incentive income includes payments under the R&D Incentive program from the government of Australia. The R&D Incentive is one of the key elements of the Australian

Government's support for Australia's innovation system. It was developed to assist businesses in recovering some of the costs of undertaking research and development. The research and development tax incentive provides a tax offset to eligible companies that engage in research and development activities.

Companies engaged in research and development may be eligible for either:

- a 43.5% refundable tax offset for entities with an aggregated turnover of less than A$20 million per annum, or
- a 38.5% non-refundable tax offset for all other entities.

We recognize as other income the amount we expect to be reimbursed for qualified expenses.

Foreign currency translation adjustment

Foreign currency translation adjustment consists of gains (losses) due to the revaluation of foreign currency transactions attributable to changes in foreign currency exchange rates associated with our Australian subsidiary.

Income taxes

Since our inception, we have not recorded any U.S. federal, state or foreign income tax benefits for the net losses we have incurred in each year, due to our uncertainty of realizing a benefit from those items. As of December 31, 2020, we had federal and state net operating loss carryforwards of $160.6 million and $141.8 million, respectively. The federal and state net operating losses begin to expire in 2030, while the foreign net operating losses carryforward indefinitely. Our federal net operating losses include $79.2 million which can also be carried forward indefinitely. We may be able to utilize our net operating loss carryforwards to reduce future federal and state income tax liabilities. However, these net operating losses are subject to various limitations under Internal Revenue Code ("IRC") Section 382, which limits the use of net operating loss carryforwards to the extent there has been an ownership change of more than 50 percentage points. In addition, the net operating loss carryforwards are subject to examination by the taxing authorities and could be adjusted or disallowed due to such exams. Although we have not undergone an IRC Section 382 Analysis, it is possible that the utilization of our net operating loss carryforwards may be limited.

As of December 31, 2020, we also had federal and state research and development tax credits of $3.8 million and $0.6 million, respectively, which begin to expire in 2030.

There is no provision for income taxes in the United States or Israel because we have historically incurred operating losses and maintain a full valuation allowance against our deferred tax assets in these jurisdictions. The deferred tax asset recorded in the consolidated balance sheets relates to our Australian operations.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which we have prepared in accordance with U.S. Generally Accepted Accounting Principles ("GAAP"). The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, as well as the reported expenses during the reporting periods. We evaluate these estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 2 to our consolidated financial statements appearing elsewhere in this report, we believe that the following accounting policies are the most critical for fully understanding and evaluating our financial condition and results of operations.

Accrued Research and Development Expenses

As part of the process of preparing consolidated financial statements, we are required to estimate accrued research and development expenses. This process involves communicating with our applicable personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual cost. The majority of our service providers invoice us monthly for services performed. We make estimates of our accrued research and development expenses as of each balance sheet date in our consolidated financial statements based on facts and circumstances known to us. We periodically confirm the accuracy of our estimates with selected service providers and make adjustments, if necessary. To date, we have not adjusted our estimate at any particular balance sheet date by any material amount. Examples of estimated accrued research and development expenses include:

- fees paid to CROs for management of our clinical trial activities;
- fees paid to investigative sites in connection with clinical trials;
- fees paid to contract manufacturers in connection with the production of clinical trial supplies; and
- professional services and fees.

We base our expenses related to clinical trials on our estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and CROs that conduct and manage clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If we do not accurately identify costs that we have begun to incur or if we underestimate or overestimate the level of services performed or the costs of these services, our actual expenses could differ from our estimates.

Stock-Based Compensation

We have issued options to purchase our common stock. We account for stock based compensation in accordance with ASC 718, Compensation—Stock Compensation. ASC 718 establishes accounting for stock-based awards exchanged for employee and non-employee services. Under the fair value recognition provisions of ASC 718, stock-based compensation cost is measured at the grant date based on the fair value of the award and is recognized as expense over the requisite service or vesting period. Determining the appropriate fair value model and calculating the fair value of stock-based payment awards require the use of highly subjective assumptions, including the expected life of the stock-based payment awards and stock price volatility.

We estimate the grant date fair value of stock options and the related compensation expense, using the Black-Scholes option valuation model. This option valuation model requires the input of subjective assumptions including: (1) expected life (estimated period of time outstanding) of the options granted, (2) volatility, (3) risk-free rate and (4) dividends. In general, the assumptions used in calculating the fair value of stock-based payment awards represent management’s best estimates, but the estimates involve inherent uncertainties and the application of management judgment. As a result, if factors change and we use different assumptions, our stock-based compensation expense could be materially different in the future.

JOBS Act

We are an “emerging growth company”, or EGC, as defined in the Jumpstart Our Business Startups Act of 2012 (the “JOBS Act”). The JOBS Act permits an “emerging growth company” such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We may elect to use the extended transition period for complying with new or revised accounting standards under Section 102(b)(1) of the JOBS Act. This election would allow us to delay the adoption of new or revised accounting standards that have different effective dates for public and private companies until those standards apply to private companies. As a result of this election, our financial statements may not be comparable to companies that comply with public company effective dates.

We may take advantage of these reporting exemptions until we are no longer an emerging growth company, which in certain circumstances could be for up to five years. We will remain an “emerging growth company” until the earliest of (a) the last day of the first fiscal year in which our annual gross revenues exceed $1.07 billion, (b) the date that we become a “large accelerated filer” as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended, or the Exchange Act, which would occur if the market value of our shares that are held by non-affiliates exceeds $700 million as of the last business day of our most recently completed second fiscal quarter, (c) the date on which we have issued more than $1.0 billion in nonconvertible debt during the preceding three-year period and (d) the last day of our 2022 fiscal year containing the fifth anniversary of the date on which shares of our common stock became publicly traded in the U.S. As of December 31, 2020, we remain an EGC.

Results of Operations

Comparison of the Years Ended December 31, 2020 and 2019

The following tables summarize our results of operations for the years ended December 31, 2020 and 2019:

	Year Ended December 31,		
	2020	2019	Change
	(in thousands)		
License revenue	$ 1,500	$ —	$ 1,500
Operating expenses:			
Research and development	20,423	24,366	(3,943)
General and administrative	9,616	9,085	531
Total operating expenses	30,039	33,451	(3,412)
Loss from operations	(28,539)	(33,451)	4,912
Interest income	93	313	(220)
Interest expense	(39)	(23)	(16)
Australian research and development incentives	231	132	99
Foreign currency gains	738	126	612
Loss before income taxes	(27,516)	(32,903)	5,387
Income taxes	2	3	(1)
Net loss	$(27,514)	$(32,900)	$ 5,386

Revenues

License revenues for the year ended December 31, 2020 were $1.5 million and relate to the BeiGene Agreement for the development and commercialization of DKN-01 in Asia (excluding Japan), Australia, and New Zealand. The BeiGene Agreement became effective on January 3, 2020. As the BeiGene Agreement is the first such license agreement, no license revenues were recorded during the year ended December 31, 2019.

Research and Development Expenses

	Year Ended December 31,		Increase (Decrease)
	2020	2019	
	(in thousands)		
Direct research and development by program:			
DKN-01 program	$17,956	$16,130	$ 1,826
TRX518 program	2,467	8,236	(5,769)
Total research and development expenses	$20,423	$24,366	$(3,943)

Research and development expenses were $20.4 million for the year ended December 31, 2020, compared to $24.4 million for the year ended December 31, 2019. The decrease of $4.0 million in research and development expenses was primarily due to a decrease of $4.9 million in clinical trial costs primarily due to deprioritizing the continued development of TRX518 in 2019 and timing of patient enrollment, a $0.2 million decrease in consulting fees associated with research and development activities, and a $0.3 million decrease in rent expense due to the closing of our research laboratory in April 2020. These decreases were partially offset by an increase of $1.1 million in payroll and other related expenses due to an increase in headcount of our research and development full time employees and a $0.3 million increase in stock based compensation expense due to new stock options granted to employees during the year ended December 31, 2020.

General and Administrative Expenses

General and administrative expenses were $9.6 million for the year ended December 31, 2020, compared to $9.1 million for the year ended December 31, 2019. The increase of $0.5 million was due to a $0.9 million increase in professional fees primarily due to increased legal, recruiting and information technology costs, a $0.8 million increase in payroll and other related expenses due to an increase in compensation expense during the year ended December 31, 2020 as compared to 2019 and a $0.3 million increase in insurance expense. These increases were partially offset by a decrease of $1.5 million in stock based compensation expense, primarily due to stock option grants made to our executive officers during the three months ended March 31, 2017 which fully vested in January 2020.

Interest Income

We recorded interest income of $0.1 million and $0.3 million, respectively, for the years ended December 31, 2020 and 2019. The decrease in interest income is primarily due to lower interest rates during the year ended December 31, 2020 as compared to 2019.

Australian Research and Development Incentives

We recorded R&D incentive income of $0.2 million and $0.1 million for the years ended December 31, 2020 and 2019, respectively, based upon the applicable percentage of eligible research and development activities under the Australian Incentive Program, net of our Australia tax liability, which expenses included the cost of manufacturing of clinical trial material.

We perform certain supporting research and development activity outside of Australia when there are no Australian facilities that support the activity (“Overseas research and development activities”). In October 2017, the Commonwealth of Australia issued us a favorable ruling on our Overseas research and development activities, considering such activities to be eligible research and development activities under the Australian Incentive Program.

During the year ended December 31, 2020, we received $0.3 million of research and development tax incentive payments from the Commonwealth of Australia as a result of the 2019 research and development activities. During the year ended December 31, 2019, we received $0.8 million of research and development tax incentive payments from the Commonwealth of Australia as a result of the 2018 research and development activities.

The remaining R&D incentive receivable has been recorded as “Research and development incentive receivable” in the consolidated balance sheets.

Foreign Currency Gains (Loss)

We recorded foreign currency gains of $0.7 million and $0.1 million, respectively, for the years ended December 31, 2020 and 2019. The increase in foreign currency gains is due to the changes in the Australian dollar exchange rate related to activities of the Australian entity.

Interest Expense

We recorded an immaterial amount of interest expense for the years ended December 31, 2020 and 2019.

Liquidity and Capital Resources

Since our inception, we have been engaged in organizational activities, including raising capital, and research and development activities. We do not yet have a product that has been approved by the Food and Drug Administration (the "FDA"), and have not yet achieved profitable operations or generated positive cash flows from operations. There is no assurance that profitable operations, if achieved, could be sustained on a continuing basis. Further, our future operations are dependent on the success of efforts to raise additional capital, our research and commercialization efforts, regulatory approval, and, ultimately, the market acceptance of our products.

In accordance with Accounting Standards Codification ("ASC") 205-40, Going Concern, we have evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern within one year after the date that the consolidated financial statements are issued. As of December 31, 2020, we had cash and cash equivalents of $52.1 million. Additionally, we had an accumulated deficit of $223.0 million at December 31, 2020, and during the year ended December 31, 2020, we incurred a net loss of $27.5 million. We expect to continue to generate operating losses in the foreseeable future. We believe that our cash and cash equivalents of $52.1 million as of December 31, 2020 will be sufficient to fund our operating expenses for at least the next 12 months from the issuance of this Annual Report on Form 10-K. In addition, we will seek additional funding through public or private equity financings or government programs and will seek funding or development program cost-sharing through collaboration agreements or licenses with larger pharmaceutical or biotechnology companies. If we do not obtain additional funding or development program cost-sharing, we could be forced to delay, reduce or eliminate certain clinical trials or research and development programs, reduce or eliminate discretionary operating expenses, and delay company and pipeline expansion, which could adversely affect our business prospects. The inability to obtain funding, as and when needed, could have a negative impact on Leap's financial condition and our ability to pursue our business strategies.

Cash Flows

The following table summarizes our sources and uses of cash for each of the periods presented:

	Year Ended December 31,	
	2020	**2019**
	(in thousands)	
Cash used in operating activities	(25,957)	$(26,902)
Cash provided by (used in) investing activities	25	(85)
Cash provided by financing activities	73,997	14,817
Effect of exchange rate changes on cash and cash equivalents	115	(223)
Net increase (decrease) in cash and cash equivalents	$ 48,180	$(12,393)

Operating activities. Net cash used in operating activities for the year ended December 31, 2020 was primarily related to our net loss from the operation of our business of $27.5 million and net changes in working capital, including a decrease in accounts payable and accrued expenses of $2.6 million, a decrease in lease liabilities of $0.5 million and an increase in contract acquisition costs of $0.3 million. There was also a non cash change of $0.7 million due to foreign currency gains. These changes were partially offset by a decrease of $0.8 million in prepaid expenses and other assets, an increase of $1.5 million in deferred revenue, a decrease in research and development receivable of $0.1 million, noncash stock based compensation expense of $2.6 million, noncash lease expense of $0.5 million and amortization of contract asset of $0.1 million.

Net cash used in operating activities for the year ended December 31, 2019 was primarily related to our net loss from the operation of our business of $32.9 million and net changes in working capital, including a decrease in lease liabilities of $0.7 million. These changes were partially offset by an increase in accounts payable and accrued expenses of $1.1 million, a decrease of $0.6 million in research and development receivable, a decrease of $0.3 million in prepaid expenses and other assets, noncash stock based compensation expense of $3.7 million and change in restricted stock liability of $0.2 million.

Investing Activities. Net cash provided by investing activities during the year ended December 31, 2020 was related to the sale of equipment. Net cash used in investing activities during the year ended December 31, 2019 was primarily related to purchases of equipment.

Financing Activities. Net cash provided by financing activities for the year ended December 31, 2020 consisted of $48.5 million in proceeds from the issuance of common stock in connection with our public offering in June of 2020, $27.0 million in proceeds from the issuance of Series A Preferred Stock and Series B Preferred Stock in connection with the January 2020 Private Placement and $0.4 million in proceeds from the issuance of common stock upon the exercise of stock options and warrants. These increases were partially offset by payments of $1.9 million for offering costs.

Net cash provided by financing activities for the year ended December 31, 2019 consisted of $12.3 million in proceeds from the issuance of common stock in connection with the public offering in February of 2019, net of underwriter commissions and discounts, $1.9 million in proceeds from the issuance of common stock under our Distribution Agreement with Raymond James & Associates, Inc. and $1.0 million in proceeds from the issuance of common stock under the Distribution Agreement with Lincoln Park Capital. These increases were partially offset by payments of $0.4 million for deferred offering costs.

Capital Requirements

We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance the preclinical activities and clinical trials of our product candidates in development. In addition, we expect to incur additional costs associated with operating as a public company.

Our expenses will also increase as we:

- pursue the clinical development of our most advanced product candidate, DKN-01;
- seek to identify and develop additional product candidates;
- maintain, expand and protect our intellectual property portfolio;
- expand our operational, financial and management systems and increase personnel, including personnel to support our clinical development, manufacturing and commercialization efforts and our operations as a public company; and
- increase our product liability and clinical trial insurance coverage as we initiate our clinical trials and commercialization efforts.

Additional funding may not be available at the time needed on commercially reasonable terms, if at all.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations as of December 31, 2020 and the effects that such obligations are expected to have on our liquidity and cash flows in future periods:

	Payments due by period				
	Total	Less than 1 year	1 - 3 years	3 - 5 years	More than 5 Years
Research commitments(1)	$ 636	$ 636	$ —	$ —	$ —
Operating lease commitments(2)	580	434	146	—	—
Total	$1,216	$1,070	$146	$ —	$ —

(1) Represents non-cancellable commitments under manufacturing agreements with vendors to manufacture DKN-01 for use in clinical trials.

(2) Represents operating lease commitments for our office space at 47 Thorndike Street in Cambridge, Massachusetts through April 30, 2022.

Pursuant to the Lilly Agreement, we agreed to pay Lilly a royalty in the low single digits of net sales of a particular product in the territory during the applicable royalty term. As the product candidate has not been approved for sale, we have not yet paid any royalties to Lilly pursuant to this agreement and do not know whether or when royalties may ultimately become payable.

Pursuant to the Lonza Agreement, we agreed to pay Lonza a royalty in the low single digits of net sales of a particular product in the territory during the applicable royalty term. As the product candidate has not been approved for sale, we have not yet paid any royalties to Lonza pursuant to this agreement and do not know whether or when royalties may ultimately become payable.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the Securities and Exchange Commission.

Recently Issued Accounting Pronouncements

We have reviewed all recently issued standards and have determined that, other than as disclosed in Note 2 to our consolidated financial statements included in this Annual Report on Form 10-K, such standards will not have a material impact on our financial statements or do not otherwise apply to our operations.

Item 7A. Quantitative and Qualitative Disclosures about Market Risks

Market risk represents the risk of loss that may impact our financial position due to adverse changes in financial market prices and rates. Our market risk exposure is primarily the result of fluctuations in interest rates and foreign exchange rates.

Interest Rate Risk

We are exposed to interest rate risk in the ordinary course of our business. Our cash and cash equivalents are held in highly liquid, readily available checking and money market accounts. As a result, these amounts are not materially affected by changes in interest rates and we do not believe that a 10% change in interest rate would materially impact these amounts.

Foreign Currency Exchange Risk

All of our employees and the majority of our major operations are currently located in the United States. We contract for manufacturing operations outside the United States through contract manufacturing organizations. The functional currency of our foreign subsidiary in Australia is the Australian dollar, and the R&D Tax Incentive payment is received from the Australian government in Australian dollars, although the majority of the Australian subsidiary’s contracts are denominated in U.S. dollars. We have engaged in contracts with contractors or other vendors in a currency other than the U.S. dollar, including our services agreement with Lonza Sales AG which is denominated in British pounds. As a result, we are subject to foreign currency risks with respect to the Australian dollar and the British pound which could have the effect of increasing our expenses or reducing the amounts collected under the R&D Tax Incentive from the amounts recorded at the time of the transaction.

Item 8. Financial Statements and Supplementary Data.

Our financial statements required by this Item, together with the report of our independent registered public accounting firm, appear on pages F-1 through F-30 of this Annual Report on Form 10-K and are incorporated herein by reference.

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 the reports that we file or submit under the Securities and Exchange Act of 1934 is (1) recorded, processed, summarized, and reported within the time periods specified in the SEC’s rules and forms and (2) accumulated and communicated to our management, including our President and Chief Executive Officer, who is also serving as our Chief Financial Officer and therefore currently serves as both our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

As of December 31, 2020, our management, with the participation of our Chief Executive Officer, who is also serving as our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities and Exchange Act of 1934, as amended). Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our principal executive officer and principal financial and accounting officer has concluded based upon the evaluation described above that, as of December 31, 2020, our disclosure controls and procedures were effective at the reasonable assurance level.

Management’s Report on Internal Control Over Financial Reporting

This Company’s management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act). Internal control over financial reporting is a process designed under the supervision and with the participation of our management, including the individuals serving as our principal executive officer and principal financial officer, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America. Management conducted an assessment of the effectiveness of the Company’s internal control over financial reporting based on the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control—Integrated Framework (2013 Framework). Based on this assessment, our management concluded that, as of December 31, 2020, our internal control over financial reporting was effective based on those criteria.

Attestation Report on Internal Control Over Financial Reporting

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm due to the deferral allowed under the JOBS Act for emerging growth companies.

Changes in Internal Control Over Financial Reporting

There were no changes to our internal control over financial reporting that occurred during the period covered by this report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this Item is set forth in our Proxy Statement for the 2021 Annual Meeting of Stockholders to be filed with the SEC within 120 days of December 31, 2020, and is incorporated into this Annual Report on Form 10-K by reference.

Item 11. Executive Compensation.

The information required by this Item is set forth in our Proxy Statement for the 2021 Annual Meeting of Stockholders to be filed with the SEC within 120 days of December 31, 2020, and is incorporated into this Annual Report on Form 10-K by reference.

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

The information required by this Item is set forth in our Proxy Statement for the 2021 Annual Meeting of Stockholders to be filed with the SEC within 120 days of December 31, 2020, and is incorporated into this Annual Report on Form 10-K by reference.

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

The information required by this Item is set forth in our Proxy Statement for the 2021 Annual Meeting of Stockholders to be filed with the SEC within 120 days of December 31, 2020, and is incorporated into this Annual Report on Form 10-K by reference.

Item 14. Principal Accounting Fees and Services.

The information required by this Item is set forth in our Proxy Statement for the 2021 Annual Meeting of Stockholders to be filed with the SEC within 120 days of December 31, 2020, and is incorporated into this Annual Report on Form 10-K by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a)(1) Financial Statements

The financial statements listed below are filed as part of this Annual Report on Form 10-K.

(a)(2) Financial Statement Schedules

All financial schedules have been omitted because the required information is either presented in the Consolidated Financial Statements or the Notes thereto or is not applicable or required.

(a)(3) Exhibits

The exhibits required by Item 601 of Regulation S-K and Item 15(b) of this Annual Report on Form 10-K are listed in the Exhibit Index immediately preceding the exhibits and are incorporated herein by reference.

EXHIBIT INDEX

Exhibit No.	Description
3.1	Fourth Amended and Restated Certificate of Incorporation of Leap Therapeutics, Inc. (incorporated by reference to Exhibit 3.3 to the Company's Current Report on Form 8-K, as filed on September 10, 2020).
3.2	Amended and Restated By-laws of Leap Therapeutics, Inc. (incorporated by reference to Exhibit 3.4 to the Company's registration statement on Form S-4, as filed on September 26, 2016 and attached as Annex D to the prospectus which forms part of such registration statement).
4.1	Form of Common Stock Certificate of the Registrant (incorporated by reference to Exhibit 4.1 to Amendment No. 2 to the Company's registration statement on Form S-4, on November 16, 2016).
4.2	Registration Rights Agreement, by and among Leap and certain stockholders, dated as of January 23, 2017 (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K, as filed on January 26, 2017).
4.3	Registration Rights Agreement dated as of July 10, 2019, by and between the Company and Lincoln Park Capital Fund, LLC (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K, as filed on July 11, 2019).
4.4	Registration Rights Agreement dated as of January 3, 2020, by and between the Company and the persons listed on the attached Schedule A thereto (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K, as filed on January 7, 2020).
4.5	Registration Rights Agreement dated as of January 3, 2020, by and between the Company and the persons listed on the attached Schedule A thereto (incorporated by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K, as filed on January 7, 2020).
4.6	Form of Warrant, dated as of November 14, 2017 by and among Leap Therapeutics, Inc. and the Holders identified on the schedule thereto (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, as filed on November 17, 2017).
4.7	Form of Warrant, dated as of February 5, 2019 by and between Leap Therapeutics, Inc. and each of the purchasers in the Registrant's 2019 Public Offering (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, as filed on February 1, 2019).
4.8	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, as filed on January 7, 2020).
4.9	Form of Series A Coverage Warrant (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K, as filed on January 7, 2020).
4.10	Form of Series B Coverage Warrant (incorporated by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K, as filed on January 7, 2020).
4.11	Amendment No. 2 to Warrant, by and among Macrocure, the Registrant and certain warrant holders, dated as of January 23, 2017 (incorporated by reference to Exhibit 4.4 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2016, as filed on March 31, 2017).
4.12	Description of the Registrant's Securities registered pursuant to Section 12 of the Securities Exchange Act of 1934 (incorporated by reference to Exhibit 4.6 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2019, as filed on March 16, 2020).
10.1**	Exclusive Option and License Agreement dated as of January 3, 2020, by and between the Company and BeiGene, Ltd. (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2020, as filed on May 14, 2020).
10.2**	License Agreement, between Eli Lilly and Company and Dekkun Corporation, effective as of January 3, 2011 (incorporated by reference to Exhibit 10.4 to the Company's registration statement on Form S-4, as filed on September 26, 2016).

Exhibit No.	Description
10.3**	License Agreement, by and between Lonza Sales AG and Healthcare Pharmaceuticals, Inc., dated as of May 28, 2015 (incorporated by reference to Exhibit 10.5 to the Company's registration statement on Form S-4, as filed on September 26, 2016).
10.4	Royalty Agreement, between Leap Therapeutics, Inc. and Leap Shareholder Royalty Vehicle, Inc. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed on January 26, 2017).
10.5	Letter Agreement, between Leap Shareholder Royalty Vehicle, Inc. and certain Leap stockholders (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, as filed on January 26, 2017).
10.6	Form of Purchase Agreement, dated as of November 14, 2017, by and among Leap Therapeutics, Inc. and the purchasers identified on the schedule thereto (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed on November 17, 2017).
10.7	Purchase Agreement dated as of July 11, 2019, by and between the Company and Lincoln Park Capital Fund, LLC (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed on July 11, 2019).
10.8	Purchase Agreement dated as of July 10, 2019, by and between the Company and Lincoln Park Capital Fund, LLC (filed as Exhibit 10.2 to the Company's Current Report on Form 8-K, as filed on July 11, 2019).
10.9	Securities Purchase Agreement, dated January 3, 2020, by and among the Company and the institutional investors named therein (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed on January 7, 2020).
10.10	Form of Indemnification Agreement (filed as Exhibit 10.10 to Amendment No. 1 to the Registrant's registration statement on Form S-4, as filed on November 2, 2016).
10.11^	Macrocure 2013 Share Incentive Plan (filed as Exhibit 10.4 to the Company's registration statement on Form S-8, as filed on January 27, 2017).
10.12^	Amendment No. 1 to Macrocure 2013 Share Incentive Plan (filed as Exhibit 10.5 to the Company's registration statement on Form S-8, as filed on January 27, 2017).
10.13^	Summary Translation of Macrocure 2008 Stock Option Plan stockholders (filed as Exhibit 10.3 to the Registrant's registration statement on Form S-8, as filed on January 27, 2017).
10.14^	Employment Agreement, by and between the Company and Douglas E. Onsi, dated as of April 10, 2020 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K/A, as filed on April 15, 2020).
10.15^	Executive Employment Agreement and accompanying Employee Proprietary Information, Inventions, Non-Competition and Non-Solicitation Agreement, by and between Leap and Christopher K. Mirabelli, dated as of August 29, 2016 (incorporated by reference to Exhibit 10.7 to the Company's registration statement on Form S-4, as filed on September 26, 2016).
10.16^	Executive Employment Agreement and accompanying Employee Proprietary Information, Inventions, Non-Competition and Non-Solicitation Agreement, by and between Leap and Augustine Lawlor, dated as of August 29, 2016 (incorporated by reference to Exhibit 10.9 to the Company's registration statement on Form S-4 , as filed on September 26, 2016).
10.17^	Employment Agreement, by and between the Company and Christine Granfield, dated as of August 16, 2020 (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2020, as filed on November 12, 2020).
10.18*^	Employment Agreement, by and between the Company and Cynthia Sirard, dated as of April 10, 2020.
10.19*^	Employment Agreement, by and between the Company and John Mark O' Mahony, dated as of April 10, 2020.

Exhibit No.	Description
10.20^	Amended and Restated 2012 Equity Incentive Plan of the Registrant (incorporated by reference to Exhibit 10.1 to the Company's registration statement on Form S-8, as filed on January 27, 2017).
10.21^	Form of Stock Option Grant Notice and Stock Option Agreement under the Registrant's Amended and Restated 2012 Equity Incentive Plan, as amended (incorporated by reference to Exhibit 10.2 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2016, as filed on March 31, 2017).
10.22^	2016 Equity Incentive Plan of Leap Therapeutics, Inc. (incorporated by reference to Exhibit 10.2 to the Company's registration statement on Form S-8, as filed on January 27, 2017).
10.23^	Form of Stock Option Grant Notice and Stock Option Agreement under Leap's 2016 Equity Incentive Plan, as amended (incorporated by reference to Exhibit 10.3 to the Company's registration statement on Form S-4, as filed on November 2, 2016).
10.24^	First Amendment to the 2016 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to the Company's registration statement on Form S-8, as filed on June 11, 2019).
21.1*	Subsidiaries of Leap Therapeutics, Inc.
23.1*	Consent of EisnerAmper LLP related to Leap Therapeutics, Inc. financial statements.
31.1*	Certification of Principal Executive and Principal Financial Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.
32.1*+	Principal Executive and Principal Financial Officer Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101*	The following materials from Leap Therapeutics, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2020, formatted in XBRL (Extensible Business Reporting Language): (i) Consolidated Balance Sheets at December 31, 2020 and 2019, (ii) Consolidated Statements of Operations for the year ended December 31, 2020 and December 31, 2019, (iii) Consolidated Statements of Shareholders' Equity (Deficit) at December 31, 2020 and December 31, 2019 (iv) Consolidated Statements of Cash Flows for the year ended December 31, 2020 and December 31, 2019, and (v) Notes to Condensed Consolidated Financial Statements, tagged as blocks of text.

* Exhibits filed herewith

^ Indicates management contract or compensation plan

** Portions of this exhibit have been redacted in compliance with Regulation S-K Item 601(b)(10).

\+ This exhibit shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of the Section, nor shall it be deemed incorporated by reference in any filings under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date hereof and irrespective of any general incorporation language in any filing.

SIGNATURES

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

LEAP THERAPEUTICS, INC.

March 12, 2021

By: /s/ DOUGLAS E. ONSI

Name: Douglas E. Onsi

Title: *President, Chief Executive Officer and Chief Financial Officer*

Pursuant to the requirements of the Securities Exchange Act of 1934, this 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/ DOUGLAS E. ONSI Douglas E. Onsi	Chief Executive Officer, President, Chief Financial Officer and Director (Principal Executive Officer and Principal Financial Officer)	March 12, 2021
/s/ CHRISTOPHER K. MIRABELLI, PH.D. Christopher K. Mirabelli, Ph.D.	Chairman of the Board of Directors	March 12, 2021
/s/ MONICA M. BERTAGNOLLI, M.D. Monica M. Bertagnolli, M.D.	Director	March 12, 2021
/s/ JAMES CAVANAUGH, PH.D. James Cavanaugh, Ph.D.	Director	March 12, 2021
/s/ THOMAS DIETZ, PH.D. Thomas Dietz, Ph.D.	Director	March 12, 2021
/s/ WILLIAM LI, M.D. William Li, M.D.	Director	March 12, 2021
/s/ JOSEPH LOSCALZO, M.D., PH.D. Joseph Loscalzo, M.D., Ph.D.	Director	March 12, 2021
/s/ NISSIM MASHIACH Nissim Mashiach	Director	March 12, 2021

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
Leap Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Leap Therapeutics, Inc. and Subsidiaries (the "Company") as of December 31, 2020 and 2019, and the related consolidated statements of operations, comprehensive loss, stockholders' equity (deficiency), and cash flows for each of the years then ended and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2020 and 2019, and the consolidated results of their operations and their cash flows for each of the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ EisnerAmper LLP

We have served as the Company's auditor since 2014.

EISNERAMPER LLP

Philadelphia, Pennsylvania
March 12, 2021

LEAP THERAPEUTICS, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share amounts)

	December 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 52,071	$ 3,891
Research and development incentive receivable	73	185
Prepaid expenses and other current assets	130	165
Total current assets	52,274	4,241
Property and equipment, net	65	124
Right of use assets, net	528	1,026
Deferred tax assets	179	127
Deferred costs	345	831
Deposits	980	1,099
Total assets	$ 54,371	$ 7,448
Liabilities and Stockholders' Equity (Deficiency)		
Current liabilities:		
Accounts payable	$ 2,717	$ 4,571
Accrued expenses	2,747	3,441
Deferred revenue— current portion	1,500	—
Lease liability— current portion	408	474
Total current liabilities	7,372	8,486
Non current liabilities:		
Restricted stock liability	204	159
Lease liability, net of current portion	144	552
Total liabilities	7,720	9,197
Stockholders' equity (deficiency):		
Common stock, $0.001 par value; 240,000,000 shares authorized; 59,657,742 and 24,194,877 shares issued and outstanding as of December 31, 2020 and 2019, respectively	60	24
Additional paid-in capital	270,155	193,319
Accumulated other comprehensive income (loss)	(579)	76
Accumulated deficit	(222,985)	(195,168)
Total stockholders' equity (deficiency)	46,651	(1,749)
Total liabilities and stockholders' equity (deficiency)	$ 54,371	$ 7,448

See notes to consolidated financial statements

LEAP THERAPEUTICS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except share and per share amounts)

	Year Ended December 31	
	2020	**2019**
License revenue	$ 1,500	$ —
Operating expenses:		
Research and development	20,423	24,366
General and administrative	9,616	9,085
Total operating expenses	30,039	33,451
Loss from operations	(28,539)	(33,451)
Interest income	93	313
Interest expense	(39)	(23)
Australian research and development incentives	231	132
Foreign currency gains	738	126
Loss before income taxes	(27,516)	(32,903)
Income taxes	2	3
Net loss	(27,514)	(32,900)
Dividend attributable to down round feature of warrants	(303)	(359)
Dividend attributable to Series A & B convertible preferred stock	(372)	—
Series A & B convertible preferred stock—beneficial conversion feature	(9,399)	—
Net loss attributable to common stockholders	$ (37,588)	$ (33,259)
Net loss per share		
Basic	$ (0.63)	$ (1.47)
Diluted	$ (0.63)	$ (1.47)
Weighted average common shares outstanding		
Basic	59,327,713	22,582,687
Diluted	59,327,713	22,582,687

See notes to consolidated financial statements

LEAP THERAPEUTICS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(In thousands)

	Year Ended December 31,	
	2020	**2019**
Net loss	$(27,514)	$(32,900)
Other comprehensive loss:		
Foreign currency translation adjustments	(655)	(226)
Comprehensive loss	$(28,169)	$(33,126)

See notes to consolidated financial statements

LEAP THERAPEUTICS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIENCY)

(In thousands, except share amounts)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficiency)
	Shares	Amount				
Balances at December 31, 2018	14,703,159	$15	$162,393	$ 302	$(153,535)	$ 9,175
Issuance of common stock in connection with February 2019 Public Offering, net of issuance costs of $1,102	7,557,142	7	12,115	—	—	12,122
Issuance of common stock through ATM sales	1,033,147	1	1,922	—	—	1,923
To record ATM issuance costs in Additional Paid-in Capital	—	—	(13)	—	—	(13)
Issuance of common stock in connection with July 2019 Lincoln Park Capital Commitment Purchase Agreement	330,000	—	—	—	—	—
Issuance of common stock in connection with July 2019 Lincoln Park Capital Registered Offering Purchase Agreement	571,429	1	999	—	—	1,000
To record Lincoln Park issuance costs in Additional Paid-in-Capital	—	—	(10)	—	—	(10)
Reclassification of 2017 warrants from liability to equity	—	—	11,822	—	(8,374)	3,448
Record the value of the effect of the down round feature as a dividend	—	—	359	—	(359)	—
Foreign currency translation adjustment	—	—	—	(226)	—	(226)
Stock-based compensation	—	—	3,732	—	—	3,732
Net loss	—	—	—	—	(32,900)	(32,900)
Balances at December 31, 2019	24,194,877	$24	$193,319	$ 76	$(195,168)	$ (1,749)

See notes to consolidated financial statements

LEAP THERAPEUTICS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIENCY) (Continued)

(In thousands, except share amounts)

	Series A Convertible Preferred Stock,		Series B Convertible Preferred Stock,		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount				
Balances at December 31, 2019	—	$ —	—	$ —	24,194,877	$24	$193,319	$ 76	$ (195,168)	$ (1,749)
Issuance of Series A & B Convertible Preferred Stock, net of underwriting discounts	1,421,801	14,062	1,137,442	11,260	—	—	—	—	—	—
Series A & B Convertible Preferred Stock discount - beneficial conversion feature	—	(5,226)	—	(4,173)	—	—	9,399	—	—	9,399
Series A & B Convertible Preferred Stock accrued dividends	—	207	—	165	—	—	(372)	—	—	(372)
Conversion of Series A & B Convertible Preferred Stock dividends to prefunded warrants and common stock	—	(207)	—	(165)	156,713	1	371	—	—	372
Conversion of Series A Convertible Preferred Stock to prefunded warrants	(1,421,801)	(8,836)	—	—	—	—	8,836	—	—	8,836
Conversion of Series B Convertible Preferred Stock to common stock	—	—	(1,137,442)	(7,087)	11,374,420	11	7,076	—	—	7,087
Issuance of common stock in connection with June 2020 Public Offering, net of issuance costs of $3,472					23,625,000	24	48,252	—	—	48,276
Issuance of common stock upon exercise of stock options	—	—	—	—	32,778	—	51	—	—	51
Issuance of common stock upon exercise of warrants	—	—	—	—	273,954	—	348	—	—	348
Dividend attributable to the down round feature of 2017 Warrants	—	—	—	—	—	—	303	—	(303)	—
Foreign currency translation adjustment	—	—	—	—	—	—	—	(655)	—	(655)
Stock-based compensation	—	—	—	—	—	—	2,572	—	—	2,572
Net loss	—	—	—	—	—	—	—	—	(27,514)	(27,514)
Balances at December 31, 2020	—	$ —	—	$ —	59,657,742	$60	$270,155	$ (579)	$ (222,985)	$ 46,651

See notes to consolidated financial statements

LEAP THERAPEUTICS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Year Ended December 31,	
	2020	**2019**
Cash flows from operating activities:		
Net loss	$(27,514)	$(32,900)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	34	47
Amortization of contract asset	135	—
Right-of-use asset	499	729
Stock-based compensation expense	2,572	3,732
Foreign currency (gain) loss	(738)	—
Change in fair value of restricted stock liability	45	159
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	774	302
Deferred tax assets	(36)	(3)
Research and development incentive receivable	117	643
Contract acquisition costs	(270)	—
Accounts payable and accrued expenses	(2,601)	1,084
Deferred revenue	1,500	—
Lease liability	(474)	(695)
Net cash used in operating activities	(25,957)	(26,902)
Cash flows from investing activities:		
Purchases of property and equipment	—	(100)
Proceeds from sale of property and equipment	25	15
Net cash provided by (used in) investing activities	25	(85)
Cash flows from financing activities:		
Proceeds from issuance of common stock—June 2020 Public Offering	48,518	—
Proceeds from the issuance of Series A convertible preferred stock	14,986	—
Proceeds from the issuance of Series B convertible preferred stock	12,000	—
Proceeds from issuance of common stock	—	12,331
Proceeds from issuance of common stock from ATM sales	—	1,923
Proceeds from issuance of common stock in connection with July 2019 Lincoln Park Capital Registered Offering Purchase Agreement, net of issuance costs	—	1,000
Proceeds from the exercise of common stock warrants	348	—
Proceeds from the exercise of stock options	51	—
Payment of deferred offering costs	(1,906)	(437)
Net cash provided by financing activities	73,997	14,817
Effect of exchange rate changes on cash and cash equivalents	115	(223)
Net decrease in cash and cash equivalents	48,180	(12,393)
Cash and cash equivalents at beginning of year	3,891	16,284
Cash and cash equivalents at end of year	$ 52,071	$ 3,891
Supplemental disclosure of non-cash financing activities:		
Reclassification of 2017 Warrants from liability to equity	$ —	$ 3,448
Dividend attributable to down round feature of warrants	$ 303	$ 359
Offering costs included in accounts payable and accrued expenses	$ —	$ 444
Right-of-use asset recorded upon adoption of ASU 2016-02	$ —	$ 1,755
Lease liability recorded upon adoption of ASU 2016-02	$ —	$ 1,720
Accrued rent reclassified upon adoption of ASU 2016-02	$ —	$ 35
Reclassification of deferred offering costs to additional paid-in-capital	$ —	$ 23
Conversion of Series A convertible preferred stock to prefunded warrants	$ 8,836	$ —
Conversion of Series B convertible preferred stock to common stock	$ 7,087	$ —
Beneficial conversion feature from Series A convertible preferred stock	$ 5,226	$ —
Beneficial conversion feature from Series B convertible preferred stock	$ 4,173	$ —

See notes to consolidated financial statements

LEAP THERAPEUTICS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(Amounts in thousands, except share and per share amounts)

1. Nature of Business, Basis of Presentation and Liquidity

Nature of Business

Leap Therapeutics, Inc. was incorporated in the state of Delaware on January 3, 2011. During 2015, HealthCare Pharmaceuticals Pty Ltd. ("HCP Australia") was formed and is a wholly owned subsidiary of the Company.

On December 10, 2015, the Company entered into a merger agreement with GITR Inc. ("GITR"), an entity under common control, whereby a wholly owned subsidiary was merged with GITR and the surviving name of the wholly owned subsidiary was GITR Inc.

On August 29, 2016, the Company entered into a merger agreement with Macrocure Ltd. ("Macrocure"), a publicly held, clinical-stage biotechnology company based in Petach Tikva, Israel. In connection with the merger, the Company applied to be listed on the Nasdaq Global Market. Nasdaq approved the listing, and trading in the Company's common stock commenced on January 24, 2017, under the trading symbol "LPTX." On February 1, 2017, Macrocure's name was changed to Leap Therapeutics Ltd. In 2020, Leap Therapeutics Ltd. was dissolved.

The Company is a biopharmaceutical company acquiring and developing novel therapeutics at the leading edge of cancer biology. The Company's approach is designed to target compelling tumor-promoting and immuno-oncology pathways to generate durable clinical benefit and enhanced outcomes for patients. The Company's programs are monoclonal antibodies that target key cellular pathways that enable cancer to grow and spread and specific mechanisms that activate the body's immune system to identify and attack cancer.

Basis of Presentation

The accompanying consolidated financial statements of the Company include the accounts of its wholly owned subsidiaries and have been prepared in conformity with accounting principles generally accepted in the United States of America. All inter-company accounts and transactions are eliminated upon consolidation.

Liquidity

Since inception, the Company has been engaged in organizational activities, including raising capital, and research and development activities. The Company does not yet have a product that has been approved by the Food and Drug Administration (the "FDA"), has not generated any product sales revenues and has not yet achieved profitable operations, nor has it ever generated positive cash flows from operations. There is no assurance that profitable operations, if achieved, could be sustained on a continuing basis. Further, the Company's future operations are dependent on the success of the Company's efforts to raise additional capital, its research and commercialization efforts, regulatory approval, and, ultimately, the market acceptance of the Company's products.

In accordance with Accounting Standards Codification ("ASC") 205-40, Going Concern, the Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the consolidated financial statements are issued. As of December 31, 2020, the Company had cash and cash equivalents of $52,071. Additionally, the Company had an accumulated deficit of $222,985 at December 31, 2020, and during the year ended December 31, 2020, the Company incurred a net loss of $27,514. The Company expects to continue to generate operating losses for the foreseeable future. The Company believes that its cash and cash equivalents of $52,071 as of December 31, 2020, will be sufficient to fund its operating expenses for at least 12 months from the issuance of these financial statements.

LEAP THERAPEUTICS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

(Amounts in thousands, except share and per share amounts)

1. Nature of Business, Basis of Presentation and Liquidity (continued)

In addition, the Company will likely seek additional funding through public or private equity financings or government programs and will seek funding or development program cost-sharing through collaboration agreements or licenses with larger pharmaceutical or biotechnology companies. If the Company does not obtain additional funding or development program cost-sharing, or exceeds its current spending forecasts or fails to receive the research and development tax incentive payment, the Company has the ability and would be forced to: delay, reduce or eliminate certain clinical trials or research and development programs, reduce or eliminate discretionary operating expenses, and delay company and pipeline expansion, any of which could adversely affect its business prospects. The inability to obtain funding, as and when needed, could have a negative impact on the Company’s financial condition and ability to pursue its business strategies.

2. Summary of Significant Accounting Policies

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All intercompany accounts and transactions are eliminated upon consolidation.

Use of Estimates

The presentation of consolidated financial statements in conformity with accounting principles generally accepted in the United States of America (“GAAP”) requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Cash and Cash Equivalents

The Company considers all highly liquid investments with maturities of three months or less when purchased to be cash equivalents.

Research and Development Expense

Research and development costs are expensed as incurred. Research and development expenses include personnel costs associated with research and development activities, including noncash share-based compensation and costs for third-party contractors to perform research, conduct clinical trials and manufacture drug supplies and materials. The Company accrues for costs incurred by external service providers, including contract research organizations and clinical investigators, based on its estimates of service performed and costs incurred. These estimates include the level of services performed by the third parties, patient enrollment in clinical trials, administrative costs incurred by the third parties, and other indicators of the services completed. Based on the timing of amounts invoiced by service providers, the Company may also record payments made to those providers as prepaid expenses that will be recognized as expense in future periods as the related services are rendered.

Research and development incentive income and receivable

The Company recognizes other income from Australian research and development incentives when there is reasonable assurance that the income will be received, the relevant expenditure has been incurred, and the consideration can be reliably measured. The research and development incentive is one of the key elements of the Australian Government’s support for Australia’s innovation system and is supported by legislative law primarily in the form of the Australian Income Tax Assessment Act 1997 as long as eligibility criteria are met.

LEAP THERAPEUTICS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

(Amounts in thousands, except share and per share amounts)

2. Summary of Significant Accounting Policies (continued)

Management has assessed the Company's research and development activities and expenditures to determine which activities and expenditures are likely to be eligible under the research and development incentive regime described above. At each period end management estimates the refundable tax offset available to the Company based on available information at the time. This estimate is also reviewed by external tax advisors on an annual basis.

Under the program, a percentage of eligible research and development expenses incurred by the Company through its subsidiary in Australia are reimbursed. This percentage was 43.5% for the years ended December 31, 2020 and 2019.

The research and development incentive receivable represents an amount due in connection with the above program. The Company has recorded a research and development incentive receivable of $73 and $185 as of December 31, 2020 and 2019, respectively, in the consolidated balance sheets and other income from Australian research and development incentives of $231 and $132, in the consolidated statements of operations for the years ended December 31, 2020 and 2019, respectively, related to refundable research and development incentive program payments in Australia.

The following table shows the change in the research and development incentive receivable from January 1, 2019 to December 31, 2020:

Balance at January 1, 2019	$ 836
Australian research and development incentive income, net	132
Cash received for 2018 eligible expenses	(757)
Foreign currency translation	(26)
Balance at December 31, 2019	185
Australian research and development incentive income, net	231
Cash received for 2019 eligible expenses	(331)
Foreign currency translation	(12)
Balance at December 31, 2020	$ 73

Concentration of Credit Risk

Financial instruments which potentially subject the Company to credit risk consist principally of cash and cash equivalents. All cash and cash equivalents are held in United States financial institutions and money market funds. At times, the Company may maintain cash balances in excess of the federally insured amount.

Income Taxes

The Company accounts for income taxes using the asset and liability method. Under the asset and liability method, deferred income taxes are recognized for differences between the financial reporting and tax bases of assets and liabilities at enacted statutory tax rates in effect for the years in which the differences are expected to reverse. The effect on deferred taxes of a change in tax rates is recognized in income in the period that includes the enactment date. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized.

The Company follows accounting guidance concerning provisions for uncertainty in income tax positions. This guidance clarifies the accounting for income taxes by prescribing a minimum probability threshold that an uncertain tax position must meet before a financial statement benefit is recognized. The

LEAP THERAPEUTICS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

(Amounts in thousands, except share and per share amounts)

2. Summary of Significant Accounting Policies (continued)

minimum threshold is defined as a tax position that is more likely than not to be sustained upon examination by the applicable taxing authority, of any related appeals or litigation processes, based on the technical merits of the position. The tax benefit to be recognized is measured as the largest amount of benefit that is greater than 50% likely of being realized upon ultimate settlement.

The Company recognizes accrued interest and penalties associated with uncertain tax position as part of the income tax provision. There were no uncertain tax positions or income tax related interest and penalties recorded for the years ended December 31, 2020 and 2019. The income tax returns of the Company for the year ended December 31, 2017 and subsequent years are subject to examination by the Internal Revenue Service and other taxing authorities, generally for three years after the work filed.

Foreign Currency Translation

The financial statements of the Company’s foreign subsidiary are measured using the local currency as the functional currency. Assets and liabilities of this subsidiary are translated into U.S. dollars at exchange rates as of the consolidated balance sheet date. Equity is translated at historical exchange rates. Revenues and expenses are translated into U.S. dollars at average rates of exchange in effect during the year. The resulting cumulative translation adjustments have been recorded as a separate component of stockholders’ deficiency. Foreign currency transaction gains and losses are included in the results of operations.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Depreciation expense is recognized using the straight-line method over the estimated useful life of each asset. Computer equipment is depreciated over three years. Laboratory equipment, office equipment and furniture and fixtures are depreciated over five years. Leasehold improvements are amortized over the shorter of the lease term or the estimated useful life of the asset. Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is included in loss from operations. Expenditures for repairs and maintenance are charged to expense as incurred.

Impairment of Long-Lived Assets

Long-lived assets consist of property and equipment. Long-lived assets to be held and used are tested for recoverability whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends and significant changes or planned changes in the use of the assets. If an impairment review is performed to evaluate a long-lived asset group for recoverability, the Company compares forecasts of undiscounted cash flows expected to result from the use and eventual disposition of the long-lived asset group to its carrying value. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of an asset group are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset group over its fair value. The Company did not record any impairment losses on long-lived assets during 2020 and 2019.

Deferred Costs

The Company capitalizes certain legal, professional, accounting and other third-party fees that are directly associated with in-process equity financings as deferred costs until such financings are consummated. After consummation of the equity financing, these costs are recorded in stockholders’ equity (deficiency) as a reduction of additional paid-in capital generated as a result of the offering.

LEAP THERAPEUTICS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

(Amounts in thousands, except share and per share amounts)

2. Summary of Significant Accounting Policies (continued)

The Company also capitalizes certain contract acquisition costs. During the year ended December 31, 2020, the Company incurred contract acquisition costs which were capitalized under ASC 340-40 as incremental costs of obtaining the contract with BeiGene. This cost is amortized on a straight-line basis over the performance period of the research and development services.

As of December 31, 2020 and December 31, 2019 there was $345 and $831, respectively, of deferred costs.

Deposits

Deposits as of December 31, 2020 and 2019 included $980 and $1,099, respectively, of deposits made by the Company with certain service providers that are to be applied to future payments due under the service agreements or returned to the Company if not utilized.

Warrants

On January 1, 2019, the Company adopted ASU No. 2017-11, Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480), and Derivatives and Hedging (Topic 815) (“ASU 2017-11”), which changes the classification analysis of certain equity-linked financial instruments (or embedded features) with down round features. The amendments require entities that present earnings per share (“EPS”) in accordance with Topic 260 to recognize the effect of the down round feature when triggered with the effect treated as a dividend and as a reduction of income available to common stockholders in basic EPS.

The Company concluded that the common stock warrants (the “2017 Warrants”) issued in connection with the private placement of common stock completed in November 2017 (the “November 2017 Private Placement”), qualify for equity classification under ASU 2017-11. The adoption guidance of ASU 2017-11 provides for a modified retrospective adoption. The Company applied the guidance retrospectively to the 2017 Warrants by means of a cumulative-effect adjustment to its statement of financial position as of the beginning of the interim and annual period beginning January 1, 2019. The Company performed a final remeasurement of the warrant liability as of January 1, 2019 and reclassified $3,448 from warrant liability to equity.

The Company will recognize on a prospective basis the value of the effect of the down round feature in the 2017 Warrants when it is triggered (i.e., when the exercise price is adjusted downward). This value is measured as the difference between (1) the financial instrument’s fair value (without the down round feature) using the pre-trigger exercise price and (2) the financial instrument’s fair value (with the down round feature) using the reduced exercise price. The value of the effect of the down round feature will be treated as a dividend and a reduction to income available to common stockholders in the basic EPS calculation. In connection with the public offering, completed in February 2019 (the “2019 Public Offering”), when the 2017 Warrants were repriced from $6.085 to $1.75 as a result of a down round, the Company recorded a dividend of $359 during the year ended December 31, 2019. In connection with the private placement of common stock completed in January 2020 (the “January 2020 Private Placement”), when the 2017 Warrants were repriced from $1.75 to $1.055 as a result of a down round, the Company recorded a dividend of $303 during the year ended December 31, 2020.

Fair Value of Financial Instruments

Certain assets and liabilities are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable

2. Summary of Significant Accounting Policies (continued)

inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1—Quoted prices in active markets for identical assets or liabilities.
- Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

During the years presented, the Company has not changed the manner in which it values assets and liabilities that are measured at fair value using Level 3 inputs. The Company recognizes transfers between levels of the fair value hierarchy as of the end of the reporting period. There were no transfers within the hierarchy during the years ended December 31, 2020 and 2019.

A summary of the assets and liabilities carried at fair value in accordance with the hierarchy defined above is as follows (in thousands):

	Total	Level 1	Level 2	Level 3
December 31, 2020				
Assets:				
Cash equivalents	$51,116	$51,116	$ —	$ —
Total assets	$51,116	$51,116	$ —	$ —
Liabilities:				
Restricted stock liability	$ 204	$ —	$204	$ —
Total liabilities	$ 204	$ —	$204	$ —
December 31, 2019				
Assets:				
Cash equivalents	$ 3,891	$ 3,891	$ —	$ —
Total assets	$ 3,891	$ 3,891	$ —	$ —
Liabilities:				
Restricted stock liability	$ 159	$ —	$159	$ —
Total liabilities	$ 159	$ —	$159	$ —

Cash equivalents of $51,116 and $3,891 as of December 31, 2020 and 2019, respectively, consisted of overnight investments and money market funds and are classified within Level 1 of the fair value hierarchy because they are valued using quoted market prices in active markets.

The carrying value of the research and development incentive receivable, accounts payable and accrued expenses approximate their fair value due to the short-term nature of these assets and liabilities.

Leases

In February 2016, the Financial Accounting Standards Board, or FASB, issued ASU 2016-02, Leases, or ASU 2016-02, to enhance the transparency and comparability of financial reporting related to leasing

2. Summary of Significant Accounting Policies (continued)

arrangements. The Company adopted ASU 2016-02 on January 1, 2019, or the effective date, and used the effective date as its date of initial application.

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances present. Most leases with a term greater than one year are recognized on the balance sheet as right-of-use assets, lease liabilities and, if applicable, long-term lease liabilities. The Company has elected not to recognize on the balance sheet leases with terms of one year or less. Operating lease liabilities and their corresponding right-of-use assets are recorded based on the present value of lease payments over the expected remaining lease term. The Company has determined that the rate implicit in the lease is not determinable and the Company does not have borrowings with similar terms and collateral. Therefore, the Company considered a variety of factors, including observable debt yields from comparable companies and the volatility in the debt market for securities with similar terms, in determining that 8% was reasonable to use as the incremental borrowing rate for purposes of the calculation of lease liabilities.

In accordance with the guidance in ASU 2016-02, components of a lease should be split into three categories: lease components (e.g. land, building, etc.), non-lease components (e.g. common area maintenance, maintenance, consumables, etc.), and non-components (e.g. property taxes, insurance, etc.). Then the fixed and in-substance fixed contract consideration (including any related to non-components) must be allocated based on fair values to the lease components and non-lease components.

Although separation of lease and non-lease components is required, certain practical expedients are available. Entities may elect the practical expedient to not separate lease and non-lease components. Rather, they would account for each lease component and the related non-lease component together as a single component. The Company has elected to account for the lease and non-lease components of each of its operating leases as a single lease component and allocate all of the contract consideration to the lease component only. The lease component results in an operating right-of-use asset being recorded on the consolidated balance sheets and amortized such that lease expense is recorded on a straight line basis over the term of the lease.

Segment Information

The Company manages its operations as a single segment for the purposes of assessing performance and making operating decisions. The Company’s singular focus is developing novel, targeted drugs for the treatment of cancer. Substantially all of the Company’s tangible assets are held in the United States.

Patent Costs

All patent related costs incurred in connection with filing and prosecuting patent applications are expensed as incurred due to the uncertainty about the recovery of the expenditure. Amounts incurred are classified as general and administrative expenses.

Stock-Based Compensation

The Company measures all stock options and other stock-based awards granted to employees based on the fair value on the date of the grant and recognizes compensation expense of those awards, net of estimated forfeitures, over the requisite service period, which is generally the vesting period of the respective award. Generally, the Company issues stock options to employees with only service-based vesting conditions and records the expense for these awards using the straight-line method.

The Company measures stock-based awards granted to consultants and nonemployees based on the fair value of the award on the date on which the related service is complete. Compensation expense is

2. Summary of Significant Accounting Policies (continued)

recognized over the period during which services are rendered by such consultants and nonemployees until completed. At the end of each financial reporting period prior to completion of the service, the fair value of these awards is remeasured using the then current fair value of the Company's common stock and updated assumption inputs in the Black-Scholes option-pricing model.

Stock-based compensation is classified in the accompanying consolidated statements of operations based on the function to which the related services are provided.

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model. The Company historically has been a private company and lacks company-specific historical and implied volatility information. Therefore, it estimates its expected stock volatility based on the historical volatility of a publicly traded set of peer companies and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded stock price. The expected term of the Company's stock options granted to employees has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The expected term of stock options granted to nonemployees is equal to the contractual term of the option award. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield of zero is based on the fact that the Company has never paid cash dividends on common stock and does not expect to pay any cash dividends in the foreseeable future.

Revenue Recognition

The Company records revenue in accordance with Accounting Standards Codification, or ASC, Topic 606, Revenue From Contracts with Customers. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. Under Topic 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of Topic 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of Topic 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations, and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

License revenue. The Company's performance obligations under its license agreements may include providing intellectual property licenses, performing technology transfer, performing research and development consulting services and notifying the customer of any enhancements to licensed technology or new technology that it discovers, among others. The Company determined that its performance obligations under its license agreements as evaluated at contract inception were not distinct and represented a single performance obligation. Upfront payments are amortized to revenue on a straight line basis over the performance period. Upfront payment contract liabilities resulting from the Company's license agreements do not represent a financing component as the payment is not financing the transfer of goods or services, and the technology underlying the licenses granted reflects research and development expenses already incurred

2. Summary of Significant Accounting Policies (continued)

by the Company. Generally, all amounts received or due other than sales-based milestones and royalties are classified as license revenues. Sales-based milestones and royalties under the Company's license agreements will be recognized as royalty revenue in the period the related sale occurred. The Company generally invoices its licensees upon the completion of the effort or achievement of a milestone, based on the terms of each agreement. Deferred revenue arises from amounts received in advance of the culmination of the earnings process and is recognized as revenue in future periods as performance obligations are satisfied. Deferred revenue expected to be recognized within the next twelve months is classified as a current liability.

Research and Development Services. The promises under the Company's license agreements may include research and development services to be performed by the Company on behalf of the customer. Payments or reimbursements resulting from the Company's research and development efforts are recognized as the services are performed and presented on a gross basis because the Company is the principal for such efforts.

Customer Options. If an arrangement is determined to contain customer options that allow the customer to acquire additional goods or services, the goods and services underlying the customer options that are not determined to be material rights are not considered to be performance obligations at the outset of the arrangement, as they are contingent upon option exercise. The Company evaluates the customer options for material rights, or options to acquire additional goods or services for free or at a discount. If the customer options are determined to represent a material right, the material right is recognized as a separate performance obligation at the outset of the arrangement. The Company allocates the transaction price to material rights based on the relative standalone selling price, which is determined based on the identified discount and the probability that the customer will exercise the option. Amounts allocated to a material right are not recognized as revenue until (1) the option is exercised and the additional goods or services are transferred or (2) the option expires.

Milestone Payments. At the inception of each arrangement that includes research or development milestone payments, the Company evaluates whether the milestones are considered probable of being achieved and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the control of the Company or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The Company evaluates factors such as the scientific, clinical, regulatory, commercial, and other risks that must be overcome to achieve the particular milestone in making this assessment. There is considerable judgment involved in determining whether it is probable that a significant revenue reversal would not occur. At the end of each subsequent reporting period, the Company reevaluates the probability of achievement of all milestones subject to constraint and, if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment.

Royalties. For arrangements that include sales-based royalties, including milestone payments upon first commercial sales and milestone payments based on a level of sales, which are the result of a customer-vendor relationship and for which the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied or partially satisfied. To date, the Company has not recognized any royalty revenue resulting from any of its licensing arrangements.

Collaborative Arrangements

The Company analyzes its collaboration arrangements to assess whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed

LEAP THERAPEUTICS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

(Amounts in thousands, except share and per share amounts)

2. Summary of Significant Accounting Policies (continued)

to significant risks and rewards dependent on the commercial success of such activities and therefore within the scope of ASC Topic 808, Collaborative Arrangements (ASC 808). This assessment is performed throughout the life of the arrangement based on changes in the responsibilities of all parties in the arrangement. For collaboration arrangements within the scope of ASC 808 that contain multiple elements, the Company first determines which elements of the collaboration are deemed to be within the scope of ASC 808 and which elements of the collaboration are more reflective of a vendor-customer relationship and therefore within the scope of ASC 606. For elements of collaboration arrangements that are accounted for pursuant to ASC 808, an appropriate recognition method is determined and applied consistently, generally by analogy to ASC 606. Amounts that are owed to collaboration partners are recognized as an offset to collaboration revenues as such amounts are incurred by the collaboration partner. Where amounts owed to a collaboration partner exceed the Company's collaboration revenues in each quarterly period, such amounts are classified as research and development expense. Reimbursements from and payments to the customer that are the result of a collaborative relationship with a partner, instead of a customer relationship, such as co-development activities, are recorded as a reduction to research and development expense. For those elements of the arrangement that are accounted for pursuant to ASC 606, the Company applies the five-step model described above under ASC 606.

See Note 3 for a complete discussion of the revenue recognition for the Company's license agreement.

Net Loss per Share

Basic net loss per share is computed using the weighted average number of common shares outstanding during the period. Diluted net loss per share is computed using the weighted average number of common shares outstanding during the period and, if dilutive, the weighted average number of potential shares of common stock, including the assumed exercise of stock options and warrants.

Subsequent Events

The Company considers events or transactions that occur after the balance sheet date but prior to the issuance of the financial statements to provide additional evidence for certain estimates or to identify matters that require additional disclosure. Subsequent events have been evaluated as required.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board, or FASB, and are early adopted by the Company or adopted as of the specified effective date.

In July 2017, the FASB issued ASU No. 2017-11, *Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480), and Derivatives and Hedging (Topic 815)* ("ASU 2017-11"), which changes the classification analysis of certain equity-linked financial instruments (or embedded features) with down round features. The amendments require entities that present earnings per share ("EPS") in accordance with Topic 260 to recognize the effect of the down round feature when triggered with the effect treated as a dividend and as a reduction of income available to common shareholders in basic EPS. The new standard is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. The Company adopted this standard effective January 1, 2019 and concluded that the 2017 Warrants qualified for equity classification. The Company applied the guidance retrospectively to the 2017 Warrants by means of a cumulative-effect adjustment to its statement of financial position as of the beginning of the interim and annual period beginning January 1, 2019. The Company performed a final remeasurement of the warrant liability as of January 1, 2019 and reclassified $3,448 to stockholders' equity.

In February 2016, the FASB issued ASU 2016-02, Leases, or ASU 2016-02. ASU 2016-02 requires a lessee to recognize on its balance sheet (for both finance and operating leases) a liability to make lease

2. Summary of Significant Accounting Policies (continued)

payments and a right-of-use asset representing its right to use the underlying asset for the lease term. ASU 2016-02 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. The Company adopted ASU 2016-02 on January 1, 2019, the effective date, and used the effective date as its date of initial application. As such, the Company did not adjust prior period amounts. The Company also elected to adopt the practical expedients upon transition, which permit companies to not reassess lease identification, classification, and initial direct costs under ASU 2016-02 for leases that commenced prior to the effective date (see Note 6).

3. BeiGene Exclusive Option and License Agreement

Terms of Agreement

On January 3, 2020, the Company entered into an exclusive option and license agreement (the “BeiGene Agreement”) with BeiGene, Ltd. (“BeiGene”) for the clinical development and commercialization of DKN-01, in Asia (excluding Japan), Australia, and New Zealand. The Company retains exclusive rights for the development, manufacturing, and commercialization of DKN-01 for the rest of the world.

Pursuant to the BeiGene Agreement, the Company received an upfront cash payment of $3,000 from BeiGene in exchange for granting BeiGene an option to an exclusive license to develop and commercialize DKN-01 in Asia (excluding Japan), Australia, and New Zealand. The Company is eligible to receive up to $132,000 in future option exercise and milestone payments, based upon the achievement of certain development, regulatory, and sales milestones, as well as tiered royalties on any product sales of DKN-01 in the licensed territory.

The Company is responsible for conducting development activities prior to the exercise of the option. After the option is exercised, BeiGene is solely responsible for the development and commercialization of DKN-01 in the licensed territory. The BeiGene Agreement continues in effect until the earlier of: (i) 120 days after the end of the option period, if BeiGene has not exercised the option by such date; and (ii) on a country-by country and Licensed Product-by-Licensed Product (as defined in the BeiGene Agreement) basis, the expiration of the Royalty Term (as defined in the BeiGene Agreement) applicable to such licensed product in such country. At any time, BeiGene may terminate the BeiGene Agreement by providing at least 60 days written notice of termination to the Company. Upon termination of the License Agreement, all rights granted by the Company to BeiGene terminate.

Revenue Recognition

The Company evaluated the BeiGene Agreement to determine whether it is a collaborative arrangement for purposes of ASC 808. The Company concluded that because both parties were active participants and were exposed to the risks and rewards of the BeiGene Agreement, that such activities are under the scope of ASC 808. The Company concluded that BeiGene was a customer with regard to the combined license and research and development activities and as such the contract should be evaluated under ASC 606.

In determining the appropriate amount of revenue to be recognized under ASC 606 as the Company fulfills its obligations under the Agreement, the Company performs the following steps: (i) identifies the promised goods or services in the contract; (ii) determines whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measures the transaction price, including any constraints on variable consideration; (iv) allocates the transaction price to the performance obligations; and (v) recognizes revenue when (or as) the Company satisfies each performance obligation.

The Company identified the following material promises under the BeiGene Agreement: (1) option to an exclusive license to develop and commercialize DKN-01 in Asia (excluding Japan), Australia, and New

LEAP THERAPEUTICS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

(Amounts in thousands, except share and per share amounts)

3. BeiGene Exclusive Option and License Agreement (continued)

Zealand, (2) participation in a joint development committee, (3) technology transfer services and (4) pre-option research and development services. The Company determined that the option to an exclusive license in the territory does not represent a material right. Additionally, the Company determined that the participation in the joint development committee, research and development services and technology transfer services are not distinct from each other, as each has limited value without the other. As such, for the purposes of ASC 606, the Company determined that these four material promises, described above, should be combined into a single performance obligation.

The Company determined the transaction price is equal to the up-front fee of $3,000. The transaction price was fully allocated to the single performance obligation and is recognized as revenue on a straight-line basis over the performance period of the research and development services. During the year ended December 31, 2020, the Company recognized $1,500 of license revenue related to the up-front fee received from BeiGene. The Company did not have any such license revenue during the year ended December 31, 2019.

Cost of Contract Acquisition

The Company incurred contract acquisition costs of $270 which were capitalized under ASC 340-40 as incremental costs of obtaining the contract with BeiGene. This cost is amortized on a straight-line basis over the performance period of the research and development services. The total amount of amortization expense during the year ended December 31, 2020 was $135 and the closing balance recorded in deferred costs as of December 31, 2020 was $135.

Royalties

As the license is deemed to be the predominant item to which sales-based royalties relate, the Company will recognize revenue when the related sales occur. No royalty revenue was recognized during the year ended December 31, 2020.

The following table presents a summary of the activity in the Company's contract liabilities, related to the upfront cash payment received of $3,000, during the year ended December 31, 2020 (in thousands):

	Balance at January 1, 2020	Additions	Revenue recognized	Balance at December 31, 2020
Total contract liabilities	$ —	$3,000	$(1,500)	$1,500

LEAP THERAPEUTICS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

(Amounts in thousands, except share and per share amounts)

4. Property and Equipment, Net

Property and equipment, net consisted of the following:

	December 31,	
	2020	2019
Computer office equipment	$ 51	$ 51
Leasehold improvements	69	69
Lab equipment	76	113
Furnitures and fixtures	30	30
	226	263
Less: accumulated depreciation	(161)	(139)
Property and equipment, net	$ 65	$ 124

Depreciation expense was $34 and $47 for the years ended December 31, 2020 and 2019, respectively.

5. Accrued Expenses

Accrued expenses consist of the following:

	December 31,	
	2019	2018
Clinical trials	$ 795	$1,828
Professional fees	255	609
Payroll and related expenses	1,697	1,004
Accrued expenses	$2,747	$3,441

6. Leases

In February 2016, the FASB issued ASU 2016-02, Leases, or ASU 2016-02. ASU 2016-02 requires a lessee to recognize on its balance sheet (for both finance and operating leases) a liability to make lease payments and a right-of-use asset representing its right to use the underlying asset for the lease term. The Company adopted ASU 2016-02 on January 1, 2019, on the effective date, and used the effective date as its date of initial application. As such, the Company did not adjust prior period amounts. The Company also elected to adopt the practical expedients upon transition, which permit companies to not reassess lease identification, classification, and initial direct costs under ASU 2016-02 for leases that commenced prior to the effective date.

The Company has operating leases for real estate in the United States and does not have any finance leases. The Company’s leases may contain options to renew and extend lease terms and options to terminate leases early. Reflected in the right-of-use asset and lease liability on the Company’s consolidated balance sheets are the periods provided by renewal and extension options that the Company is reasonably certain to exercise, as well as the periods provided by termination options that the Company is reasonably certain to not exercise.

The Company has existing leases that include variable lease and non-lease components that are not included in the right-of-use asset and lease liability and are reflected as an expense in the period incurred. Such payments primarily include common area maintenance charges and increases in rent payments that are driven by factors such as future changes in an index (e.g., the Consumer Price Index).

LEAP THERAPEUTICS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

(Amounts in thousands, except share and per share amounts)

6. Leases (continued)

In calculating the present value of future lease payments, the Company utilized its incremental borrowing rate based on the remaining lease term at the date of adoption. The Company has elected to account for each lease component and its associated non-lease components as a single lease component and has allocated all of the contract consideration across lease components only. This will potentially result in the initial and subsequent measurement of the balances of the right-of-use asset and lease liability for leases being greater than if the policy election was not applied. The Company has existing net leases in which the non-lease components (e.g. common area maintenance, maintenance, consumables, etc.) are paid separately from rent based on actual costs incurred and therefore are not included in the right-of-use asset and lease liability and are reflected as an expense in the period incurred. On January 1, 2019, the Company recorded a right-of-use asset of $1,720 and a lease liability of $1,720 on its consolidated balance sheets and reclassified prepaid rent to the right-of-use asset of $35. As of December 31, 2020, a right-of-use asset of $528 and lease liability of $552 are reflected on the consolidated balance sheet. The Company recorded rent expense of $549 and $837, respectively, during the years ended December 31, 2020 and 2019.

Future lease payments under non-cancelable operating leases as of December 31, 2020 are detailed as follows:

	Future Operating Lease Payments
2021	434
2022	146
Total Lease Payments	**580**
Less: imputed interest	(28)
Total operating lease liabilities	**$552**

7. Warrants

As of December 31, 2020, outstanding warrants to purchase common stock, all of which are classified as equity warrants, consisted of the following:

	December 31, 2020	
Date Exercisable	Number of Shares Issuable	Exercise Price
1/23/2017	54,516	$ 0.01
11/14/2017	2,549,840	$1.055
2/5/2019	7,491,442	$ 1.95
3/5/2020	14,413,902	$0.001
3/5/2020	25,945,035	$ 2.11
6/22/2020	2,250,000	$0.001
	52,704,735	

2017 Warrants

The 2017 Warrants contain full ratchet anti-dilution protection provisions. Prior to January 1, 2019, the Company classified the 2017 Warrants as a liability on its consolidated balance sheet because each warrant represented a freestanding financial instrument that, due to the potential variable nature of the exercise price, is not considered to be indexed to the Company’s own shares. The warrant liability was initially recorded at fair value upon entering into the November 2017 Private Placement and has been subsequently

7. Warrants (continued)

remeasured to fair value at each reporting date. Changes in the fair value of the warrant liability were recognized as gains (losses) in the Company's consolidated statement of operations.

On January 1, 2019, the Company adopted ASU 2017-11 and concluded that the 2017 Warrants now qualify for equity classification. The Company applied the guidance retrospectively to the 2017 Warrants by means of a cumulative-effect adjustment to its statement of financial position as of the beginning of the interim and annual period beginning January 1, 2019. The Company performed a final remeasurement of the warrant liability as of January 1, 2019 and reclassified $3,448 to additional paid in capital.

The Company will recognize on a prospective basis the value of the effect of the down round feature in the warrant when it is triggered (i.e., when the exercise price is adjusted downward). This value is measured as the difference between (1) the financial instrument's fair value (without the down round feature) using the pre-trigger exercise price and (2) the financial instrument's fair value (with the down round feature) using the reduced exercise price. The value of the effect of the down round feature will be treated as a dividend and a reduction to income available to common shareholders in the basic EPS calculation. In connection with the 2019 Public Offering, when the 2017 Warrants were repriced from $6.085 to $1.75, the Company recorded a dividend of $359 during the year ended December 31, 2019. In connection with the January 2020 Private Placement, when the 2017 Warrants were repriced from $1.75 to $1.055, the Company recorded a dividend of $303 during the year ended December 31, 2020.

During the year ended December 31, 2020, 208,254 of the 2017 Warrants were exercised for cash resulting in gross proceeds to the Company of $220.

2019 Warrants

On February 5, 2019, in connection with the 2019 Public Offering, the Company issued immediately exercisable warrants (the "2019 Warrants") to purchase 7,557,142 shares of common stock to investors. The 2019 Warrants have an exercise price of $1.95 per share and expire on February 5, 2026. The 2019 Warrants qualify for equity classification.

During the year ended December 31, 2020, 65,700 of the 2019 Warrants were exercised for cash resulting in gross proceeds to the Company of $128.

March 2020 Warrants

On January 3, 2020, the Company entered into a Securities Purchase Agreement with investors, providing for a private placement transaction exempt from the Securities Act of 1933, as amended, pursuant to which the Company issued and sold 1,421,801 shares of its Series A Preferred Stock, at a purchase price of $10.54 per share, 1,137,442 shares of its Series B Preferred Stock at a purchase price of $10.55 per share, and one (1) share of the Company's Special Voting Stock entitling the purchaser of Series A Preferred Stock to elect one member of the Company's board of directors.

On March 5, 2020, the Company's stockholders approved the conversion of the Series A Preferred Stock into a pre-funded warrant to purchase 14,413,902 shares of common stock at an exercise price of $0.001 (the "March 2020 Pre-funded Warrants") and the conversion of the Series B Preferred Stock into 11,531,133 shares of common stock. Each investor also received a warrant to purchase an equal number of shares of common stock at an exercise price of $2.11 per share (the "Coverage Warrants"). The March 2020 Pre-funded Warrants and the Coverage Warrants expire on March 5, 2027 and qualify for equity classification.

LEAP THERAPEUTICS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

(Amounts in thousands, except share and per share amounts)

7. Warrants (continued)

June 2020 Warrants

On June 22, 2020, the Company completed a Public Offering ("the 2020 Public Offering") whereby the Company issued 20,250,000 shares of its common stock, at $2.00 per share and, in lieu of common stock, offered pre-funded warrants (the "June 2020 Pre-funded Warrants") to purchase up to 2,250,000 shares of its common stock to certain investors. The June 2020 Pre-funded Warrants have an exercise price of $0.001 per share, expire on June 22, 2027 and qualify for equity classification.

8. Common Stock

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Common stockholders are entitled to receive dividends, as may be declared by the board of directors, if any, subject to the preferential dividend rights of the preferred stockholders. Through December 31, 2020, no dividends have been declared for shares of common stock.

Public Offering of Common Stock—February 2019

On February 5, 2019, the Company completed the 2019 Public Offering whereby the Company issued 7,557,142 shares of its common stock at a price of $1.75 per share, which included 985,714 shares issued pursuant to the underwriters' exercise of their option to purchase additional shares of common stock, each share issued with a warrant to purchase one share of common stock. Each warrant has an exercise price of $1.95 per share with an exercise period expiring seven years from the date of issuance. The aggregate net proceeds received by the Company from the 2019 Public Offering were approximately $12,122, net of underwriting discounts and commissions and estimated offering expenses payable by the Company.

Issuance of Common Stock under Distribution Agreement—2019

On September 7, 2018, the Company filed a Prospectus Supplement to register the offer and sale of shares of common stock having an aggregate offering price of up to $30,000 pursuant to the terms of a distribution agreement, or the Distribution Agreement, with Raymond James & Associates, Inc. During the year ended December 31, 2019, the Company issued 1,033,147 shares under the Distribution Agreement, for net proceeds of $1,923. In June 2020, the Company terminated the Distribution Agreement and did not issue any shares under the Distribution Agreement during the year ended December 31, 2020.

Lincoln Park Purchase Agreements

On July 10, 2019, the Company entered into a Commitment Purchase Agreement and a Registration Rights Agreement with Lincoln Park, pursuant to which the Company has the right to sell to Lincoln Park up to $20,000 in shares of its common stock, $0.001 par value per share, subject to certain limitations and conditions set forth in the Commitment Purchase Agreement. As consideration for Lincoln Park's commitment to purchase shares of common stock pursuant to the Commitment Purchase Agreement, the Company issued to Lincoln Park 330,000 shares of common stock. The Company did not receive any cash proceeds from the issuance of such shares. During the year ended December 31, 2020, the Company did not issue any shares under the Commitment Purchase Agreement.

On July 11, 2019, the Company entered into a Registered Offering Purchase Agreement, under which the Company agreed to sell to Lincoln Park, and Lincoln Park agreed to purchase 571,429 shares of common stock, at a price of $1.75 per share for an aggregate purchase price of $1,000.

January 2020 Private Placement

On January 3, 2020, the Company issued and sold 1,421,801 shares of its Series A Preferred Stock at a purchase price of $10.54 per share, 1,137,442 shares of its Series B Preferred Stock at a purchase price of

8. Common Stock (continued)

$10.55 per share, and one (1) share of its Special Voting Stock, entitling the purchaser of Series A Preferred Stock to elect one member of the Company's board of directors, for aggregate net proceeds to the Company of approximately $25,322.

On March 5, 2020, the Company's stockholders approved the conversion of the Series A Preferred Stock into a pre-funded warrant to purchase 14,413,902 shares of common stock at an exercise price of $0.001 per share and the conversion of the Series B Preferred Stock into 11,531,133 shares of its common stock, par value $0.001 per share. Each investor also received the Coverage Warrants to purchase an equal number of shares at an exercise price of $2.11 per share.

In connection with the January 2020 Private Placement, Series A Preferred Stock holders and Series B Preferred Stock holders were entitled to cash dividends at a fixed cumulative percentage of 8% per annum plus any dividends declared on outstanding common stock on an as-converted basis, effective on the issuance date of the Series A Preferred Stock and Series B Preferred Stock. The cash dividends were converted to shares of common stock upon the conversion of the Series A Preferred Stock to pre-funded warrants and Series B Preferred Stock to common stock. During the year ended December 31, 2020, the Company recorded $372 of Series A Preferred Stock and Series B Preferred Stock dividends, which qualify as cumulative dividends, and in the calculation of EPS are subtracted from net income in arriving at income attributable to common stockholders.

The Company determined that the embedded conversion features of the Series A Preferred Stock and Series B Preferred Stock to receive the Coverage Warrants each met the definition of a contingent beneficial conversion feature and should be accounted for separately as a derivative. The recognition of the beneficial conversion feature occurred upon the conversion of the Series A Preferred Stock into pre-funded warrants and Series B Preferred Stock into common stock and the issuance of the Coverage Warrants. The Company measured the contingent beneficial conversion features' intrinsic values on January 3, 2020 and determined that the beneficial conversion features were valued at $5,226 for Series A and $4,173 for Series B, respectively. Upon conversion, the discount originated by the contingent beneficial conversion feature, at its intrinsic value for Series A Preferred Stock and Series B Preferred Stock, was immediately recognized as a dividend. The dividend is reflected as an adjustment to basic and diluted net loss per share attributable to common stockholders.

Public Offering of Common Stock—June 2020

On June 22, 2020, the Company completed the 2020 Public Offering, whereby the Company issued 20,250,000 shares of its common stock at $2.00 per share and, in lieu of common stock, issued certain investors 2,250,000 of its June 2020 Pre-funded Warrants. The June 2020 Pre-funded Warrants have an exercise price of $0.001 per share, expire on June 22, 2027 and qualify for equity classification.

On June 25, 2020, the underwriters exercised their right to purchase 3,375,000 additional shares of the Company's common stock at the public offering price per share of common stock, less underwriting discounts and commissions. The aggregate net proceeds received by the Company from the 2020 Public Offering were approximately $48,276, net of underwriting discounts and commissions and offering expenses payable by the Company.

9. Stock-Based Compensation

Equity Incentive Plans

In September 2012, the Company adopted the 2012 Equity Incentive Plan, as amended, which provides designated employees of the Company and its affiliates, certain consultants and advisors who perform

LEAP THERAPEUTICS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

(Amounts in thousands, except share and per share amounts)

9. Stock-Based Compensation (continued)

services for the Company and its affiliates, and nonemployee members of the Board of Directors of the Company and its affiliates with the opportunity to receive grants of incentive stock options, nonqualified stock options and stock awards.

On January 20, 2017, the Company's stockholders approved the 2016 Equity Incentive Plan (the "2016 Plan"). Beginning on January 1, 2018, the number of shares of common stock authorized for issuance pursuant to the 2016 Plan was increased each January 1 by an amount equal to four percent (4%) of the Company's outstanding common stock as of the end of the immediately preceding calendar year or such other amount as determined by the compensation committee of the Company's board of directors. During the year ended December 31, 2019, the compensation committee of the board of directors authorized an additional 3,000,000 shares of common stock to be added to the shares authorized for issuance under the 2016 Plan.

As of December 31, 2020, there were 340,144 shares available for grant under the Company's Equity Incentive Plans.

A summary of stock option activity under the Company's Equity Incentive Plans is as follows:

	Options	Weighted Average Exercise Price Per Share	Weighted Average Remaining Life in Years	Aggregate Intrinsic Value
Outstanding at December 31, 2018	2,761,912	$11.30	8.01	$ —
Granted	1,481,975	$ 1.48		
Forfeited	(219,321)	$15.14		
Outstanding at December 31, 2019	4,024,566	$ 7.48	7.98	$ 2
Granted	2,662,500	$ 2.10		
Exercised	(32,778)	$ 1.53		
Forfeited	(260,435)	$ 6.95		
Outstanding at December 31, 2020	6,393,853	$ 5.29	7.96	$1,961
Options exercisable at December 31, 2020	3,482,169	$ 7.83	7.07	$ 722
Options vested and expected to vest at December 31, 2020	6,393,853	$ 5.29	7.96	$1,961

The assumptions that the Company used to determine the grant-date fair value of stock options granted to employees and directors during the years ended December 31, 2020 and 2019 were as follows, presented on a weighted average basis:

	Year Ended December 31, 2020	Year Ended December 31, 2019
Expected volatility	66.94%	66.94%
Weighted average risk-free interest rate	0.66%	2.07%
Expected dividend yield	0.00%	0.00%
Expected term (in years)	6.85	6.77

Stock options generally vest over a three or four year period, as determined by the compensation committee of the board of directors at the time of grant. The options expire ten years from the grant date.

LEAP THERAPEUTICS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

(Amounts in thousands, except share and per share amounts)

9. Stock-Based Compensation (continued)

As of December 31, 2020, there was approximately $3,947 of unrecognized compensation cost related to non-vested stock options, which is expected to be recognized over a remaining weighted-average period of approximately 2.08 years.

The Company recognized stock-based compensation expense related to the issuance of stock option awards to employees and non-employees in the consolidated statements of operations as follows:

	Year Ended December 31,	
	2020	2019
Research and development	$1,028	$ 714
General and administrative	1,296	3,018
Total	$2,324	$3,732

Restricted Stock Units

During the years ended December 31, 2020 and 2019, the Company issued 92,500 and 181,000 restricted stock units ("RSUs"), respectively, to employees under the 2016 Plan. Upon vesting of the RSUs, the Company has the option to settle the award by either issuing shares of the Company's common stock or paying an amount of cash equal to the fair value of the Company's common stock on the settlement date. During the years ended December 31, 2020 and 2019, the Company recorded stock based compensation expense related to liability classified RSUs of $204 and $265, respectively. In each of October 2019 and January 2020, the Company cash settled 90,500 RSUs. In January 2021, the Company cash settled 92,500 RSUs. As of December 31, 2020 and 2019, these RSUs are classified as restricted stock liability in the consolidated balance sheets of $204 and $159, respectively, as they contain a cash settlement option.

During the year ended December 31, 2020, the Company granted 660,606 RSUs to an executive officer that will cliff vest and will be settled after three years of continuous service, or upon a change of control of the Company, whichever is earlier, pursuant to the 2016 Plan. During the year ended December 31, 2020, the Company recognized $248 of stock based compensation expense related to equity classified RSUs, as they do not contain a cash settlement option.

The following table presents a summary of outstanding RSUs under the 2016 Plan as of December 31, 2020:

	Number of Shares	Weighted Average Fair Value
Outstanding at December 31, 2018	—	$ —
Awarded	181,000	$1.74
Settled in cash	(90,500)	$1.17
Outstanding at December 31, 2019	90,500	$1.76
Awarded	753,106	$1.49
Settled in cash	(90,500)	$1.76
Outstanding at December 31, 2020	753,106	$1.52

As of December 31, 2020, there were 753,106 shares outstanding covered by RSUs that were vested and expected to vest. The weighted average grant date fair value of these shares of restricted stock was

LEAP THERAPEUTICS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

(Amounts in thousands, except share and per share amounts)

9. Stock-Based Compensation (continued)

$1.49 per share and the aggregate grant date fair value of these shares of restricted stock was approximately $1,112. As of December 31, 2020, there was approximately $690 of unrecognized compensation costs related to RSUs granted to employees, which are expected to be recognized as expense over a remaining weighted average period of 2.21 years.

10. Income Taxes

During the year end December 31, 2020, the Company's Israeli operations were dissolved and as a result, the Company wrote off all existing deferred tax assets related to the Israeli operations which consisted primarily of net operating loss carryforwards. The write off of the deferred tax assets was offset by an equal reduction in the valuation allowance.

As of December 31, 2020, the Company had federal and state net operating loss carryforwards of approximately $160,531 and $141,751, respectively, which begin to expire in 2030 for federal and state purposes. The Company's federal net operating losses include $79,223 which can be also carried forward indefinitely.

The Company may be able to utilize its net operating loss carryforwards to reduce future federal and State income tax liabilities. However, these net operating losses are subject to various limitations under Internal Revenue Code ("IRC") section 382, which limit the use of net operating loss carryforwards to the extent there has been an ownership change of more than 50 percentage points. In addition, the net operating loss carryforwards are subject to examination by taxing authorities and could be adjusted or disallowed due to such exams. Although the Company has not undergone an IRC section 382 analysis, it is possible that the utilization of the Company's net operating loss carryforwards may be limited.

In addition, the Company has federal and state research and development tax credits of approximately $3,770 and $645, respectively, that begin to expire in 2030 for federal and state tax purposes.

There is no provision for income taxes in the United States or Israel, because the Company has historically incurred operating losses and maintains a full valuation allowance against its deferred tax assets in these jurisdictions. The deferred tax asset recorded in the consolidated balance sheet relates to our Australian operations.

Income (loss) before income taxes consisted of the following:

	Year Ended December 31,	
	2020	2019
U.S.	$(28,699)	$(32,875)
Foreign	1,183	(28)
Loss before income taxes	$(27,516)	$(32,903)

LEAP THERAPEUTICS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

(Amounts in thousands, except share and per share amounts)

10. Income Taxes (continued)

A summary of the Company's current and deferred expense for income tax is as follows:

	Year Ended December 31,	
	2020	2019
Current expense (benefit):		
Federal	$ —	$—
State	—	—
Foreign	40	—
Total current expense (benefit):	$ 40	$—
Deferred expense (benefit):		
Federal	$ —	$—
State	—	—
Foreign	(42)	(3)
Total deferred expense (benefit):	$(42)	$ (3)
Total income tax expense (benefit):	$ (2)	$ (3)

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

	Year Ended December 31,	
	2020	2019
Income at US Statutory Rate	21.00%	21.00%
State Taxes, net of Federal benefit	6.97%	6.79%
Permanent Differences	-1.09%	-0.33%
Tax Credits	5.98%	3.30%
Tax Law Change	-0.04%	0.00%
Foreign Rate Differential	-0.46%	0.07%
Israel DTA write-off	-70.15%	0.00%
Valuation Allowance	36.56%	-40.18%
Other	1.23%	9.35%
	0.00%	0.00%

LEAP THERAPEUTICS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

(Amounts in thousands, except share and per share amounts)

10. Income Taxes (continued)

The significant components of the Company’s deferred tax assets as of December 31, 2020 and 2019 were as follows:

	Year Ended December 31,	
	2020	**2019**
Accrued expenses	455	277
License Fees	1,168	1,332
Stock Options	3,759	2,584
Other	228	115
State net operating loss carryforwards	8,959	7,431
State research tax credits	625	510
Federal net operating loss carryforwards	33,711	47,845
Federal research tax credits	4,943	3,770
Total deferred tax assets	53,848	63,864
Valuation allowance	(53,669)	(63,737)
Net deferred tax asset (liability)	179	127

As of December 31, 2020 and 2019, the Company had provided a full valuation allowance against its net deferred tax assets, except for its Australian deferred tax assets, because realization of any future tax benefit cannot be reasonably assured. The valuation allowance increased during the year ended December 31, 2019 by $13,220 and decreased during the year ended December 31, 2020 by $10,068. The decrease for the year ended December 31, 2020 is primarily attributed to the write-off of the Israel net operating loss carryforwards.

The Company follows the authoritative guidance on accounting for and disclosure of uncertainty in tax positions, which requires the Company to determine whether a tax position of the Company is more likely than not to be sustained upon examination, including resolution of any related appeals of litigation processes, based on the technical merits of the position. For tax positions meeting the more likely than not threshold, the tax amount recognized in the financial statements is reduced by the largest benefit that has a greater than 50% likelihood of being realized upon the ultimate settlement with the relevant taxing authority. As of December 31, 2020 the Company has not recorded any uncertain tax positions.

The Company files tax returns as prescribed by the tax laws of the jurisdictions in which it operates. In the normal course of business the Company is subject to examination by federal and state jurisdictions, where applicable. There are currently no pending tax examinations. The earliest tax years that may be subject to examination by jurisdiction are 2016 for both federal and state purposes. The Company’s policy is to record interest and penalties related to income taxes as part of the tax provision. There were no interest and penalties pertaining to uncertain tax positions for the years ended December 31, 2020 or 2019.

LEAP THERAPEUTICS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

(Amounts in thousands, except share and per share amounts)

11. Net Loss Per Share

Basic and diluted net loss per share for the years ended December 31, 2020 and 2019 was calculated as follows:

	Year Ended December 31, 2020	Year Ended December 31, 2019
Numerator:		
Net loss	$ (27,514)	$ (32,900)
Dividend attributable to down round feature of warrants	(303)	(359)
Dividend attributable to Series A & B convertible preferred stock	(372)	—
Series A & B convertible preferred stock—beneficial conversion feature	(9,399)	—
Net loss attributable to common stockholders for basic and diluted loss per share	$ (37,588)	$ (33,259)
Denominator:		
Weighted average number of common shares outstanding—basic and diluted	59,327,713	22,582,687
Net loss per share attributable to common stockholders—basic and diluted	$ (0.63)	$ (1.47)

Included within weighted average common shares outstanding are 16,718,418 common shares issuable upon the exercise of the pre-funded warrants and penny warrants, as the warrants are exercisable at any time for nominal consideration, and as such, the shares are considered outstanding for the purpose of calculating basic and diluted net loss per share attributable to common stockholders.

The Company's potentially dilutive securities include RSUs, stock options and warrants. These securities were excluded from the computations of diluted net loss per share for the years ended December 31, 2020 and 2019, as the effect would be to reduce the net loss per share. The following table includes the potential common shares of common stock, presented based on amounts outstanding at each period end, that were excluded from the computation of diluted net loss per share attributable to common stockholders for the periods indicated because including them would have had an anti-dilutive effect:

	Year Ended December 31, 2020	Year Ended December 31, 2019
Restricted stock units to purchase common stock	753,106	90,500
Options to purchase common stock	6,393,853	4,024,566
Warrants to purchase common stock	35,986,317	10,369,752
	43,133,276	14,484,818

LEAP THERAPEUTICS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

(Amounts in thousands, except share and per share amounts)

12. Commitments and Contingencies

Manufacturing Agreements—The Company is party to manufacturing agreements with vendors to manufacture DKN-01, its lead product candidate, for use in clinical trials. As of December 31, 2020, noncancelable commitments under these agreements totaled $636.

License and Service Agreements—On January 3, 2011, the Company entered into a license agreement with Eli Lilly and Company (“Lilly”), a shareholder, to grant a license to the Company for certain intellectual property rights relating to pharmaceutically active compounds that may be useful in the treatment of bone healing, cancer and, potentially, other medical conditions. As defined in the license agreement, the Company would be required to pay royalties to Lilly based upon a percentage in the low single digits of net sales of developed products, if and when achieved. However, there can be no assurance that clinical or commercialization success of developed products will occur, and no royalties have been paid or accrued through December 31, 2020.

License Agreement—On May 28, 2015, the Company entered into a license agreement with Lonza Sales AG (“Lonza”), pursuant to which Lonza granted the Company a world-wide, non-exclusive license for certain intellectual property relating to a gene expression system for manufacturing DKN-01. As defined in the license agreement, the Company would be required to pay royalties to Lonza based on a percentage in the low single digits of net sales of DKN-01, if and when achieved. However, there can be no assurance that clinical or commercialization success will occur, and no royalties have been paid or accrued through December 31, 2020.

Legal Proceedings—At each reporting date, the Company evaluates whether or not a potential loss amount or a potential range of loss is probable and reasonably estimable under the provisions of the authoritative guidance that addresses accounting for contingencies. The Company expenses as incurred the costs related to its legal proceedings.

A patent covering the TRX518 antibody and its uses in methods of inducing or enhancing an immune response in a subject was granted in 2013 to the Company by the European Patent Office (EPO). Three notices of opposition to this patent were filed: two by major pharmaceutical companies and a third by an individual, possibly on behalf of a major pharmaceutical company. At the conclusion of the opposition proceedings before the Opposition Division of the EPO, the Opposition Division issued a decision indicating that the Company’s patent was maintained with modified claims that differ from the claims as originally granted. These narrowed claims cover the TRX518 antibody and uses of the TRX518 antibody in methods of inducing or enhancing an immune response in a subject. The Company filed an appeal of the decision of the Opposition Division seeking to obtain broader claims that more closely reflect the claims as granted in the patent. A hearing before the EPO Boards of Appeal took place on September 16, 2020, which resulted in the Boards of Appeal dismissing the appeal and maintaining the Decision of the Opposition Division. A written Decision by the Boards of Appeal was issued on September 25, 2020.

In 2016, a patent covering the use of the TRX518 antibody in combination with a chemotherapeutic agent for treating cancer was granted to the Company by the EPO. In March 2017, notices of opposition to this patent were filed at the EPO by ten different entities, including several major pharmaceutical companies. Oral proceedings at the EPO took place on December 4 and 5, 2018. At the conclusion of the oral proceedings, the Opposition Division decided that the patent should be revoked in its entirety on the ground that the claims as granted contained added matter. Subsequently, the Opposition Division issued an interlocutory decision restating its conclusion that the claims as granted contained added matter and revoking the patent. The Company has filed an appeal of the decision of the Opposition Division seeking to obtain a reversal of the Opposition Division’s decision on added matter. The EPO Board of Appeal has not yet scheduled the appeal hearing.

In December of 2019, a patent covering the use of the TRX518 antibody in combination with the chemotherapeutic agent, gemcitabine, for treating a colon tumor or adenocarcinoma of the colon, was

LEAP THERAPEUTICS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

(Amounts in thousands, except share and per share amounts)

12. Commitments and Contingencies (continued)

granted to the Company by the EPO. A Notice of Opposition was filed against the patent by a single opponent, Sanofi, on September 25, 2020. The EPO issued a Communication on October 9, 2020 setting a deadline of February 9, 2021 for the Patentee to file a response to the Notice of Opposition. The Company filed a timely reply to the opponent's Notice of Opposition on February 9, 2021. Oral proceedings at the EPO have not yet been scheduled.

Indemnification Agreements—In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company is not aware of any claims under indemnification arrangements, and it has not accrued any liabilities related to such obligations in its consolidated financial statements as of December 31, 2020 and 2019.

13. Defined Contribution Plan

The Company has a 401(k) defined contribution plan (the "401(k) Plan") for substantially all of its employees. Eligible employees may make pretax contributions to the 401(k) Plan up to statutory limits.

The Company makes matching employee contributions in cash to the 401(k) Plan at a rate of 100% of the first 3% of earnings contributed and 50% of the next 2% of earnings contributed. Employees participating in the 401(k) Plan are fully vested in the Company matching contributions, and investments are directed by participants. The Company made matching contributions of $195 and $170 for the years ended December 31, 2020 and 2019, respectively.

14. Related Party Transactions

The Company has a license agreement with a stockholder (See Note 12).

On February 5, 2019, the Company completed the 2019 Public Offering pursuant to which the Company issued 7,557,142 shares of its common stock at a price of $1.75 per share, which included 985,714 shares issued pursuant to the underwriters' exercise of their option to purchase additional shares of common stock, each share issued with a warrant to purchase one share of common stock. Each warrant has an exercise price of $1.95 per share with an exercise period expiring seven years from the date of issuance. The aggregate net proceeds received by the Company from the offering were approximately $12,122, net of underwriting discounts and commissions and estimated offering expenses payable by the Company. HealthCare Ventures IX, L.P. purchased common stock and warrants in the 2019 Public Offering on the same terms and conditions as the other Purchasers. Three of the Company's directors and executive officers are affiliated with HealthCare Ventures IX, L.P. and its affiliates.

EXECUTIVE EMPLOYMENT AGREEMENT

This Executive Employment Agreement ("***Agreement***") is made and entered into as of this 10th day of April, 2020, by and between Leap Therapeutics, Inc., a Delaware corporation (the "***Company***"), and Cynthia Sirard (hereinafter, the "***Executive***").

WITNESSETH:

WHEREAS, the Company currently employs the Executive as the Vice President, Clinical Research and Development, of the Company.

WHEREAS, the Company desires to promote and continue to employ the Executive as the Chief Medical Officer of the Company effective as of April 1, 2020 (the "**Effective Date**"), and the Executive desires to continue to be employed by the Company as the Chief Medical Officer of the Company effective as of the Effective Date, on the terms herein described.

NOW, THEREFORE, in consideration of the premises and mutual covenants set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which are mutually acknowledged, the Company and the Executive hereby agree as follows:

1. ***Definitions***. When used in this Agreement, the following terms shall have the following meanings:

(a) "***Accrued Obligations***" means:

(i) all accrued but unpaid Base Salary through the end of the Term of Employment;

(ii) any unpaid or unreimbursed expenses incurred in accordance with Company policy, including amounts due under Section 5(a) hereof, to the extent incurred during the Term of Employment;

(iii) any accrued but unpaid benefits provided under the Company's employee benefit plans, subject to and in accordance with the terms of those plans;

(iv) any earned and unpaid Bonus in respect to any completed fiscal year that has ended on or prior to the end of the Term of Employment;

(v) any accrued but unpaid rights to indemnification by virtue of the Executive's position as an officer or director of the Company or its subsidiaries and the benefits under any directors' and officers' liability insurance policy maintained by the Company, in accordance with its terms thereof; and

(vi) any accrued but unused vacation pay.

(b) "***Base Salary***" means the salary amount provided for in Section 4(a) hereof or any increase thereto as salary granted to Executive pursuant to Section 4(a) hereof.

(c) “***Beneficial Ownership***” shall have the meaning ascribed to such term in Rule 13d-3 promulgated under the Exchange Act.

(d) “***Board***” means the Board of Directors of the Company.

(e) “***Bonus***” means any bonus earned and payable to the Executive pursuant to Section 4(b) hereof.

(f) “***Cause***” means the occurrence of any of the following: (i) a conviction of the Executive, or a plea of nolo contendere, to a felony (other than a felony related to the operation of a motor vehicle); or (ii) willful misconduct or gross negligence by the Executive resulting, in either case, in material harm to the Company or any Related Entities; or (iii) a willful failure by the Executive to carry out the reasonable and lawful directions of the Board and failure by the Executive to remedy such willful failure within thirty (30) days after receipt of written notice of same from the Board; or (iv) fraud, embezzlement, theft or dishonesty of a material nature by the Executive, or a willful material violation by the Executive of a written policy or procedure of the Company or any Related Entity, resulting, in any case, in material harm to the Company or any Related Entity; (v) any action or omission by the Executive resulting in the loss or suspension of Executive’s license to practice medicine; (vi) the exclusion, suspension or debarment of Executive from participation in a federal health care program or before the United States Food and Drug Administration or other similar regulatory authority or the existence of any pending debarment or similar proceedings against Executive; or (vii) a material breach by the Executive of this Agreement, and failure by the Executive to remedy the material breach within thirty (30) days after receipt of written notice of same, by the Board. For clarity, the inability of Executive to perform any or all of her duties, responsibilities or obligations under this Agreement on account of Executive’s death or disability shall not be deemed or treated as a material breach of this Agreement by the Executive and shall not constitute Cause for any purpose of this Agreement.

(g) “***Change in Control***” means:

(i) The acquisition by any Person of Beneficial Ownership of at least twenty percent (20%) of either (A) the value of the then outstanding shares of common stock of the Company (the “***Outstanding Company Common Stock***”) or (B) the combined voting power of the then outstanding voting securities of the Company entitled to vote generally in the election of directors (the “***Outstanding Company Voting Securities***”) (the foregoing Beneficial Ownership hereinafter being referred to as a “***Controlling Interest***”); *provided*, *however*, that for purposes of this definition, the following acquisitions shall not constitute or result in a Change in Control: (v) any acquisition directly from the Company; (w) any acquisition by the Company; (x) any acquisition by any person that owns, or by any person that collectively with such person’s affiliates own, Beneficial Ownership of a Controlling Interest on the Effective Date; (y) any acquisition by any employee benefit plan (or related trust) sponsored or maintained by the Company or any subsidiary of the Company; or (z) any acquisition by any corporation or other Person pursuant to a transaction which complies with clauses (A), (B) and (C) of subsection (ii) below; or

(ii) Consummation of a reorganization, merger, statutory share exchange or consolidation or similar corporate transaction involving the Company or any of its subsidiaries, a sale or other disposition of all or substantially all of the assets of the Company, or the acquisition of assets or stock or equity interests of another entity by the Company or any of its subsidiaries (each a "***Business Combination***"), in each case, unless, immediately following such Business Combination, (A) all or substantially all of the Persons who were the Beneficial Owners, respectively, of the Outstanding Company Common Stock and Outstanding Company Voting Securities immediately prior to such Business Combination beneficially own, directly or indirectly, more than fifty percent (50%) of the then combined voting power of the then outstanding voting securities entitled to vote generally in the election of directors (or equivalent persons) of the corporation or other Person resulting from such Business Combination (including, without limitation, a corporation or other Person which as a result of such transaction owns the Company or all or substantially all of the Company's assets either directly or through one or more subsidiaries) (such resulting or acquiring corporation or other Person is referred to herein as the "***Acquiring Person***") in substantially the same proportions as their beneficial ownership, immediately prior to such Business Combination, of the combined voting power of the Outstanding Company Voting Securities, and (B) at least a majority of the members of the Board of Directors or equivalent body of the corporation or other Person resulting from such Business Combination were members of the incumbent Board at the time of the execution of the initial agreement, or of the action of the Board, providing for such Business Combination; or

(iii) approval by the stockholders of the Company of a complete liquidation or dissolution of the Company.

(h) "***COBRA***" means the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended from time to time.

(i) "***Code***" means the Internal Revenue Code of 1986, as amended.

(j) "***Date of Termination***" means the earliest of: (i) immediately after the Company gives notice to Executive of Executive's termination, with or without Cause, unless the Company specifies a later date, in which case, termination shall be effective as of such later date; (ii) immediately upon the Executive's death; (iii) thirty (30) days after the Company gives notice to Executive of Executive's termination on account of Executive's Disability, unless the Company specifies a later date, in which case, termination shall be effective as of such later date, provided, that Executive has not returned to the full time performance of Executive's duties prior to such date; or (iv) thirty (30) days after the Executive gives written notice to the Company of Executive's resignation with or without Good Reason. Executive will receive compensation through any required notice period. In the event notice of a termination under subsections (i), (iii) and (iv) is given orally, at the other party's request, the party giving notice must provide written confirmation of such notice within five business days of the request in compliance with the requirement of Section 14 below. In the event of a termination for Cause or Good Reason written confirmation shall specify the subsection(s) of the definition of Cause or Good Reason relied on to support the decision to terminate but shall not include further explanation.

(k) "***Disability***" means the Executive's inability, or failure, to perform the essential functions of her position, with or without reasonable accommodation, for any period of ninety (90) consecutive days, or (ii) for one-hundred and eighty (180) days in the aggregate during any twelve (12) month period or based on the written certification by two licensed physicians of the likely continuation of such condition for either such period. This definition shall be interpreted and applied consistent with the Americans with Disabilities Act, the Family and Medical Leave Act, and other applicable law.

(l) ***"Equity Awards***" means any stock options, restricted stock, restricted stock units, stock appreciation rights, phantom stock or other equity based awards granted by the Company to the Executive.

(m) "***Exchange Act***" means the Securities Exchange Act of 1934, as amended.

(n) "***Excise Tax***" means any excise tax imposed by Section 4999 of the Code, together with any interest and penalties imposed with respect thereto, or any interest or penalties that are incurred by the Executive with respect to any such excise tax.

(o) "***Good Reason***" means the occurrence of any of the following: (i) a material diminution in the Executive's Base Salary; or (ii) the Company's or Related Entity's requiring the Executive to be based at any office or location outside of fifty (50) miles from Cambridge, Massachusetts, except for travel reasonably required in the performance of the Executive's responsibilities; or (iii) any other action or inaction that constitutes a material breach by the Company of this Agreement. For purposes of this Agreement, Good Reason shall not be deemed to exist unless the Executive's termination of employment for Good Reason occurs within one hundred eighty days following the initial existence of one of the conditions specified in clauses (i) through (v) above, the Executive provides the Company with written notice of the existence of such condition within ninety (90) days after the initial existence of the condition, and the Company fails to remedy the condition within thirty (30) days after its receipt of such notice.

(p) "***Person***" shall have the meaning ascribed to such term in Section 3(a)(9) of the Exchange Act and used in Sections 13(d) and 14(d) thereof.

(q) "***Related Entity***" means any Person controlling, controlled by or under common control with the Company or any of its subsidiaries. For this purpose, the terms "controlling," "controlled by" and "under common control with" mean the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of a Person, whether through the ownership of voting securities, as trustee or executor, by contract or otherwise, including (without limitation) the ownership, directly or indirectly, of securities having the power to elect a majority of the board of directors or similar body governing the affairs of such Person.

(r) "***Severance Amount***" shall mean an amount equal to one-half (1/2) of the Executive's annualized Base Salary, as in effect immediately prior to the Termination Date.

(s) "***Target Bonus***" has the meaning described in Section 4(b).

(t) "***Term of Employment***" means the period during which the Executive shall be employed by the Company pursuant to the terms of this Agreement, which period shall begin effective as of the Effective Date and continue until terminated in accordance with Section 6 hereof.

(u) "***Termination Date***" means the date on which the Term of Employment ends.

2. ***<u>Employment</u>***. The Company hereby agrees to continue to employ the Executive, and the Executive hereby agrees to continue to serve the Company, during the Term of Employment on the terms and conditions set forth herein.

3. ***Duties of Executive***.

(a) ***Position and Position Duties***. During the Term of Employment, the Executive shall be employed and serve as the Chief Medical Officer of the Company, and shall have such duties typically associated with such title.

(b) ***Duties in General***. The Executive shall faithfully and diligently perform all services as may be assigned to her by the Board, and shall exercise such power and authority as may from time to time be delegated to her by the Board. The Executive shall devote time, attention and efforts to the performance of her duties under this Agreement, render such services to the best of her ability, and use her reasonable best efforts to promote the interests of the Company. The Executive shall not engage in any other business or occupation during the Term of Employment that (i) conflicts with the interests of the Company or its subsidiaries, (ii) interferes with the proper and efficient performance of her duties for the Company, or (iii) interferes with the exercise of her judgment in the Company's best interests.

(c) ***Company Policies and Procedures***. The employment relationship between the parties also shall be subject to the Company's personnel and compliance policies and procedures as they may be interpreted, adopted, revised or deleted from time to time in the Company's sole discretion. The Company reserves the right to change, alter, or terminate any such policy or procedure in its sole discretion. Notwithstanding the foregoing, in the event that the terms of this Agreement differ from or are in conflict with the Company's general employment policies or practices, this Agreement shall control.

4. ***Compensation***.

(a) ***Base Salary***. The Executive shall receive a Base Salary at the annualized rate of $405,719 during the Term of Employment, with such Base Salary payable in installments consistent with the Company's normal payroll schedule, subject to applicable withholding and other taxes. The Base Salary shall be reviewed, at least annually, for merit increases and may, by action and in the discretion of the Board, be increased at any time or from time to time, but may not be decreased from the then current Base Salary.

(b) ***Bonuses***. During the Term of Employment, the Executive shall participate in the Company's annual incentive compensation plan, program and/or arrangements applicable to senior-level executives, as established and modified from time to time by the Compensation Committee of the Board (for the avoidance of doubt, for any period during which there is not a Compensation Committee, all matters under this Agreement shall be addressed by the Board) in its sole discretion. During the Term of Employment, the Executive shall have a target bonus opportunity under such plan or program equal to 35% of her current Base Salary (the "***Target Bonus***"), based on satisfaction of performance criteria to be established by the Compensation Committee of the Board within the first three months of each fiscal year that begins during the Term of Employment. Payment of annual incentive compensation awards shall be made in the same manner and at the same time that other senior-level executives receive their annual incentive compensation awards and, except as otherwise provided herein, will be subject to the Executive's continued employment through the applicable payment date.

(c) ***Equity Awards***. Any and all existing Equity Awards that the Executive has or holds in the Company will be treated consistent with the terms of the applicable plans and agreements under which such Equity Awards have been granted. The Executive may be granted additional Equity Awards from time to time in accordance with the Company's normal business practice and in the sole discretion of the Compensation Committee of the Board. The terms of any future Equity Awards granted to the Executive will be consistent with any plan under which such Equity Awards are granted and the terms of the applicable agreement for such Equity Awards. Notwithstanding the foregoing, any and all outstanding unvested Equity Awards shall automatically become fully vested and exercisable on an accelerated basis immediately prior to any Change of Control that is consummated at any time after the Effective Date.

5. ***Expense Reimbursement and Other Benefits***.

(a) ***Reimbursement of Expenses***. Upon the submission of proper substantiation by the Executive, and subject to such rules and guidelines as the Company may from time to time adopt with respect to the reimbursement of expenses of executive personnel, the Company shall reimburse the Executive for all reasonable expenses actually paid or incurred by the Executive during the Term of Employment in the course of and pursuant to the business of the Company. The Executive shall account to the Company in writing for all expenses for which reimbursement is sought and shall supply to the Company copies of all relevant invoices, receipts or other evidence reasonably requested by the Company.

(b) ***Compensation/Benefit Programs***. During the Term of Employment, the Executive shall be entitled to participate in all benefit plans on the same basis as similarly situated executives in the Company's benefit plans in effect from time to time during Executive's employment. All matters of eligibility for coverage or benefits under any benefit plan shall be determined in accordance with the provisions of such plan.

(c) ***Working Facilities***. During the Term of Employment, the Company shall furnish the Executive with an office, administrative help, and such other facilities and services suitable to her position and adequate for the performance of her duties hereunder. The Executive's principal place of employment (subject to reasonable travel) shall be Cambridge, Massachusetts.

(d) ***Vacation***. The Executive shall be entitled to paid vacation each calendar year during the Term of Employment pursuant to the policies of the Company applicable to Executives, to be taken at such times as the Executive and the Company shall mutually determine and provided that no vacation time shall significantly interfere with the duties required to be rendered by the Executive hereunder.

6. ***Termination***.

(a) ***General***. The Term of Employment shall terminate upon the earliest to occur of (i) the Executive's death, (ii) a termination by the Company by reason of the Executive's Disability, (iii) a termination by the Company with or without Cause, or (iv) a termination by Executive with or without Good Reason. Upon any termination of Executive's employment for any reason, except as may otherwise be requested by the Company in writing and agreed upon in writing by Executive, the Executive shall resign from any and all directorships, committee memberships or any other positions Executive holds with the Company or any of its Related Entities.

(b) ***Termination By Company for Cause.*** In the event the Executive is terminated by the Company for Cause, the Company's obligation to make payments under this Agreement shall cease upon the Date of Termination, except that the Company shall pay Executive any Base Salary earned but unpaid prior to termination, all accrued but unused vacation and any business expenses that were incurred but not reimbursed as of the Date of Termination. Vesting of any unvested stock options and/or other equity securities shall cease on the Date of Termination, unless otherwise provided in any plan, instrument or agreement to which such unvested stock options and/or other equity securities may be subject.

(c) ***Disability***. The Company shall have the option, in accordance with applicable law, to terminate the Term of Employment upon written notice to the Executive, at any time during which the Executive is suffering from a Disability. In the event that the Term of Employment is terminated due to the Executive's Disability, the Executive shall be entitled to (i) the Accrued Obligations, payable as and when those amounts would have been paid had the Term of Employment not ended, and (ii) any insurance benefits to which she and her beneficiaries are entitled as a result of her Disability. Vesting of any unvested stock options and/or other equity securities shall cease on the Date of Termination, unless otherwise provided in any plan, instrument or agreement to which such unvested stock options and/or other equity securities may be subject.

(d) ***Death***. In the event that the Term of Employment is terminated due to the Executive's death, the Executive's estate shall be entitled to (i) the Accrued Obligations, payable as and when those amounts would have been paid had the Term of Employment not ended, and (ii) any insurance benefits to which she and her beneficiaries are entitled as a result of her death. Vesting of any unvested stock options and/or other equity securities shall cease on the Date of Termination, unless otherwise provided in any plan, instrument or agreement to which such unvested stock options and/or other equity securities may be subject.

(e) ***Termination Without Cause or Resignation With Good Reason***. The Company may terminate the Term of Employment without Cause, and the Executive may terminate the Term of Employment for Good Reason, at any time upon written notice, and upon compliance with Section 6(g) below. If the Term of Employment is terminated by the Company without Cause (other than due to the Executive's death or Disability) or by the Executive for Good Reason, the Executive shall be entitled to the following:

(i) The Accrued Obligations, payable as and when those amounts would have been paid had the Term of Employment not ended;

(ii) The Severance Amount, payable in equal installments consistent with the Company's normal payroll schedule over the six (6)-month period beginning with the first regularly scheduled payroll date that occurs more than thirty (30) days following the Termination Date; and

(iii) Provided that the Executive timely elects continued coverage under COBRA, the Company will reimburse the Executive for the monthly COBRA cost of continued health and dental coverage of the Executive and her qualified beneficiaries paid by the Executive under the health and dental plans of the Company, less the amount that the Executive would be required to contribute for health and dental coverage if the Executive were an active employee of the Company, for six (6) months (or, if less, for the duration that such COBRA coverage is available to Executive), payable in equal installments consistent with the Company's normal payroll schedule over the six (6)-month period beginning with the first regularly scheduled payroll date that occurs more than thirty (30) days following the Termination Date.

(f) ***Termination by Executive Without Good Reason***. The Executive may terminate her employment without Good Reason at any time by providing the Company 30 days' written notice of such termination. In the event of a termination of employment by the Executive under this Section 6(f), the Executive shall be entitled only to the Accrued Obligations payable as and when those amounts would have been payable had the Term of Employment not ended. In the event of termination of the Executive's employment under this Section 6(f), the Company may, in its sole and absolute discretion, by written notice, accelerate the Date of Termination and still have it treated as a termination without Good Reason.

(g) ***Release***. All rights, payments and benefits due to the Executive under this Article 6 (other than the Accrued Obligations) shall be conditioned on the Executive's execution of a general release of claims against the Company and its affiliates substantially in the form attached hereto as Exhibit A within 60 days of the Date of Termination (the "***Release***") and on that Release becoming irrevocable within sixty (60) days following the Termination Date.

(h) ***Section 280G Certain Reductions of Payments by the Company***.

(i) In the event that a Change in Control occurs at any time during the Term of Employment, and the severance and other benefits provided for in this Agreement or otherwise payable to Executive (a) constitute "parachute payments" within the meaning of Section 280G of the Code and (b) but for this Section, would be subject to the excise tax imposed by Section 4999 of the Code, then Executive's severance and other benefits constituting parachute payments will be either:

(1) delivered in full, or

(2) delivered as to such lesser extent which would result in no portion of such severance and other benefits being subject to the excise tax under Section 4999 of the Code,

whichever of the foregoing amounts, taking into account the applicable federal, state and local income taxes and the excise tax imposed by Section 4999 of the Code, results in the receipt by Executive, on an after-tax basis, of the greatest amount of severance and other benefits, notwithstanding that all or some portion of such severance and other benefits may be taxable under Section 4999 of the Code. If a reduction in the severance and other benefits constituting "parachute payments" is necessary so that no portion of such severance and other benefits is subject to the excise tax under Section 4999 of the Code, the reduction shall occur in the following order: (a) reduction of the cash severance payments; (b) cancellation of accelerated vesting of equity awards; and (c) reduction of continued employee benefits. In the event that acceleration of vesting of equity award compensation is to be reduced, such acceleration of vesting shall be cancelled in the reverse order of the date of grant of Executive's equity awards.

(ii) A nationally recognized certified professional services firm selected by the Company, the Company's legal counsel or such other person or entity to which the parties mutually agree (the "**Firm**") shall perform the foregoing calculations related to the Excise Tax. The Company shall bear all expenses with respect to the determinations by the Firm required to be made hereunder. For purposes of making the calculations required by this Section 6(h), the Firm may make reasonable assumptions and approximations concerning applicable taxes and may rely on reasonable, good faith interpretations concerning the application of Sections 280G and 4999 of the Code. The Company and Executive will furnish to the Firm such information and documents as the Firm may reasonably request in order to make a determination under this Section 6(h). The Firm engaged to make the determinations hereunder shall provide its calculations, together with detailed supporting documentation, to the Company and Executive within 15 calendar days after the date on which Executive's right to the severance benefits or other payments is triggered (if requested at that time by the Company or Executive) or such other time as requested by the Company or Executive. Any good faith determinations of the Firm made hereunder shall be final, binding, and conclusive upon the Company and Executive.

(i) ***Cooperation***. Following the Term of Employment, the Executive shall give her assistance and cooperation willingly, upon reasonable advance notice with due consideration for her other business or personal commitments, in any matter relating to her position with the Company, or her expertise or experience as the Company may reasonably request, including her attendance and truthful testimony where deemed appropriate by the Company, with respect to any investigation or the Company's defense or prosecution of any existing or future claims or litigations or other proceedings relating to matters in which she was involved or potentially had knowledge by virtue of her employment with the Company. In no event shall her cooperation materially interfere with her services for a subsequent employer or other similar service recipient. To the extent permitted by law, the Company agrees that (i) it shall promptly reimburse the Executive for her reasonable and documented expenses in connection with her rendering assistance and/or cooperation under this Section 6(i) upon her presentation of documentation for such expenses and (ii) the Executive shall be reasonably compensated for any continued material services as required under this Section 6(i).

(j) ***Return of Company Property***. Following the Termination Date, the Executive or her personal representative shall immediately return all Company property in her possession, including but not limited to all computer equipment (hardware and software), telephones, facsimile machines, tablets and other communication devices, credit cards, office keys, security access cards, badges, identification cards and all copies (including drafts) of any documentation or information (however stored) relating to the business of the Company, its customers and clients or its prospective customers and clients (provided that the Executive may retain a copy of the addresses contained in her rolodex, smartphone or similar device or the Company and, at the Executive's request, the Company shall provide a thumb drive of her contacts).

(k) ***Compliance with Section 409A***.

(i) ***General***. It is the intention of both the Company and the Executive that the benefits and rights to which the Executive could be entitled pursuant to this Agreement comply with Section 409A of the Code and the Treasury Regulations and other guidance promulgated or issued thereunder ("***Section 409A***"), to the extent that the requirements of Section 409A are applicable thereto, and the provisions of this Agreement shall be construed in a manner consistent with that intention.

(ii) ***Distributions on Account of Separation from Service***. If and to the extent required to comply with Section 409A, no payment or benefit required to be paid under this Agreement on account of termination of the Executive's employment shall be made unless and until the Executive incurs a "separation from service" within the meaning of Section 409A.

(iii) ***Six Month Delay for Specified Employees***. If the Executive is a "specified employee" (within the meaning of Section 409A(a)(2)(B)(i) of the Code), then no payment or benefit that is payable on account of the Executive's "separation from service", as that term is defined for purposes of Section 409A, shall be made before the date that is six (6) months after the Executive's "separation from service" (or, if earlier, the date of the Executive's death) if and to the extent that such payment or benefit constitutes deferred compensation (or may be nonqualified deferred compensation) under Section 409A and such deferral is required to comply with the requirements of Section 409A. Any payment or benefit delayed by reason of the prior sentence shall be paid out or provided in a single lump sum at the end of such required delay period in order to catch up to the original payment schedule.

(iv) ***Treatment of Each Installment as a Separate Payment***. For purposes of applying the provisions of Section 409A to this Agreement, each separately identified amount to which the Executive is entitled under this Agreement shall be treated as a separate payment. In addition, any series of installment payments under this Agreement shall be treated as a right to a series of separate payments.

(v) ***Taxable Reimbursements and In-Kind Benefits***.

(A) Any reimbursements by the Company to the Executive of any eligible expenses under this Agreement that are not excludable from the Executive's income for Federal income tax purposes (the "***Taxable Reimbursements***") shall be made by no later than the last day of the taxable year of the Executive following the year in which the expense was incurred.

(B) The amount of any Taxable Reimbursements, and the value of any in-kind benefits to be provided to the Executive, during any taxable year of the Executive shall not affect the expenses eligible for reimbursement, or in-kind benefits to be provided, in any other taxable year of the Executive.

(C) The right to Taxable Reimbursement, or in-kind benefits, shall not be subject to liquidation or exchange for another benefit.

(vi) ***Company Discretion***. Notwithstanding the foregoing, if at any time the Company determines, in its sole discretion, that the payment of the COBRA premiums under Section 6(e)(iv) above would result in a violation of the nondiscrimination rules of Section 105(h)(2) of the Code or any statute or regulation of similar effect (including but not limited to the 2010 Patient Protection and Affordable Care Act, as amended by the 2010 Health Care and Education Reconciliation Act), then in lieu of providing the COBRA premiums, the Company may instead pay Executive, fully taxable cash payments equal to and paid at the same time as the COBRA premiums that otherwise would have been paid, subject to applicable tax withholdings. In the event the COBRA premium reimbursement is made on an after-tax basis, the Company will provide a tax gross-up to the Executive equal to the amount of taxes withheld on the COBRA premium reimbursement with such amount to be paid at the same time of the COBRA premium reimbursement. To receive the payments under Section 6(e)(ii) above, Executive's termination or resignation must constitute a "separation from service" within the meaning of Section 409A, and Executive must execute and allow the Release to become effective within sixty (60) days of Executive's termination or resignation. Such payments shall not be paid prior to the sixtieth (60th) day following Executive's termination or resignation, rather, subject to the aforementioned conditions, on the sixtieth (60th) day following Executive's termination or resignation, the Company will pay Executive such payments in a lump sum that Executive would have received on or prior to such date under the original schedule, with the balance of such payments being paid as originally scheduled.

(vii) ***Timing of Payment and Execution of Release*****.** Notwithstanding any provision of this Agreement to the contrary, in no event shall the timing of the execution of the Release, directly or indirectly, result in the Executive designating the calendar year of a payment, and if a payment that is subject to execution of the Release could be made in more than one taxable year, payment shall be made in the later taxable year to the extent required under Section 409A. In no event may the Executive, directly or indirectly, designate the calendar year of a payment.

(viii) ***No Guaranty of 409A Compliance***. Notwithstanding the foregoing, the Company does not make any representation to the Executive that the payments or benefits provided under this Agreement are exempt from, or satisfy, the requirements of Section 409A, and the Company shall have no liability or other obligation to indemnify or hold harmless the Executive or any beneficiary of the Executive for any tax, additional tax, interest or penalties that the Executive or any beneficiary of the Executive may incur in the event that any provision of this Agreement, or any amendment or modification thereof, or any other action taken with respect thereto, is deemed to violate any of the requirements of Section 409A.

7. ***Proprietary Information, Invention, Non-Competition, and Non-Solicitation***. The Executive and the Company have previously entered into that certain Employee Proprietary Information, Invention, Non-Competition and Non-Solicitation Agreement, dated as of December 10, 2015, between the Company and the Executive (the "Confidentiality Agreement"), and the terms and provisions of the Confidentiality Agreement shall be incorporated into this Agreement by reference for all purposes.

8. ***Representations and Warranties of Executive***. The Executive represents and warrants to the Company that:

(a) The Executive's employment has not conflicted with or resulted in, and will not conflict with or result in, her breach of any agreement to which she is a party or otherwise may be bound;

(b) The Executive has not violated, and in connection with her employment with the Company will not violate, any non-solicitation, non-competition or other similar covenant or agreement of a prior employer by which she is or may be bound; and

(c) In connection with Executive's employment with the Company, she has not used, and will not use, any confidential or proprietary information that she may have obtained in connection with employment with any prior employer.

9. ***Taxes***. All payments or transfers of property made by the Company to the Executive or her estate or beneficiaries shall be subject to the withholding of such amounts relating to taxes as the Company may reasonably determine it should withhold pursuant to any applicable law or regulation.

10. ***Assignment***. The Company shall have the right to assign this Agreement and its rights and obligations hereunder in whole, but not in part, to any corporation or other entity with or into which the Company may hereafter merge or consolidate or to which the Company may transfer all or substantially all of its assets, if in any such case said corporation or other entity shall by operation of law or expressly in writing assume all obligations of the Company hereunder as fully as if it had been originally made a party hereto, but may not otherwise assign this Agreement or its rights and obligations hereunder. The Executive may not assign or transfer this Agreement or any rights or obligations hereunder.

11. ***Governing Law***. This Agreement shall be governed by and construed and enforced in accordance with the internal laws of the Commonwealth of Massachusetts, without regard to principles of conflict of laws.

12. ***Jurisdiction and Venue***. The parties acknowledge that a substantial portion of the negotiations, anticipated performance and execution of this Agreement occurred or shall occur in Cambridge, Massachusetts, and that, therefore, without limiting the jurisdiction or venue of any other federal or state courts, each of the parties irrevocably and unconditionally (i) agrees that any suit, action or legal proceeding arising out of or relating to this Agreement which is expressly permitted by the terms of this Agreement to be brought in a court of law, may be brought in the courts of record of the Commonwealth of Massachusetts (Middlesex or Suffolk Counties) or the court of the United States, District of Massachusetts; (ii) consents to the jurisdiction of each such court in any such suit, action or proceeding; (iii) waives any objection which it or she may have to the laying of venue of any such suit, action or proceeding in any of such courts; and (iv) agrees that service of any court papers may be effected on such party by mail, as provided in this Agreement, or in such other manner as may be provided under applicable laws or court rules in such courts.

13. ***Entire Agreement; Termination of Other Employment Agreement; Amendment***. This Agreement, together with the exhibit attached hereto, constitutes the entire agreement between the patties hereto with respect to the subject matter hereof and, upon its effectiveness, shall supersede all prior agreements, understandings and arrangements, both oral and written, between the Executive and the Company (or any of its Related Entities) with respect to such subject matter, including, without limitation, any other employment agreement currently in effect between the Company and the Executive. The Company and the Executive hereby agree that any other employment agreement currently in effect between the Company and the Executive is hereby terminated immediately upon the execution and delivery of this Agreement. This Agreement may not be modified in any way unless by a written instrument signed by both the Company and the Executive.

14. ***Notices***. All notices required or permitted to be given hereunder shall be in writing and shall be personally delivered by courier, sent by registered or certified mail, return receipt requested or sent by confirmed facsimile transmission addressed as set forth herein. Notices personally delivered, sent by facsimile or sent by overnight courier shall be deemed given on the date of delivery and notices mailed in accordance with the foregoing shall be deemed given upon receipt by the addressee, as evidenced by the return receipt thereof. Notice shall be sent (i) if to the Company, addressed to its headquarters, Attention: President, and (ii) if to the Executive, to her address as reflected on the payroll records of the Company, or to such other address as either party shall request by notice to the other in accordance with this provision.

15. ***Benefits; Binding Effect.*** This Agreement shall be for the benefit of and binding upon the parties hereto and their respective heirs, personal representatives, legal representatives, successors and, where permitted and applicable, assigns, including, without limitation, any successor to the Company, whether by merger, consolidation, sale of stock, sale of assets or otherwise.

16. ***Right to Consult with Counsel; No Drafting Party***. The Executive acknowledges having read and considered all of the provisions of this Agreement carefully, and having had the opportunity to consult with counsel of her own choosing, and, given this, the Executive agrees that the obligations created hereby are not unreasonable. The Executive acknowledges that she has had an opportunity to negotiate any and all of these provisions and no rule of construction shall be used that would interpret any provision in favor of or against a patry on the basis of who drafted the Agreement.

17. ***Severability***. The invalidity of any one or more of the words, phrases, sentences, clauses, provisions, sections or articles contained in this Agreement shall not affect the enforceability of the remaining portions of this Agreement or any part thereof, all of which are inserted conditionally on their being valid in law, and, in the event that any one or more of the words, phrases, sentences, clauses, provisions, sections or articles contained in this Agreement shall be declared invalid, this Agreement shall be construed as if such invalid word or words, phrase or phrases, sentence or sentences, clause or clauses, provisions or provisions, section or sections or article or articles had not been inserted. If such invalidity is caused by length of time or size of area, or both, the otherwise invalid provision will be considered to be reduced to a period or area which would cure such invalidity.

18. ***Waivers***. The waiver by either party hereto of a breach or violation of any term or provision of this Agreement shall not operate nor be construed as a waiver of any subsequent breach or violation.

19. ***Damages; Attorneys' Fees***. Nothing contained herein shall be construed to prevent the Company or the Executive from seeking and recovering from the other damages sustained by either or both of them as a result of its or her breach of any term or provision of this Agreement. Each party shall bear its own costs and attorneys' fees.

20. ***Waiver of Jury Trial***. The Executive hereby knowingly, voluntarily and intentionally waives any right that the Executive may have to a trial by jury in respect of any litigation based hereon, or arising out of, under or in connection with this Agreement and any agreement, document or instrument contemplated to be executed in connection herewith, or any course of conduct, course of dealing statements (whether verbal or written) or actions of any party hereto.

21. ***No Set-off or Mitigation***. The Company's obligation to make the payments provided for in this Agreement and otherwise to perform its obligations hereunder shall not be affected by any set-off, counterclaim, recoupment, defense or other claim, right or action which the Company may have against the Executive or others. In the event of any termination of the Executive's employment under this Agreement, she shall be under no obligation to seek other employment or otherwise in any way to mitigate the amount of any payment provided for hereunder.

22. **Defend Trade Secrets Act**. Pursuant to 18 U.S.C. § 1833(b), Executive will not be held criminally or civilly liable under any Federal or State trade secret law for the disclosure of a trade secret of the Company or its affiliates that (a) is made (i) in confidence to a Federal, State, or local government official, either directly or indirectly, or to Executive's attorney and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (b) is made in a complaint or other document that is filed under seal in a lawsuit or other proceeding. If Executive files a lawsuit for retaliation by the Company for reporting a suspected violation of law, Executive may disclose the trade secret to Executive's attorney and use the trade secret information in the court proceeding, if Executive (x) files any document containing the trade secret under seal, and (y) does not disclose the trade secret, except pursuant to court order. Nothing in this Agreement is intended to conflict with 18 U.S.C. § 1833(b) or create liability for disclosures of trade secrets that are expressly allowed by such section.

23. ***Section Headings***. The article, section and paragraph headings contained in this Agreement are for reference purposes only and shall not affect in any way the meaning or interpretation of this Agreement.

24. ***No Third Party Beneficiary***. The Related Entities are intended third party beneficiaries of this Agreement. Otherwise, nothing expressed or implied in this Agreement is intended, or shall be construed, to confer upon or give any person other than the Company, the parties hereto and their respective heirs, personal representatives, legal representatives, successors and permitted assigns, any rights or remedies under or by reason of this Agreement.

25. ***Counterparts***. This Agreement may be executed in one or more counterparts, each of which shall be deemed to be an original but all of which together shall constitute one and the same instrument and agreement.

[Signatures on Following Page]

IN WITNESS WHEREOF, the undersigned have executed this Agreement on the date first above written.

COMPANY:

LEAP THERAPEUTICS, INC.

By: /s/ Douglas E. Onsi
Name: Douglas E. Onsi
Title: Chief Executive Officer

EXECUTIVE:

/s/ Cynthia Sirard
Name:Cynthia Sirard

<u>Exhibit A</u>

General Release of Claims

1. [_________] ("***Executive***"), for herself and her family, heirs, executors, administrators, legal representatives and their respective successors and assigns, in exchange for the consideration (other than the Accrued Obligations) received pursuant to Article 6 of the Employment Agreement (the "***Severance Benefits***") to which this release is attached as <u>Exhibit A</u> (the "***Employment Agreement***"), does hereby release and forever discharge Leap Therapeutics, Inc. (the "***Company***"), its subsidiaries, affiliated companies, successors and assigns, and its current or former directors, officers, employees, stockholders or agents in such capacities (collectively with the Company, the "***Released Parties***") from any and all actions, causes of action, suits, controversies, claims and demands whatsoever, whether known or unknown, from the beginning of time through the date upon which Executive signs this General Release of Claims, including, without limitation, claims under any applicable laws, in each case in connection with Executive's employment or termination thereof, whether for tort, breach of express or implied employment contract, wrongful discharge, intentional infliction of emotional distress, or defamation or injuries incurred on the job or incurred as a result of loss of employment. Without limiting the generality of the release provided above, Executive expressly waives any and all claims under Age Discrimination in Employment Act ("***ADEA***") that she may have as of the date hereof. Executive further understands that, by signing this General Release of Claims, she is in fact waiving, releasing and forever giving up any claim under the ADEA as well as all other laws within the scope of this paragraph 1 that may have existed on or prior to the date hereof, including, but not limited to, [*additional citations to be added prior to execution at the time of separation*]. Notwithstanding anything in this paragraph 1 to the contrary, this General Release of Claims shall not apply to (i) any rights to receive any payments or benefits to which the Executive is entitled under the Employment Agreement or COBRA, (ii) any rights or claims that may arise as a result of events occurring after the date this General Release of Claims is executed, (iii) any indemnification and advancement rights Executive may have as a former employee, officer or director of the Company or its subsidiaries or affiliated companies (including any rights under any directors' and officers' indemnification agreement or under the Company's charter or bylaws), (iv) any claims for benefits under any directors' and officers' liability policy maintained by the Company or its subsidiaries or affiliated companies in accordance with the terms of such policy, (v) rights to vested benefits under the Company's 401(k) plan or other employee benefits plans, (vi) any rights as a holder of equity securities or debt securities/notes of the Company and (vii) any rights that Executive may have under any contracts or agreements with the Company or any of its subsidiaries or affiliated companies (other than the Employment Agreement) to the extent that such rights do not pertain to compensation or remuneration in connection with Executive's employment with the Company or any of its subsidiaries or affiliated companies or the termination of such employment.

2. Executive represents that she has not filed against the Released Parties any complaints, charges, or lawsuits arising out of her employment, or any other matter arising on or prior to the date of this General Release of Claims, and covenants and agrees that she will never individually or with any person file, or commence the filing of any lawsuits, complaints or proceedings with any governmental agency, or against the Released Parties with respect to any of the matters released by Executive pursuant to paragraph 1 hereof; provided, that nothing herein shall prevent Executive from filing a charge or complaint with the Equal Employment Opportunity Commission ("***EEOC***") or similar federal or state agency or Executive's ability to participate in any investigation or proceeding conducted by such agency. Executive does agree, however, that she is waiving her right to recover any money in connection with such an investigation or charge filed by her or by any other individual, or a charge filed by the Equal Employment Opportunity Commission or any other federal, state or local agency.

3. Executive acknowledges that, in the absence of her execution of this General Release of Claims, the Severance Benefits would not otherwise be due to her.

4. Executive acknowledges and agrees that she received adequate consideration in exchange for agreeing to the covenants contained in the Confidentiality Agreement and incorporated into the Employment Agreement by virtue of Section 7 of the Employment Agreement, that such covenants remain reasonable and necessary to protect the legitimate business interests of the Company and its affiliates and that she will continue to comply with those covenants.

5. Executive hereby acknowledges that the Company has informed her that she has up to twenty-one (21) days to sign this General Release of Claims and she may knowingly and voluntarily waive that twenty-one (21)-day period by signing this General Release of Claims earlier. Executive is advised to consult with an attorney before signing this General Release of Claims. Executive also understands that she shall have seven (7) days following the date on which she signs this General Release of Claims within which to revoke it by providing a written notice of her revocation to the Company in the manner described in Section 14 of the Employment Agreement.

6. Executive expressly acknowledges and agrees that Executive will not make any statements that are professionally or personally disparaging about, or adverse to, the Company or its business (including its officers, directors, employees and consultants) including, but not limited to, any statements that disparage any person, product, service, finances, financial condition, capability or any other aspect of the business of the Company, and that Executive shall not engage in any conduct which could reasonably be expected to harm professionally or personally the reputation of the Company (including its officers, directors, employees and consultants). Notwithstanding the foregoing, Executive shall not be (i) required to make any statement Executive believes to be false or inaccurate or (ii) restricted in connection with any litigation, arbitration or similar proceeding or with respect to Executive’s response to any legal process.

7. Executive acknowledges and agrees that this General Release of Claims will be governed by and construed and enforced in accordance with the internal laws of the Commonwealth of Massachusetts applicable to contracts made and to be performed entirely within such state.

8. Executive acknowledges that she has read this General Release of Claims, that she has been advised that she should consult with an attorney before she executes this general release of claims, and that she understands all of its terms and executes it voluntarily and with full knowledge of its significance and the consequences thereof.

9. This General Release of Claims shall become irrevocable on the eighth day following Executive's execution of this General Release of Claims, unless previously revoked in accordance with paragraph 5, above.

Intending to be legally bound hereby, Executive has executed this General Release of Claims on ___________ ____, ______.

EXECUTIVE:

Name:

Exhibit 10.19

EXECUTIVE EMPLOYMENT AGREEMENT

This Executive Employment Agreement ("***Agreement***") is made and entered into as of this 10th day of April, 2020, by and between Leap Therapeutics, Inc., a Delaware corporation (the "***Company***"), and John Mark O'Mahony (hereinafter, the "***Executive***").

WITNESSETH:

WHEREAS, the Company currently employs the Executive as the Vice President, Manufacturing, of the Company.

WHEREAS, the Company desires to promote and continue to employ the Executive as the Chief Manufacturing Officer of the Company effective as of April 1, 2020 (the "**Effective Date**"), and the Executive desires to continue to be employed by the Company as the Chief Manufacturing Officer of the Company effective as of the Effective Date, on the terms herein described.

NOW, THEREFORE, in consideration of the premises and mutual covenants set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which are mutually acknowledged, the Company and the Executive hereby agree as follows:

1. ***Definitions***. When used in this Agreement, the following terms shall have the following meanings:

(a) "***Accrued Obligations***" means:

(i) all accrued but unpaid Base Salary through the end of the Term of Employment;

(ii) any unpaid or unreimbursed expenses incurred in accordance with Company policy, including amounts due under Section 5(a) hereof, to the extent incurred during the Term of Employment;

(iii) any accrued but unpaid benefits provided under the Company's employee benefit plans, subject to and in accordance with the terms of those plans;

(iv) any earned and unpaid Bonus in respect to any completed fiscal year that has ended on or prior to the end of the Term of Employment;

(v) any accrued but unpaid rights to indemnification by virtue of the Executive's position as an officer or director of the Company or its subsidiaries and the benefits under any directors' and officers' liability insurance policy maintained by the Company, in accordance with its terms thereof; and

(vi) any accrued but unused vacation pay.

(b) "***Base Salary***" means the salary amount provided for in Section 4(a) hereof or any increase thereto as salary granted to Executive pursuant to Section 4(a) hereof.

(c) “***Beneficial Ownership***” shall have the meaning ascribed to such term in Rule 13d-3 promulgated under the Exchange Act.

(d) “***Board***” means the Board of Directors of the Company.

(e) “***Bonus***” means any bonus earned and payable to the Executive pursuant to Section 4(b) hereof.

(f) “***Cause***” means the occurrence of any of the following: (i) a conviction of the Executive, or a plea of nolo contendere, to a felony (other than a felony related to the operation of a motor vehicle); or (ii) willful misconduct or gross negligence by the Executive resulting, in either case, in material harm to the Company or any Related Entities; or (iii) a willful failure by the Executive to carry out the reasonable and lawful directions of the Board and failure by the Executive to remedy such willful failure within thirty (30) days after receipt of written notice of same from the Board; or (iv) fraud, embezzlement, theft or dishonesty of a material nature by the Executive, or a willful material violation by the Executive of a written policy or procedure of the Company or any Related Entity, resulting, in any case, in material harm to the Company or any Related Entity; or (v) a material breach by the Executive of this Agreement, and failure by the Executive to remedy the material breach within thirty (30) days after receipt of written notice of same, by the Board. For clarity, the inability of Executive to perform any or all of his duties, responsibilities or obligations under this Agreement on account of Executive’s death or disability shall not be deemed or treated as a material breach of this Agreement by the Executive and shall not constitute Cause for any purpose of this Agreement.

(g) “***Change in Control***” means:

(i) The acquisition by any Person of Beneficial Ownership of at least twenty percent (20%) of either (A) the value of the then outstanding shares of common stock of the Company (the “***Outstanding Company Common Stock***”) or (B) the combined voting power of the then outstanding voting securities of the Company entitled to vote generally in the election of directors (the “***Outstanding Company Voting Securities***”) (the foregoing Beneficial Ownership hereinafter being referred to as a “***Controlling Interest***”); *provided, however*, that for purposes of this definition, the following acquisitions shall not constitute or result in a Change in Control: (v) any acquisition directly from the Company; (w) any acquisition by the Company; (x) any acquisition by any person that owns, or by any person that collectively with such person’s affiliates own, Beneficial Ownership of a Controlling Interest on the Effective Date; (y) any acquisition by any employee benefit plan (or related trust) sponsored or maintained by the Company or any subsidiary of the Company; or (z) any acquisition by any corporation or other Person pursuant to a transaction which complies with clauses (A), (B) and (C) of subsection (ii) below; or

(ii) Consummation of a reorganization, merger, statutory share exchange or consolidation or similar corporate transaction involving the Company or any of its subsidiaries, a sale or other disposition of all or substantially all of the assets of the Company, or the acquisition of assets or stock or equity interests of another entity by the Company or any of its subsidiaries (each a “***Business Combination***”), in each case, unless, immediately following such Business Combination, (A) all or substantially all of the Persons who were the Beneficial Owners, respectively, of the Outstanding Company Common Stock and Outstanding Company Voting Securities immediately prior to such Business Combination beneficially own, directly or indirectly, more than fifty percent (50%) of the then combined voting power of the then outstanding voting securities entitled to vote generally in the election of directors (or equivalent persons) of the corporation or other Person resulting from such Business Combination (including, without limitation, a corporation or other Person which as a result of such transaction owns the Company or all or substantially all of the Company’s assets either directly or through one or more subsidiaries) (such resulting or acquiring corporation or other Person is referred to herein as the “***Acquiring Person***”) in substantially the same proportions as their beneficial ownership, immediately prior to such Business Combination, of the combined voting power of the Outstanding Company Voting Securities, and (B) at least a majority of the members of the Board of Directors or equivalent body of the corporation or other Person resulting from such Business Combination were members of the incumbent Board at the time of the execution of the initial agreement, or of the action of the Board, providing for such Business Combination; or

(iii) approval by the stockholders of the Company of a complete liquidation or dissolution of the Company.

(h) "***COBRA***" means the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended from time to time.

(i) "***Code***" means the Internal Revenue Code of 1986, as amended.

(j) "***Date of Termination***" means the earliest of: (i) immediately after the Company gives notice to Executive of Executive's termination, with or without Cause, unless the Company specifies a later date, in which case, termination shall be effective as of such later date; (ii) immediately upon the Executive's death; (iii) thirty (30) days after the Company gives notice to Executive of Executive's termination on account of Executive's Disability, unless the Company specifies a later date, in which case, termination shall be effective as of such later date, provided, that Executive has not returned to the full time performance of Executive's duties prior to such date; or (iv) thirty (30) days after the Executive gives written notice to the Company of Executive's resignation with or without Good Reason. Executive will receive compensation through any required notice period. In the event notice of a termination under subsections (i), (iii) and (iv) is given orally, at the other party's request, the party giving notice must provide written confirmation of such notice within five business days of the request in compliance with the requirement of Section 14 below. In the event of a termination for Cause or Good Reason written confirmation shall specify the subsection(s) of the definition of Cause or Good Reason relied on to support the decision to terminate but shall not include further explanation.

(k) "***Disability***" means the Executive's inability, or failure, to perform the essential functions of his position, with or without reasonable accommodation, for any period of ninety (90) consecutive days, or (ii) for one-hundred and eighty (180) days in the aggregate during any twelve (12) month period or based on the written certification by two licensed physicians of the likely continuation of such condition for either such period. This definition shall be interpreted and applied consistent with the Americans with Disabilities Act, the Family and Medical Leave Act, and other applicable law.

(l) ***"Equity Awards***" means any stock options, restricted stock, restricted stock units, stock appreciation rights, phantom stock or other equity based awards granted by the Company to the Executive.

(m) "***Exchange Act***" means the Securities Exchange Act of 1934, as amended.

(n) "***Excise Tax***" means any excise tax imposed by Section 4999 of the Code, together with any interest and penalties imposed with respect thereto, or any interest or penalties that are incurred by the Executive with respect to any such excise tax.

(o) "***Good Reason***" means the occurrence of any of the following: (i) a material diminution in the Executive's Base Salary; or (ii) the Company's or Related Entity's requiring the Executive to be based at any office or location outside of fifty (50) miles from Cambridge, Massachusetts, except for travel reasonably required in the performance of the Executive's responsibilities; or (iii) any other action or inaction that constitutes a material breach by the Company of this Agreement. For purposes of this Agreement, Good Reason shall not be deemed to exist unless the Executive's termination of employment for Good Reason occurs within one hundred eighty days following the initial existence of one of the conditions specified in clauses (i) through (v) above, the Executive provides the Company with written notice of the existence of such condition within ninety (90) days after the initial existence of the condition, and the Company fails to remedy the condition within thirty (30) days after its receipt of such notice.

(p) "***Person***" shall have the meaning ascribed to such term in Section 3(a)(9) of the Exchange Act and used in Sections 13(d) and 14(d) thereof.

(q) "***Related Entity***" means any Person controlling, controlled by or under common control with the Company or any of its subsidiaries. For this purpose, the terms "controlling," "controlled by" and "under common control with" mean the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of a Person, whether through the ownership of voting securities, as trustee or executor, by contract or otherwise, including (without limitation) the ownership, directly or indirectly, of securities having the power to elect a majority of the board of directors or similar body governing the affairs of such Person.

(r) "***Severance Amount***" shall mean an amount equal to one-half (1/2) of the Executive's annualized Base Salary, as in effect immediately prior to the Termination Date.

(s) "***Target Bonus***" has the meaning described in Section 4(b).

(t) "***Term of Employment***" means the period during which the Executive shall be employed by the Company pursuant to the terms of this Agreement, which period shall begin effective as of the Effective Date and continue until terminated in accordance with Section 6 hereof.

(u) "***Termination Date***" means the date on which the Term of Employment ends.

2. ***<u>Employment</u>***. The Company hereby agrees to continue to employ the Executive, and the Executive hereby agrees to continue to serve the Company, during the Term of Employment on the terms and conditions set forth herein.

3. ***<u>Duties of Executive</u>***.

(a) ***Position and Position Duties***. During the Term of Employment, the Executive shall be employed and serve as the Chief Manufacturing Officer of the Company, and shall have such duties typically associated with such title.

(b) ***Duties in General***. The Executive shall faithfully and diligently perform all services as may be assigned to him by the Board, and shall exercise such power and authority as may from time to time be delegated to him by the Board. The Executive shall devote time, attention and efforts to the performance of his duties under this Agreement, render such services to the best of his ability, and use his reasonable best efforts to promote the interests of the Company. The Executive shall not engage in any other business or occupation during the Term of Employment that (i) conflicts with the interests of the Company or its subsidiaries, (ii) interferes with the proper and efficient performance of his duties for the Company, or (iii) interferes with the exercise of his judgment in the Company's best interests.

(c) ***Company Policies and Procedures***. The employment relationship between the parties also shall be subject to the Company's personnel and compliance policies and procedures as they may be interpreted, adopted, revised or deleted from time to time in the Company's sole discretion. The Company reserves the right to change, alter, or terminate any such policy or procedure in its sole discretion. Notwithstanding the foregoing, in the event that the terms of this Agreement differ from or are in conflict with the Company's general employment policies or practices, this Agreement shall control.

4. ***Compensation***.

(a) ***Base Salary***. The Executive shall receive a Base Salary at the annualized rate of $323,346 during the Term of Employment, with such Base Salary payable in installments consistent with the Company's normal payroll schedule, subject to applicable withholding and other taxes. The Base Salary shall be reviewed, at least annually, for merit increases and may, by action and in the discretion of the Board, be increased at any time or from time to time, but may not be decreased from the then current Base Salary.

(b) ***Bonuses***. During the Term of Employment, the Executive shall participate in the Company's annual incentive compensation plan, program and/or arrangements applicable to senior-level executives, as established and modified from time to time by the Compensation Committee of the Board (for the avoidance of doubt, for any period during which there is not a Compensation Committee, all matters under this Agreement shall be addressed by the Board) in its sole discretion. During the Term of Employment, the Executive shall have a target bonus opportunity under such plan or program equal to 35% of his current Base Salary (the "***Target Bonus***"), based on satisfaction of performance criteria to be established by the Compensation Committee of the Board within the first three months of each fiscal year that begins during the Term of Employment. Payment of annual incentive compensation awards shall be made in the same manner and at the same time that other senior-level executives receive their annual incentive compensation awards and, except as otherwise provided herein, will be subject to the Executive's continued employment through the applicable payment date.

(c) ***Equity Awards***. Any and all existing Equity Awards that the Executive has or holds in the Company will be treated consistent with the terms of the applicable plans and agreements under which such Equity Awards have been granted. The Executive may be granted additional Equity Awards from time to time in accordance with the Company's normal business practice and in the sole discretion of the Compensation Committee of the Board. The terms of any future Equity Awards granted to the Executive will be consistent with any plan under which such Equity Awards are granted and the terms of the applicable agreement for such Equity Awards. Notwithstanding the foregoing, any and all outstanding unvested Equity Awards shall automatically become fully vested and exercisable on an accelerated basis immediately prior to any Change in Control that is consummated at any time after the Effective Date.

5. ***Expense Reimbursement and Other Benefits***.

(a) ***Reimbursement of Expenses***. Upon the submission of proper substantiation by the Executive, and subject to such rules and guidelines as the Company may from time to time adopt with respect to the reimbursement of expenses of executive personnel, the Company shall reimburse the Executive for all reasonable expenses actually paid or incurred by the Executive during the Term of Employment in the course of and pursuant to the business of the Company. The Executive shall account to the Company in writing for all expenses for which reimbursement is sought and shall supply to the Company copies of all relevant invoices, receipts or other evidence reasonably requested by the Company.

(b) ***Compensation/Benefit Programs***. During the Term of Employment, the Executive shall be entitled to participate in all benefit plans on the same basis as similarly situated executives in the Company's benefit plans in effect from time to time during Executive's employment. All matters of eligibility for coverage or benefits under any benefit plan shall be determined in accordance with the provisions of such plan.

(c) ***Working Facilities***. During the Term of Employment, the Company shall furnish the Executive with an office, administrative help, and such other facilities and services suitable to his position and adequate for the performance of his duties hereunder. The Executive's principal place of employment (subject to reasonable travel) shall be Cambridge, Massachusetts.

(d) ***Vacation***. The Executive shall be entitled to paid vacation each calendar year during the Term of Employment pursuant to the policies of the Company applicable to Executives, to be taken at such times as the Executive and the Company shall mutually determine and provided that no vacation time shall significantly interfere with the duties required to be rendered by the Executive hereunder.

6. ***Termination***.

(a) ***General***. The Term of Employment shall terminate upon the earliest to occur of (i) the Executive's death, (ii) a termination by the Company by reason of the Executive's Disability, (iii) a termination by the Company with or without Cause, or (iv) a termination by Executive with or without Good Reason. Upon any termination of Executive's employment for any reason, except as may otherwise be requested by the Company in writing and agreed upon in writing by Executive, the Executive shall resign from any and all directorships, committee memberships or any other positions Executive holds with the Company or any of its Related Entities.

(b) ***Termination By Company for Cause.*** In the event the Executive is terminated by the Company for Cause, the Company's obligation to make payments under this Agreement shall cease upon the Date of Termination, except that the Company shall pay Executive any Base Salary earned but unpaid prior to termination, all accrued but unused vacation and any business expenses that were incurred but not reimbursed as of the Date of Termination. Vesting of any unvested stock options and/or other equity securities shall cease on the Date of Termination, unless otherwise provided in any plan, instrument or agreement to which such unvested stock options and/or other equity securities may be subject.

(c) ***Disability***. The Company shall have the option, in accordance with applicable law, to terminate the Term of Employment upon written notice to the Executive, at any time during which the Executive is suffering from a Disability. In the event that the Term of Employment is terminated due to the Executive's Disability, the Executive shall be entitled to (i) the Accrued Obligations, payable as and when those amounts would have been paid had the Term of Employment not ended, and (ii) any insurance benefits to which he and his beneficiaries are entitled as a result of his Disability. Vesting of any unvested stock options and/or other equity securities shall cease on the Date of Termination, unless otherwise provided in any plan, instrument or agreement to which such unvested stock options and/or other equity securities may be subject.

(d) ***Death***. In the event that the Term of Employment is terminated due to the Executive's death, the Executive's estate shall be entitled to (i) the Accrued Obligations, payable as and when those amounts would have been paid had the Term of Employment not ended, and (ii) any insurance benefits to which he and his beneficiaries are entitled as a result of his death. Vesting of any unvested stock options and/or other equity securities shall cease on the Date of Termination, unless otherwise provided in any plan, instrument or agreement to which such unvested stock options and/or other equity securities may be subject.

(e) ***Termination Without Cause or Resignation With Good Reason***. The Company may terminate the Term of Employment without Cause, and the Executive may terminate the Term of Employment for Good Reason, at any time upon written notice, and upon compliance with Section 6(g) below. If the Term of Employment is terminated by the Company without Cause (other than due to the Executive's death or Disability) or by the Executive for Good Reason, the Executive shall be entitled to the following:

(i) The Accrued Obligations, payable as and when those amounts would have been paid had the Term of Employment not ended;

(ii) The Severance Amount, payable in equal installments consistent with the Company's normal payroll schedule over the six (6)-month period beginning with the first regularly scheduled payroll date that occurs more than thirty (30) days following the Termination Date; and

(iii) Provided that the Executive timely elects continued coverage under COBRA, the Company will reimburse the Executive for the monthly COBRA cost of continued health and dental coverage of the Executive and his qualified beneficiaries paid by the Executive under the health and dental plans of the Company, less the amount that the Executive would be required to contribute for health and dental coverage if the Executive were an active employee of the Company, for six (6) months (or, if less, for the duration that such COBRA coverage is available to Executive), payable in equal installments consistent with the Company's normal payroll schedule over the six (6)-month period beginning with the first regularly scheduled payroll date that occurs more than thirty (30) days following the Termination Date.

(f) ***Termination by Executive Without Good Reason***. The Executive may terminate his employment without Good Reason at any time by providing the Company 30 days' written notice of such termination. In the event of a termination of employment by the Executive under this Section 6(f), the Executive shall be entitled only to the Accrued Obligations payable as and when those amounts would have been payable had the Term of Employment not ended. In the event of termination of the Executive's employment under this Section 6(f), the Company may, in its sole and absolute discretion, by written notice, accelerate the Date of Termination and still have it treated as a termination without Good Reason.

(g) ***Release***. All rights, payments and benefits due to the Executive under this Article 6 (other than the Accrued Obligations) shall be conditioned on the Executive's execution of a general release of claims against the Company and its affiliates substantially in the form attached hereto as Exhibit A within 60 days of the Date of Termination (the "***Release***") and on that Release becoming irrevocable within sixty (60) days following the Termination Date.

(h) ***Section 280G Certain Reductions of Payments by the Company***.

(i) In the event that a Change in Control occurs at any time during the Term of Employment, and the severance and other benefits provided for in this Agreement or otherwise payable to Executive (a) constitute "parachute payments" within the meaning of Section 280G of the Code and (b) but for this Section, would be subject to the excise tax imposed by Section 4999 of the Code, then Executive's severance and other benefits constituting parachute payments will be either:

(1) delivered in full, or

(2) delivered as to such lesser extent which would result in no portion of such severance and other benefits being subject to the excise tax under Section 4999 of the Code,

whichever of the foregoing amounts, taking into account the applicable federal, state and local income taxes and the excise tax imposed by Section 4999 of the Code, results in the receipt by Executive, on an after-tax basis, of the greatest amount of severance and other benefits, notwithstanding that all or some portion of such severance and other benefits may be taxable under Section 4999 of the Code. If a reduction in the severance and other benefits constituting "parachute payments" is necessary so that no portion of such severance and other benefits is subject to the excise tax under Section 4999 of the Code, the reduction shall occur in the following order: (a) reduction of the cash severance payments; (b) cancellation of accelerated vesting of equity awards; and (c) reduction of continued employee benefits. In the event that acceleration of vesting of equity award compensation is to be reduced, such acceleration of vesting shall be cancelled in the reverse order of the date of grant of Executive's equity awards.

(ii) A nationally recognized certified professional services firm selected by the Company, the Company's legal counsel or such other person or entity to which the parties mutually agree (the "**Firm**") shall perform the foregoing calculations related to the Excise Tax. The Company shall bear all expenses with respect to the determinations by the Firm required to be made hereunder. For purposes of making the calculations required by this Section 6(h), the Firm may make reasonable assumptions and approximations concerning applicable taxes and may rely on reasonable, good faith interpretations concerning the application of Sections 280G and 4999 of the Code. The Company and Executive will furnish to the Firm such information and documents as the Firm may reasonably request in order to make a determination under this Section 6(h). The Firm engaged to make the determinations hereunder shall provide its calculations, together with detailed supporting documentation, to the Company and Executive within 15 calendar days after the date on which Executive's right to the severance benefits or other payments is triggered (if requested at that time by the Company or Executive) or such other time as requested by the Company or Executive. Any good faith determinations of the Firm made hereunder shall be final, binding, and conclusive upon the Company and Executive.

(i) ***Cooperation***. Following the Term of Employment, the Executive shall give his assistance and cooperation willingly, upon reasonable advance notice with due consideration for his other business or personal commitments, in any matter relating to his position with the Company, or his expertise or experience as the Company may reasonably request, including his attendance and truthful testimony where deemed appropriate by the Company, with respect to any investigation or the Company's defense or prosecution of any existing or future claims or litigations or other proceedings relating to matters in which he was involved or potentially had knowledge by virtue of his employment with the Company. In no event shall his cooperation materially interfere with his services for a subsequent employer or other similar service recipient. To the extent permitted by law, the Company agrees that (i) it shall promptly reimburse the Executive for his reasonable and documented expenses in connection with his rendering assistance and/or cooperation under this Section 6(i) upon his presentation of documentation for such expenses and (ii) the Executive shall be reasonably compensated for any continued material services as required under this Section 6(i).

(j) ***Return of Company Property***. Following the Termination Date, the Executive or his personal representative shall immediately return all Company property in his possession, including but not limited to all computer equipment (hardware and software), telephones, facsimile machines, tablets and other communication devices, credit cards, office keys, security access cards, badges, identification cards and all copies (including drafts) of any documentation or information (however stored) relating to the business of the Company, its customers and clients or its prospective customers and clients (provided that the Executive may retain a copy of the addresses contained in his rolodex, smartphone or similar device or the Company and, at the Executive's request, the Company shall provide a thumb drive of his contacts).

(k) ***Compliance with Section 409A***.

(i) ***General***. It is the intention of both the Company and the Executive that the benefits and rights to which the Executive could be entitled pursuant to this Agreement comply with Section 409A of the Code and the Treasury Regulations and other guidance promulgated or issued thereunder ("***Section 409A***"), to the extent that the requirements of Section 409A are applicable thereto, and the provisions of this Agreement shall be construed in a manner consistent with that intention.

(ii) ***Distributions on Account of Separation from Service***. If and to the extent required to comply with Section 409A, no payment or benefit required to be paid under this Agreement on account of termination of the Executive's employment shall be made unless and until the Executive incurs a "separation from service" within the meaning of Section 409A.

(iii) ***Six Month Delay for Specified Employees***. If the Executive is a "specified employee" (within the meaning of Section 409A(a)(2)(B)(i) of the Code), then no payment or benefit that is payable on account of the Executive's "separation from service", as that term is defined for purposes of Section 409A, shall be made before the date that is six (6) months after the Executive's "separation from service" (or, if earlier, the date of the Executive's death) if and to the extent that such payment or benefit constitutes deferred compensation (or may be nonqualified deferred compensation) under Section 409A and such deferral is required to comply with the requirements of Section 409A. Any payment or benefit delayed by reason of the prior sentence shall be paid out or provided in a single lump sum at the end of such required delay period in order to catch up to the original payment schedule.

(iv) ***Treatment of Each Installment as a Separate Payment***. For purposes of applying the provisions of Section 409A to this Agreement, each separately identified amount to which the Executive is entitled under this Agreement shall be treated as a separate payment. In addition, any series of installment payments under this Agreement shall be treated as a right to a series of separate payments.

(v) ***Taxable Reimbursements and In-Kind Benefits***.

(A) Any reimbursements by the Company to the Executive of any eligible expenses under this Agreement that are not excludable from the Executive's income for Federal income tax purposes (the "***Taxable Reimbursements***") shall be made by no later than the last day of the taxable year of the Executive following the year in which the expense was incurred.

(B) The amount of any Taxable Reimbursements, and the value of any in-kind benefits to be provided to the Executive, during any taxable year of the Executive shall not affect the expenses eligible for reimbursement, or in-kind benefits to be provided, in any other taxable year of the Executive.

(C) The right to Taxable Reimbursement, or in-kind benefits, shall not be subject to liquidation or exchange for another benefit.

(vi) ***Company Discretion***. Notwithstanding the foregoing, if at any time the Company determines, in its sole discretion, that the payment of the COBRA premiums under Section 6(e)(iii) above would result in a violation of the nondiscrimination rules of Section 105(h)(2) of the Code or any statute or regulation of similar effect (including but not limited to the 2010 Patient Protection and Affordable Care Act, as amended by the 2010 Health Care and Education Reconciliation Act), then in lieu of providing the COBRA premiums, the Company may instead pay Executive, fully taxable cash payments equal to and paid at the same time as the COBRA premiums that otherwise would have been paid, subject to applicable tax withholdings. In the event the COBRA premium reimbursement is made on an after-tax basis, the Company will provide a tax gross-up to the Executive equal to the amount of taxes withheld on the COBRA premium reimbursement with such amount to be paid at the same time of the COBRA premium reimbursement. To receive the payments under Section 6(e)(ii) above, Executive's termination or resignation must constitute a "separation from service**"** within the meaning of Section 409A, and Executive must execute and allow the Release to become effective within sixty (60) days of Executive's termination or resignation. Such payments shall not be paid prior to the sixtieth (60th) day following Executive's termination or resignation, rather, subject to the aforementioned conditions, on the sixtieth (60th) day following Executive's termination or resignation, the Company will pay Executive such payments in a lump sum that Executive would have received on or prior to such date under the original schedule, with the balance of such payments being paid as originally scheduled.

(vii) ***Timing of Payment and Execution of Release*****.** Notwithstanding any provision of this Agreement to the contrary, in no event shall the timing of the execution of the Release, directly or indirectly, result in the Executive designating the calendar year of a payment, and if a payment that is subject to execution of the Release could be made in more than one taxable year, payment shall be made in the later taxable year to the extent required under Section 409A. In no event may the Executive, directly or indirectly, designate the calendar year of a payment.

(viii) ***No Guaranty of 409A Compliance***. Notwithstanding the foregoing, the Company does not make any representation to the Executive that the payments or benefits provided under this Agreement are exempt from, or satisfy, the requirements of Section 409A, and the Company shall have no liability or other obligation to indemnify or hold harmless the Executive or any beneficiary of the Executive for any tax, additional tax, interest or penalties that the Executive or any beneficiary of the Executive may incur in the event that any provision of this Agreement, or any amendment or modification thereof, or any other action taken with respect thereto, is deemed to violate any of the requirements of Section 409A.

7. ***Proprietary Information, Invention, Non-Competition, and Non-Solicitation***. The Executive and the Company have previously entered into that certain Employee Proprietary Information, Invention, Non-Competition and Non-Solicitation Agreement, dated as of December 10, 2015, between the Company and the Executive (the "Confidentiality Agreement"), and the terms and provisions of the Confidentiality Agreement shall be incorporated into this Agreement by reference for all purposes.

8. ***Representations and Warranties of Executive***. The Executive represents and warrants to the Company that:

(a) The Executive's employment has not conflicted with or resulted in, and will not conflict with or result in, his breach of any agreement to which he is a party or otherwise may be bound;

(b) The Executive has not violated, and in connection with his employment with the Company will not violate, any non-solicitation, non-competition or other similar covenant or agreement of a prior employer by which he is or may be bound; and

(c) In connection with Executive's employment with the Company, he has not used, and will not use, any confidential or proprietary information that he may have obtained in connection with employment with any prior employer.

9. ***Taxes***. All payments or transfers of property made by the Company to the Executive or his estate or beneficiaries shall be subject to the withholding of such amounts relating to taxes as the Company may reasonably determine it should withhold pursuant to any applicable law or regulation.

10. ***Assignment***. The Company shall have the right to assign this Agreement and its rights and obligations hereunder in whole, but not in part, to any corporation or other entity with or into which the Company may hereafter merge or consolidate or to which the Company may transfer all or substantially all of its assets, if in any such case said corporation or other entity shall by operation of law or expressly in writing assume all obligations of the Company hereunder as fully as if it had been originally made a party hereto, but may not otherwise assign this Agreement or its rights and obligations hereunder. The Executive may not assign or transfer this Agreement or any rights or obligations hereunder.

11. ***Governing Law***. This Agreement shall be governed by and construed and enforced in accordance with the internal laws of the Commonwealth of Massachusetts, without regard to principles of conflict of laws.

12. ***Jurisdiction and Venue***. The parties acknowledge that a substantial portion of the negotiations, anticipated performance and execution of this Agreement occurred or shall occur in Cambridge, Massachusetts, and that, therefore, without limiting the jurisdiction or venue of any other federal or state courts, each of the parties irrevocably and unconditionally (i) agrees that any suit, action or legal proceeding arising out of or relating to this Agreement which is expressly permitted by the terms of this Agreement to be brought in a court of law, may be brought in the courts of record of the Commonwealth of Massachusetts (Middlesex or Suffolk Counties) or the court of the United States, District of Massachusetts; (ii) consents to the jurisdiction of each such court in any such suit, action or proceeding; (iii) waives any objection which it or he may have to the laying of venue of any such suit, action or proceeding in any of such courts; and (iv) agrees that service of any court papers may be effected on such party by mail, as provided in this Agreement, or in such other manner as may be provided under applicable laws or court rules in such courts.

13. ***Entire Agreement; Termination of Other Employment Agreement; Amendment***. This Agreement, together with the exhibit attached hereto, constitutes the entire agreement between the patties hereto with respect to the subject matter hereof and, upon its effectiveness, shall supersede all prior agreements, understandings and arrangements, both oral and written, between the Executive and the Company (or any of its Related Entities) with respect to such subject matter, including, without limitation, any other employment agreement currently in effect between the Company and the Executive. The Company and the Executive hereby agree that any other employment agreement currently in effect between the Company and the Executive is hereby terminated immediately upon the execution and delivery of this Agreement. This Agreement may not be modified in any way unless by a written instrument signed by both the Company and the Executive.

14. ***Notices***. All notices required or permitted to be given hereunder shall be in writing and shall be personally delivered by courier, sent by registered or certified mail, return receipt requested or sent by confirmed facsimile transmission addressed as set forth herein. Notices personally delivered, sent by facsimile or sent by overnight courier shall be deemed given on the date of delivery and notices mailed in accordance with the foregoing shall be deemed given upon receipt by the addressee, as evidenced by the return receipt thereof. Notice shall be sent (i) if to the Company, addressed to its headquarters, Attention: President, and (ii) if to the Executive, to his address as reflected on the payroll records of the Company, or to such other address as either party shall request by notice to the other in accordance with this provision.

15. ***Benefits; Binding Effect.*** This Agreement shall be for the benefit of and binding upon the parties hereto and their respective heirs, personal representatives, legal representatives, successors and, where permitted and applicable, assigns, including, without limitation, any successor to the Company, whether by merger, consolidation, sale of stock, sale of assets or otherwise.

16. ***Right to Consult with Counsel; No Drafting Party***. The Executive acknowledges having read and considered all of the provisions of this Agreement carefully, and having had the opportunity to consult with counsel of his own choosing, and, given this, the Executive agrees that the obligations created hereby are not unreasonable. The Executive acknowledges that he has had an opportunity to negotiate any and all of these provisions and no rule of construction shall be used that would interpret any provision in favor of or against a patry on the basis of who drafted the Agreement.

17. ***Severability***. The invalidity of any one or more of the words, phrases, sentences, clauses, provisions, sections or articles contained in this Agreement shall not affect the enforceability of the remaining portions of this Agreement or any part thereof, all of which are inserted conditionally on their being valid in law, and, in the event that any one or more of the words, phrases, sentences, clauses, provisions, sections or articles contained in this Agreement shall be declared invalid, this Agreement shall be construed as if such invalid word or words, phrase or phrases, sentence or sentences, clause or clauses, provisions or provisions, section or sections or article or articles had not been inserted. If such invalidity is caused by length of time or size of area, or both, the otherwise invalid provision will be considered to be reduced to a period or area which would cure such invalidity.

18. ***Waivers***. The waiver by either party hereto of a breach or violation of any term or provision of this Agreement shall not operate nor be construed as a waiver of any subsequent breach or violation.

19. ***Damages; Attorneys' Fees***. Nothing contained herein shall be construed to prevent the Company or the Executive from seeking and recovering from the other damages sustained by either or both of them as a result of its or his breach of any term or provision of this Agreement. Each party shall bear its own costs and attorneys' fees.

20. ***Waiver of Jury Trial***. The Executive hereby knowingly, voluntarily and intentionally waives any right that the Executive may have to a trial by jury in respect of any litigation based hereon, or arising out of, under or in connection with this Agreement and any agreement, document or instrument contemplated to be executed in connection herewith, or any course of conduct, course of dealing statements (whether verbal or written) or actions of any party hereto.

21. ***No Set-off or Mitigation***. The Company's obligation to make the payments provided for in this Agreement and otherwise to perform its obligations hereunder shall not be affected by any set off, counterclaim, recoupment, defense or other claim, right or action which the Company may have against the Executive or others. In the event of any termination of the Executive's employment under this Agreement, he shall be under no obligation to seek other employment or otherwise in any way to mitigate the amount of any payment provided for hereunder.

22. ***Defend Trade Secrets Act***. Pursuant to 18 U.S.C. § 1833(b), Executive will not be held criminally or civilly liable under any Federal or State trade secret law for the disclosure of a trade secret of the Company or its affiliates that (a) is made (i) in confidence to a Federal, State, or local government official, either directly or indirectly, or to Executive's attorney and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (b) is made in a complaint or other document that is filed under seal in a lawsuit or other proceeding. If Executive files a lawsuit for retaliation by the Company for reporting a suspected violation of law, Executive may disclose the trade secret to Executive's attorney and use the trade secret information in the court proceeding, if Executive (x) files any document containing the trade secret under seal, and (y) does not disclose the trade secret, except pursuant to court order. Nothing in this Agreement is intended to conflict with 18 U.S.C. § 1833(b) or create liability for disclosures of trade secrets that are expressly allowed by such section.

23. ***Section Headings***. The article, section and paragraph headings contained in this Agreement are for reference purposes only and shall not affect in any way the meaning or interpretation of this Agreement.

24. ***No Third Party Beneficiary***. The Related Entities are intended third party beneficiaries of this Agreement. Otherwise, nothing expressed or implied in this Agreement is intended, or shall be construed, to confer upon or give any person other than the Company, the parties hereto and their respective heirs, personal representatives, legal representatives, successors and permitted assigns, any rights or remedies under or by reason of this Agreement.

25. ***Counterparts***. This Agreement may be executed in one or more counterparts, each of which shall be deemed to be an original but all of which together shall constitute one and the same instrument and agreement.

[Signatures on Following Page]

IN WITNESS WHEREOF, the undersigned have executed this Agreement on the date first above written.

COMPANY:

LEAP THERAPEUTICS, INC.

By: /s/ Douglas E. Onsi
Name: Douglas E. Onsi
Title: Chief Executive Officer

EXECUTIVE:

/s/ John Mark O'Mahony
Name: John Mark O'Mahony

General Release of Claims

1. [_________] ("***Executive***"), for himself and his family, heirs, executors, administrators, legal representatives and their respective successors and assigns, in exchange for the consideration (other than the Accrued Obligations) received pursuant to Article 6 of the Employment Agreement (the "***Severance Benefits***") to which this release is attached as Exhibit A (the "***Employment Agreement***"), does hereby release and forever discharge Leap Therapeutics, Inc. (the "***Company***"), its subsidiaries, affiliated companies, successors and assigns, and its current or former directors, officers, employees, stockholders or agents in such capacities (collectively with the Company, the "***Released Parties***") from any and all actions, causes of action, suits, controversies, claims and demands whatsoever, whether known or unknown, from the beginning of time through the date upon which Executive signs this General Release of Claims, including, without limitation, claims under any applicable laws, in each case in connection with Executive's employment or termination thereof, whether for tort, breach of express or implied employment contract, wrongful discharge, intentional infliction of emotional distress, or defamation or injuries incurred on the job or incurred as a result of loss of employment. Without limiting the generality of the release provided above, Executive expressly waives any and all claims under Age Discrimination in Employment Act ("***ADEA***") that he may have as of the date hereof. Executive further understands that, by signing this General Release of Claims, he is in fact waiving, releasing and forever giving up any claim under the ADEA as well as all other laws within the scope of this paragraph 1 that may have existed on or prior to the date hereof, including, but not limited to, [*additional citations to be added prior to execution at the time of separation*]. Notwithstanding anything in this paragraph 1 to the contrary, this General Release of Claims shall not apply to (i) any rights to receive any payments or benefits to which the Executive is entitled under the Employment Agreement or COBRA, (ii) any rights or claims that may arise as a result of events occurring after the date this General Release of Claims is executed, (iii) any indemnification and advancement rights Executive may have as a former employee, officer or director of the Company or its subsidiaries or affiliated companies (including any rights under any directors' and officers' indemnification agreement or under the Company's charter or bylaws), (iv) any claims for benefits under any directors' and officers' liability policy maintained by the Company or its subsidiaries or affiliated companies in accordance with the terms of such policy, (v) rights to vested benefits under the Company's 401(k) plan or other employee benefits plans, (vi) any rights as a holder of equity securities or debt securities/notes of the Company and (vii) any rights that Executive may have under any contracts or agreements with the Company or any of its subsidiaries or affiliated companies (other than the Employment Agreement) to the extent that such rights do not pertain to compensation or remuneration in connection with Executive's employment with the Company or any of its subsidiaries or affiliated companies or the termination of such employment.

2. Executive represents that he has not filed against the Released Parties any complaints, charges, or lawsuits arising out of his employment, or any other matter arising on or prior to the date of this General Release of Claims, and covenants and agrees that he will never individually or with any person file, or commence the filing of any lawsuits, complaints or proceedings with any governmental agency, or against the Released Parties with respect to any of the matters released by Executive pursuant to paragraph 1 hereof; provided, that nothing herein shall prevent Executive from filing a charge or complaint with the Equal Employment Opportunity Commission ("***EEOC***") or similar federal or state agency or Executive's ability to participate in any investigation or proceeding conducted by such agency. Executive does agree, however, that he is waiving his right to recover any money in connection with such an investigation or charge filed by him or by any other individual, or a charge filed by the Equal Employment Opportunity Commission or any other federal, state or local agency.

3. Executive acknowledges that, in the absence of his execution of this General Release of Claims, the Severance Benefits would not otherwise be due to him.

4. Executive acknowledges and agrees that he received adequate consideration in exchange for agreeing to the covenants contained in the Confidentiality Agreement and incorporated into the Employment Agreement by virtue of Section 7 of the Employment Agreement, that such covenants remain reasonable and necessary to protect the legitimate business interests of the Company and its affiliates and that he will continue to comply with those covenants.

5. Executive hereby acknowledges that the Company has informed him that he has up to twenty-one (21) days to sign this General Release of Claims and he may knowingly and voluntarily waive that twenty-one (21)-day period by signing this General Release of Claims earlier. Executive is advised to consult with an attorney before signing this General Release of Claims. Executive also understands that he shall have seven (7) days following the date on which he signs this General Release of Claims within which to revoke it by providing a written notice of his revocation to the Company in the manner described in Section 14 of the Employment Agreement.

6. Executive expressly acknowledges and agrees that Executive will not make any statements that are professionally or personally disparaging about, or adverse to, the Company or its business (including its officers, directors, employees and consultants) including, but not limited to, any statements that disparage any person, product, service, finances, financial condition, capability or any other aspect of the business of the Company, and that Executive shall not engage in any conduct which could reasonably be expected to harm professionally or personally the reputation of the Company (including its officers, directors, employees and consultants). Notwithstanding the foregoing, Executive shall not be (i) required to make any statement Executive believes to be false or inaccurate or (ii) restricted in connection with any litigation, arbitration or similar proceeding or with respect to Executive’s response to any legal process.

7. Executive acknowledges and agrees that this General Release of Claims will be governed by and construed and enforced in accordance with the internal laws of the Commonwealth of Massachusetts applicable to contracts made and to be performed entirely within such state.

8. Executive acknowledges that he has read this General Release of Claims, that he has been advised that he should consult with an attorney before he executes this general release of claims, and that he understands all of its terms and executes it voluntarily and with full knowledge of its significance and the consequences thereof.

9. This General Release of Claims shall become irrevocable on the eighth day following Executive's execution of this General Release of Claims, unless previously revoked in accordance with paragraph 5, above.

Intending to be legally bound hereby, Executive has executed this General Release of Claims on ___________ ____, ______.

EXECUTIVE:

____

Name:

Exhibit 21.1

SUBSIDIARIES OF
LEAP THERAPEUTICS, INC.

Subsidiary	Jurisdiction of Incorporation/Organization
GITR, Inc.	Delaware
HealthCare Pharmaceuticals Pty Ltd	Australia

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements of Leap Therapeutics, Inc. on Form S-3 (No. 333-221968 and 333-223419) and Form S-8 (No. 333-215787, 333-223707 and 333-232066) of our report dated March 12, 2021, on our audits of the consolidated financial statements as of December 31, 2020 and 2019 and for each of the years then ended, which report is included in this Annual Report on Form 10-K to be filed on or about March 12, 2021.

/s/ EisnerAmper LLP

EISNERAMPER LLP
Philadelphia, Pennsylvania
March 12, 2021

Exhibit 31.1

**CERTIFICATION PURSUANT TO
SECURITIES EXCHANGE ACT RULES 13a-14(a) AND 15d-14(a)**

I, Douglas E. Onsi, certify that:

1. I have reviewed this Annual Report on Form 10-K of Leap Therapeutics, 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. I am 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 my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to me 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 my 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 my 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. I have disclosed, based on my 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 12, 2021	/s/ DOUGLAS E. ONSI
	Douglas E. Onsi
	President, Chief Executive Officer, Chief Financial Officer and Director
	(Principal Executive and Financial Officer)

Exhibit 32.1

CERTIFICATIONS PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Leap Therapeutics, Inc. (the "Corporation") on Form 10-K for the fiscal year ended December 31, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Douglas E. Onsi, as Chief Executive Officer, President and Chief Financial Officer of the Corporation, 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 Corporation.

Date: March 12, 2021	By:	/s/ DOUGLAS E. ONSI
		Douglas E. Onsi *President, Chief Executive Officer, Chief Financial Officer and Director*
		(Principal Executive and Financial Officer)

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.