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

FORM 8-K

(Amendment No. 1)

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): September 14, 2022

LISATA THERAPEUTICS, INC.

(Exact Name of Registrant as Specified in Charter)

Delaware	001-33650	22-2343568
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

110 Allen Road, Second Floor, Basking Ridge, NJ 07920
(Address of Principal Executive Offices)(Zip Code)

(908) 842-0100
Registrant's Telephone Number

Caladrius Biosciences, Inc.
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	LSTA	The Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).
☐ 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.

Explanatory Note

On September 15, 2022, Lisata Therapeutics, Inc. (the "**Company**") filed a Current Report on Form 8-K (the "**Initial Form 8-K**") to report the completion of the merger of CS Cedar Merger Sub, Inc., a Delaware corporation and a wholly owned subsidiary of the Company ("**Merger Sub**") with and into Cend Therapeutics, Inc. ("**Cend**"), with Cend continuing as a wholly owned subsidiary of the Company and the surviving corporation of the merger (the "**Merger**"). The Company is filing this Amendment No. 1 on Form 8-K/A to the Initial Form 8-K to provide certain historical financial information of Cend and unaudited pro forma condensed combined financial information of the Company after giving pro forma effect to the Merger as required by Items 9.01(a) and 9.01(b) of Form 8-K. No other changes have been made to the Initial Form 8-K.

Item 8.01 Other Events

For the general information of investors, the Company is filing herewith information that was previously disclosed as part of the prospectus contained in the Form S-4 registration statement, as amended (File No. 333-265638), relating to the Merger, as declared effective by the SEC on July 28, 2022 (the "**Registration Statement**"). Specifically, filed herewith as Exhibits 99.1 and 99.2, respectively, are lightly edited excerpts of the "Cend Business" and "Risk Factors" sections thereof, which are incorporated by reference herein. Such information is as of the date hereof (unless an earlier date is indicated).

Item 9.01. Financial Statements and Exhibits.

(a) Financial Statements

The audited financial statements of Cend as of December 31, 2021 and 2020 and for the years then ended required by Item 9.01(a) were previously filed with the SEC as part of the Registration Statement and are incorporated herein by reference.

The unaudited condensed interim financial statements of Cend as of June 30, 2022 and for the six months ended June 30, 2022 and 2021 are attached as Exhibit 99.3 and are incorporated herein by reference.

(b) Pro Forma Financial Information

The unaudited pro forma condensed combined financial information of the Company as of June 30, 2022 and for the six months ended June 30, 2022 are attached as Exhibit 99.4 and are incorporated herein by reference

(d) Exhibits.

Exhibit Number	Exhibit Description
99.1	"Cend Business" section excerpt from Registration Statement
99.2	"Risk Factors" section excerpt from Registration Statement
99.3	Unaudited condensed interim financial statements of Cend as of June 30, 2022 and for the six months ended June 30, 2022 and 2021
99.4	Unaudited pro forma condensed combined financial information of the Company as of June 30, 2022 and for the six months ended June 30, 2022

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

LISATA THERAPEUTICS, INC.

By: /s/ David J. Mazzo, PhD
Name: David J. Mazzo, PhD
Title: Chief Executive Officer

Dated: October 4, 2022

Exhibit 99.1

CEND BUSINESS

Overview

Cend Therapeutics, Inc. (formerly DrugCendR, Inc.) is a Delaware corporation, formed in October 2015 ("Cend" or "the Company") and based in San Diego, California. Cend is focused on a tumor microenvironment ("TME")-modifying approach to enable more effective treatment for a range of solid tumor cancers. Cend is advancing a pipeline of product and partnering opportunities based on the CendR Platform™ to potentially improve outcomes for patients with a range of solid tumor cancers that are currently poorly treated, representing high unmet medical needs.

Cend Approach

Many solid tumor cancers, including pancreatic ductal adenocarcinoma ("PDAC"), gastric cancers and many other solid tumor cancers are surrounded by dense fibrotic tissue, or stroma. This limits the efficacy of current chemotherapies for these cancers. Emerging immunotherapy treatments, including checkpoint inhibitors, adoptive cell therapies such as chimeric antigen receptor T ("CAR-T") cells, as well as nucleic acid-based therapies, such as short interfering RNA ("siRNA"), antisense, and messenger RNAs ("mRNAs") face particular challenges in penetrating solid tumors. Many tumors also exhibit an immunosuppressive tumor immuno-microenvironment, which suppresses patients' immune systems' ability to fight their cancer and can limit effectiveness of immunotherapies. These factors negatively impact the ability of many therapeutic agents, including immunotherapies, to effectively treat these cancers.

To address the tumor stroma's role as a primary impediment to effective treatment, Cend's approach activates a natural transport system that normally brings nutrients into a tissue under emergency situations such as an injury. Cancers highjack this system to promote their own growth. Cend's lead investigational drug, CEND-1 (an internalizing R-G-D or iRGD peptide) activates this transport system in a tumor-specific manner (Sugahara, *Science*, 2010). This results in tumors taking up systemically administered anticancer drugs as if they were nutrients. As a result, more drug accumulates in the tumor than would accumulate without CEND-1, while normal tissues are not affected. Moreover, the drugs penetrate tumor cells further away from blood vessels with CEND-1 than without. The overall result is enhanced anticancer activity without an increase in side effects. Anticancer drugs can be coupled or conjugated to CEND-1 or other CendR peptides in Cend's portfolio, but can be also simply given together with CEND-1. Cend believes that the co-administration option is an advantage because it is not necessary to create a new chemical entity with its attendant regulatory hurdles, providing a potentially faster-to-clinic and potentially faster-to-market product opportunity for a range of solid tumor cancers and for co-administration with a range of therapies.

Clinical progress with other approaches to address delivery to highly fibrotic tumors, such as PEGylated hyaluronidase and hedgehog inhibitors, has been limited by toxicity and side effects. CEND-1 has demonstrated favorable safety/tolerability and activity in clinical trials to enhance delivery of standard-of-care chemotherapy for PDAC. Cend and its collaborators have also amassed non-clinical data demonstrating enhanced delivery of a range of emerging anticancer therapies, including immunotherapies, and RNA-based therapeutics. CEND-1's cancer-targeted delivery may enable such emerging treatment modalities to potentially more effectively treat a range of solid tumor cancers.

Patients in Cend's PDAC Phase 1b clinical trial received CEND-1 plus standard gemcitabine/nab-paclitaxel (Abraxane) therapy. CEND-1 was well tolerated and the combination generated a promising response rate as well as encouraging progression-free and overall survival results. Preliminary clinical results were presented at the European Society for Molecular Oncology meeting in 2020 and provided clinical validation of safety/tolerability and clinical utility. Full results from that study have been accepted for publication in a major medical journal in the third quarter of 2022. Cend and its collaborators have initiated a randomized Phase 2 trial in first-line ("1L"), metastatic PDAC ("mPDAC") with CEND-1/gemcitabine/nab-paclitaxel versus placebo/gemcitabine/nab-paclitaxel. Enrollment has begun and the first patients have initiated treatment in the Phase 2b trial.

Over 20 scientific papers from laboratories all over the world provide non-clinical validation for Cend's technology and suggest that CEND-1 can enhance antitumor activity of a variety of therapeutics in a variety of solid tumor types. The drugs that have been targeted to tumors in preclinical tumor models include siRNA, antisense, microRNAs, immunostimulatory oligonucleotides, chemotherapeutics, kinase inhibitors, antibodies, nanoparticle drugs, cytokines and even adoptive cell immunotherapies, indicating the potential broad applicability of CEND's technology. Cend believes that the CendR Platform™ holds potential to improve the efficacy of a broad range of cancer therapies.

RNA-based therapies, including antisense, siRNA, microRNA and mRNA have faced particular delivery issues for solid tumor cancer applications. These drugs also encounter issues in non-specific binding to serum proteins as well as degradation by nucleases. Once taken up by cells, they may also become sequestered in endosomes that, in some cases, may keep them from reaching their targeted intracellular compartments in adequate concentrations. Cend's Tumor-Penetrating Nanocomplex, or TPN technology platform utilized the same tumor-targeted tissue penetrating capabilities that CEND-1 has demonstrated in the clinic to enable effective delivery of nucleic acid-based drugs into solid tumors. In TPNs, these targeting moieties are combined with other elements to form nanocomplexes that self-assemble with RNA-based drugs to encapsulate them to protect from undesired serum protein binding and/or degradation. The TPN platform includes endosome-release moieties that can be employed for applications where release from such endosomes will enhance activity in other cellular compartments. TPN technology has been shown to enhance tumor-targeted delivery of constructs such as siRNA to the G12D mutant of K-Ras, which drives approximately 90% of PDAC, as well as other RNA-based drugs targeted to high interest anticancer tumor targets. With alternative CendR targeting moieties, it has also been used by Cend and its collaborators to deliver RNA-based drugs to immunomodulatory genes selectively targeting certain immune cells.

In 2021, Cend entered a license and collaboration agreement with a major pharmaceutical company in China, Qilu Pharmaceutical Co., Ltd., in which Qilu gained rights to CEND-1 for development and commercialization in Greater China. Under terms of the agreement, Cend received $10 million in up-front license fees and is eligible to receive development and commercial milestone payments up to $100 million and $125 million, respectively, tiered royalties on net sales in the Qilu territory ranging from 10% to 15%, and tiered sublicensing revenues ranging from 12% to 35%. The parties also have an active collaboration in which Qilu provides funding for development and regulatory activities within China.

Product	Indication	Status	Rights
CEND-1/gemcitabine/nab-paclitaxel	Pancreatic cancer (1L mPDAC)	Phase 2b	Cend / Qilu (China)
CEND-1/FOLFIRINOX	Pancreatic cancer (Locally advanced/potentially resectable PDAC)	Phase 1b/2	Cend / Qilu (China)
CEND-1/FOLFIRINOX/ panitumumab (non-Ras mutated pts)	Colorectal and appendiceal cancers	Phase 1b/2	Cend / Qilu (China)
CEND1/gemcitabine/nab-paclitaxel +/- atezolizumab (in collaboration with Roche/Genentech)	Pancreatic cancer (1L mPDAC)	Phase 1b/2 expected to commence in first quarter of 2023	Cend / Qilu (China)
CEND-1/SoC	Solid tumor basket study	Phase 1b/2 expected to commence in first half of 2023	Cend / Qilu (China)
TPN	Solid tumor cancer(s)	Preclinical	Cend

To fully exploit the CendR Platform™, Cend anticipates that it will enter into additional partnerships that may include significant upfront licensing fee, milestone and royalty revenues as well as research and development funding for Cend. In some circumstances, Cend may elect to enter joint venture or other strategic relationships with partners who possess complementary assets or capabilities. This approach enables Cend stakeholders to participate in broad application of Cend's technology in a capital-efficient business model.

About CEND-1

CEND-1 is an investigational drug that modifies the TME. It is targeted to tumor vasculature by its affinity for *alpha*-v integrins that are selectively expressed in tumor, but not healthy tissue vasculature. CEND-1 is a cyclic internalizing RGD ("iRGD") peptide that, once bound to these integrins, is cleaved by proteases expressed in tumors to release a peptide fragment, called a CendR fragment, which binds to a second receptor, called neuropilin-1, to activate a novel uptake pathway that allows anticancer drugs to more selectively penetrate solid tumors. The ability of CEND-1and iRGD peptides to modify the TME to enhance delivery and efficacy of co-administered drugs has been demonstrated in models of a range of solid tumors. Results from Cend, collaborators and research groups around the world have been the subject of over 200 scientific publications.

Clinical development

CEND-1 Phase 1b Data

Cend conducted its Phase 1b clinical trial on 29 evaluable first-line metastatic pancreatic ductal adenocarcinoma patients. The safety profile of CEND-1 combination regimen was similar to standard of care ("SoC") alone. CEND-1 was shown to be well-tolerated with no-dose limiting toxicities. Favorable pharmacokinetic profile with median circulating half-life of ~2 hours. An Objective Response Rate ("ORR") of fifty nine percent was observed, including a rare complete response, which compares favorably to the twenty three percent ORR observed in the "MPACT" clinical trial that served as the basis for approval of nab-paclitaxel for use in combination with gemcitabine for the treatment of first line, metastatic pancreatic ductal adenocarcinoma. The Disease Control Rate (partial and complete responses plus stable disease) of over seventy nine percent was observed, which compares favorably to forty eight percent observed in the MPACT trial. Reduction in the level of circulating tumor biomarker CA19-1 was observed in ninety six percent of patients versus sixty one percent in the MPACT trial. Median progression-free survival of nearly ten months was observed and compares favorably to less than six months in the MPACT trial. Median overall survival of over thirteen months was observed and compares favorably to less than nine months in the MPACT trial.

Sales and Marketing

Target Market and Customers.

Cend's initial target market for its drug delivery technology is expected to be the pancreatic cancer market, initially the enhancement of gemcitabine and nab-paclitaxel combination chemotherapy with potential to expand for combination with other chemotherapy regimens as well as targeted therapies and immunotherapies. In terms of patient population, the potential market for CEND-1 includes 62,210 new pancreatic cancer patients per year in the U.S., as reported by the American Cancer Society, and 496,000 new cases per year and 466,000 deaths per year due to pancreatic cancer worldwide, as reported by the International Agency for Research on Cancer.

Production and Marketing Plan.

CEND-1 is manufactured via relationships with CDMO partners, who Cend believes possess sufficient scale and experience to cost-effectively address projected commercial demand.

Cend plans to commercialize via standard distribution relationships by itself or via partnerships to bring its products to cancer patients around the world.

Research and Development

Cend believes that there are many opportunities to leverage its expertise to develop new treatments for significant unmet medical needs. Cend will also continue to seek research and development synergies across all its programs and indications. Cend's research and development accrued expenses were $65 thousand and $174 thousand in the years ended December 31, 2020 and 2021, respectively. Cend's research and development expenses were $1.3 million and $3.2 million in the three months ended March 31, 2022 and 2021, respectively.

Competition

The commercialization of new drugs is competitive, and Cend may face worldwide competition from major pharmaceutical companies, specialty pharmaceutical companies, biotechnology companies and ultimately generic companies. Cend's competitors may develop or market therapies that are more effective, safer or less costly than any that Cend is commercializing, or may obtain regulatory or reimbursement approval for their therapies more rapidly than Cend may obtain approval for those of Cend's.

Strategies that specifically aim at dealing with the stromal barrier in tumors by reducing the synthesis (inhibition of Notch signaling; (e.g. Olive et al., 2009; Provenzano et al., 2012)) and by increasing the degradation of the stroma (hyaluronidase treatment; Halozyme PEGPH20) would most directly compete with CEND-1, but have failed in the clinic. Cend's technology is based on a different principle: CEND-1 targets its effects to tumor via affinity for integrins that are selectively expressed on tumor vasculature and initiates an active transport pathway that converts the stromal barrier into a drug conduit without destroying the surrounding tissue. It can also be used without the need to couple the drug to the targeting agent. Although effective in mouse cancer models, Notch inhibitors appear to have failed in human trials. Cend believes that these matrix remodeling methods lack the targeting aspect provided by CEND-1.

Tumor-targeted variations of cell-penetrating peptides, such as TAT, are a potential competing technology that does involve tumor targeting[2]. However, as the cell-penetrating peptide lacks tumor specificity, Cend believes that these compounds are likely to be less specific for tumors than iRGD/CEND-1. Also, their cell internalization pathway is different from the CendR pathway used by iRGD[3], and they have not been shown to possess the ability of the tumor-penetrating peptides to promote drug penetration without covalent coupling.

Intellectual Property

As of December 31, 2021, Cend had eight issued U.S. patents, seven U.S. patent applications pending, no U.S. trademark registrations and one trademark applications pending in the United States and other countries. Cend also licenses certain technologies from third parties on an exclusive basis in order to make, use and/or sell certain products in the United States and some foreign jurisdictions. Cend's material issued U.S. patents generally expire between 2029 and 2030.

Cend's success will significantly depend upon its ability to obtain and maintain patent and other intellectual property and proprietary protection for Cend's drug candidates in the U.S. and internationally. In addition to trademarks and patents, Cend relies upon unpatented trade secrets, know-how, and continuing technological innovation to develop and maintain Cend's competitive position. Cend protects its proprietary information, in part, using confidentiality agreements with its commercial partners, collaborators, employees and consultants and invention assignment agreements with its employees. Cend also has confidentiality agreements or invention assignment agreements with its commercial partners and selected consultants. Despite these measures, any of Cend's intellectual property and proprietary rights could be challenged, invalidated, circumvented, infringed or misappropriated, or such intellectual property and proprietary rights may not be sufficient to permit Cend to take advantage of current market trends or otherwise to provide competitive advantages. In addition, such confidentiality agreements and invention assignment agreements can be breached and Cend may not have adequate remedies for any such breach.

License Agreements

SBP Exclusive License Agreement. On December 1, 2015, Cend (then DrugCendR LLC) entered into an Exclusive License Agreement (the "SBP License Agreement") with the Sanford Burnham Prebys Medical Discovery Institute ("SBP"), a California not-for-profit, public benefit corporation based in San Diego, California. Pursuant to the SBP License Agreement, SBP licensed to Cend the exclusive right to use certain patents to further Cend's research and development efforts. As partial consideration, Cend paid a license fee, and is obligated to pay SBP a royalty on sub-license revenues as well as royalty on net sales of identified products as well as development-based milestone payments (as defined therein).

Qilu Exclusive License Agreement. On February 11, 2021 ("Effective Date"), Cend and Qilu entered into an Exclusive License and Collaboration Agreement ("Qilu Agreement") wherein Cend agreed to license to Qilu, certain patents and other rights relating to CEND-1 exclusively in the territory of the Greater Area of China (including China, Macau, Hong Kong and Taiwan, each a Region (collectively, the "Territory")). Under the terms of the agreement, Cend received $10 million in up-front license fees and is eligible to receive developmental and commercial milestone payments up to $100 million and $125 million, respectively, tiered royalties on net sales in the Qilu territory ranging from 10% to 15%, and tiered sublicensing revenues ranging from 12% to 35%.

2 Myrdal et al., 2008; Savariar et al., 2013; Liu et al., 2014

3 Pang et al., 2014; 2015

UC Exclusive Patent License Agreement. On March 9, 2021, Cend entered into an Exclusive License Agreement (the "UC License Agreement") with the Regents of the University of California ("UC"). Pursuant to the UC License Agreement, UC licensed to Cend the exclusive right to use certain patents to further Cend's research and development efforts. As partial consideration, Cend paid a license fee, and is obligated to pay UC a royalty on sub-license revenues as well as royalty on net sales of products as well as development-based milestone payments (as defined therein).

MIT Exclusive Patent License Agreement. On October 4, 2021, Cend entered into an Exclusive License Agreement (the "MIT License Agreement") with the Massachusetts Institute of Technology ("MIT"). Pursuant to the MIT License Agreement, MIT licensed to Cend the exclusive right to use certain patents to further Cend's research and development efforts. As partial consideration, Cend paid a license fee, and is obligated to pay MIT a royalty on sub-license revenues as well as royalty on net sales of products as well as development-based milestone payments (as defined therein).

SBP Exclusive Patent License Agreement 2. On October 19, 2021, Cend entered into an Exclusive License Agreement (the SBP License Agreement 2) with the Sanford Burnham Prebys Medical Discovery Institute ("SBP"), a California not-for-profit, public benefit corporation based in San Diego, California. Pursuant to the SBP License Agreement 2, SBP licensed to Cend the exclusive right to use certain patents to further Cend's research and development efforts. As partial consideration, Cend paid a license fee, and is obligated to pay UC a royalty on sub-license revenues as well as royalty on net sales of products as well as development-based milestone payments (as defined therein).

Manufacturing

Cend relies on CDMOs to produce its drug candidates in accordance with cGMP, regulations for use in Cend's preclinical and clinical trials. The manufacture of pharmaceuticals is subject to extensive cGMP regulations, which impose various procedural and documentation requirements and govern all areas of record keeping, production processes and controls, personnel and quality control.

To meet Cend's projected needs for clinical supplies to support its activities through regulatory approval and commercial manufacturing, the CDMOs with whom Cend currently works currently possess the scale of production to support development and commercialization of CEND-1. Cend believes that there are multiple potential sources for its contract manufacturing. Cend retains the option to engage alternate suppliers in the event that its current CDMOs fail to scale production or are not cost competitive. Cend's relationships with CDMOs are managed by personnel with extensive experience in pharmaceutical development and manufacturing.

If Cend is unable to obtain sufficient quantities of drug candidates or receive raw materials in a timely manner, Cend could be required to delay its ongoing clinical trials and seek alternative manufacturers, which would be costly and time-consuming.

Government Regulation and Approval

United States-FDA process

In the United States, the FDA regulates drugs. The FD&C Act and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of drugs. To obtain regulatory approvals in the United States and in foreign countries, and subsequently comply with applicable statutes and regulations, Cend will need to spend substantial time and financial resources.

Approval process

The FDA must approve any new drug or a drug with certain changes to a previously approved drug before a manufacturer can market it in the United States. If a company does not comply with applicable United States requirements it may be subject to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending applications, warning or untitled letters, clinical holds, drug recalls, drug seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, and criminal prosecution.

The steps Cend must complete before it can market a drug include:

- completion of preclinical laboratory tests, animal studies, and formulation studies, all performed in accordance with the FDA's good laboratory practice, or Good Laboratory Practice ("GLP"), regulations;

- submission to the FDA of an Investigational New Drug ("IND") application for human clinical testing, which must become effective before human clinical studies start. The sponsor must update the IND annually;

- approval of the study by an independent IRB or ethics committee representing each clinical site before each clinical study begins;

- performance of adequate and well-controlled human clinical studies to establish the safety and efficacy of the drug for each indication to the FDA's satisfaction;
- submission to the FDA of a New Drug Application (“NDA”);
- potential review of the drug application by an FDA advisory committee, where appropriate and if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities to assess compliance with cGMP or regulations; and
- FDA review and approval of the NDA.

It generally takes companies many years to satisfy the FDA approval requirements, but this varies substantially based upon the type, complexity, and novelty of the drug or disease. Preclinical tests include laboratory evaluation of a drug's chemistry, formulation, and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the drug. The conduct of the preclinical tests must comply with federal regulations and requirements, including GLP. The company submits the results of the preclinical testing to the FDA as part of an IND along with other information, including information about the product drug's chemistry, manufacturing and controls, and a proposed clinical study protocol. Long term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after submitting the initial IND.

The FDA requires a 30-day waiting period after the submission of each IND before the company can begin clinical testing in humans. The FDA may, within the 30-day time period, raise concerns or questions relating to one or more proposed clinical studies and place the study on a clinical hold. In such a case, the company and the FDA must resolve any outstanding concerns before the company begins the clinical study. Accordingly, the submission of an IND may or may not be sufficient for the FDA to permit the sponsor to start a clinical study. The company must also make a separate submission to an existing IND for each successive clinical study conducted during drug development.

Clinical studies

Clinical studies involve administering the investigational new drug to healthy volunteers or patients under the supervision of a qualified investigator. The company must conduct clinical studies:

- in compliance with federal regulations;
- in compliance with good clinical practice, or GCP, an international standard meant to protect the rights and health of patients and to define the roles of clinical study sponsors, administrators, and monitors; as well as
- under protocols detailing the objectives of the trial, the safety monitoring parameters, and the effectiveness criteria.

The sponsoring company must submit each protocol involving testing on United States patients and subsequent protocol amendments to the FDA as part of the IND. The FDA may order the temporary, or permanent, discontinuation of a clinical study at any time, or impose other sanctions, if it believes that the sponsor is not conducting the clinical study in accordance with FDA requirements or presents an unacceptable risk to the clinical study patients. The sponsor must also submit the study protocol and informed consent information for patients in clinical studies to an institutional review board for approval. An IRB may halt the clinical study, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions.

Companies generally divide the clinical investigation of a drug into three or four phases. While companies usually conduct these phases sequentially, they are sometimes overlapped or combined.

- *Phase 1.* The company evaluates the drug in healthy human subjects or patients with the target disease or condition. These studies typically evaluate the safety, dosage tolerance, metabolism and pharmacologic actions of the investigational new drug in humans, the side effects associated with increasing doses, and if possible, gain early evidence on effectiveness.
- *Phase 2.* The company administers the drug to a limited patient population to evaluate dosage tolerance and optimal dosage, identify possible adverse side effects and safety risks, and preliminarily evaluate efficacy.

- *Phase 3.* The company administers the drug to an expanded patient population, generally at geographically dispersed clinical study sites, to generate enough data to statistically evaluate dosage, clinical effectiveness and safety, to establish the overall benefit-risk relationship of the investigational drug, and to provide an adequate basis for product approval.

- *Phase 4.* In some cases, the FDA may condition approval of an NDA for a drug on the company's agreement to conduct additional clinical studies after approval. In other cases, a sponsor may voluntarily conduct additional clinical studies after approval to gain more information about the drug. Cend typically refers to such post-approval studies as Phase 4 clinical studies.

A pivotal study is a clinical study that adequately meets regulatory agency requirements to evaluate a drug's efficacy and safety to justify the approval of the drug. Generally, pivotal studies are Phase 3 studies, but the FDA may accept results from Phase 2 studies if the study design provides a well-controlled and reliable assessment of clinical benefit, particularly in situations in which there is an unmet medical need and the results are sufficiently robust.

The FDA, the IRB, or the clinical study sponsor may suspend or terminate a clinical study at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Additionally, an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board or committee, may oversee some clinical studies. This group provides authorization for whether or not a study may move forward at designated checkpoints based on access to certain data from the study. Cend may also suspend or terminate a clinical study based on evolving business objectives and the competitive climate.

CEND-1 is currently in Phase 2b and that is expected to continue until 1H’2024. In parallel with that study, Cend and its partners are advancing additional clinical studies to explore additional solid tumor cancer applications and additional combination therapies including CEND-1. The Company and partners may also initiate registrational (Phase 3 or other) clinical trials to serve as a basis for filing for regulatory approvals in the U.S. and other geographies.

Submission of an NDA

After Cend completes the required clinical testing, Cend can prepare and submit an NDA to the FDA, who must approve the NDA before Cend can start marketing the drug in the United States. An NDA must include all relevant data available from pertinent preclinical and clinical studies, including negative or ambiguous results as well as positive findings, together with detailed information relating to the drug's chemistry, manufacturing, controls, and proposed labeling, among other things. Data can come from company-sponsored clinical studies on a drug, or from a number of alternative sources, including studies initiated by investigators. To support marketing authorization, the data Cend submit must be sufficient in quality and quantity to establish the safety and effectiveness of the investigational drug to the FDA's satisfaction.

The cost of preparing and submitting an NDA is substantial. The submission of most NDAs is additionally subject to a substantial application user fee, and the manufacturer and/or sponsor under an approved new drug application are also subject to annual program user fees. The FDA typically increases these fees annually. Orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical study costs, tax advantages, and user-fee waivers.

The FDA has 60 days from its receipt of an NDA to determine whether it will accept the application for filing based on the agency's threshold determination that the application is sufficiently complete to permit substantive review. Once the FDA accepts the filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of NDAs. Under the Prescription Drug User Fee Act, the FDA has a goal of responding to standard review NDAs within ten months after the 60-day filing review period, but this timeframe is often extended. The FDA reviews most applications for standard review drugs within ten to 12 months and most applications for priority review drugs within six to eight months. Priority review can be applied to drugs that the FDA determines offer major advances in treatment, or provide a treatment where no adequate therapy exists.

The FDA may also refer applications for novel drugs that present difficult questions of safety or efficacy, to an advisory committee. This is typically a panel that includes clinicians and other experts that will review, evaluate, and recommend whether the FDA should approve the application. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP, and will inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the drug unless compliance with cGMP is satisfactory and the NDA contains data that provide evidence that the drug is safe and effective in the indication studied.

The FDA's decision on an NDA

After the FDA evaluates the NDA and the manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter indicates that the FDA has completed its review of the application, and the agency has determined that it will not approve the application in its present form. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional clinical data and/or other significant, expensive, and time-consuming requirements related to clinical studies, preclinical studies and/or manufacturing. The FDA has committed to reviewing resubmissions of the NDA addressing such deficiencies in two or six months, depending on the type of information included. Even if Cend submits such data the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Also, the government may establish additional requirements, including those resulting from new legislation, or the FDA's policies may change, which could delay or prevent regulatory approval of Cend's drugs under development.

An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of NDA approval, the FDA may require a REMS to help ensure that the benefits of the drug outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The requirement for REMS can materially affect the potential market and profitability of the drug. Moreover, the FDA may condition approval on substantial post-approval testing and surveillance to monitor the drug's safety or efficacy. Once granted, the FDA may withdraw drug approvals if the company fails to comply with regulatory standards or identifies problems following initial marketing.

Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement before Cend can implement the change. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing new NDAs. As with new NDAs, the FDA often significantly extends the review process with requests for additional information or clarification.

Post-approval requirements

The FDA regulates drugs that are manufactured or distributed pursuant to FDA approvals and has specific requirements pertaining to recordkeeping, periodic reporting, drug sampling and distribution, advertising and promotion and reporting of adverse experiences with the drug. After approval, the FDA must provide review and approval for most changes to the approved drug, such as adding new indications or other labeling claims. There also are continuing, annual user fee requirements for any marketed drugs and the establishments who manufacture its drugs, as well as new application fees for supplemental applications with clinical data.

In some cases, the FDA may condition approval of an NDA for a drug on the sponsor's agreement to conduct additional clinical studies after approval. In other cases, a sponsor may voluntarily conduct additional clinical studies after approval to gain more information about the drug. Such post-approval studies are typically referred to as Phase 4 clinical studies.

Drug manufacturers are subject to periodic unannounced inspections by the FDA and state agencies for compliance with cGMP requirements. There are strict regulations regarding changes to the manufacturing process, and, depending on the significance of the change, it may require prior FDA approval before Cend can implement it. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon Cend and any third-party manufacturers that Cend may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

The FDA may withdraw approval if a company does not comply with regulatory requirements and maintain standards or if problems occur after the drug reaches the market. If a company or the FDA discovers previously unknown problems with a drug, including adverse events of unanticipated severity or frequency, issues with manufacturing processes, or the company's failure to comply with regulatory requirements, the FDA may revise the approved labeling to add new safety information; impose post-marketing studies or other clinical studies to assess new safety risks; or impose distribution or other restrictions under a REMS program. Other potential consequences may include:

- restrictions on the marketing or manufacturing of the drug, complete withdrawal of the drug from the market or drug recalls;
- fines, warning letters or holds on post-approval clinical studies;
- the FDA refusing to approve pending NDAs or supplements to approved NDAs, or suspending or revoking of drug license approvals;
- drug seizure or detention, or refusal to permit the import or export of drugs; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising, and promotion of drugs that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Cend could be subject to significant liability if it violated these laws and regulations.

Orphan drug designation

CEND-1 has been granted both Orphan Drug and Fast Track Designations by the FDA for the treatment of pancreatic cancer. The Company plans to file for similar designations for additional indications and in additional geographies.

The FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition that affects fewer than 200,000 individuals in the United States, or if it affects more than 200,000 individuals in the United States, there is no reasonable expectation that the cost of developing and making the drug for this type of disease or condition will be recovered from sales in the United States.

Orphan drug 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 drug receives FDA approval for the indication for which it has orphan designation, the drug may be entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the drug with orphan exclusivity.

Pediatric information

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

Healthcare reform

In the United States and foreign jurisdictions, the legislative landscape continues to evolve. There have been a number of legislative and regulatory changes to the healthcare system that could affect its future results of operations. In particular, there have been and continue to be a number of initiatives at the United States federal and state levels that seek to reform the way in which healthcare is funded and reduce healthcare costs. In March 2010, the PPACA was enacted, which includes measures that have significantly changed health care financing by both governmental and private insurers. The provisions of PPACA of importance to the pharmaceutical and biotechnology industry are, among others, the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs agents, apportioned among these entities according to their market share in certain government healthcare programs;
- an increase in the rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price for branded and generic drugs, respectively;

- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% (and 70% starting January 1, 2019) point-of-sale discounts to negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;

- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations, unless the drug is subject to discounts under the 340B drug discount program;

- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the Federal Poverty Level, thereby potentially increasing manufacturers' Medicaid rebate liability;

- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;

- expansion of healthcare fraud and abuse laws, including the Federal False Claims Act and the federal Anti-Kickback Statue, new government investigative powers and enhanced penalties for noncompliance;

- new requirements under the federal Physician Payments Sunshine Act for drug manufacturers to report information related to payments and other transfers of value made to physicians and teaching hospitals as well as ownership or investment interests held by physicians and their immediate family members; and

- new requirement to annually report certain drug samples that manufacturers and distributors provide to licensed practitioners, or to pharmacies of hospitals or other healthcare entities.

In addition, other health reform measures have been proposed and adopted in the United States since PPACA was enacted. For example, as a result of the Budget Control Act of 2011, as amended, providers are subject to Medicare payment reductions of 2% per fiscal year through 2027 unless additional Congressional action is taken. Further, the American Taxpayer Relief Act of 2012 reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments from providers from three to five years.

Employees

As of March 31, 2022, Cend had three employees, all of whom were full-time employees.

Facilities

Cend’s corporate headquarters are located in San Diego, California. Cend plans to add facilities in the future as it continues to build its research, development, commercial, and support teams.

Legal Proceedings

From time to time, Cend may be involved in various claims and legal proceedings relating to claims arising out of its operations, in the normal course of business. Cend is currently a party to one pending legal proceeding.

On April 28, 2022, Lingmed, LTD, a limited liability corporation with its principal place of business in Shanghai, China (“Lingmed”), filed a complaint in the Superior Court of California, San Diego against Cend, Harri Järveläinen (Cend’s Chief Operating Officer) and various unnamed defendants alleging breach of contract, fraud and declaratory relief. Pursuant to a May 2020 contract between Lingmed and Cend (the “Lingmed Agreement”), between May 2020 and August 2020, Lingmed acted as Cend’s exclusive agent in China for the purpose of identifying potential partners and assisting in negotiating deals, including licensing arrangements and research collaborations for the development of CEND-1 in China. Lingmed alleges that it established the first contact between Cend and Qilu and that pursuant to the Lingmed Agreement, this should have triggered payments to Lingmed when Cend entered into the Qilu Agreement. Lingmed is seeking interest, costs, punitive damages and other relief the court deems proper. Cend management believes this suit is without merit and intends to vigorously defend against the action. Additionally, Cend has filed a cross-complaint seeking declaratory relief that it owes no further payments to Lingmed based on discussions Cend had with Qilu prior to entering into the Lingmed Agreement and thus Lingmed did not establish the first contact between the companies. Regardless of outcome, litigation can have an adverse impact on Cend because of defense and settlement costs, diversion of management resources and other factors.

Exhibit 99.2

Risks Related to Cend

Risks Related to Cend's Business

Cend has incurred net losses for all but one year since inception and anticipates that it will continue to incur losses for the foreseeable future and may never achieve or maintain profitability.

Cend is a development-stage drug discovery and development company with a limited operating history, and, with the exception of the year ended December 31, 2021 in which Cend did have net income as a result of a one-time license payment, Cend has not yet generated consistent revenues from the sales or licensing of its product candidates. Investment in drug discovery and development companies is highly speculative because it entails substantial upfront capital expenditures and significant risk that the product candidate(s) will fail to obtain regulatory approval or become commercially viable. Cend has not advanced product candidates to obtain marketing approvals, manufacture a commercial-scale product or conduct sales and marketing activities necessary for successful commercialization. Cend anticipates incurring significant expenses related to research and development, and other operations leading to partnering and commercialization of its product candidates.

Cend expects that it could be several years, if ever, before it has a commercialized product candidate. Cend expects to continue to incur significant expenses and increasing operating losses for the foreseeable future. The net losses it incurs may fluctuate significantly from quarter to quarter. Cend anticipates that its expenses will increase substantially if, and as, it:

- licenses foundational intellectual property, or IP, and continues development of CEND-1, including conducting additional clinical trials for pancreatic and other cancers;
- initiates preclinical studies for additional product candidates;
- continues its process research and development activities, as well as establishes its research-grade, clinical- and commercial-scale manufacturing capabilities (should it choose to do so directly);
- seeks collaboration agreements (geographic licensing agreements, or co-development and -commercialization agreements) involving CEND-1 and other product candidates;
- completes additional clinical trials for CEND-1, following acceptance by the FDA;
- identifies additional diseases for treatment with CEND-1 and other product candidates;
- seeks partnering agreements (sub-licensing or asset divestitures) for continued clinical development and/or commercialization and market support;
- maintains, expands and protects its intellectual property portfolio; and
- identifies, acquires or in-licenses other product candidates and/or enabling technologies.

To become and remain profitable, Cend must develop and eventually realize, either through its own efforts or those of its collaboration partners, commercialized product candidates with significant market potential, which will require it to be successful in a range of challenging activities.

These activities can include completing formulation and delivery approaches to meet target product profiles, completing preclinical studies, conducting early stage clinical trials, and securing partnering agreements to advance programs to late-stage clinical development and/or commercialization. Cend may never succeed in any or all of these activities and, even if it does, Cend may never generate revenues significant or large enough to achieve profitability. If it does achieve profitability, Cend may not be able to sustain or increase profitability. Cend's failure to become and remain profitable would decrease the value of Cend and could impair its ability to raise capital, maintain its research and development efforts, expand its business or continue its operations, any of which could cause you to lose all or part of your investment.

Cend may not be able to generate sufficient revenue from the commercialization of product candidates and may never be profitable.

Cend's ability to generate revenue and achieve profitability depends on its ability, alone or with its collaborative partners, to successfully complete the development of, and obtain the regulatory approvals necessary to commercialize, current and future product candidates. CEND-1 has advanced into Phase 2 clinical trials, but is still in a pre-commercial stage, and Cend does not anticipate generating revenues from commercial sales for the next several years, and it may never succeed in doing so. Cend's ability to generate future revenues from product sales or licensing revenues depends heavily on its and its collaborators' success in:

- completing clinical development of product candidates;
- Cend's partners may not complete clinical development or commercialization of product candidates, which could reduce Cend revenues from such partnerships;
- seeking and obtaining regulatory and marketing approvals for product candidates for which clinical trials are completed;
- launching and commercializing product candidates, including those for which Cend obtains regulatory and marketing approval, by collaborating with a commercialization partner(s);
- qualifying for adequate coverage, coding and payment, where applicable, by government and third-party payors for product candidates if and when approved;
- maintaining and enhancing a sustainable, scalable, reproducible and transferable manufacturing process for Cend's product candidates;
- establishing and maintaining supply and manufacturing relationships with third parties that can provide adequate, in both amount and quality, products and services to support development and commercial demand for product candidates, if approved;
- obtaining market acceptance of product candidates as a viable treatment option;
- addressing any competing technological and market developments;
- implementing additional internal systems and infrastructure, as needed;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which Cend may enter and performing its obligations in such collaborations;
- maintaining, protecting and expanding Cend's portfolio of intellectual property rights, including patents, trade secrets and know-how;
- avoiding and defending against third-party interference or infringement claims; and
- attracting and retaining qualified personnel.

Cend's expenses could increase beyond expectations if Cend is required by the FDA, or other regulatory authorities to perform preclinical studies and/or clinical trials in addition to those that it currently anticipates.

Even if Cend is able to generate revenues from the licensing or sale of product candidates, it may not become profitable and may need to obtain additional funding to continue operations.

Cend is involved in a litigation matter that may consume resources and management time, and an adverse resolution could require us to pay damages or otherwise adversely impact its business, financial condition or results of operations.

Cend is currently involved in one litigation matter alleging breach of contract and fraud against Cend and Harri Järveläinen, Cend's chief operating officer. Resolving this matter could require Cend to incur substantial costs and divert the attention of management and technical personnel. Any adverse ruling or perception of an adverse ruling could have an adverse impact on Cend's business, financial condition or results of operations. Cend could incur substantial costs and expenses which could negatively affect its gross margins and earnings per share.

Cend conducts significant operations through its Australian wholly-owned subsidiary. If it loses its ability to operate in Australia, or if that subsidiary is unable to receive the research and development tax credit allowed by Australian regulations, Cend's business and results of operations will suffer.

Cend develops its programs in part through its wholly-owned Australian subsidiary, DrugCendR Australia Pty Ltd. Due to the geographical distance and limited employees currently in Australia, as well as Cend's limited of experience operating in Australia, Cend may not be able to efficiently or successfully monitor, develop or commercialize its products or programs in Australia, including conducting clinical trials. Furthermore, Cend has no assurance that the results of any clinical trials that it conducts for its product candidates in Australia will be accepted by the FDA or foreign regulatory authorities for development and commercialization approvals. In addition, current Australian tax regulations provide for a refundable research and development tax credit equal to 43.5% of qualified expenditures. If Cend is ineligible or unable to receive the research and development tax credit, or past credits are determined ineligible upon audit, or if it loses its ability to operate DrugCendR Australia Pty Ltd. in Australia, or the Australian government significantly reduces or eliminates the tax credit, Cend's business and results of operation would be adversely affected. In the event Cend determined it advisable to stop operating through this subsidiary, Cend may be required to migrate such operations, employees and intellectual property from this subsidiary to Cend. Any such action may be difficult and cause Cend to incur additional expenses, as well as give rise to tax liabilities for Cend or erode Cend's tax attributes (such as tax credits or net operating losses).

Risks Related to Cend Intellectual Property

Cend's rights to develop and commercialize product candidates are subject to, in part, the terms and conditions of licenses granted to Cend by others.

On December 1, 2015, Cend Therapeutics, Inc. entered into an Exclusive License Agreement (the "SBP License Agreement") with the Sanford Burnham Prebys Medical Discovery Institute ("SBP"), a California not-for-profit, public benefit corporation based in San Diego, California. Pursuant to the SBP License Agreement, SBP licensed to Cend the exclusive right to use certain patents to further Cend's research and development efforts. Because Cend does not have the right to control the preparation, filing and prosecution of all of the patent applications, or to maintain the patents, covering CEND-1, Cend cannot be certain that these patents and applications will be prosecuted, maintained and enforced in a manner consistent with the best interests of its business. If Cend's licensors fail to maintain such patents, or lose rights to those patents or patent applications, the rights Cend has licensed may be reduced or eliminated and its right to develop and commercialize any products that are the subject of such licensed rights could be adversely affected. In addition to the foregoing, the risks associated with patent rights that Cend licenses from third parties will also apply to patent rights it may own in the future.

Further, in Cend's license agreements it may be held responsible for bringing actions against infringers. Certain of Cend's license agreements could also require it to meet development thresholds to maintain the license, including establishing a set timeline for developing and commercializing products and minimum yearly diligence obligations in developing and commercializing the product. Disputes may also arise regarding intellectual property subject to a licensing agreement.

If disputes over intellectual property that Cend has licensed prevent or impair Cend's ability to maintain its current licensing arrangements on acceptable terms, Cend may be unable to successfully develop and commercialize the affected product candidates.

If Cend fails to comply with its obligations under these license agreements, or Cend is subject to a bankruptcy, the licensor may have the right to terminate the license, in which event Cend would not be able to market products covered by the license.

If Cend is unable to obtain and maintain patent protection for its products and technology, or if the scope of the patent protection obtained is not sufficiently broad, Cend's competitors could develop and commercialize products and technology similar or identical to Cend's, and its ability to successfully partner and commercialize its products and technology may be adversely affected.

Cend's success depends on its ability to obtain and maintain patent protection in the United States and other countries with respect to proprietary product candidates and manufacturing technology. Cend's proposed licensors have sought and Cend intends to seek to protect proprietary position by filing patent applications in the United States and abroad related to the novel technologies and product candidates that are important to its business.

The patent prosecution process is expensive, time-consuming and complex, and Cend may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. For example, in some cases, the work of certain academic researchers in the field of oncology could enter the public domain, which may compromise Cend's ability to obtain patent protection for certain inventions related to or building upon such prior work. Consequently, Cend may not be able to obtain any such patent rights to prevent others from using its technology for, and developing and marketing competing products to treat, these indications. It is also possible that Cend will fail to identify patentable aspects of its research and development output before it is too late to obtain patent protection.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has, in recent years, been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of patent rights are highly uncertain. Any pending and future patent applications may not result in patents being issued which protect the related technology or product candidates or which effectively prevent others from commercializing competitive technologies and product candidates. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of patents or narrow the scope of patent protection.

Cend may not be aware of all third-party intellectual property rights potentially relating to its targeted product candidates. Publications of discoveries in the scientific literature often lag the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or, in some cases, not at all. Therefore, Cend cannot be certain that it was the first to make the inventions claimed in any owned or any licensed patents or pending patent applications, or that it was the first to file for patent protection of such inventions.

Even if the patent applications Cend licenses or may own in the future do issue as patents, they may not issue in a form that will provide Cend with any meaningful protection, prevent competitors or other third parties from competing with Cend or otherwise provide Cend with any competitive advantage. Cend's competitors or other third parties may be able to circumvent key patents by developing similar or alternative technologies or products in a non-infringing manner.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and key patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, which could limit Cend's ability to stop others from using or commercializing similar or identical technology and products; or limit the duration of the patent protection of its technology and product candidates. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, Cend's intellectual property may not provide Cend with sufficient rights to exclude others from commercializing products similar or identical to Cend's.

Further, in the event Cend breaches the terms of the SBP License Agreement, Cend could lose the ability to continue the development and potential commercialization of CEND-1, and Cend's operations and profitability will be significantly negatively impacted.

If Cend fails to comply with its obligations in any future agreements under which it may license intellectual property rights from third parties or otherwise experience disruptions to its business relationships with future licensors, Cend could lose license rights that are important to its business.

In the future, Cend may be party to license or collaboration agreements with third parties to advance its research or allow commercialization of product candidates. Such future agreements may impose numerous obligations, such as development, diligence, payment, commercialization, funding, milestone, royalty, sublicensing, insurance, patent prosecution, enforcement and other obligations on Cend and may require it to meet development timelines, or to exercise commercially reasonable efforts to develop and commercialize licensed products, in order to maintain the licenses. In spite of Cend's best efforts, future licensors might conclude that Cend has materially breached future license agreements and might therefore terminate the license agreements, thereby removing or limiting Cend's ability to develop and commercialize products and technologies covered by these license agreements.

Any termination of these licenses, or if the underlying patents fail to provide the intended exclusivity, could result in the loss of significant rights and could harm Cend's ability to commercialize its product candidates, and competitors or other third parties would have the freedom to seek regulatory approval of, and to market, products identical to Cend's and it may be required to cease its development and commercialization of certain of its product candidates. Any of the foregoing could have a material adverse effect on Cend's competitive position, business, financial conditions, results of operations, and prospects.

Disputes may also arise between Cend and its future licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;

- whether and the extent to which Cend's technology and processes infringe, misappropriate or otherwise violate intellectual property rights of the licensor that is not subject to the licensing agreement;

- Cend's right to sublicense patent and other rights to third parties under collaborative development relationships;

- Cend's diligence obligations with respect to the use of the licensed technology in relation to its development and commercialization of its product candidates, and what activities satisfy those diligence obligations;

- the priority of invention of any patented technology; and

- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by Cend's future licensors and Cend and its partners.

In addition, the agreements under which Cend may license intellectual property or technology from third parties in the future are likely to be complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what Cend believes to be the scope of its rights to the relevant intellectual property or technology, or increase what Cend believes to be its financial or other obligations under the relevant agreement, either of which could have a material adverse effect on Cend's business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that Cend may license in the future prevent or impair its ability to maintain future licensing arrangements on acceptable terms, Cend may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on Cend's business, financial conditions, results of operations and prospects.

Cend may not be successful in obtaining necessary additional rights to its product candidates through acquisitions and in-licenses.

Cend may discover that it needs to obtain additional rights to the foundational IP associated with the product candidates it plans to develop, manufacture and market. If this occurs, Cend intends to license or purchase the rights to those candidates, which may nor may not prove successful at all, or on acceptable terms. If Cend's programs require the use of proprietary rights held by third parties, such as academic institutions, the growth of Cend's business will critically depend on its ability to acquire, in-license or use these proprietary rights, which may not prove possible on acceptable terms. The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights that Cend may consider attractive. These established companies may have a competitive advantage over Cend due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive Cend to be a competitor may be unwilling to assign or license rights to us. If Cend is unable to license or acquire third-party intellectual property rights on terms that would allow it to execute its business plan, your investment may be lost.

Cend may collaborate with non-profit and academic institutions to accelerate its preclinical research or development under written agreements with these institutions. Typically, these institutions would provide Cend with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Regardless of such option, Cend may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to it. If Cend is unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking Cend's ability to pursue its program.

If Cend is unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights it has, it may be required to expend significant time and resources to redesign its product candidates, identify other candidates, or to develop or license replacement technology, none of which may be feasible on a technical or commercial basis, especially with Cend's limited resources. If Cend is unable to do so, it may be unable to develop or commercialize the affected product candidates, which could critically harm Cend's business.

Obtaining and maintaining Cend's patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by government patent agencies, and Cend's patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and/or applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of Cend's licensed patents and/or applications and any patent rights it may own in the future. Cend may rely on its outside counsel or licensing partners to pay these fees due to non-U.S. patent agencies. The USPTO and various non-U.S. government patent agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. Cend will employ reputable law firms and other professionals to help it comply, but it will also be dependent on its licensors to take the necessary action to comply with these requirements with respect to their licensed intellectual property. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non- compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market and this circumstance could harm Cend's business.

Cend may not be able to protect intellectual property rights throughout the world, including but not limited to China.

Filing, prosecuting and defending patents on product candidates in all countries throughout the world, including China, would be prohibitively expensive, and intellectual property rights in some countries outside the United States could be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, Cend may not be able to prevent third parties from practicing any of its inventions in all countries outside the United States, or from selling or importing products made using any of its inventions in and into the United States or other jurisdictions. Competitors may use Cend's technologies in jurisdictions where Cend has not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where Cend has patent protection, but enforcement is not as strong as that in the United States. These products may compete with Cend's products and Cend's patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to life sciences products, which could make it difficult for Cend to stop the infringement of patents or marketing of competing products in violation of proprietary rights generally. Proceedings to enforce patent rights in foreign jurisdictions could result in substantial costs and divert Cend's efforts and attention from other aspects of Cend's business, could put Cend's patents at risk of being invalidated or interpreted narrowly and Cend's patent applications at risk of not issuing and could provoke third parties to assert claims against Cend. Cend may not prevail in any lawsuits that it initiates and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, Cend's efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that Cend develops or licenses.

In addition to the protection afforded by patents, Cend will rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that Cend elects not to patent, processes for which patents are difficult to enforce and any other elements of Cend's product candidate discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. However, trade secrets can be difficult to protect and some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Cend seeks to protect its proprietary technology and processes, in part, by entering into confidentiality agreements with its employees, consultants, scientific advisors and contractors. Cend cannot guarantee that it has entered into such agreements with each party that may have or have had access to Cend's trade secrets or proprietary technology and processes. Agreements or security measures may be breached, and Cend may not have adequate remedies for any breach. In addition, Cend's trade secrets may otherwise become known or be independently discovered by competitors.

Changes to patent law in the United States and in foreign jurisdictions could diminish the value of patents in general, thereby impairing Cend's ability to protect its products.

As is the case with other drug discovery and development companies, Cend's success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the pharmaceutical industry involve both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to Cend's ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken Cend's ability to obtain new patents or to enforce patents that Cend might obtain in the future. For example, in the case *Assoc. for Molecular Pathology v. Myriad Genetics, Inc.*, the U.S. Supreme Court held that certain claims to DNA molecules are not patentable. Any adverse changes in the patent laws of other jurisdictions could have a material adverse effect on Cend's business and financial condition. Changes in the laws and regulations governing patents in other jurisdictions could similarly have an adverse effect on Cend's ability to obtain and effectively enforce any rights it may have in its patent applications or any patents Cend may own or in-license in the future.

Recent or future patent reform legislation could also increase the uncertainties and costs surrounding the prosecution of Cend's patent applications and the enforcement or defense of any patents Cend may own or in-license in the future. The United States has enacted and implemented wide-ranging patent reform legislation. On September 16, 2011, the Leahy-Smith America Invents Act, or America Invents Act, was signed into law, which includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art, may affect patent litigation, establish a new post-grant review system and switch the U.S. patent system from a "first-to-invent" system to a "first-to-file" system. Under a "first-to-file" system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to a patent on the invention regardless of whether another inventor had made the invention earlier. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, Cend cannot be certain that it was the first to either (i) file any patent application related to its product candidates or other technologies or (ii) invent any of the inventions claimed in its patent applications or any patents it may own or in-license. These changes also allow third party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action.

Accordingly, a third party may attempt to use the USPTO procedures to invalidate Cend's patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. An adverse determination in any such proceeding could reduce the scope of, or invalidate, Cend's patent rights, allow third parties to commercialize its technology or products and compete directly with Cend, without payment to Cend, or result in Cend's inability to manufacture or commercialize products without infringing third-party patent rights. Accordingly, the America Invents Act and its implementation interjects uncertainties and costs surrounding the prosecution of Cend's patent applications and the enforcement or defense of any issued patents Cend may own or in-license in the future, all of which could have a material adverse effect on Cend's business and financial condition.

Cend may be subject to claims asserting that its employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what Cend regards as its own intellectual property.

Cend anticipates that many of its consultants or advisors will currently be, or were previously, employed at universities, industry service providers (e.g., CDMOs, CROs, CDOs, etc.), or other biotechnology or pharmaceutical companies, including Cend's competitors or potential competitors. Although Cend tries to ensure that its employees, consultants and advisors do not use the proprietary information or know-how of others in their work for Cend, Cend may be subject to claims that these individuals or Cend has used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against these claims. If Cend fails in defending any such claims, in addition to paying monetary damages, Cend may lose valuable intellectual property rights or personnel. Even if Cend is successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

If Cend is unable to protect the confidentiality of its trade secrets, its business and competitive position would be harmed.

In addition to the protection afforded by patents Cend may own or in-license in the future, Cend seeks to rely on trade secret protection, confidentiality agreements, and license agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of Cend's product discovery and development processes, that involve proprietary know-how, information, or technology that is not covered by patents. Although Cend requires all of its employees, consultants, advisors and any third parties who have access to Cend proprietary know-how, information, or technology to enter into confidentiality agreements, trade secrets can be difficult to protect and Cend has limited the protection of trade secrets used by its collaborators and suppliers. Cend cannot be certain that it has or will obtain these agreements in all circumstances and cannot guarantee that it has entered into such agreements with each party that may have or have had access to Cend's trade secrets or proprietary information.

Moreover, any of these parties might breach the agreements and intentionally or inadvertently disclose Cend trade secret information and Cend may not be able to obtain adequate remedies for such breaches. In addition, competitors may otherwise gain access to Cend's trade secrets or independently develop substantially equivalent information and techniques. Furthermore, the laws of some foreign countries do not protect proprietary rights and trade secrets to the same extent or in the same manner as the laws of the United States. As a result, Cend may encounter significant problems in protecting and defending its intellectual property both in the United States and abroad. If Cend is unable to prevent unauthorized material disclosure of its intellectual property to third parties, Cend will not be able to establish or maintain a competitive advantage in its market, which could materially adversely affect Cend's business, financial condition, results of operations and future prospects.

Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. If Cend chooses to go to court to stop a third party from using any of its trade secrets, it may incur substantial costs. These lawsuits may consume Cend's time and other resources even if it is successful. For example, significant elements, including aspects of drug manufacturing processes, experiments to validate mechanisms and pharmacology, drug design, and related processes, are based on unpatented trade secrets that are not publicly disclosed. Although Cend takes steps to protect its proprietary information and trade secrets, including through contractual means with its employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to Cend's trade secrets or disclose its technology. If any of Cend's trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, Cend would have no right to prevent them from using that technology or information to compete with Cend.

Thus, Cend may not be able to meaningfully protect its trade secrets. It is Cend's policy to require its employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with Cend. These agreements provide that all confidential information concerning Cend's business or financial affairs developed or made known to the individual or entity during the course of the party's relationship with Cend is to be kept confidential and not disclosed to third parties except in specific circumstances. In addition, Cend takes other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of Cend's proprietary technology by third parties. In the case of employees, the agreements provide that all inventions conceived by the individual, and which are related to Cend's current or planned business or research and development or made during normal working hours, on Cend's premises or using Cend's equipment or proprietary information, are Cend's exclusive property. Although Cend requires all of its employees to assign their inventions to it, Cend may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that Cend regards as its own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and Cend may be forced to bring claims against third parties, or defend claims that they may bring against Cend, to determine the ownership of what Cend regards as its intellectual property. Such claims could have a material adverse effect on Cend's business, financial condition, results of operations, and prospects.

Cend may not be successful in obtaining or maintaining necessary rights to product components and processes for its development pipeline through acquisitions and in-licenses.

Presently Cend has seven pending patent applications in the United States. Because additional product candidates may require the use of proprietary rights held by third parties, the growth of Cend's business will likely depend in part on its ability to acquire, in-license or use these proprietary rights.

Cend's product candidates may also require specific formulations to work effectively and efficiently and these rights may be held by others. Similarly, efficient production or delivery of Cend product candidates may also require specific compositions or methods, and the rights to these may be owned by third parties. Cend may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that Cend identifies as necessary or important to its business operations. Cend may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all, which would harm its business. Cend may need to cease use of the compositions or methods covered by such third-party intellectual property rights, and may need to seek to develop alternative approaches that do not infringe on such intellectual property rights which may entail additional costs and development delays, even if Cend was able to develop such alternatives, which may not be feasible. Even if Cend is able to obtain a license, it may be nonexclusive, thereby giving Cend competitors access to the same technologies licensed to it. In that event, Cend may be required to expend significant time and resources to develop or license replacement technology. Moreover, the molecules that will be used with Cend's product candidates may be covered by the intellectual property rights of others.

Additionally, Cend sometimes collaborated with academic institutions to accelerate its clinical research or development under written agreements with these institutions. In certain cases, these institutions provide Cend with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Regardless of such option, Cend may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to it. If it is unable to do so, the institution may offer the intellectual property rights to others, potentially blocking Cend's ability to pursue its program and allowing third parties to compete with it. If Cend is unable to successfully obtain rights to required third-party intellectual property or to maintain the existing intellectual property rights Cend has, Cend may have to abandon development of such program and its business and financial condition could suffer.

The licensing and acquisition of third-party intellectual property rights is a competitive area, and companies that are more established, or have greater resources than Cend does, may also be pursuing strategies to license or acquire third-party intellectual property rights that Cend may consider necessary or attractive in order to commercialize its product candidates. More established companies may have a competitive advantage over Cend due to their size, cash resources and greater clinical development and commercialization capabilities. In addition, companies that perceive Cend to be a competitor may be unwilling to assign or license rights to it. Cend also may be unable to license or acquire third-party intellectual property rights on terms that would allow it to make an appropriate return on its investment or at all. There can be no assurance that Cend will be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that it may seek to acquire. If Cend is unable to successfully obtain rights to required third-party intellectual property or to maintain the existing intellectual property rights it has, to may have to abandon development of such program and its business, results of operations, financial condition and prospects could suffer.

If Cend does not obtain patent term extension and data exclusivity for any of its current or future product candidates it may develop, its business may be materially harmed.

Depending upon the timing, duration and specifics of any FDA marketing approval of any of its current or future product candidates Cend may develop, one or more U.S. patents Cend may own or in-license in the future may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent term extension of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, Cend may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than Cend requests. If Cend is unable to obtain patent term extension or the term of any such extension is shorter than what Cend requests, its competitors may obtain approval of competing products following expiration of any patents that issue from Cend's patent applications, and Cend's business, financial condition, results of operations, and prospects could be materially harmed.

If Cend's trademarks and trade names are not adequately protected, then it may not be able to build name recognition in its marks of interest and its business may be adversely affected.

Cend's trademarks or trade names may be challenged, infringed, diluted, circumvented or declared generic or determined to be infringing on other marks. Cend intends to rely on both registration and common law protection for its trademarks. Cend may not be able to protect its rights to these trademarks and trade names or may be forced to stop using these names, which it needs for name recognition by potential partners or customers in its markets of interest. During the trademark registration process, Cend may receive Office Actions from the USPTO objecting to the registration of its trademarks. Although Cend would be given an opportunity to respond to those objections, it may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and/or to seek the cancellation of registered trademarks. Opposition or cancellation proceedings may be filed against Cend's trademarks, and its trademarks may not survive such proceedings. If Cend is unable to obtain a registered trademark or establish name recognition based on its trademarks and trade names, it may not be able to compete effectively and its business may be adversely affected.

Third-party claims of intellectual property infringement, misappropriation or other violations may be costly and time consuming and may prevent or delay Cend's product discovery and development efforts.

The intellectual property landscape around precision medicine is crowded, and third parties may initiate legal proceedings alleging that Cend is infringing, misappropriating, or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of Cend's business. Cend's commercial success depends upon its ability to develop, manufacture, market and sell its current and future product candidates and use its proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including derivation, interference, reexamination, *inter partes* review, and post grant review proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. Cend or any of its future licensors or strategic partners may be party to, exposed to, or threatened with, future adversarial proceedings or litigation by third parties having patent or other intellectual property rights alleging that its current or future product candidates and/or proprietary technologies infringe, misappropriate or otherwise violate their intellectual property rights. Cend cannot assure you that its product candidates and other technologies that it has developed, are developing or may develop in the future do not or will not infringe, misappropriate or otherwise violate existing or future patents or other intellectual property rights owned by third parties. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which Cend is developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that Cend's product candidates may give rise to claims of infringement of the patent rights of others. Moreover, it is not always clear to industry participants, including Cend, which patents cover various types of drugs, products or their methods of use or manufacture. Thus, because of the large number of patents issued and patent applications filed in Cend's fields, there may be a risk that third parties may allege they have patent rights encompassing Cend's product candidates, technologies or methods.

If a third party claims that Cend infringes, misappropriates or otherwise violates its intellectual property rights, Cend may face a number of issues, including, but not limited to:

- infringement, misappropriation and other intellectual property claims which, regardless of merit, may be expensive and time-consuming to litigate and may divert management's attention from Cend's core business and may impact its reputation;

- substantial damages for infringement, misappropriation or other violations, which Cend may have to pay if a court decides that the product candidate or technology at issue infringes, misappropriates or violates the third party's rights, and, if the court finds that the infringement was willful, Cend could be ordered to pay treble damages and the patent owner's attorneys' fees;

- a court prohibiting Cend from developing, manufacturing, marketing or selling its product candidates, including CEND-1, or from using its proprietary technologies, unless the third party licenses its product rights to Cend, which it is not required to do, on commercially reasonable terms or at all;

- if a license is available from a third party, Cend may have to pay substantial royalties, upfront fees and other amounts, and/or grant cross-licenses to intellectual property rights for its products, or the license to Cend may be non-exclusive, which would permit third parties to use the same intellectual property to compete with Cend;

- redesigning Cend's product candidates or processes so they do not infringe, misappropriate or violate third party intellectual property rights, which may not be possible or may require substantial monetary expenditures and time; and

- there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and, if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of Cend's common stock.

Some of Cend's competitors may be able to sustain the costs of complex patent litigation more effectively than Cend can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on Cend's ability to raise the funds necessary to continue Cend's operations or could otherwise have a material adverse effect on Cend's business, results of operations, financial condition and prospects. The occurrence of any of the foregoing could have a material adverse effect on Cend's business, financial condition, results of operations or prospects.

Cend may choose to challenge the patentability of claims in a third party's U.S. patent by requesting that the USPTO review the patent claims in an *ex-parte* re-exam, *inter partes* review or post-grant review proceedings. These proceedings are expensive and may consume Cend's time or other resources. Cend may choose to challenge a third party's patent in patent opposition proceedings in the EPO, or other foreign patent office. The costs of these opposition proceedings could be substantial, and may consume Cend's time or other resources. If Cend fails to obtain a favorable result at the USPTO, EPO or other patent office then Cend may be exposed to litigation by a third party alleging that the patent may be infringed by Cend's product candidates or proprietary technologies.

Third parties may assert that Cend is employing their proprietary technology without authorization. Patents issued in the United States by law enjoy a presumption of validity that can be rebutted only with evidence that is "clear and convincing," a heightened standard of proof. There may be issued third-party patents of which Cend is currently unaware with claims to compositions, formulations, methods of manufacture or methods for treatment related to the use or manufacture of Cend's product candidates. Patent applications can take many years to issue. In addition, because some patent applications in the United States may be maintained in secrecy until the patents are issued, patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, and publications in the scientific literature often lag behind actual discoveries, Cend cannot be certain that others have not filed patent applications covering Cend's product candidates or technology. If any such patent applications issue as patents, and if such patents have priority over Cend's patent applications or patents Cend may own or in-license, Cend may be required to obtain rights to such patents owned by third parties which may not be available on commercially reasonable terms or at all, or may only be available on a non-exclusive basis. There may be currently pending patent applications which may later result in issued patents that Cend's product candidates may infringe. It is also possible that patents owned by third parties of which Cend is aware, but which it does not believe are relevant to Cend's product candidates or other technologies, could be found to be infringed by Cend's product candidates or other technologies. In addition, third parties may obtain patents in the future and claim that use of Cend's technologies infringes upon these patents. Moreover, Cend may fail to identify relevant patents or incorrectly conclude that a patent is invalid, not enforceable, exhausted, or not infringed by Cend's activities. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of Cend's product candidates, molecules used in or formed during the manufacturing process, or any final product itself, the holders of any such patents may be able to block Cend's ability to commercialize the product candidate unless it obtained a license under the applicable patents, or until such patents expire or they are finally determined to be held invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of Cend's formulations, processes for manufacture or methods of use, including combination therapy or patient selection methods, the holders of any such patent may be able to block Cend's ability to develop and commercialize the product candidate unless Cend obtained a license or until such patent expires or is finally determined to be held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all. If Cend is unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, its ability to commercialize its product candidates may be impaired or delayed, which could in turn significantly harm its business. Even if Cend obtains a license, it may be nonexclusive, thereby giving Cend's competitors access to the same technologies licensed to Cend. In addition, if the breadth or strength of protection provided by Cend's patent applications or any patents it may own or in-license in the future is threatened, it could dissuade companies from collaborating with Cend to license, develop or commercialize current or future product candidates.

Parties making claims against Cend may seek and obtain injunctive or other equitable relief, which could effectively block Cend's ability to further develop and commercialize its product candidates. Defense of these claims, regardless of their merit, could involve substantial litigation expense and would be a substantial diversion of employee resources from Cend's business. In the event of a successful claim of infringement, misappropriation or other violation against Cend, Cend may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign its infringing products, which may be impossible or require substantial time and monetary expenditure. Cend cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, Cend may need or may choose to obtain licenses from third parties to advance its research or allow commercialization of its product candidates. Cend may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, Cend would be unable to further develop and commercialize its product candidates, which could harm its business significantly.

Cend may become involved in lawsuits to protect or enforce its intellectual property rights, including any patents it may own or in-license in the future, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe any patents Cend may own or in-license in the future. In addition, any patents Cend may own or in-license also may become involved in inventorship, priority, validity or unenforceability disputes. To counter infringement or unauthorized use, Cend may be required to file infringement claims, which can be expensive and time-consuming. Cend may not prevail in any lawsuits that it initiates, and the damages or other remedies awarded, if any, may not be commercially meaningful. In addition, in an infringement proceeding, a court may decide that one or more of any patents Cend may own or in-license in the future is not valid or is unenforceable or that the other party's use of Cend's technology that may be patented falls under the safe harbor to patent infringement under 35 U.S.C. §271(e)(1). There is also the risk that, even if the validity of these patents is upheld, the court may refuse to stop the other party from using the technology at issue on the grounds that any patents Cend may own or in-license in the future do not cover the technology in question or that such third party's activities do not infringe Cend's patent applications or any patents it may own or in-license in the future. An adverse result in any litigation or defense proceedings could put one or more of any patents Cend may own or in-license in the future at risk of being invalidated, held unenforceable, or interpreted narrowly and could put Cend's patent applications at risk of not issuing. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from Cend's business. In the event of a successful claim of infringement against Cend, Cend may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign Cend's infringing products, which may be impossible or require substantial time and monetary expenditure. Such litigation or proceedings could substantially increase Cend's operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities. Cend may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of Cend's competitors may be able to sustain the costs of such litigation or proceedings more effectively than Cend can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on Cend's ability to compete in the marketplace.

Post-grant proceedings provoked by third parties or brought by the USPTO may be necessary to determine the validity or priority of inventions with respect to Cend's patent applications or any patents Cend may own or in-license in the future. These proceedings are expensive and an unfavorable outcome could result in a loss Cend's current patent rights and could require Cend to cease using the related technology or to attempt to license rights to it from the prevailing party. Cend's business could be harmed if the prevailing party does not offer Cend a license on commercially reasonable terms. In addition to potential USPTO review proceedings, Cend may become a party to patent opposition proceedings in the European Patent Office or similar proceedings in other foreign patent offices, where either Cend's foreign patents are challenged. The costs of these opposition or similar proceedings could be substantial, and may result in a loss of scope of some claims or a loss of the entire patent. An unfavorable result at the USPTO, EPO or other patent office may result in the loss of Cend's right to exclude others from practicing one or more of its inventions in the relevant country or jurisdiction, which could have a material adverse effect on Cend's business.

Litigation or post-grant proceedings may result in a decision adverse to Cend's interests and, even if Cend is successful, may result in substantial costs and distract its management and other employees. Cend may not be able to prevent, misappropriation of its trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States.

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

Cend may not be able to detect infringement against any patents it may own or in-license in the future. Even if Cend detects infringement by a third party of any patents it may own or in-license in the future, Cend may choose not to pursue litigation against or settlement with the third party. If Cend later sues such third party for patent infringement, the third party may have certain legal defenses available to it, which otherwise would not be available except for the delay between when the infringement was first detected and when the suit was brought. Such legal defenses may make it impossible for Cend to enforce any patents it may own or in-license against such third party.

Risks related to the development of Cend's product candidates

Cend is early in its development efforts and is substantially dependent on its lead product candidate, CEND-1. If Cend is unable to advance CEND-1 or any of its other product candidates through clinical development, obtain regulatory approval and ultimately commercialize CEND-1 or any of its other product candidates, or experience significant delays in doing so, Cend's business will be materially harmed.

Cend is early in its development efforts. Cend's lead product candidate is still in clinical development. Cend's earlier stage drug discovery and development programs have not yet resulted in product candidates that have been tested in human subjects. Cend's ability to generate product revenues, which it does not expect will occur for many years, if ever, will depend heavily on the successful clinical development and eventual commercialization of CEND-1 and one or more of its other product candidates. The success of Cend's product candidates will depend on several factors, including the following:

- successful completion of preclinical and clinical studies;
- approval of INDs for Cend's planned clinical trials or future clinical trials;
- FDA acceptance of Cend's development strategy and resultant clinical data;
- successful initiation of clinical trials;
- successful patient enrollment in and completion of clinical trials;
- safety, tolerability and efficacy profiles for Cend's product candidates that are satisfactory to the FDA or any foreign regulatory authority for marketing approval;
- receipt of marketing approvals for Cend's product candidates from applicable regulatory authorities;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for Cend's product candidates;
- making arrangements with third-party manufacturers, or establishing manufacturing capabilities, for both clinical and commercial supplies of Cend's product candidates, if any product candidates are approved;
- establishing sales, marketing and distribution capabilities and launching commercial sales of Cend's products, if and when approved, whether alone or in collaboration with others;
- acceptance of Cend's products, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other cancer therapies;
- obtaining and maintaining third-party coverage and adequate reimbursement;
- maintaining a continued acceptable safety profile of Cend's products following approval; and

- factors Cend may not be able to control, such as current or potential pandemics that may limit patients, principal investigators or staff or clinical site availability (e.g. the COVID-19 pandemic).

There is no guarantee that the results obtained in current clinical studies will be sufficient to obtain regulatory approval or marketing authorization for such product candidate. Negative results in the development of Cend's lead product candidate may also impact its ability to obtain regulatory approval for its other product candidates, either at all or within anticipated timeframes because, although other product candidates may target different indications, the underlying technology platform, manufacturing process and development process is the same for all of Cend's product candidates. Accordingly, a failure in any one program may affect the ability to obtain regulatory approval to continue or conduct clinical programs for other product candidates. For example, although Cend believes based on its clinical studies that a combination of CEND-1 with certain anti-cancer therapeutics is more effective than the use of those therapeutics in alone, this may not prove true in clinical testing of CEND-1 for all or any of the targeted tumors or types of cancer. Anti-tumor activity may prove different in each of the different tumor and cancer types Cend plans on evaluating in the clinical trial. Therefore, even though Cend plans on pursuing tumor-agnostic clinical development of CEND-1, the tumor response may be low in patients with some cancers compared to others. This may result in discontinuation of development of CEND-1 for patients with these tumor types and/or mutations due to insufficient clinical benefit while continuing development for a more limited population of patients more likely to benefit. As a consequence, Cend may have to negotiate with the FDA to reach agreement on defining the optimal patient population, study design and size in order to obtain regulatory approval, any of which may require significant additional resources and delay the timing of Cend's clinical trials and ultimately the approval, if any, of any of Cend's product candidates.

In addition, because Cend has limited financial and personnel resources and is placing significant focus on the development of its lead product candidate, Cend may forego or delay pursuit of opportunities with other future product candidates that later prove to have greater commercial potential. Cend's resource allocation decisions may cause it to fail to capitalize on viable commercial products or profitable market opportunities. Cend's spending on current and future research and development programs and other future product candidates for specific indications may not yield any commercially viable future product candidates. If Cend does not accurately evaluate the commercial potential or target market for a particular future product candidate, it may relinquish valuable rights to those future product candidates through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for it to retain sole development and commercialization rights to such future product candidates.

Difficulty in enrolling patients could delay or prevent clinical trials of Cend's product candidates. Cend may find it difficult to enroll patients in its clinical trial for CEND-1 with the tumor cancers that CEND-1 is designed to target.

Identifying and qualifying patients to participate in clinical studies of Cend's product candidates is critical to Cend's success. The timing of completion of Cend's clinical studies depends in part on the speed at which it can recruit patients to participate in testing its product candidates, and Cend may experience delays in its clinical trials if it encounters difficulties in enrollment. Cend may not be able to initiate or continue clinical trials for its product candidates if it is 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. In particular, because Cend is focused on patients with specific solid tumor cancers, Cend's ability to enroll eligible patients may be limited or may result in slower enrollment than it anticipates. For example, with respect to CEND-1, Cend cannot be certain how many patients will have each of the solid tumor cancers that CEND-1 is designed to target or that the number of patients enrolled will suffice for regulatory approval and inclusion of each such mutation in the approved label. In addition, some of Cend's competitors have ongoing clinical trials for product candidates that treat the same indications as Cend's product candidates, and patients who would otherwise be eligible for Cend's clinical trials may instead enroll in clinical trials of Cend's competitors' product candidates.

The eligibility criteria of Cend's planned clinical trials will limit the pool of available study participants as Cend will require that patients have specific characteristics that it can measure to assure their disease is either severe enough or not too advanced to include them in a study. Additionally, the process of finding and diagnosing patients may prove costly. Cend also may not be able to identify, recruit and enroll a sufficient number of patients to complete its clinical studies because of the perceived risks and benefits of the product candidate under study, the availability and efficacy of competing therapies and clinical trials, the proximity and availability of clinical study sites for prospective patients, the availability of genetic sequencing information for patient tumors so that Cend can identify patients with the targeted conditions, and the patient referral practices of physicians. If patients are unwilling to participate in Cend's studies for any reason, the timeline for recruiting patients, conducting studies and obtaining regulatory approval of potential products may be delayed.

Further, if Cend is unable to include patients with the targeted conditions, this could compromise its ability to seek participation in FDA's expedited review and development programs, or otherwise seek to accelerate clinical development and regulatory timelines.

The enrollment of patients further depends on many factors, including:

- the proximity of patients to clinical trial sites;
- the design of the clinical trial;
- Cend's ability to recruit clinical trial investigators with the appropriate competencies and experience;
- Cend's ability to obtain and maintain patient consents;
- reporting of the preliminary results of any of Cend's clinical trials;
- the risk that patients enrolled in clinical trials will drop out of the clinical trials before clinical trial completion; and
- other unforeseeable conditions, such as COVID-19, which had a significantly negative impact on the availability of enrollment in clinical trials.

In addition, Cend's clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as its product candidates, and this competition will reduce the number and types of patients available to Cend because some patients who might have opted to enroll in Cend's clinical trials may instead opt to enroll in a clinical trial being conducted by one of Cend's competitors. Since the number of qualified clinical investigators is limited, Cend may conduct some of its clinical trials at the same clinical trial sites that some of its competitors use, which could reduce the number of patients who are available for Cend's clinical trials at such clinical trial sites.

If Cend experiences delays in the completion of, or termination of, any clinical trial of its product candidates, the commercial prospects of Cend's product candidates will be harmed, and Cend's ability to generate product revenue from any of these product candidates could be delayed or prevented.

Cend has limited experience as a company in conducting clinical trials.

Cend has limited experience as a company in conducting clinical trials. In part because of this lack of experience, Cend cannot be certain that its ongoing preclinical and clinical studies will be completed on time or if the planned preclinical studies and clinical trials will begin or be completed on time, if at all. Large-scale clinical trials would require significant additional financial and management resources and reliance on third-party clinical investigators, contract research organizations, or CROs, and consultants. Relying on third-party clinical investigators, CROs and consultants may force Cend to encounter delays that are outside of its control. Cend may be unable to identify and contract with sufficient investigators, CROs and consultants on a timely basis or at all. There can be no assurance that Cend will be able to negotiate and enter into any additional master services agreement with other CROs, as necessary, on terms that are acceptable to Cend on a timely basis or at all.

Cend's non-clinical studies and clinical trials may fail to demonstrate adequately the safety, potency, purity and efficacy of any of its product candidates, which would prevent or delay development, regulatory approval and commercialization.

Before obtaining regulatory approvals for the commercial license or sale of Cend's product candidates, including CEND-1, Cend must demonstrate through lengthy, complex and expensive preclinical studies and clinical trials that its product candidates are both safe and effective for use in each target indication. Preclinical and 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 preclinical study and clinical trial processes, and, because Cend's product candidates are in an early stage of development, there is a high risk of failure and Cend may never succeed in developing marketable products.

The results of preclinical studies and early clinical trials of Cend's product candidates may not be predictive of the results of later-stage clinical trials. Although product candidates may demonstrate promising results in preclinical studies and early clinical trials, they may not prove to be effective in subsequent clinical trials. For example, testing on animals occurs under different conditions than testing in humans and therefore the results of animal studies may not accurately predict human experience. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through preclinical studies and clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety, potency, purity and efficacy profile despite having progressed through preclinical studies and initial clinical trials. Likewise, early, smaller-scale clinical trials may not be predictive of eventual safety or effectiveness in large-scale pivotal clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of potency or efficacy, insufficient durability of potency or efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that commence preclinical studies and clinical trials are never approved as products.

Any preclinical studies or clinical trials that Cend may conduct may not demonstrate the safety, potency, purity and efficacy necessary to obtain regulatory approval to market Cend's product candidates. If the results of Cend's ongoing or future preclinical studies and clinical trials are inconclusive with respect to the safety, potency, purity and efficacy of its product candidates, if Cend does not meet the clinical endpoints with statistical and clinically meaningful significance, or if there are safety concerns associated with Cend's product candidates, Cend may be prevented or delayed in obtaining marketing approval for such product candidates. In some instances, there can be significant variability in safety, potency, purity or efficacy results between different preclinical studies and clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants. As is the case with all oncology drugs, it is likely that there may be side effects associated with their use. Results of Cend's trials could reveal a high and unacceptable severity and prevalence of these or other side effects. In such an event, Cend's trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of Cend's product candidates for any or all targeted indications. Drug-related side effects could also 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 harm Cend's business, financial condition and prospects significantly.

Cend may not be able to file INDs or IND amendments to commence additional clinical trials on the timelines it expects, and even if Cend is able to, the FDA may not permit it to proceed.

Cend submitted an IND for CEND-1 on April 14, 2021, which was allowed by the FDA on May 14, 2021 but Cend may not be able to file INDs for its other product candidates on the timelines it expects. For example, Cend may experience manufacturing delays or other delays with IND-enabling studies. Moreover, Cend cannot be sure that submission of an IND will result in the FDA allowing further clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate clinical trials. Additionally, even if such regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND, Cend cannot guarantee that such regulatory authorities will not change their requirements in the future. These considerations also apply to new clinical trials Cend may submit as amendments to existing INDs or to a new IND. Any failure to file INDs on the timelines Cend expects or to obtain regulatory approvals for Cend's trials may prevent Cend from completing its clinical trials or commercializing its products on a timely basis, if at all.

Since the number of patients that Cend plans to dose in its Phase 2b clinical trial of CEND-1 is small, the results from such a clinical trial, once completed, may be less reliable than results achieved in larger clinical trials, which may hinder Cend's efforts to obtain regulatory approval for its product candidates.

In the current, ongoing Phase 2b clinical trial of CEND-1, Cend is evaluating the safety and anti-tumor activity profile of CEND-1 at the recommended Phase 2b dose in combination with standard-of-care chemotherapy in patients with pancreatic cancer. The Phase 2b portion of the trial is expected to enroll up to 125 patients. The Phase 2b portion may have to evaluate different dosing schedules if the pharmacokinetic or safety data suggest once daily dosing is suboptimal. The preliminary results of clinical trials with smaller sample sizes, such as Cend's previous Phase 1b clinical trial of CEND-1, can be disproportionately influenced by various biases associated with the conduct of small clinical trials, such as the potential failure of the smaller sample size to accurately depict the features of the broader patient population, which limits the ability to generalize the results across a broader community, thus making the clinical trial results less reliable than clinical trials with a larger number of patients. As a result, there may be less certainty that such product candidates would achieve a statistically significant effect in any future clinical trials. If Cend conducts any future clinical trials of CEND-1, it may not achieve a statistically significant result or the same level of statistical significance, if any, that it might have anticipated based on the results observed in Cend's initial clinical trial.

Further, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of patients and limited duration of exposure, rare and severe side effects of Cend's product candidates may only be uncovered with a significantly larger number of patients exposed to the drug candidate. If Cend's product candidates receive marketing approval and Cend or others identify undesirable side effects caused by such product candidates (or any other similar drugs) after such approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw or limit their approval of such product candidates;
- regulatory authorities may require the addition of labeling statements, such as a "boxed" warning or a contraindication;
- Cend may be required to change the way such product candidates are distributed or administered, conduct additional clinical trials or change the labeling of the product candidates;
- regulatory authorities may require a REMS plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools;
- Cend may be subject to regulatory investigations and government enforcement actions;
- Cend may decide to remove such product candidates from the marketplace;
- Cend could be sued and held liable for injury caused to individuals exposed to or taking its product candidates; and
- Cend's reputation may suffer.

Cend believes that any of these events could prevent it from achieving or maintaining market acceptance of the affected product candidates and could substantially increase the costs of commercializing Cend's product candidates, if approved, and significantly impact Cend's ability to successfully commercialize its product candidates and generate revenues.

Clinical development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future clinical trial results. Cend may encounter substantial delays in clinical trials, or may not be able to conduct or complete clinical trials on the expected timelines, if at all. If Cend's preclinical studies and clinical trials are not sufficient to support regulatory approval of any of its product candidates, it may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development of such product candidate.

Cend's lead product candidate is in clinical studies, and additional product candidates are at earlier stages of development, and their risk of failure is high. It is impossible to predict when or if any of Cend's product candidates will prove effective and safe in humans or will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of any drug candidate, Cend must complete preclinical studies and then conduct extensive clinical trials to demonstrate the safety and efficacy of its product candidates in humans. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical development testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their product candidates. Cend's preclinical studies and future clinical trials may not be successful.

Cend cannot be certain that its non-clinical study and clinical trial results will be sufficient to support regulatory approval of its product candidates. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Human clinical trials are expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. Failure or delay can occur at any time during the clinical trial process.

Additionally, some of the clinical trials Cend conducts may be open-label in study design and may be conducted at a limited number of clinical sites on a limited number of patients. An "open-label" clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. Most typically, open-label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label clinical trials are aware when they are receiving treatment. Open-label clinical trials may be subject to a "patient bias" where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. Moreover, patients selected for early clinical studies often include the most severe sufferers and their symptoms may have been bound to improve notwithstanding the new treatment. In addition, open-label clinical trials may be subject to an "investigator bias" where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. Cend's Phase 2b and additional later stage clinical trials are planned to be conducted as controlled, blinded studies.

Cend may experience delays in obtaining the FDA's authorization to initiate clinical trials under future INDs, completing ongoing preclinical studies of Cend's other product candidates, and initiating Cend's planned preclinical studies and clinical trials. Additionally, Cend cannot be certain that non-clinical studies or clinical trials for its product candidates will begin on time, not require redesign, enroll an adequate number of subjects on time, or be completed on schedule, if at all.

Clinical trials can be delayed or terminated for a variety of reasons, including delays or failures related to:

- the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of Cend's clinical trials;
- the FDA or comparable foreign regulatory authorities disagreeing with Cend's tumor-agnostic development strategy;
- delays in obtaining regulatory approval to commence a clinical trial;
- reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- obtaining IRB approval at each clinical trial site;
- recruiting an adequate number of suitable patients to participate in a clinical trial;
- the number of patients required for clinical trials of Cend's product candidates may be larger than it anticipates;
- having subjects complete a clinical trial or return for post-treatment follow-up;
- clinical trial sites deviating from clinical trial protocol or dropping out of a clinical trial;
- addressing subject safety concerns that arise during the course of a clinical trial;
- adding a sufficient number of clinical trial sites; or
- obtaining sufficient product supply of product candidate for use in non-clinical studies or clinical trials from third-party suppliers.

Cend may experience numerous adverse or unforeseen events during, or as a result of, preclinical studies and clinical trials that could delay or prevent Cend's ability to receive marketing approval or commercialize Cend's product candidates, including:

- Cend may receive feedback from regulatory authorities that requires it to modify the design of its clinical trials;
- clinical trials of Cend's product candidates may produce negative or inconclusive results, and Cend may decide, or regulators may require it, to conduct additional clinical trials or abandon its research efforts for its other product candidates;
- clinical trials of Cend's product candidates may not produce differentiated or clinically significant results across tumor types or indications;

- the number of patients required for clinical trials of Cend's product candidates may be larger than it anticipates, enrollment in these clinical trials may be slower than it anticipates or participants may drop out of its clinical trials at a higher rate than it anticipates;

- Cend's third-party contractors may fail to comply with regulatory requirements, fail to maintain adequate quality controls or be unable to provide it with sufficient product supply to conduct and complete preclinical studies or clinical trials of Cend's product candidates in a timely manner, or at all;

- Cend or its investigators might have to suspend or terminate clinical trials of Cend's product candidates for various reasons, including non-compliance with regulatory requirements, a finding that Cend's product candidates have undesirable side effects or other unexpected characteristics or a finding that the participants are being exposed to unacceptable health risks;

- the cost of clinical trials of Cend's product candidates may be greater than it anticipates, for example, if it experiences delays or challenges in identifying patients with the mutations required for its clinical trials, it may have to reimburse sites for genetic sequencing costs in order to encourage sequencing of additional patients;

- the quality of Cend's product candidates or other materials necessary to conduct preclinical studies or clinical trials of Cend's product candidates may be insufficient or inadequate, and any transfer of manufacturing activities may require unforeseen manufacturing or formulation changes;

- regulators may revise the requirements for approving Cend's product candidates, or such requirements may not be as it anticipates; and

- future collaborators may conduct clinical trials in ways they view as advantageous to them but that are suboptimal for Cend.

If Cend is required to conduct additional clinical trials or other testing of Cend's product candidates beyond those that it currently contemplates, if Cend is unable to successfully complete clinical trials of Cend's product candidates or other testing, if the results of these trials or tests are not positive or are only moderately positive or if there are safety concerns, Cend's business and results of operations may be adversely affected and it may incur significant additional costs.

Cend could also encounter delays if a clinical trial is suspended or terminated by it, by the IRBs of the institutions in which such clinical trials are being conducted, by the Data Safety Monitoring Board, if any, for such clinical trial or by the FDA or other regulatory authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or Cend's clinical trial protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from the product candidates, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

Moreover, principal investigators for Cend's future clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, Cend may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authority may conclude that a financial relationship between Cend and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA or comparable foreign regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of Cend's marketing applications by the FDA or comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of Cend's product candidates.

If Cend experiences delays in the completion, or termination, of any preclinical study or clinical trial of Cend's product candidates, the commercial prospects of Cend's product candidates may be harmed, and Cend's ability to generate revenues from any of these product candidates will be delayed or not realized at all. In addition, any delays in completing Cend's preclinical studies or clinical trials may increase its costs, slow down its product candidate development and approval process and jeopardize its ability to commence product sales and generate revenues. Any of these occurrences may significantly harm Cend's business, financial condition and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of Cend's product candidates. If one or more of Cend's product candidates generally prove to be ineffective, unsafe or commercially unviable, Cend's entire pipeline could have little, if any, value, which would have a material and adverse effect on Cend's business, financial condition, results of operations and prospects.

Cend and its partners are conducting clinical trials for product candidates outside the United States, and the FDA and comparable foreign regulatory authorities may not accept data from such trials.

Cend may in the future choose to conduct one or more clinical trials outside the United States, including in Australia or Europe. The acceptance of study data from clinical trials conducted outside the United States or another jurisdiction by the FDA or comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; and (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which could be costly and time-consuming, and which may result in product candidates that Cend may develop not receiving approval for commercialization in the applicable jurisdiction.

Risks related to the COVID-19 pandemic

Business or economic disruptions or global health concerns could seriously harm Cend's development efforts and increase its costs and expenses.

Broad-based business or economic disruptions could adversely affect Cend's ongoing or planned research and development activities. For example, in December 2019, an outbreak of a novel strain of a virus named SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2), or coronavirus, which causes coronavirus disease (COVID-19) was reported to have surfaced in Wuhan, China, and has since spread to other regions and countries worldwide. In March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic. Almost all U.S. states and many local jurisdictions issued "shelter-in-place" orders, quarantines, executive orders and similar government orders, restrictions, and recommendations for their residents to control the spread of COVID-19. Such orders, restrictions and recommendations, and the perception that additional orders, restrictions or recommendations could occur, resulted in widespread closures of businesses not deemed "essential," work stoppages, slowdowns and delays, work-from-home policies, travel restrictions and cancellation of events, as well as volatility in stock prices, among other effects. There is a risk that government actions will not be effective at containing such infectious diseases, and that government actions will have a negative impact on the world economy at large, in which case the risks to Cend's operating results and financial condition described herein would be elevated significantly.

The continued spread of COVID-19 or other global health matters, has impacted and may continue to impact Cend's target patient populations as well as the hospitals and clinical sites in which Cend conducts any of its clinical trials, which could lead to delays in completing enrollment of Cend's clinical trials. For instance, the COVID-19 outbreak may continue to impair Cend's ability to recruit and retain patients and engage principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 if an outbreak occurs in their geography or due to prioritization of hospital resources toward the outbreak and restrictions on travel. Furthermore, some patients may be unwilling to enroll in Cend's trials or be unable to comply with clinical trial protocols if quarantines or travel restrictions impede patient movement or interrupt healthcare services. COVID-19 already has affected and may further negatively affect the operations of third party contract research organizations that Cend relies upon to carry out its discovery work, clinical trials or the operations of its third party manufacturers, which could result in delays or disruptions in the supply of Cend's product candidates and the conduct of experiments and studies. Any negative impact COVID-19 has to patient enrollment or treatment or the timing and execution of Cend's preclinical studies or clinical trials could cause costly delays to Cend's development programs, which could adversely affect Cend's ability to obtain regulatory approval for and to commercialize Cend's product candidates, increase Cend's operating expenses and have a material adverse effect on Cend's business and financial results. COVID-19 has also caused, and may continue to cause for an extended period, volatility in the global financial markets and threatened a slowdown in the global economy, which would reduce Cend's ability to access capital and could negatively affect its liquidity.

Although states have, in the past, implemented “shelter-in-place” orders, quarantines and similar restrictions, the regulations vary on a state by state basis and the effectiveness of those restrictions on controlling the spread of COVID-19 varies. Cend’s office-based employees continue to work primarily from hybrid and Cend expects this to continue for an extended period. Furthermore, resurgence of COVID-19 cases could possibly prompt a reinstatement of certain “shelter-in-place” orders and restrictions at the state and local levels, impacting Cend’s reentry to the workplace and causing hospital and clinical sites to suspend Cend’s clinical trials or deterring patients from continuing to participate in Cend’s trials.

Risks related to manufacturing and supply

Cend will rely on third parties to manufacture its clinical product supplies, and it may rely on third parties to produce and process its product candidates, if approved.

Cend does not currently own any facility that may be used as its clinical scale manufacturing facility and expects to rely on outside vendors to manufacture supplies of its product candidates. Cend will need to negotiate and maintain contractual arrangements with these outside vendors for the supply of its product candidates and Cend may not be able to do so on favorable terms. Cend has not yet caused any product candidates to be manufactured on a commercial scale and may not be able to do so for any of its product candidates.

The facilities used by Cend’s contract manufacturers to manufacture its product candidates must be approved by the FDA or other foreign regulatory authorities following inspections that will be conducted after Cend submits an application to the FDA or other foreign regulatory authorities. Cend may not control the manufacturing process of, and may be completely dependent on, Cend’s contract manufacturing partners for compliance with cGMPs and any other regulatory requirements of the FDA or other regulatory authorities for the manufacture of its product candidates. Beyond periodic audits, Cend has no control over the ability of its contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of Cend’s product candidates or if it withdraws any approval in the future, Cend may need to find alternative manufacturing facilities, which would require the incurrence of significant additional costs and significantly impact its ability to develop, obtain regulatory approval for or market its product candidates, if approved. Similarly, if any third-party manufacturers on which Cend will rely fail to manufacture quantities of its product candidates at quality levels necessary to meet regulatory requirements and at a scale sufficient to meet anticipated demand at a cost that allows Cend to achieve profitability, Cend’s business, financial condition and prospects could be materially and adversely affected.

Manufacturing Cend’s product candidates is complex and it may encounter difficulties in production. If Cend encounters such difficulties, its ability to provide supply of its product candidates for preclinical studies and clinical trials or for commercial purposes could be delayed or stopped.

The process of manufacturing of Cend’s product candidates is complex and highly regulated.

Cend relies on third parties for the manufacture of its product candidates. These third-party manufacturers may incorporate their own proprietary processes into Cend’s product candidate manufacturing processes. Cend has limited control and oversight of a third party’s proprietary process, and a third party may elect to modify its process without Cend’s consent or knowledge. These modifications could negatively impact Cend’s manufacturing, including product loss or failure that requires additional manufacturing runs or a change in manufacturer, both of which could significantly increase the cost of and significantly delay the manufacture of Cend’s product candidates.

As Cend’s product candidates progress through preclinical studies and clinical trials toward approval and commercialization, it is expected that various aspects of the manufacturing process will be altered in an effort to optimize processes and results. Such changes may require amendments to be made to regulatory applications which may further delay the timeframes under which modified manufacturing processes can be used for any of Cend’s product candidates and additional bridging studies or trials may be required.

Cend does not have its own clinical-scale manufacturing facility and is currently reliant on a limited number of manufacturers for its product candidates. These third-party manufacturing providers may not be able to provide adequate resources or capacity to meet Cend’s needs.

Risks related to sales, marketing, and competition

Cend currently has no marketing and sales organization and has no experience in marketing products. If Cend is unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell its product candidates, if approved, it may not be able to generate product revenue.

Cend currently has no sales, marketing or distribution capabilities and has no experience in marketing products. Cend intends to develop an in-house marketing organization and sales force, which will require significant capital expenditures, management resources and time. Cend will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel.

If Cend is unable or decides not to establish internal sales, marketing and distribution capabilities, it will pursue arrangements with third-party sales, marketing, and distribution collaborators regarding the sales and marketing of its products, if approved. However, there can be no assurance that Cend will be able to establish or maintain such arrangements on favorable terms or if at all, or if Cend is able to do so, that these third-party arrangements will provide effective sales forces or marketing and distribution capabilities. Any revenue Cend receives will depend upon the efforts of such third parties, which may not be successful. Cend may have little or no control over the marketing and sales efforts of such third parties and its revenue from product sales may be lower than if Cend had commercialized its product candidates itself. Cend also faces competition in its search for third parties to assist it with the sales and marketing efforts of its product candidates.

There can be no assurance that Cend will be able to develop in-house sales and distribution capabilities or establish or maintain relationships with third-party collaborators to commercialize any product in the United States or overseas.

A variety of risks associated with marketing Cend's product candidates internationally could materially adversely affect its business.

Cend and its partners plan to seek regulatory approval of Cend's product candidates outside of the United States and, accordingly, Cend expects that it will be subject to additional risks related to operating in foreign countries if it obtains the necessary approvals, including:

- differing regulatory requirements in foreign countries, for example, no country other than the United States has a pathway for accelerated drug approval and so obtaining regulatory approvals outside of the United States will take longer and be more costly than obtaining approval in the United States;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the Foreign Corrupt Practices Act of 1977 or comparable foreign regulations;
- challenges enforcing Cend's contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism.

These and other risks associated with international operations may materially adversely affect Cend's ability to attain or maintain profitable operations.

Even if Cend obtains regulatory approval of its product candidates, the products may not gain market acceptance among physicians, patients, hospitals, cancer treatment centers and others in the medical community.

The use of Cend's product candidates as a potential cancer treatment is a recent development and may not become broadly accepted by physicians, patients, hospitals, cancer treatment centers and others in the medical community. Various factors will influence whether Cend's product candidates are accepted in the market, including:

- the clinical indications for which Cend's product candidates are licensed;
- physicians, hospitals, cancer treatment centers and patients considering Cend's product candidates as a safe and effective treatment;
- the potential and perceived advantages of Cend's product candidates over alternative treatments;
- Cend's ability to demonstrate the advantages of its product candidates over other cancer medicines;
- the prevalence and severity of any side effects;
- the prevalence and severity of any side effects for other precision medicines and public perception of other precision medicines;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- limitations or warnings contained in the labeling approved by the FDA;
- the timing of market introduction of Cend's product candidates as well as competitive products;
- the cost of treatment in relation to alternative treatments;
- the availability of adequate coverage, reimbursement and pricing by third-party payors and government authorities;
- the willingness of patients to pay out-of-pocket in the absence of coverage by third-party payors and government authorities;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and
- the effectiveness of Cend's sales and marketing efforts.

If Cend's product candidates are licensed but fail to achieve market acceptance among physicians, patients, hospitals, cancer treatment centers or others in the medical community, Cend will not be able to generate significant revenue.

In addition, although Cend's product candidates differ in certain ways from other approaches, serious adverse events or deaths in other clinical trials involving precision medicines, even if not ultimately attributable to Cend's product or product candidates, could result in increased government regulation, unfavorable public perception and publicity, potential regulatory delays in the testing or licensing of Cend's product candidates, stricter labeling requirements for those product candidates that are licensed, and a decrease in demand for any such product candidates.

Even if Cend's products achieve market acceptance, it may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than its products, are more cost effective or render its products obsolete.

Cend faces substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than it does.

The biotechnology and pharmaceutical industries utilize rapidly advancing technologies and are characterized by intense competition. While Cend believes that its scientific knowledge, technology and development expertise provide it with competitive advantages, it faces potential competition from many different sources, including major pharmaceuticals, specialty pharmaceuticals and biotechnology companies, academic institutions and government agencies, and public and private research institutes that conduct research, development, manufacturing and commercialization. Many of Cend's competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, regulatory approvals and product marketing than it does. Cend's competitors may compete with it 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, Cend's programs. As a result, Cend's competitors may discover, develop, license or commercialize products before or more successfully than it does.

Product candidates that Cend successfully develops and commercializes may compete with existing therapies and new therapies that may become available in the future. Specifically, other EnduRx and potentially other companies are conducting pre-clinical research with an alternative integrin-targeted peptides.

If Cend's drug candidates are approved for the indications for which Cend is currently planning clinical trials, they will likely compete with existing drugs and other drugs that are currently in development. Key product features that would affect Cend's ability to effectively compete with other therapeutics include the efficacy, safety and convenience of its products. Cend's competitors may obtain patent protection or other intellectual property rights that limit its ability to develop or commercialize its product candidates. The availability of reimbursement from government and other third-party payors will also significantly affect the pricing and competitiveness of Cend's products. Cend's competitors may also obtain FDA or other regulatory approval for their products more rapidly than Cend may obtain approval for its products, which could result in Cend's competitors establishing a strong market position before Cend is able to enter the market.

Risks related to Cend's financial position and capital requirements

Cend's limited operating history may make it difficult for you to evaluate the success of Cend's business to date and to assess Cend's future viability.

Cend is a drug discovery and development company with a limited operating history. Cend commenced operations in October 2015, and its operations to date have been limited to organizing and staffing its company, business planning, raising capital, conducting discovery and research activities, filing patent applications, identifying potential product candidates, undertaking preclinical studies and establishing arrangements with third parties for the manufacture of initial quantities of its product candidates and component materials. CEND-1 is currently the subject of Phase 2b clinical studies. Cend has not fully demonstrated its ability to successfully conduct or complete clinical trials, obtain marketing approvals, manufacture a commercial-scale product or arrange for a third party to do so on its behalf, or conduct sales, marketing and distribution activities necessary for successful product commercialization. Consequently, any predictions you make about Cend's future success or viability may not be as accurate as they could be if Cend had a longer operating history.

In addition, as a young business, Cend may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. Cend will need to transition at some point from a company with a research and development focus to a company capable of supporting commercial activities. Cend may not be successful in such a transition.

Cend has incurred significant losses since inception, and it expects to incur losses over the next several years and may not be able to achieve or sustain revenues or profitability in the future.

Investment in pharmaceutical product development is a highly speculative undertaking and entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval and become commercially viable. Cend is still in the early stages of development of its product candidates. CEND-1 is currently the subject of clinical Phase 2b studies. Cend has no products approved for commercial sale and has not generated any revenue from product sales to date, and Cend continues to incur significant research and development and other expenses related to its ongoing operations. Cend has financed its operations primarily through private placements of its preferred stock and its one outbound license relationship. There can be no assurance Cend will be successful at future fund-raising efforts.

Cend has incurred significant net losses in each period since it commenced operations, aside from the year ended December 31, 2021, as a result of a one-time license payment and a milestone payment from the Exclusive License and Collaboration Agreement with Qilu. For the years ended December 31, 2020 and 2021, Cend reported a net loss of $8.7 million and net income of $3.7 million, respectively. As of December 31, 2021, Cend had an accumulated deficit of $10.2 million. Cend expects to continue to incur significant losses for the foreseeable future, and it expects these losses to increase substantially if and as it:

- continues its research and development efforts and submits INDs for its lead product candidates;

- conducts preclinical studies and clinical trials for its current and future product candidates
- seeks marketing approvals for any product candidates that successfully complete clinical trials;
- experiences any delays or encounter any issues with any of the above, including but not limited to failed studies, complex results, safety issues or other regulatory challenges;
- establishes a sales, marketing and distribution infrastructure and scale-up manufacturing capabilities, whether alone or with third parties, to commercialize any product candidates for which it may obtain regulatory approval, if any;
- obtains, expands, maintains, enforces and protects its intellectual property portfolio; and
- hires additional clinical, regulatory and scientific personnel.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, Cend is unable to accurately predict the timing or amount of increased expenses it will incur or when, if ever, it will be able to achieve profitability. Even if Cend succeeds in commercializing one or more of its product candidates, Cend will continue to incur substantial research and development and other expenditures to develop, seek regulatory approval for and market additional product candidates. Cend may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect its business. The size of Cend's future net losses will depend, in part, on the rate of future growth of its expenses and its ability to generate revenue. Cend's prior losses and expected future losses have had and will continue to have an adverse effect on its stockholders' equity and working capital.

Risks related to government regulation

Cend's clinical trials may fail to demonstrate adequately the safety and efficacy of any of its product candidates, which would prevent or delay regulatory approval and commercialization.

To obtain the requisite regulatory approvals to market and sell any of its product candidates, including CEND-1 and any other future product candidates, Cend must demonstrate through extensive preclinical studies and clinical trials that its products are safe and effective in humans. Cend's product candidates may fail to demonstrate efficacy in humans, and particularly across tumor types. 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 and Cend's future clinical trial results may not be successful. Further, the process of obtaining regulatory approval is expensive, often takes many years following the commencement of clinical trials and can vary substantially based upon the type, complexity and novelty of the product candidates involved, as well as the target indications, patient population and regulatory agency. Prior to obtaining approval to commercialize a product candidate in the United States or abroad, Cend or its potential future collaborators must demonstrate with substantial evidence from adequate and well-controlled clinical trials, and to the satisfaction of the FDA, the European Medicines Agency ("EMA") or other comparable foreign regulatory authorities, that such product candidates are safe and effective for their intended uses.

Clinical trials that Cend conducts may not demonstrate the efficacy and safety necessary to obtain regulatory approval to market Cend's product candidates. 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, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants. If the results of Cend's ongoing or future clinical trials are inconclusive with respect to the efficacy of Cend's product candidates, if Cend does not meet the clinical endpoints with statistical and clinically meaningful significance, or if there are safety concerns associated with Cend's product candidates, Cend may be delayed in obtaining marketing approval, if at all.

Even if the trials are successfully completed, clinical data are often susceptible to varying interpretations and analyses, and Cend cannot guarantee that the FDA, or other comparable foreign regulatory authorities will interpret the results as Cend does, and more trials could be required before Cend submits its product candidates for approval. Cend cannot guarantee that the FDA, or other comparable foreign regulatory authorities will view its product candidates as having sufficient efficacy to support a tumor-agnostic indication even if positive results are observed in clinical trials. To the extent that the results of the trials are not satisfactory to the FDA, the EMA or other comparable foreign regulatory authorities for support of a marketing application, approval of Cend's product candidates may be significantly delayed, or Cend may be required to expend significant additional resources, which may not be available to Cend, to conduct additional trials in support of potential approval of Cend's product candidates. Additionally, any safety or efficacy concerns observed in any tumor-specific subgroup of Cend's clinical trials could limit the prospects for regulatory approval of its product candidates for a tumor-agnostic indication, which could have a material adverse effect on Cend's business, financial condition and results of operations.

A Breakthrough Therapy designation by the FDA, even if granted for any of Cend's product candidates, may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that Cend's product candidates will receive marketing approval.

Cend may seek Breakthrough Therapy designation for CEND-1 and some or all of its future product candidates. A breakthrough therapy is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug or biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For product candidates that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA may also be eligible for other expedited approval programs, including accelerated approval.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if Cend believes one of its product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a Breakthrough Therapy designation for a product candidate may not result in a faster development process, review or approval compared to candidate products considered for approval under non-expedited FDA review procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of Cend's product candidates qualify as breakthrough therapies, the FDA may later decide that the product no longer meets the conditions for qualification. Thus, even though Cend intends to seek Breakthrough Therapy designation for CEND-1 and some or all of its future product candidates for the treatment of various cancers, there can be no assurance that it will receive breakthrough therapy designation.

A Fast Track designation by the FDA may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that Cend's product candidates will receive marketing approval.

If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for FDA Fast Track designation for a particular indication. Cend has been granted Fast Track designation for CEND-1 for pancreatic cancer. Cend may seek Fast Track designation for other indications or for certain of Cend's future product candidates, but there is no assurance that the FDA will grant this status to any of Cend's other proposed product candidates. Marketing applications filed by sponsors of products in Fast Track development may qualify for priority review under the policies and procedures offered by the FDA, but the Fast Track designation does not assure any such qualification or ultimate marketing approval by the FDA. The FDA has broad discretion whether or not to grant Fast Track designation, so even if Cend believes a particular product candidate is eligible for this designation, there can be no assurance that the FDA would decide to grant it. Even if Cend does receive Fast Track designation, it may not experience a faster development process, review or approval compared to conventional FDA procedures, and receiving a Fast Track designation does not provide assurance of ultimate FDA approval. In addition, the FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from Cend's clinical development program. In addition, the FDA may withdraw any Fast Track designation at any time.

Accelerated approval by the FDA, even if granted for CEND-1 or any other future product candidates, may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that Cend's product candidates will receive marketing approval.

Cend plans to seek approval of CEND-1 and may seek approval of future product candidates using the FDA's accelerated approval pathway. A product may be eligible for accelerated approval if it treats a serious or life-threatening condition and generally provides a meaningful advantage over available therapies. In addition, it must demonstrate an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. These confirmatory trials must be completed with due diligence. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. Even if Cend does receive accelerated approval, it may not experience a faster development or regulatory review or approval process, and receiving accelerated approval does not provide assurance of ultimate full FDA approval.

Obtaining and maintaining regulatory approval of Cend's product candidates in one jurisdiction does not mean that it will be successful in obtaining regulatory approval of its product candidates in other jurisdictions.

Obtaining and maintaining regulatory approval of Cend's product candidates in one jurisdiction does not guarantee that it will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional non-clinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that Cend intends to charge for its products is also subject to approval.

Cend may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which Cend must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for Cend and could delay or prevent the introduction of its products in certain countries. If Cend fails to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, its target market will be reduced and its ability to realize the full market potential of its product candidates will be harmed.

Risks related to ongoing regulatory obligations

Even if Cend receives regulatory approval of its product candidates, it will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and Cend may be subject to penalties if it fails to comply with regulatory requirements or experience unanticipated problems with its product candidates.

Any regulatory approvals that Cend receives for its product candidates will require surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a REMS in order to approve Cend's product candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves Cend's product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for Cend's product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with applicable cGMP, GLP and GCP requirements, for any clinical trials that Cend conducts post-approval. Later discovery of previously unknown problems with Cend's product candidates, including adverse events of unanticipated severity or frequency, or with Cend's third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of Cend's product candidates, withdrawal of the product from the market or voluntary or mandatory product recalls;
- manufacturing delays and supply disruptions where regulatory inspections identify observations of noncompliance requiring remediation;
- revisions to the labeling, including limitation on approved uses or the addition of additional warnings, contraindications or other safety information, including boxed warnings;
- imposition of a REMS, which may include distribution or use restrictions;
- requirements to conduct additional post-market clinical trials to assess the safety of the product;

- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by Cend or suspension or revocation of approvals;
- product seizure or detention, or refusal to permit the import or export of Cend's product candidates; and
- injunctions or the imposition of civil or criminal penalties.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of Cend's product candidates. Cend cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If Cend is slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if Cend is not able to maintain regulatory compliance, it may lose any marketing approval that it may have obtained and it may not achieve or sustain profitability.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.

If any of Cend's product candidates are approved and Cend is found to have improperly promoted off-label uses of those products, it may become subject to significant liability. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, if approved. In particular, while the FDA permits the dissemination of truthful and non-misleading information about an approved product, a manufacturer may not promote a product for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. If Cend is found to have promoted such off-label uses, it may become subject to significant liability. The federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees, corporate integrity agreements or permanent injunctions under which specified promotional conduct must be changed or curtailed. If Cend cannot successfully manage the promotion of its product candidates, if approved, Cend could become subject to significant liability, which would materially adversely affect its business and financial condition.

The insurance coverage and reimbursement status of newly-approved products is uncertain. Cend's product candidates may become subject to unfavorable pricing regulations, third-party coverage and reimbursement practices, or healthcare reform initiatives, which would harm Cend's business. Failure to obtain or maintain adequate coverage and reimbursement for new or current products could limit Cend's ability to market those products and decrease its ability to generate revenue.

The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drugs vary widely from country to country. In the United States, recently enacted legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, Cend might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay its commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenue it is able to generate from the sale of the product in that country. Adverse pricing limitations may hinder Cend's ability to recoup its investment in one or more product candidates, even if any product candidates it may develop obtain marketing approval.

In the United States and markets in other countries, patients generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Cend's ability to successfully commercialize its product candidates will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. The availability of coverage and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford treatments such as gene therapy products. Sales of these or other product candidates that Cend may identify will depend substantially, both domestically and abroad, on the extent to which the costs of Cend's product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. If coverage and adequate reimbursement is not available, or is available only to limited levels, Cend may not be able to successfully commercialize its product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow Cend to establish or maintain pricing sufficient to realize a sufficient return on its investment.

Reimbursement by a third-party payor may depend upon a number of factors, including, but not limited to, the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. In general, the prices of medicines under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for medicines, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that Cend is able to charge for its product candidates. Accordingly, in markets outside the United States, the reimbursement for products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenues and profits.

There is also significant uncertainty related to the insurance coverage and reimbursement of newly approved products and coverage may be more limited than the purposes for which the medicine is approved by the FDA or comparable foreign regulatory authorities. In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services ("CMS"), an agency within the U.S. Department of Health and Human Services ("HHS"). CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. No uniform policy of coverage and reimbursement for products exists among third-party payors and coverage and reimbursement levels for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time consuming and costly process that may require Cend to provide scientific and clinical support for the use of its products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. It is difficult to predict what CMS will decide with respect to reimbursement for fundamentally novel products such as Cend's. Reimbursement agencies in Europe may be more conservative than CMS. For example, a number of cancer drugs have been approved for reimbursement in the United States and have not been approved for reimbursement in certain European countries. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers Cend's costs, including research, development, manufacture, sale, and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover Cend's costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Cend's inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved products Cend may develop could have a material adverse effect on Cend's operating results, its ability to raise capital needed to commercialize product candidates, and its overall financial condition.

Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Cend's inability to promptly obtain coverage and profitable reimbursement rates third-party payors for any approved products that Cend develops could have a material adverse effect on its operating results, its ability to raise capital needed to commercialize products and its overall financial condition.

Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Cend cannot be sure that reimbursement will be available for any product candidate that it commercializes and, if reimbursement is available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, any product candidate for which Cend obtains marketing approval. In order to obtain reimbursement, physicians may need to show that patients have superior treatment outcomes with Cend's products compared to standard of care drugs, including lower-priced generic versions of standard of care drugs. Cend expects to experience pricing pressures in connection with the sale of any of its product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

Additionally, Cend and/or collaborators may develop companion diagnostic tests for use with Cend's product candidates. Cend, or its collaborators, may be required to obtain coverage and reimbursement for these tests separate and apart from the coverage and reimbursement Cend seeks for its product candidates, once approved. Even if Cend obtains regulatory approval or clearance for such companion diagnostics, there is significant uncertainty regarding its ability to obtain coverage and adequate reimbursement for the same reasons applicable to its product candidates. Medicare reimbursement methodologies, whether under Part A, Part B, or clinical laboratory fee schedule may be amended from time to time, and Cend cannot predict what effect any change to these methodologies would have on any product candidate or companion diagnostic for which it receives approval. Cend's inability to promptly obtain coverage and adequate reimbursement from both third-party payors for the companion diagnostic tests that it develops and for which it obtains regulatory approval could have a material and adverse effect on Cend's business, financial condition, results of operations and prospects.

Healthcare legislative measures aimed at reducing healthcare costs may have a material adverse effect on Cend's business and results of operations.

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of our current product candidates and any future product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell a product for which we obtain marketing approval. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example, changes to our manufacturing arrangements, additions or modifications to product labeling, the recall or discontinuation of our products, or additional record-keeping or reporting requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, the Affordable Care Act substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the U.S. pharmaceutical industry. The ACA, among other things, subjected biological products to potential competition by lower-cost biosimilars, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs and biologics that are inhaled, infused, instilled, implanted or injected, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees and taxes on manufacturers of certain branded prescription drugs and biologics, and created a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% (increased from 50% pursuant to the Bipartisan Budget Act of 2018, effective as of 2019) point-of-sale discounts off negotiated prices of applicable brand drugs and biologics to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs or biologics to be covered under Medicare Part D.

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, re-examining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how other healthcare reform measures of the Biden administration or other efforts, if any, to challenge, repeal or replace the ACA will impact the ACA or our business.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, resulted in reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through June 30, 2022 (a 1% sequester will apply from April 1, 2022 through June 30, 2022) due to the COVID-19 pandemic, unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. As another example, the 2021 Consolidated Appropriations Act signed into law on December 27, 2020 incorporated extensive healthcare provisions and amendments to existing laws, including a requirement that all manufacturers of drugs and biological products covered under Medicare Part B report the product's average sales price, or ASP, to HHS beginning on January 1, 2022, subject to enforcement via civil money penalties.

Further, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. Although a number of these and other measures may require additional authorization to become effective, Congress and the current U.S. administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payors. Moreover, in July 2021, President Biden issued a sweeping executive order on promoting competition in the American economy that includes several mandates pertaining to the pharmaceutical and health care insurance industries. Among other things, the executive order directs the FDA to work towards implementing a system for importing drugs from Canada (following on a Trump administration notice-and-comment rulemaking on Canadian drug importation that was finalized in October 2020). The Biden order also called on HHS to release a comprehensive plan to combat high prescription drug prices, and it includes several directives regarding the Federal Trade Commission's oversight of potentially anticompetitive practices within the pharmaceutical industry. The drug pricing plan released by HHS in September 2021 in response to the executive order makes clear that the Biden Administration supports aggressive action to address rising drug prices, including allowing HHS to negotiate the cost of Medicare Part B and D drugs, but such significant changes will require either new legislation to be passed by Congress or time-consuming administrative actions. Accordingly, there remains a large amount of uncertainty regarding the federal government's approach to making pharmaceutical treatment costs more affordable for patients.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. For example, California requires pharmaceutical manufacturers to notify certain purchasers, including health insurers and government health plans at least 60 days before any scheduled increase in the wholesale acquisition cost (WAC), of their product if the increase exceeds 16%, and further requires pharmaceutical manufacturers to explain whether a change or improvement in the product necessitates such an increase. Similarly, Vermont requires pharmaceutical manufacturers to disclose price information on certain prescription drugs, and to provide notification to the state if introducing a new drug with a WAC in excess of the Medicare Part D specialty drug threshold. In December 2020, the U.S. Supreme Court also held unanimously that federal law does not preempt the states' ability to regulate pharmaceutical benefit managers, or PBMs, and other members of the healthcare and pharmaceutical supply chain, an important decision that may lead to further and more aggressive efforts by states in this area. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our product candidates, if approved, or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects.

Cend expects that the ACA, the recent laws described above, and other healthcare reform measures that may be adopted in the future may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that Cend receives for any approved product. Further, it is possible that additional governmental action will be taken in response to the COVID-19 pandemic. Cend cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our product candidates, if Cend obtains regulatory approval;
- Cend's ability to receive or set a price that it believes is fair for its products;
- Cend's ability to generate revenue and achieve or maintain profitability;
- Cend's ability to enjoy or maintain market exclusivity;
- the level of taxes that Cend is required to pay; and
- the availability of capital.

Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect Cend's future profitability.

Inadequate funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of Cend's business may rely, which could negatively impact Cend's business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect Cend's business. In addition, government funding of the SEC and other government agencies on which Cend's operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. Additionally, as of June 23, 2020, the FDA noted it is continuing to ensure timely reviews of applications for medical products during the COVID-19 pandemic in line with its user fee performance goals; however, FDA may not be able to continue its current pace and approval timelines could be extended, including where a pre-approval manufacturing inspection or an inspection of clinical sites is required and due to the COVID-19 pandemic and travel restrictions FDA is unable to complete such required inspections during the review period. The FDA has developed a rating system to assist in determining when and where it is safest to conduct prioritized domestic inspections. Should FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel, FDA has stated that it generally intends to issue a complete response letter. Further, if there is inadequate information to make a determination on the acceptability of a facility, FDA may defer action on the application until an inspection can be completed. In 2020, several companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. Regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic and may experience delays in their regulatory activities. If a prolonged government shutdown occurs again, it could significantly impact the ability of the FDA to timely review and process Cend's regulatory submissions, which could have a material adverse effect on its business. Further, future government shutdowns could impact Cend's ability to access the public markets and obtain necessary capital in order to properly capitalize and continue its operations.

Cend's employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

Cend is exposed to the risk of fraud or other illegal activity by its employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to: comply with the regulations of the FDA and other similar foreign regulatory authorities, provide true, complete and accurate information to the FDA and other similar foreign regulatory authorities, comply with manufacturing standards Cend has established, comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws or report financial information or data accurately or to disclose unauthorized activities to Cend. If Cend obtains FDA approval of any of its product candidates and begins commercializing those products in the United States, Cend's potential exposure under such laws and regulations will increase significantly, and its costs associated with compliance with such laws and regulations are also likely to increase. These laws may impact, among other things, Cend's current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. The laws that may affect Cend's ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the Federal False Claims Act. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution;

- federal civil and criminal false claims laws and civil monetary penalty laws, including the Federal False Claims Act, which impose criminal and civil penalties, including through civil "qui tam" or "whistleblower" actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid, or other federal health care programs that are false or fraudulent; knowingly making or causing a false statement material to a false or fraudulent claim or an obligation to pay money to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing such an obligation. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The FCA also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery. When an entity is determined to have violated the Federal False Claims Act, the government may impose civil fines and penalties for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;

- HIPAA, which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating HIPAA without actual knowledge of the statute or specific intent to violate it;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;

- the federal Physician Payment Sunshine Act, created under the ACA and its implementing regulations, which require manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to HHS information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Effective January 1, 2022, these reporting obligations extend to include transfers of value made to certain non-physician providers such as physician assistants and nurse practitioners;

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and

- analogous state and foreign laws and regulations, such as state and foreign anti-kickback, false claims, consumer protection and unfair competition laws which may apply to pharmaceutical business practices, including but not limited to, research, distribution, sales and marketing arrangements as well as submitting claims involving healthcare items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government that otherwise restricts payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to file reports with states regarding pricing and marketing information, such as the tracking and reporting of gifts, compensations and other remuneration and items of value provided to healthcare professionals and entities; state and local laws requiring the registration of pharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Cend has adopted a code of business conduct and ethics, but it is not always possible to identify and deter employee misconduct, and the precautions Cend takes to detect and prevent inappropriate conduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting it from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations.

Efforts to ensure that Cend's business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of Cend's business activities could be subject to challenge under one or more of such laws. It is possible that governmental authorities will conclude that Cend's business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If Cend's operations are found to be in violation of any of these laws or any other governmental regulations that may apply to Cend, it may be subject to significant criminal, civil and administrative sanctions including monetary penalties, damages, fines, disgorgement, individual imprisonment, and exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if it becomes subject to a corporate integrity agreement or similar agreement to resolve allegations of noncompliance with these laws, contractual damages, reputational harm, diminished profits and future earnings, and it may be required to curtail or restructure its operations, any of which could adversely affect its ability to operate its business and its results of operations.

Any action against Cend for violation of these laws, even if Cend successfully defends against it, could cause Cend to incur significant legal expenses and divert its management's attention from the operation of its business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and/or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization.

Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

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

Cend is subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Cend's operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Cend's operations also produce hazardous waste products. Cend generally contracts with third parties for the disposal of these materials and wastes. Cend cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from Cend's use of hazardous materials, it could be held liable for any resulting damages, and any liability could exceed its resources. Cend also could incur significant costs associated with civil or criminal fines and penalties.

Although Cend maintains workers' compensation insurance to cover it for costs and expenses it may incur due to injuries to its employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. Cend does not maintain insurance for environmental liability or toxic tort claims that may be asserted against it in connection with its storage or disposal of biological, hazardous or radioactive materials.

Risks related to Cend's reliance on third parties

Cend may form or seek collaborations or strategic alliances or enter into additional licensing arrangements in the future, and it may not realize the benefits of such collaborations, alliances or licensing arrangements.

Cend may form or seek strategic alliances, create joint ventures or collaborations, or enter into additional licensing arrangements with third parties that it believes will complement or augment its development and commercialization efforts with respect to its product candidates and any future product candidates that it may develop. Any of these relationships may require Cend to incur non-recurring and other charges, increase its near and long-term expenditures, issue securities that dilute its existing stockholders or disrupt its management and business.

In addition, Cend faces significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, Cend may not be successful in its efforts to establish a strategic partnership or other alternative arrangements for its product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view Cend's product candidates as having the requisite potential to demonstrate safety, potency, purity and efficacy and obtain marketing approval.

Further, collaborations involving Cend's product candidates are subject to numerous risks, which may include the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration;
- collaborators may not pursue development and commercialization of Cend's product candidates or may elect not to continue or renew development or commercialization of Cend's product candidates based on clinical trial results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;

- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with Cend's product candidates;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to their marketing and distribution;
- collaborators may not properly maintain or defend Cend's intellectual property rights or may use Cend's intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate Cend's intellectual property or proprietary information or expose Cend to potential liability;
- disputes may arise between Cend and a collaborator that cause the delay or termination of the research, development or commercialization of Cend's product candidates, or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates; and
- collaborators may own or co-own intellectual property covering Cend's products that results from Cend's collaborating with them, and in such cases, Cend would not have the exclusive right to commercialize such intellectual property.

As a result, if Cend enters into additional collaboration agreements and strategic partnerships or licenses its product candidates, it may not be able to realize the benefit of such transactions if it is unable to successfully integrate them with its existing operations and company culture, which could delay its timelines or otherwise adversely affect its business. Cend also cannot be certain that, following a strategic transaction or license, it will achieve the revenue or specific net income that justifies such transaction. Any delays in entering into new collaborations or strategic partnership agreements related to Cend's product candidates could delay the development and commercialization of its product candidates in certain geographies for certain indications, which would harm its business prospects, financial condition and results of operations.

Cend plans to rely on third parties to conduct its preclinical studies and clinical trials. If these third parties do not properly and successfully carry out their contractual duties or meet expected deadlines, Cend may not be able to obtain regulatory approval of or commercialize its product candidates.

Cend plans to utilize and depend upon independent investigators and collaborators, such as medical institutions, CROs, contract manufacturing organizations, or CMOs, and strategic partners to conduct and support its preclinical studies and clinical trials under agreements with it. For example, Cend contracts with Bachem Americas for Drug Substance manufacture, and Alcami for Drug Product manufacture.

Cend expects to have to negotiate budgets and contracts with CROs, trial sites and CMOs and may not be able to do so on favorable terms, which may result in delays to Cend's development timelines and increased costs. Cend will rely heavily on these third parties over the course of its preclinical studies and clinical trials, and Cend controls only certain aspects of their activities. As a result, Cend will have less direct control over the conduct, timing and completion of these preclinical studies and clinical trials and the management of data developed through preclinical studies and clinical trials than would be the case if it were relying entirely upon its own staff.

Nevertheless, Cend is responsible for ensuring that each of its studies is conducted in accordance with applicable protocol, legal and regulatory requirements and scientific standards, and its reliance on third parties does not relieve Cend of its regulatory responsibilities. Cend and these third parties are required to comply with GCPs, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If Cend or any of these third parties fail to comply with applicable GCP regulations, the clinical data generated in Cend's clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require Cend to perform additional clinical trials before approving Cend's marketing applications. Cend cannot assure you that, upon inspection, such regulatory authorities will determine that any of its clinical trials comply with the GCP regulations. In addition, Cend's clinical trials must be conducted with pharmaceutical product produced under cGMP regulations and will require a large number of test patients. Cend's failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, Cend's business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Any third parties conducting Cend's clinical trials are not and will not be Cend's employees and, except for remedies available to Cend under its agreements with such third parties, Cend cannot control whether or not they devote sufficient time and resources to Cend's ongoing, clinical and non-clinical product candidates. These third parties may also have relationships with other commercial entities, including Cend's competitors, for whom they may also be conducting clinical trials or other drug development activities, which could affect their performance on Cend's behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to Cend's clinical protocols or regulatory requirements or for other reasons, Cend's clinical trials may be extended, delayed or terminated and Cend may not be able to complete development of, obtain regulatory approval of or successfully commercialize its product candidates. As a result, Cend's financial results and the commercial prospects for Cend's product candidates would be harmed, Cend's costs could increase and Cend's ability to generate revenue could be delayed.

Switching or adding third parties to conduct Cend's preclinical studies and clinical trials involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays occur, which can materially impact Cend's ability to meet its desired clinical development timelines.

Cend's manufacturing process needs to comply with FDA regulations relating to the quality and reliability of such processes. Any failure to comply with relevant regulations could result in delays in or termination of Cend's clinical programs and suspension or withdrawal of any regulatory approvals.

In order to commercially produce Cend's products either at Cend's own facility or at a third party's facility, Cend will need to comply with the FDA's cGMP regulations and guidelines. Cend may encounter difficulties in achieving quality control and quality assurance and may experience shortages in qualified personnel. Cend is subject to inspections by the FDA and comparable foreign regulatory authorities to confirm compliance with applicable regulatory requirements. Any failure to follow cGMP or other regulatory requirements or delay, interruption or other issues that arise in the manufacture, fill-finish, packaging, or storage of Cend's precision medicines as a result of a failure of Cend's facilities or the facilities or operations of third parties to comply with regulatory requirements or pass any regulatory authority inspection could significantly impair Cend's ability to develop and commercialize Cend's product candidates, including leading to significant delays in the availability of Cend's precision medicines for Cend's clinical trials or the termination of or suspension of a clinical trial, or the delay or prevention of a filing or approval of marketing applications for Cend's product candidates. Significant non-compliance could also result in the imposition of sanctions, including warning or untitled letters, fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approvals for Cend's product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could damage Cend's reputation and Cend's business.

If Cend's third-party manufacturers use hazardous and biological materials in a manner that causes injury or violates applicable law, Cend may be liable for damages.

Cend's research and development activities involve the controlled use of potentially hazardous substances, including chemical and biological materials, by Cend's third-party manufacturers. Cend's manufacturers are subject to federal, state and local laws and regulations in the United States governing the use, manufacture, storage, handling and disposal of medical and hazardous materials. Although Cend believes that its manufacturers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, Cend cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, Cend may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt Cend's business operations. In the event of an accident, Cend could be held liable for damages or penalized with fines, and the liability could exceed Cend's resources. Cend does not have any insurance for liabilities arising from medical or hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair Cend's research, development and production efforts, which could harm its business, prospects, financial condition or results of operations.

Risks related to managing growth and employee matters

Cend is highly dependent on its key personnel and anticipate hiring new key personnel. If Cend is not successful in attracting and retaining highly qualified personnel, it may not be able to successfully implement its business strategy.

Cend's ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon its ability to attract and retain highly qualified managerial, scientific and medical personnel. Cend is highly dependent on its management, scientific and medical personnel, including Cend's Scientific Founder and Chairman, Erkki Ruoslahti, MD, David Slack, Cend's President and CEO, and Harri Järveläinen, our Chief Operating Officer. Erkki Ruoslahti, MD is not Cend's employee and provides services primarily as a consultant and a member of the Cend Board of Directors. In addition, the loss of the services of any of Cend's executive officers, other key employees and other scientific and medical advisors, and an inability to find suitable replacements could result in delays in product development and harm Cend's business.

Cend will need to grow the size of its organization, and may experience difficulties in managing this growth.

As of December 31, 2021 Cend had three full-time employees. Cend intends to hire new employees to conduct its research and development activities/administrative/scientific in the future. Any delay in hiring such new employees could result in delays in Cend's research and development activities and would harm Cend's business. As Cend's development and commercialization plans and strategies develop, and as Cend transitions into operating as a public company, Cend expects to need additional managerial, operational, sales, marketing, financial and other personnel, as well as additional facilities to expand its operations. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- Advance applications of Cend's drug discovery and development platform;
- managing Cend's internal development efforts effectively, including the clinical and FDA review process for Cend's product candidates, while complying with Cend's contractual obligations to contractors and other third parties; and
- improving Cend's operational, financial and management controls, reporting systems and procedures.

Cend's future financial performance and Cend's ability to commercialize Cend's product candidates will depend, in part, on its ability to effectively manage any future growth, and Cend's management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

Cend currently relies, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services, including substantially all aspects of regulatory approval, clinical trial management and manufacturing. There can be no assurance that the services of independent organizations, advisors and consultants will continue to be available to Cend on a timely basis when needed, or that Cend can find qualified replacements. In addition, if Cend is unable to effectively manage Cend's outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, Cend's clinical trials may be extended, delayed or terminated, and it may not be able to obtain regulatory approval of its product candidates or otherwise advance its business. There can be no assurance that Cend will be able to manage its existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If Cend is not able to effectively expand its organization by hiring new employees and expanding its groups of consultants and contractors, or it is not able to effectively build out new facilities to accommodate this expansion, it may not be able to successfully implement the tasks necessary to further develop and commercialize its product candidates and, accordingly, may not achieve its research, development and commercialization goals.

If product liability lawsuits are brought against Cend, it may incur substantial liabilities and may be required to limit commercialization of its product candidates.

Cend faces an inherent risk of product liability as a result of the planned clinical testing of its product candidates and will face an even greater risk if it commercializes any products. For example, Cend may be sued if its product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If Cend cannot successfully defend itself against product liability claims, it may incur substantial liabilities or be required to limit commercialization of its product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for Cend's product candidates or products that it may develop;
- injury to Cend's reputation;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and Cend's resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and Cend's capital resources;
- the inability to commercialize any product candidate; and
- a decline in share price.

Failure to obtain or retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products Cend develops, alone or with corporate collaborators. Although Cend has clinical trial insurance, Cend's insurance policies also have various exclusions, and it may be subject to a product liability claim for which it has no coverage. Cend may have to pay any amounts awarded by a court or negotiated in a settlement that exceed its coverage limitations or that are not covered by its insurance, and it may not have, or be able to obtain, sufficient capital to pay such amounts. Even if Cend's agreements with any future corporate collaborators entitle it to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

General risk factors

Data collection is governed by restrictive regulations governing the use, storage, processing and transfer of personal information.

In the event Cend decides to conduct clinical trials or continue to enroll subjects in its ongoing or future clinical trials, it may be subject to additional privacy restrictions. The collection, use, storage, disclosure, transfer, or other processing of personal data is subject to the California Consumer Privacy Act, or CCPA, which creates new individual privacy rights for California consumers (as defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA requires covered companies to provide new disclosure to consumers about such companies' data collection, use and sharing practices, provide such consumers new ways to opt-out of certain sales or transfers of personal information, and provide consumers with additional causes of action. The CCPA went into effect on January 1, 2020, and the California Attorney General commenced enforcement actions for violations beginning July 1, 2020. The CCPA was amended on September 23, 2018, and it remains unclear what, if any, further modifications will be made to this legislation or how it will be interpreted. As currently written, the CCPA may impact Cend's business activities and exemplifies the vulnerability of Cend's business to the evolving regulatory environment related to personal data and protected health information.

Compliance with U.S. and international data protection laws and regulations could require Cend to take on more onerous obligations in its contracts, restrict its ability to collect, use and disclose data, or in some cases, impact its ability to operate in certain jurisdictions. Failure to comply with U.S. and international data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation or adverse publicity and could negatively affect Cend's operating results and business. Moreover, clinical trial subjects about whom Cend or its potential collaborators obtain information, as well as the providers who share this information with Cend, may contractually limit Cend's ability to use and disclose the information. Claims that Cend has violated individuals' privacy rights, failed to comply with data protection laws, or breached Cend's contractual obligations, even if Cend is not found liable, could be expensive and time consuming to defend and could result in adverse publicity that could harm Cend's business.

Cend may be unable to adequately protect its information systems from cyberattacks, which could result in the disclosure of confidential or proprietary information, including personal data, damage Cend's reputation, and subject Cend to significant financial and legal exposure.

Cend relies on information technology systems that it or its third-party providers operate to process, transmit and store electronic information in Cend's day-to-day operations. In connection with Cend's product discovery efforts, Cend may collect and use a variety of personal data, such as name, mailing address, email addresses, phone number and clinical trial information. A successful cyberattack could result in the theft or destruction of intellectual property, data, or other misappropriation of assets, or otherwise compromise Cend's confidential or proprietary information and disrupt Cend's operations. Cyberattacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. Cyberattacks could include wrongful conduct by hostile foreign governments, industrial espionage, wire fraud and other forms of cyber fraud, the deployment of harmful malware, denial-of-service, social engineering fraud or other means to threaten data security, confidentiality, integrity and availability. A successful cyberattack could cause serious negative consequences for us, including, without limitation, the disruption of operations, the misappropriation of confidential business information, including financial information, trade secrets, financial loss and the disclosure of corporate strategic plans. Although Cend devotes resources to protect its information systems, Cend realizes that cyberattacks are a threat, and there can be no assurance that its efforts will prevent information security breaches that would result in business, legal, financial or reputational harm to Cend, or would have a material adverse effect on its results of operations and financial condition. Any failure to prevent or mitigate security breaches or improper access to, use of, or disclosure of Cend's clinical data or patients' personal data could result in significant liability under state (*e.g.*, state breach notification laws), federal (*e.g.*, HIPAA, as amended by HITECH), and international law (*e.g.*, the GDPR) and may cause a material adverse impact to Cend's reputation, affect Cend's ability to conduct new studies and potentially disrupt Cend's business.

In addition, the computer systems of various third parties on which Cend relies, and other contractors, consultants and law and accounting firms, may sustain damage from computer viruses, unauthorized access, data breaches, phishing attacks, cybercriminals, natural disasters (including hurricanes and earthquakes), terrorism, war and telecommunication and electrical failures. Cend relies on its third-party providers to implement effective security measures and identify and correct for any such failures, deficiencies or breaches. If Cend or its third-party providers fail to maintain or protect Cend's information technology systems and data integrity effectively or fail to anticipate, plan for or manage significant disruptions to Cend's information technology systems, Cend or its third-party providers could have difficulty preventing, detecting and controlling such cyber-attacks and any such attacks could result in losses described above as well as disputes with physicians, patients and Cend's partners, regulatory sanctions or penalties, increases in operating expenses, expenses or lost revenues or other adverse consequences, any of which could have a material adverse effect on Cend's business, results of operations, financial condition, prospects and cash flows. Any failure by such third parties to prevent or mitigate security breaches or improper access to or disclosure of such information could have similarly adverse consequences for us. If Cend is unable to prevent or mitigate the impact of such security or data privacy breaches, it could be exposed to litigation and governmental investigations, which could lead to a potential disruption to its business.

Risks Related to the Combined Company

In determining whether you should approve the issuance of shares of Caladrius Common Stock and other matters related to the Merger, as applicable, you should carefully read the following risk factors in addition to the risks described above.

The market price of the Caladrius Common Stock is expected to be volatile, and the market price of the Caladrius Common Stock may drop following the Merger.

The market price of the Caladrius Common Stock following the Merger could be subject to significant fluctuations. Some of the factors that may cause the market price of the Caladrius Common Stock to fluctuate include:

- results of clinical trials and preclinical studies of the combined company's product candidates, or those of the combined company's competitors or the combined company's existing or future collaborators;

- failure to meet or exceed financial and development projections the combined company may provide to the public;
- failure to meet or exceed the financial and development projections of the investment community;
- if the combined company does not achieve the perceived benefits of the Merger as rapidly or to the extent anticipated by financial or industry analysts;
- announcements of significant acquisitions, strategic collaborations, joint ventures or capital commitments by the combined company or its competitors;
- actions taken by regulatory agencies with respect to the combined company's product candidates, clinical studies, manufacturing process or sales and marketing terms;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and the combined company's ability to obtain patent protection for its technologies;
- additions or departures of key personnel;
- significant lawsuits, including patent or stockholder litigation;
- if securities or industry analysts do not publish research or reports about the combined company's business, or if they issue adverse or misleading opinions regarding its business and stock;
- changes in the market valuations of similar companies;
- general market or macroeconomic conditions or market conditions in the pharmaceutical and biotechnology sectors;
- sales of securities by the combined company or its securityholders in the future;
- if the combined company fails to raise an adequate amount of capital to fund its operations and continued development of its product candidates;
- trading volume of the Caladrius Common Stock;
- announcements by competitors of new commercial products, clinical progress or lack thereof, significant contracts, commercial relationships or capital commitments;
- adverse publicity relating to precision medicine product candidates, including with respect to other products in such markets;
- the introduction of technological innovations or new therapies that compete with the products and services of the combined company; and
- period-to-period fluctuations in the combined company's financial results.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of the Caladrius Common Stock. In addition, a recession, depression or other sustained adverse market event resulting from the spread of COVID-19 or otherwise could materially and adversely affect the combined company's business and the value of its common stock. In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against such companies. Furthermore, market volatility may lead to increased shareholder activism if the combined company experiences a market valuation that activists believe is not reflective of its intrinsic value. Activist campaigns that contest or conflict with the combined company's strategic direction or seek changes in the composition of its board of directors could have an adverse effect on its operating results and financial condition.

Following the Merger, the combined company may be unable to integrate successfully and realize the anticipated benefits of the Merger.

The Merger involves the combination of two companies which currently operate as independent companies. The combined company may fail to realize some or all of the anticipated benefits of the Merger if the integration process takes longer than expected or is more costly than expected. In addition, Caladrius and Cend have operated and, until the completion of the Merger, will continue to operate, independently. It is possible that the integration process also could result in the diversion of each company's management's attention, the disruption or interruption of, or the loss of momentum in, each company's ongoing businesses or inconsistencies in standards, controls, procedures and policies, any of which could adversely affect the combined company's ability to maintain relationships with customers, suppliers and employees or the ability to achieve the anticipated benefits of the Merger, or could otherwise adversely affect the business and financial results of the combined company.

The combined company will need substantial additional funding before it can complete the development of its product candidates. If the combined company is unable to obtain such additional capital on favorable terms, on a timely basis or at all, it would be forced to delay, reduce or eliminate its product development and clinical programs and may not have the capital required to otherwise operate its business.

Developing cancer therapies and cell therapy products, including conducting pre-clinical studies and clinical trials and establishing manufacturing capabilities, is expensive. The combined company has not generated any revenues from the commercial sale of products and will not be able to generate any product revenues until, and only if, the combined company receives approval to sell its product candidates from the FDA or other regulatory authorities. The cash expected from both Caladrius and Cend at closing are expected to fund the further development of the combined company's programs and operate the combined company into early 2023. However, as the combined company has not generated any revenue from commercial sales to date and does not expect to generate any revenue for several years, if ever, the combined company will need to raise substantial additional capital in order to fund its general corporate activities and to fund its research and development, including its currently planned clinical trials and plans for new clinical trials and product development.

The combined company may seek to raise additional funds through various potential sources, such as equity and debt financings, or through strategic collaborations and license agreements. The combined company can give no assurances that it will be able to secure such additional sources of funds to support its operations or, if such funds are available, that such additional financing will be sufficient to meet its needs. Moreover, to the extent that the combined company raises additional funds by issuing equity securities, its stockholders may experience additional significant dilution, and debt financing, if available, may involve restrictive covenants. To the extent that the combined company raises additional funds through collaboration and licensing arrangements, it may be necessary to relinquish some rights to its technologies or product candidates, or grant licenses on terms that may not be favorable.

Given the combined company's capital constraints, it will need to prioritize spending on its clinical and pre-clinical programs. If the combined company is unable to raise sufficient funds to support its current and planned operations, it may elect to discontinue certain of its ongoing activities or programs. The combined company's inability to raise additional funds could also prevent it from taking advantage of opportunities to pursue promising new or existing programs in the future.

The combined company's forecasts regarding its beliefs in the sufficiency of its financial resources to support its current and planned operations are forward-looking statements and involve significant risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed elsewhere in this "*Risk Factors*" section. These estimates are based on assumptions that may prove to be wrong, and the combined company could utilize its available capital resources sooner than currently expected.

The combined company may be exposed to increased litigation, including stockholder litigation, which could have an adverse effect on the combined company's business and operations.

The combined company may be exposed to increased litigation from stockholders, customers, suppliers, consumers and other third parties due to the combination of Caladrius' business and Cend's business following the Merger. Such litigation may have an adverse impact on the combined company's business and results of operations or may cause disruptions to the combined company's operations. In addition, in the past, stockholders have initiated class action lawsuits against biotechnology companies following periods of volatility in the market prices of these companies' stock. Such litigation, if instituted against the combined company, could cause the combined company to incur substantial costs and divert management's attention and resources, which could have a material adverse effect on the combined company's business, financial condition and results of operations.

The combined company may be exposed to continued litigation. Such lawsuits, if remaining outstanding following the closing, could cause the combined company to incur substantial costs and divert management's attention and resources, which could have a material adverse effect on the combined company's business, financial condition and results of operations.

The unaudited pro forma condensed combined financial data for Caladrius and Cend included herein is preliminary, and the combined company's actual financial position and operations after the Merger may differ materially from the unaudited pro forma financial data included herein.

The unaudited pro forma financial data for Caladrius and Cend included herein is presented for illustrative purposes only and is not necessarily indicative of the combined company's actual financial condition or results of operations of future periods, or the financial condition or results of operations that would have been realized had the entities been combined during the periods presented. The unaudited pro forma financial statements have been derived from the historical financial statements of Caladrius and Cend and adjustments and assumptions have been made regarding the combined company after giving effect to the transaction. The information upon which these adjustments and assumptions have been made is preliminary, and these kinds of adjustments and assumptions are difficult to make with accuracy. Moreover, the unaudited pro forma financial statements do not reflect all costs that are expected to be incurred by the combined company in connection with the transactions or that have been incurred since the date of such unaudited pro forma financial statements. The assumptions used in preparing the unaudited pro forma financial information may not prove to be accurate, and other factors may affect the combined company's financial condition following the transaction.

Anti-takeover provisions in the combined organization's charter documents and under Delaware law could make the acquisition of the combined organization more difficult and may prevent attempts by the combined organization's stockholders to replace or remove the combined organization's management.

Provisions in the combined organization's certificate of incorporation and bylaws may delay or prevent an acquisition or a change in management. These provisions include a classified board of directors, a prohibition on actions by written consent of the combined organization's stockholders, and the ability of the board of directors to issue preferred stock without stockholder approval. In addition, because the combined organization will be incorporated in Delaware, it is governed by the provisions of Section 203 of the DGCL, which prohibits stockholders owning in excess of 15% of the outstanding combined organization's voting stock from merging or combining with the combined organization. Although Caladrius and Cend believe these provisions collectively will provide for an opportunity to receive higher bids by requiring potential acquirers to negotiate with the combined organization's board of directors, they would apply even if the offer may be considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by the combined organization's stockholders to replace or remove then current management by making it more difficult for stockholders to replace members of the board of directors, which is responsible for appointing the members of management.

Caladrius and Cend do not anticipate the combined organization will pay any cash dividends in the foreseeable future.

The current expectation is the combined organization will retain its future earnings to fund the development and growth of the combined organization's business. As a result, capital appreciation, if any, of the Caladrius Common Stock will be your sole source of gain, if any, for the foreseeable future.

Future sales of shares by existing stockholders could cause the Caladrius Common Stock price to decline.

If existing securityholders of Caladrius and Cend sell, or indicate an intention to sell, substantial amounts of the Caladrius Common Stock in the public market after legal restrictions on resale discussed herein lapse, the trading price of the Caladrius Common Stock could decline. Based on shares outstanding as of June 13, 2022 and approximately 60,518,478 shares of Caladrius Common Stock expected to be issued upon completion of the Merger, the combined company is expected to have outstanding, a total of approximately 121,036,956 shares of Caladrius Common Stock immediately following the completion of the Merger. Of the shares of Caladrius Common Stock, approximately 19,747,081 shares will be available for sale in the public market beginning 120 days after the closing of the Merger as a result of the expiration of lock-up agreements between Caladrius and Cend on the one hand and certain securityholders of Caladrius and Cend on the other hand. All other outstanding shares of Caladrius Common Stock, other than shares held by affiliates of the combined company, will be freely tradable, without restriction, in the public market. In addition, shares of Caladrius Common Stock that are subject to outstanding options of Cend will become eligible for sale in the public market to the extent permitted by the provisions of various vesting agreements and Rules 144 and 701 under the Securities Act. If these shares are sold, the trading price of the Caladrius Common Stock could decline.

If the ownership of the Caladrius Common Stock is highly concentrated, it may prevent you and other stockholders from influencing significant corporate decisions and may result in conflicts of interest that could cause the combined organization's stock price to decline.

Executive officers and directors of the combined organization, and affiliates of executive officers and directors of the combined organization, are expected to beneficially own or control approximately 21.6% of the outstanding shares of the Caladrius Common Stock following the completion of the Merger. Accordingly, these executive officers, directors, and their affiliates, acting as a group, will have substantial influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, any merger, consolidation, or sale of all or substantially all of the combined organization's assets or any other significant corporate transactions. These stockholders may also delay or prevent a change of control of the combined organization, even if such a change of control would benefit the other stockholders of the combined organization. The significant concentration of stock ownership may adversely affect the trading price of Caladrius Common Stock due to investors' perception that conflicts of interest may exist or arise.

If the combined organization fails to maintain proper and effective internal controls, the combined organization's ability to produce accurate and timely financial statements could be impaired, which could harm its operating results, its ability to operate its business and investors' views of the combined organization.

The combined organization will be required to comply with Section 404 of the Sarbanes-Oxley Act. Section 404 of the Sarbanes-Oxley Act requires public companies to conduct an annual review and evaluation of their internal controls and attestations of the effectiveness of internal controls by independent auditors. Ensuring that the combined organization has adequate internal financial and accounting controls and procedures in place so that it can produce accurate financial statements on a timely basis is a costly and time-consuming effort that will need to be evaluated frequently. The combined organization's failure to maintain the effectiveness of its internal controls in accordance with the requirements of the Sarbanes-Oxley Act could have a material adverse effect on its business. The combined organization could lose investor confidence in the accuracy and completeness of its financial reports, which could have an adverse effect on the price of its common stock. In addition, if the combined organization's efforts to comply with new or changed laws, regulations, and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against the combined organization and its business may be harmed.

If securities or industry analysts do not publish, or cease publishing, research or reports about the combined organization, its business or its market, or if they change their recommendations regarding the Caladrius Common Stock adversely, the Caladrius Common Stock price and trading volume could decline.

If a trading market for the combined organization's Caladrius Common Stock develops, the trading market for its Caladrius Common Stock will be influenced by whether industry or securities analysts publish research and reports about the combined organization, its business, its market or its competitors and, if any analysts do publish such reports, what they publish in those reports. The combined organization may not obtain analyst coverage in the future. Any analysts that do cover the combined organization may make adverse recommendations regarding the Caladrius Common Stock, adversely change their recommendations from time to time, and/or provide more favorable relative recommendations about the combined organization's competitors. If any analyst who may cover the combined organization in the future were to cease coverage of the combined organization or fail to regularly publish reports on the combined organization, or if analysts fail to cover the combined organization or publish reports about the combined organization at all, the combined organization could lose, or never gain, visibility in the financial markets, which in turn could cause the stock price or trading volume of the Caladrius Common Stock to decline.

Caladrius' ability to utilize its net operating loss carryforwards and tax credit carryforwards may be subject to limitations.

Caladrius' ability to use its federal and state net operating losses ("NOLs") to offset potential future taxable income and related income taxes that would otherwise be due is dependent upon the combined company's generation of future taxable income, and Caladrius and Cend cannot predict with certainty when, or whether, the combined company will generate sufficient taxable income to use all of its NOLs.

Under Section 382 and Section 383 of the Code and corresponding provisions of state law, if a corporation undergoes an “ownership change,” its ability to use its pre-change NOL carryforwards and other pre-change tax attributes (such as research tax credits) to offset its post-change income may be limited. A Section 382 “ownership change” is generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period. Cend may have experienced ownership changes in the past, may experience an ownership change as a result of the Merger, and may experience ownership changes in the future due to subsequent shifts in the combined company’s stock ownership (some of which are outside of its control). Furthermore, the Merger, if consummated, may constitute an ownership change (within the meaning of Section 382 of the Code) of Caladrius which could eliminate or otherwise substantially limit the combined company’s ability to use Caladrius’ federal and state NOLs to offset its future taxable income. Consequently, even if the combined company achieves profitability, it may not be able to utilize a material portion of Cend’s, Caladrius’ or the combined company’s NOL carryforwards and other tax attributes, which could have a material adverse effect on cash flow and results of operations. Similar provisions of state tax law may also apply to limit the combined company’s use of accumulated state tax attributes. There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs, or other unforeseen reasons, the combined company’s existing NOLs could expire or otherwise be unavailable to offset future income tax liabilities.

Exhibit 99.3

CEND THERAPEUTICS, INC.

INDEX TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

CEND THERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(IN THOUSANDS, EXCEPT SHARE AND PAR VALUE AMOUNTS)

	December 31, 2021	June 30, 2022
Assets		
Current assets:		
Cash	$ 6,288	$ 11,202
Tax incentive receivable	509	879
Other current assets (including related party amounts of $14 and $9, respectively)	690	1,610
Total current assets	7,487	13,691
Total assets	$ 7,487	$ 13,691
Liabilities, convertible preferred stock, and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable (including related party amounts of $0 and $10, respectively)	$ 259	$ 303
Accrued expenses (including related party amounts of $27 and $17, respectively)	535	1,165
Other current liabilities	66	210
Total current liabilities	860	1,678
Other long-term liabilities	216	22
Total liabilities	1,076	1,700
Commitments and contingencies (Note 7)		
Redeemable convertible preferred stock:		
Series A redeemable convertible preferred stock, $0.00001 par value; 371,396 shares authorized as of December 31, 2021 and June 30, 2022; 371,396 shares issued and outstanding as of December 31, 2021 and June 30, 2022; $1.1 million liquidation preference as of December 31, 2021 and June 30, 2022	1,100	1,100
Series B redeemable convertible preferred stock, $0.00001 par value; 1,250,304 and 1,071,240 shares authorized as of December 31, 2021 and June 30, 2022, respectively; 1,071,237 shares issued and outstanding as of December 31, 2021 and June 30, 2022; $3.9 million liquidation preference as of December 31, 2021 and June 30, 2022	3,941	3,941
Stockholders' equity (deficit):		
Series C convertible preferred stock, $0.00001 par value; 1,478,807 and 1,345,700 shares authorized as of December 31, 2021 and June 30, 2022, respectively; 1,345,699 shares issued and outstanding as of December 31, 2021 and June 30, 2022; $7.3 million liquidation preference as of December 31, 2021 and June 30, 2022	-	-
Series D convertible preferred stock, $0.00001 par value; 0 and 1,135,650 shares authorized as of December 31, 2021 and June 30, 2022; 0 and 1,135,628 shares issued and outstanding as of December 31, 2021 and June 30, 2022; $0 and $10 million liquidation preference as of December 31, 2021 and June 30, 2022	-	-
Common stock, $0.00001 par value; 10,500,000 and 11,500,000 shares authorized as of December 31, 2021 and June 30, 2022, respectively; 4,279,705 shares issued and outstanding as of December 31, 2021 and June 30, 2022	-	-
Additional paid-in capital	11,656	21,982
Accumulated other comprehensive loss	(79)	(135)
Accumulated deficit	(10,207)	(14,897)
Total stockholders' equity	1,370	6,950
Total liabilities, convertible preferred stock, and stockholders' equity	$ 7,487	$ 13,691

See accompanying notes to the condensed consolidated financial statements.

CEND THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(IN THOUSANDS, EXCEPT SHARE AND PAR VALUE AMOUNTS)

	Six Months Ended June 30,	
	2021	**2022**
Net revenues	$ 9,736	$ 591
Operating expenses:		
Research and development (including related party amounts of $2,545 and $72, respectively)	3,865	3,572
In-process research and development (including related party amounts of $128 and $0, respectively)	520	-
General and administrative	531	1,709
Total operating expenses	4,916	5,281
Operating income (loss)	4,820	(4,690)
Income (loss) before income taxes	4,820	(4,690)
Income tax expense	169	-
Net income (loss)	$ 4,651	$ (4,690)
Income allocable to participating securities	$ (1,816)	$ -
Net income (loss) attributable to common shareholders	$ 2,835	$ (4,690)
Net income (loss) per share attributable to common shareholders:		
Basic	$ 0.68	$ (1.10)
Diluted	$ 0.60	$ (1.10)
Weighted-average common shares outstanding:		
Basic	4,196,716	4,279,705
Diluted	5,052,147	4,279,705

See accompanying notes to the condensed consolidated financial statements.

CEND THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)
(IN THOUSANDS)

	Six Months Ended June 30,	
	2021	**2022**
Net income (loss)	$ 4,651	$ (4,690)
Cumulative translation adjustment arising during the period	(72)	(56)
Comprehensive income (loss)	$ 4,579	$ (4,746)

See accompanying notes to the condensed consolidated financial statements.

CEND THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)
(IN THOUSANDS, EXCEPT SHARE AMOUNTS)

	Series A Redeemable Convertible Preferred Stock		Series B Redeemable Convertible Preferred Stock		Series C Convertible Preferred Stock		Series D Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Balance as of December 31, 2020	371,396	$ 1,100	1,071,237	$ 3,941	1,212,609	$ -	-	$ -	4,168,705	$ -	$ 9,917	$ 40	$ (13,946)	$ (3,989)
Issuance of Series C convertible preferred stock	-	-	-	-	66,545	-	-	-	-	-	520	-	-	520
Stock-based compensation expense	-	-	-	-	-	-	-	-	-	-	185	-	-	185
Exercise of stock options	-	-	-	-	-	-	-	-	30,000	-	-	-	-	-
Net income	-	-	-	-	-	-	-	-	-	-	-	-	4,651	4,651
Foreign currency translation adjustment	-	-	-	-	-	-	-	-	-	-	-	(72)	-	(72)
Balance at June 30, 2021	371,396	$ 1,100	1,071,237	$ 3,941	1,279,154	$ -	-	$ -	4,198,705	$ -	$ 10,622	$ (32)	$ (9,295)	$ 1,295
Balance at December 31, 2021	371,396	$ 1,100	1,071,237	$ 3,941	1,345,699	$ -	-	$ -	4,279,705	$ -	$ 11,656	$ (79)	$ (10,207)	$ 1,370
Issuance of Series D convertible preferred stock	-	-	-	-	-	-	1,135,628	-	-	-	10,000	-	-	10,000
Stock-based compensation expense	-	-	-	-	-	-	-	-	-	-	326	-	-	326
Net income	-	-	-	-	-	-	-	-	-	-	-	-	(4,690)	(4,690)
Foreign currency translation adjustment	-	-	-	-	-	-	-	-	-	-	-	(56)	-	(56)
Balance at June 30, 2022	371,396	$ 1,100	1,071,237	$ 3,941	1,345,699	$ -	1,135,628	$ -	4,279,705	$ -	$ 21,982	$ (135)	$ (14,897)	$ 6,950

See accompanying notes to the condensed consolidated financial statements.

CEND THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(IN THOUSANDS)

	Six Months Ended June 30,	
	2021	**2022**
Cash flows from operating activities:		
Net income (loss)	$ 4,651	$ (4,690)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Stock-based compensation	185	326
In-process research and development expenses	520	-
Changes in operating assets and liabilities:		
Tax benefit receivable	(254)	(396)
Other current assets	(608)	(925)
Other current liabilities	(19)	144
Other long-term liabilities	281	(194)
Accounts payable	59	51
Accrued expenses	68	632
Net cash provided by (used in) operating activities	4,883	(5,052)
Cash flows from financing activities:		
Proceeds form issuance of Series D convertible preferred stock	-	10,000
Net cash provided by financing activities	-	10,000
Effect of exchange rate changes on cash	(56)	(34)
Net increase in cash	4,827	4,914
Cash at beginning of period	684	6,288
Cash at end of period	$ 5,511	$ 11,202
Supplemental noncash financing activities		
Issuance of Series C convertible preferred stock in connnection with in-process research and development	$ 520	$ -

See accompanying notes to the condensed consolidated financial statements.

1. Organization and Description of Business

Cend Therapeutics, Inc. (the "Company" or "Cend"), headquartered in San Diego, California, is a biopharmaceutical company dedicated to developing next generation cancer therapies that are designed to overcome the barriers of drug delivery to solid tumors.

The Company was initially formed as DrugCendR, LLC. ("DrugCendR"), on October 22, 2015, and subsequently changed from an LLC to a corporation, and changed its name to Cend Therapeutics. On February 28, 2018, DrugCendR established a wholly-owned Australian subsidiary, DrugCendR Australia Pty Ltd. ("DrugCendR AUS"), in order to conduct clinical activities in Australia for its development candidates.

Merger Agreement

On April 26, 2022, the Company entered into an agreement and plan of merger ("Merger Agreement") with Caladrius Biosciences, Inc. ("Caladrius"), a Delaware corporation and CS Cedar Merger Sub, Inc., a wholly-owned subsidiary of Caladrius ("Merger Sub"). Pursuant to the Merger Agreement, among other matters, and subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Merger Sub merged with and into the Company, with the Company continuing as a wholly owned subsidiary of Caladrius and the surviving corporation of the merger (the "Merger"). Upon closing of the Merger on September 15, 2022, the combined company was renamed Lisata Therapeutics, Inc. ("Lisata") and began trading on the Nasdaq Global Select Market under the ticker symbol "LSTA." Caladrius is considered to be the accounting acquirer based on the terms of the Merger Agreement. The Merger is intended to qualify for federal income tax purposes as a tax-free reorganization under the provisions of Section 368(a) of the Internal Revenue Code of 1986, as amended.

Subject to the terms and conditions of the Merger Agreement, at the closing of the Merger, (a) each outstanding share of Company common stock and Company preferred stock (except shares of Series D preferred stock) was converted into a number of shares of Caladrius common stock ("Caladrius Common Stock") equal to the exchange ratio specified in the Merger Agreement ; and (b) each outstanding Company stock option that had not previously been exercised prior to the closing of the Merger was assumed by Caladrius. Effective on the closing of the Merger, the Company's former stockholders owned approximately 48.2% of the combined company.

Liquidity

The Company has experienced net losses and negative cash flows from operating activities since its inception, aside from the year ended December 31, 2021, as a result of a one-time license payment and a milestone payment from the Exclusive License and Collaboration Agreement with Qilu Pharmaceutical Co., Ltd. ("Qilu"), which rendered net income in 2021 (Note 6). The Company has an accumulated deficit of $14.9 million as of June 30, 2022. For the six months ended June 30, 2022, the Company used $5.1 million of cash in operations. As of June 30, 2022, the Company had cash of $11.2 million. With the closing of the Merger, as described above, future research and development activities and capital requirements will be determined by the management of Lisata.

2. Summary of Significant Accounting Policies

Basis of Presentation and Consolidation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP"). The unaudited condensed consolidated financial statements include the accounts of Cend (a U.S. Corporation) and its wholly owned subsidiary DrugCendR (an Australian corporation). All intercompany accounts and transactions have been eliminated in consolidation.

In the opinion of the Company, the accompanying unaudited condensed consolidated financial statements contain all adjustments, consisting of only normal recurring adjustments, necessary for a fair presentation of the interim periods presented. These unaudited interim condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements and related notes for the year ended December 31, 2021.

The Company's significant accounting policies are disclosed in the audited consolidated financial statements for the years ended December 31, 2020 and 2021, included elsewhere in this registration statement. Since the date of those consolidated financial statements, there have been no changes to its significant accounting policies.

Net Income (Loss) Per Share

The Company computes net income (loss) per share in accordance with the FASB guidance for Earnings Per Share, which established standards regarding the computation of earnings per share by companies that have issued securities other than common stock that contractually entitle the holder to participate in earnings and dividends. The guidance requires earnings available to common shareholders for the period, after deduction of preferred stock preferences, to be allocated between the common and preferred shareholders based on their respective rights to receive dividends. The Company is not required to present basic and diluted net income (loss) per share for securities other than common stock; therefore, the net income (loss) per share amounts only pertain to the Company's common stock.

Basic net income (loss) per share is calculated by dividing income (loss) allocable to common shareholders (net income after reduction for any required returns to preferred stock shareholders prior to paying dividends to the common shareholders, assuming current income for the period had been distributed) by the weighted-average number of common shares outstanding, during the period.

The Company has used the two-class method to calculate diluted net income (loss) per share for the six months ended June 30, 2021 and 2022. Diluted net income per share for the six months ended June 30, 2021, also reflects the assumed conversion of options outstanding during the period using the treasury stock method, to the extent dilutive. For purposes of calculating the net loss per share for the six months ended June 30, 2022, stock options were not included as their effect would be antidilutive.

The following table sets forth the computation of basic and diluted net income (loss) per share:

	Six Months Ended June 30,	
	2021	**2022**
Basic Net Income (Loss) per share		
Net income (loss)	$ 4,651	$ (4,690)
Less: income allocated to participating securities	(1,816)	-
Net income (loss) attributable to common shareholders	$ 2,835	$ (4,690)
Weighted average common shares outstanding - basic	4,196,716	4,279,705
Net income (loss) per share - basic	$ 0.68	$ (1.10)
Diluted Net Income (Loss) per share		
Net income (loss)	$ 4,651	$ (4,690)
Less: income allocated to participating securities	(1,616)	-
Net income (loss) attributable to common shareholders	$ 3,035	$ (4,690)
Weighted average common shares outstanding - basic	4,196,716	4,279,705
Weighted average effect of dilutive stock options	855,431	-
Weighted average common shares outstanding - diluted	5,052,147	4,279,705
Net income (loss) per share - diluted	$ 0.60	$ (1.10)

Potentially dilutive securities as of June 30, 2021 and 2022 are as follows (in common stock equivalent shares):

	Six Months Ended June 30,	
	2021	2022
Series A redeemable convertible preferred stock	371,396	371,396
Series B redeemable convertible preferred stock	1,071,237	1,071,237
Series C convertible preferred stock	1,279,154	1,345,699
Series D convertible preferred stock	-	1,135,628
Stock Options	2,111,079	2,300,079
Total	4,832,866	6,224,039

3. Accrued Expenses

Accrued expenses consist of the following (in thousands):

	December 31, 2021	June 30, 2022
Research and development	$ 174	$ 880
Employee related	177	137
Taxes	148	-
Other	36	148
Total accrued expenses	$ 535	$ 1,165

4. Asset Acquisition

In September 2020, the Company entered into an Asset Purchase Agreement (the “Impilo Agreement”) with Impilo Therapeutics, Inc. (“Impilo”). In accordance with the Impilo Agreement, the Company purchased all the intellectual property rights, know-how and product data of Impilo, as well as certain assumed contracts. The acquired assets expand the Company’s drug delivery capabilities for targeted tissue penetrating delivery of nucleic acid-based medicines for the treatment of solid tumor cancers. The Company’s founding shareholder was a significant shareholder in Impilo prior to the acquisition.

In connection with the Impilo Agreement, the Company issued 1,212,609 shares of a newly created class of Series C convertible preferred stock, with a value of $5.41 per share, for a total value of $6.6 million. The Company recorded the purchase price as in-process research and development expense during the year ended December 31, 2020.

The Impilo Agreement and assumed contracts also allowed for the Company to pursue four license options that were under negotiation by the former shareholders of Impilo at the time of acquisition. If executed by the Company, additional shares (“License Shares”) were to be issued to the original Impilo shareholders. In addition, the Company also assumed the right to pursue a license with the Massachusetts Institute of Technology (“MIT”).

In March 2021 and October 2021, two of the four license options, University of California San Diego (“UCSD”) and Sanford Burnham Prebys (“SBP”), respectively, were executed, and additional License Shares of 66,545 each (Series C shares) were issued to the original Impilo shareholders. The License Shares were valued at $7.82 per share, based on a third-party valuation, for a total value of $1.0 million, of which $0.5 million was recorded as in-process research and development expense during the six months ended June 30, 2021.

In October 2021, the Company executed a license with MIT, and 81,000 shares of common stock were issued to MIT at $3.82 per share, based on a third-party valuation, for a total value of $0.3 million

The Company's founding shareholder held shares in Impilo prior to occurrence of the Impilo Agreement. A total of 331,108 shares of Series C convertible preferred stock were issued to the Company's founding shareholder in connection with the Impilo acquisition, of which 298,361 were issued in 2020 and 32,747 were issued in 2021. The shares transferred had the same terms as other investors and the amounts recorded as in-process research and development expenses for the six months ended June 30, 2021 and 2022, totaled $0.1 million and $0, respectively.

5. License Agreements

Sanford Burnham Prebys

In December 2015, the Company entered into a license agreement with Sanford Burnham Prebys under which the Company was granted an exclusive, worldwide, royalty-bearing license to certain patent rights and know-how controlled by SBP related to the development of CEND-1. At the time the license agreement was entered into, the Company's founding shareholder was an executive at SBP. The agreement provides the Company with the rights to grant and authorize sublicenses to use, sell, and otherwise exploit the patent rights. As consideration for the license, the Company made an initial upfront payment in the form of common stock, issuing 540,000 shares in September 2016, at $0.00001 per share (the "License Fee"). In addition, the Company was required to reimburse SBP for past expenses totaling $0.6 million, of which $0.2 million was paid and the remainder was settled with the issuance of 175,707 shares of common stock. The Company is required to pay an annual license maintenance fee of $5,000, increasing to $10,000 on year four of the agreement, and increasing to $20,000 on year seven of the agreement. The Company could also be required to make milestone payments to SBP upon completion of certain regulatory and commercial milestones. The aggregate potential milestone payments are approximately $10.6 million. The Company has also agreed to pay SBP royalties of 4% of net sales of products sold by the Company, or through a sublicense, subject to certain reductions. Additionally, the Company agreed to pay SBP 25% of any sublicensing income.

During the six months ended June 30, 2021 and 2022, the Company amortized $0 and $5,000 of license maintenance fees and accrued for $2.5 million and $0 in sublicense fees related to the Qilu upfront payment (Note 6), which were recorded to research and development expense. SBP owns 715,707 shares of the Company's common stock as of December 31, 2021 and June 30, 2022, and is a related party.

In October 2021, the Company entered into a license agreement with SBP under which the Company was granted an exclusive, royalty-bearing license to certain patent rights and know-how controlled by SBP. The agreement provides the Company with the rights to grant and authorize sublicenses to use, sell, and otherwise exploit the patent rights. As consideration for the license, the Company made an initial upfront payment of $50,000, which was paid and recorded to in-process research and development expense in November 2021. In addition, the Company is required to pay an annual license maintenance fee of $20,000, increasing to $30,000 on year four of the agreement. Further, the Company could be required to make milestone payments to SBP upon completion of certain regulatory and commercial milestones. The aggregate potential milestone payments are approximately $23.2 million. The Company has also agreed to pay SBP royalties of 4% of net sales of products sold by the Company or through a sublicense, subject to certain reductions. Additionally, the Company agreed to pay SBP varying sublicense fees, ranging from 10% to 25%, dependent on when the related milestones are reached.

The agreements will expire upon the later of (i) the final abandonment of all pending patent applications within the licensed patents or (ii) the expiration of the last to expire patent within the licensed patents. The agreements may be terminated in their entirety by the Company at any time by giving SBP sixty days' prior written notice. The agreements may be terminated in their entirety by SBP if the Company, at any time, defaults in the payment of any sum when due and fails to make such payment within thirty days after receipt of written notice. The agreements may be terminated in their entirety by SBP or the Company in (i) the event of an uncured material breach by the other party, or (ii) in the event the other party (a) files for, or is involuntarily petitioned with, bankruptcy (other than dissolution or winding up for the purposes of reconstruction or amalgamation), (b) makes an assignment of all or substantially all of its assets for the benefit of creditors, or (c) has a receiver or trustee is appointed and is unable to secure a dismissal, stay or other suspension of such proceedings within thirty days. Upon termination of the agreements for any reason, all rights and obligations of the Company with respect to the patents and patent applications shall terminate and revert to SBP.

University of California at San Diego

In March 2021, the Company entered into a license agreement with the University of California at San Diego under which the Company was granted an exclusive, royalty-bearing license to certain patent rights related to the development of nano particles to modulate immune response. The agreement provides the Company with the rights to grant and authorize sublicenses to use, sell and otherwise exploit the patent rights. As consideration for the license, the Company made an initial upfront payment of $10,000, which was paid and recorded to in-process research and development expense as of June 30, 2021. In addition, the Company was required to reimburse UCSD for past expenses totaling $18,000, $9,100 of which was accrued for and recorded to in-process research and development expense as of June 30, 2021. In addition, the Company is required to pay an annual license maintenance fee of $5,000 beginning in March 2022, which was paid in February 2022, $1,700 of which was amortized to research and development expense during the six months ended June 30, 2022. Further, the Company could be required to make milestone payments to UCSD upon completion of certain regulatory and commercial milestones. The aggregate potential milestone payments are approximately $1.2 million. The Company has also agreed to pay UCSD royalties of 1.5% of net sales of products sold by the Company or through a sublicense, subject to certain reductions. Additionally, the Company agreed to pay UCSD varying sublicense fees, ranging from 10% to 20%, dependent on when the related milestones are reached.

The agreement will expire upon the expiration of the longest-lived patent rights. The agreement may be terminated in its entirety by the Company at any time by giving UCSD ninety days' prior written notice. The agreement may be terminated in its entirety by UCSD if the Company, at any time, (i) fails to perform or violates any term of the agreement and fails to cure the default within sixty days. Upon termination of the agreement for any reason, UCSD may terminate a sublicensee but will allow the Company to assign any sublicenses to UCSD provided a) that the sublicensee is in good standing upon termination of the agreement with the Company; and b) the sublicensee is not currently involved in litigation as an adverse party to UCSD.

Massachusetts Institute of Technology

In October 2021, the Company entered into a license agreement with the Massachusetts Institute of Technology under which the Company was granted an exclusive, royalty-bearing license to certain patent rights related to the development of tissue specific delivery of interfering RNA. The agreement provides the Company with the rights to grant and authorize sublicenses to use, sell, and otherwise exploit the patent rights. As consideration for the license, the Company made an initial upfront payment of $15,000, which was paid and recorded to in-process research and development expense in December 2021. In addition, the Company is required to pay an annual license maintenance fee of $20,000, increasing to $25,000 for year two and three of the agreement, increasing to $50,000 on year four of the agreement and thereafter until the first commercial sale, and increasing to $150,000 each year of the agreement after the first sale. The Company paid the $20,000 annual license maintenance fee in February 2022, and amortized $10,000 to research and development expense during the six months ended June 30, 2022. Further, the Company could be required to make milestone payments to MIT upon completion of certain regulatory and commercial milestones. The aggregate potential milestone payments are approximately $5.0 million. The Company has also agreed to pay MIT royalties of 2% of net sales of products sold by the Company or through a sublicense, subject to certain reductions. Additionally, the Company agreed to pay MIT varying sublicense fees, ranging from 3% to 20%, dependent on when the related milestones are reached. Lastly, the Company could be required to pay MIT a change in control fee of $0.3 million if the control of the Company or the agreement is assigned to a third-party. As of June 30, 2022, the Company concluded the change in control event was not probable and therefore no obligation was recorded.

The agreement will expire upon the expiration or abandonment of all valid claims. The agreement may be terminated in its entirety by the Company at any time by giving MIT six months prior written notice. The agreement may be terminated in its entirety by MIT if the Company, at any time, (i) defaults in the payment of any sum when due and fails to make such payment within thirty days after receipt of written notice, or (ii) in the event the Company commits a material breach of its obligations under the agreement (aside from item (i)) and fails to cure that breach within sixty days after receipt of written notice. Upon termination of the agreement for any reason, the rights and licenses granted to the Company shall terminate and revert to MIT. Upon termination of the agreement for any reason, MIT may terminate a sublicensee but will allow the Company to assign any sublicenses to MIT provided that the sublicensee is in good standing upon termination of the agreement with the Company.

6. Research Collaboration and License Agreement

Exclusive License and Collaboration Agreement

In February 2021, the Company entered into an Exclusive License and Collaboration Agreement (the "Qilu Agreement") in which the Company granted an exclusive license to Qilu for the development and commercialization of CEND-1 in the Territory (defined as the Greater Area of China including China, Macau, Hong Kong, and Taiwan). Under the terms of the agreement, Qilu is solely responsible for the development of CEND-1 in its Territory. In consideration for the license, Qilu made a one-time, non-refundable, non-creditable upfront payment of $10 million to the Company. The Company is also eligible to receive developmental and commercial milestone payments up to $100 million and $125 million, respectively, tiered royalties on net sales ranging from 10% to 15%, and tiered sublicensing revenues ranging from 12% to 35%.

Under the terms of the Qilu Agreement, Qilu was also required to file an Investigational New Drug Application ("IND") and receive approval by the National Medical Products Administration ("NMPA") in the People's Republic of China in the Territory within 12 months of the effective date of the arrangement, which would result in a $5 million milestone payment. Qilu was also required to dose its first patient in a Phase I clinical trial in the Territory within six months of the acceptance of the IND, subject to certain extensions, or the Company would have had the option to terminate the Qilu Agreement. In August of 2021, Qilu achieved the regulatory milestone, and the Company received the $5 million milestone payment. Qilu also dosed its first patient within the six-month period.

The Company may also earn an additional $1 million upon completing process optimization and scale up activities and delivering three validation batches of CEND-1in full commercial scale by Qilu or its subcontractor (the "Technology Transfer"). After completing the Technology Transfer, Qilu will be responsible for manufacturing CEND-1 for use in subsequent clinical trials. In the event the Company and its contract manufacturers fail to complete the process optimization and scale up activities, Qilu would have the right to manufacture CEND-1 using its independent manufacturing process and would have no obligation to pay the Technology Transfer milestone payment. Prior to the completion of the Technology Transfer, the Company has agreed to supply CEND-1 to Qilu at its cost.

Unless terminated early, the Qilu Agreement will continue in effect until the expiration of all Qilu payment obligations. Either party may terminate the Qilu Agreement if an undisputed material breach by the other party is not cured within a defined period of time, or upon notice for insolvency-related events of the other party that are not discharged within a defined time period. Qilu may terminate the Qilu Agreement in its entirety, at any time with at least sixty days written notice. All right and obligations of Qilu with respect to such licensed patents and patent applications would terminate.

Under the framework of ASC Topic 606, "Revenue from Contracts with Customers" ("ASC 606"), the Company identified two performance obligations, which was the delivery of the license, and a material right related to the supply of CEND-1 prior to the completion of the Technology Transfer. At the onset of the Qilu Agreement, the Technology Transfer was only an option of Qilu, and the Company further determined the fee for the Technology Transfer approximated the standalone selling price and therefore the option would not represent a material right and accordingly, did not represent a performance obligation at the onset of the arrangement. The Company recognized $9.7 million in revenue upon delivery of the license to Qilu in February 2021. The Company initially deferred $0.3 million in revenue for the material right, which will subsequently be recognized as revenue as the clinical supply is delivered.

In August 2021, the Company received $5.0 million from Qilu upon achievement of the first development milestone. In March 2022, the Company provided Qilu with clinical supply material and recognized $0.2 million in revenue. In April 2022, the Company provided Qilu with clinical supply material and recognized $0.4 million in revenue. As of June 30, 2022, the Company had $0.2 million recorded as deferred revenue, all of which was included in other current liabilities. As of December 31, 2021, the Company had $0.3 million recorded as deferred revenue, of which $66,000 was included in other current liabilities and $0.2 million was included in other long-term liabilities.

As of June 30, 2022, the Technology Transfer had not been completed and no payment had been made by Qilu. Additionally, all remaining future development and sales milestones (variable consideration) were fully constrained and will only be recognized upon achievement of the milestones.

7. Commitments and Contingencies

Legal proceedings

In May 2021, the Company received a written threat of litigation on behalf of a Chinese entity called Lingmed Limited ("Lingmed") claiming Lingmed was entitled to a success fee based on the Company's Collaboration and License Agreement with Qilu Pharmaceuticals. The Company responded by denying that Lingmed is entitled to a success fee under the terms of their agreement. In May 2022, the Company was served with a complaint filed by Lingmed in the San Diego County Superior Court, alleging claims for breach of contract, fraud and declaratory relief. The Company's response to the complaint was filed on June 6, 2022. Lingmed filed an answer to the Company's response on July 11, 2022. A case management conference is scheduled for October 7, 2022.

In addition, the Company may be involved in litigation or claims arising out of its operations in the normal course of business. Other than the Lingmed matter, there are currently no such other matters, and any such other matters that would, in the opinion of management, be expected to be immaterial with respect to the Company's consolidated financial position, liquidity, or results of operations.

8. Stockholders' Equity (Deficit)

Under the Restated Certificate of Incorporation dated April 26, 2022, the Company has a total of 15,850,000 shares of capital stock authorized for issuance, consisting of 11,500,000 shares of common stock, par value of $0.00001 per share, and 4,350,000 shares of preferred stock, par value $0.00001 per share. Shares of authorized preferred stock are designated as 371,396 shares of Series A redeemable convertible preferred stock, 1,071,240 shares of Series B redeemable convertible preferred stock, 1,345,700 shares of Series C convertible preferred stock, and 1,135,650 shares of Series D convertible preferred stock.

Preferred Stock

Redeemable convertible preferred stock

In March 2018, the Company executed the Series A Stock Purchase Agreement and issued 371,396 shares of Series A redeemable convertible preferred stock at $2.96 per share for proceeds of $1.1 million.

In September 2019, the Company executed the Series B Stock Purchase Agreement and issued 1,071,237 shares of Series B redeemable convertible preferred stock at $3.68 per share for proceeds of $3.9 million.

Convertible preferred stock

In connection with the Impilo Asset Purchase Agreement (Note 4), the Company issued a total of 1,345,699 shares of Series C convertible preferred stock.

In connection with the Merger Agreement (Note 1), the Company issued a total of 1,135,628 shares of Series D convertible preferred stock at $8.81 per share for proceeds of $10 million.

The Company's preferred stock has the following characteristics applicable to all classes, unless otherwise specified:

Dividends

Each holder of preferred stock is entitled to receive dividends when and if declared by the board of directors, pro rata and on a pari passu basis according to the number of shares of common stock then issuable upon conversion of all shares of preferred stock held by such holders. Dividends are noncumulative, and no cash dividends have been declared to date.

Conversion

Each share of preferred stock is convertible without payment of additional consideration at the option of the holder any time after the issuance date into shares of common stock determined by dividing the original issuance price by the conversion price. The conversion price of the preferred stock is initially equal to the original issuance price and is subject to certain adjustments. The preferred stock is subject to a mandatory conversion in the event (i) that there is a closing of the sale of shares of common stock to the public at a pre-equity valuation of at least $250 million, resulting in at least $50 million in gross proceeds to the Company, in an underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended, and in connection with such offering the common stock is listed for trading on the Nasdaq Stock Market's National Market, the New York Stock Exchange or another exchange or marketplace approved by the board of directors or (ii) upon the vote or written consent for such conversion from the Requisite Holders (defined as holders of at least a majority of the outstanding shares of preferred stock, voting as a single class on an as-converted basis). As of June 30, 2022, all series of preferred stock are convertible into shares of common stock on a one-to-one basis.

Liquidation

Holders of the Series D preferred stock are entitled to receive liquidation preferences at the Series D original issue price, plus all accrued and declared but unpaid dividends. After full payment of the liquidation preference to the holders of the Series D preferred stock, the holders of the Series B preferred stock are entitled to receive liquidation preferences at the Series B original issue price, plus all accrued and declared but unpaid dividends. After full payment of the liquidation preference to the holders of the Series D preferred stock and Series B preferred stock, the holders of the Series A preferred stock are entitled to receive liquidation preferences at the Series A original issue price, plus all accrued and declared but unpaid dividends. After full payment of the liquidation preference to the holders of the Series D preferred stock, Series B preferred stock, and Series A preferred stock, the holders of the Series C preferred stock are entitled to receive liquidation preferences at the Series C original issue price, plus all accrued and declared but unpaid dividends.

The remaining assets, if any, will be distributed ratably to the holders of the Series D preferred stock, Series B preferred stock, Series A preferred stock and common stock, pro rata, based on the number of shares held by each such holder, treating for this purpose all such securities as if they had been converted to common stock immediately prior to such liquidation.

Voting rights

The holder of each share of preferred stock is entitled to one vote for each share of common stock into which it would convert and to vote as one class with the common stockholders on all matters.

Redemption rights and classification

The holders of Series A and Series B redeemable convertible preferred stock have redemption rights. At any time on or after the sixth anniversary of the March 6, 2018 Restated Certificate of Incorporation, the Requisite Holders may provide written notice requesting redemption of all shares of redeemable convertible preferred stock at a price equal to the original issue price, plus all declared but unpaid dividends. Subject to the Company's election for an initial nine-month deferral, the redemption shall be paid in three annual installments commencing not more than sixty days after the written notice. As a result, the Company has classified the redeemable convertible preferred stock outside of stockholders' equity on the condensed consolidated balance sheets as the stock is contingently redeemable.

The holders of Series C preferred stock and Series D preferred stock do not have any redemption rights. Additionally, as the majority of the Company's voting shares are held by common stock shareholders, the preferred shareholders cannot use their vote to force a liquidation. Therefore, the Company has classified the convertible Series C preferred stock and Series D preferred stock within stockholders' equity on the condensed consolidated balance sheets.

Common stock

As of December 31, 2021 and June 30, 2022, the Company had 10,500,000 and 11,500,000 shares, respectively, of its common stock authorized. As of December 31, 2021 and June 30, 2022, the Company had 4,279,705 shares of its common stock issued and outstanding.

Each share of common stock has the right to one vote. The holders of common stock are also entitled to receive dividends when and if declared by the board of directors. No cash dividends have been declared by the board of directors during the six months ended June 30, 2021 and 2022. In the event of a liquidation, dissolution or winding-up, the holders of common stock are entitled to share ratably in the net assets remaining after payment of liabilities and the liquidation value of the preferred stock then outstanding. The common stock has no preemptive rights, conversion rights or redemption rights. All shares of common stock have equal distribution, liquidation and voting rights, and have no preferences or exchange rights.

The Company has reserved the following shares of common stock for issuance, on an as-converted basis, as follows:

	December 31, 2021	June 30, 2022
Redeemable contervible preferred stock	1,442,633	1,442,633
Convertible preferred stock	1,345,699	2,481,327
Stock options issued and outstanding	2,270,079	2,300,079
Authorized for future stock awards or option grants	882,621	852,621
Total	5,941,032	7,076,660

9. Stock-Based Compensation

2016 Equity Incentive Plan

In September 2016, the Company adopted the 2016 Equity Incentive Plan (the “Plan”), which provides for the grant of incentive stock options, non-statutory stock options, stock bonuses, and rights to acquire restricted stock to employees, directors, and consultants of the Company. As of June 30, 2022, the number of shares reserved under the Plan was 3,217,700 and the number of shares issued and outstanding under the Plan was 2,300,079, respectively. As of June 30, 2022, the number of shares available for grant under the Plan was 852,621.

Options granted under the Plan are exercisable at various dates as determined upon grant and will expire no more than ten years from their date of grant, or in the case of grants to a 10% shareholder, five years from the date of grant. The exercise price of each option shall be determined by the Board of Directors based on the estimated fair value of the Company’s stock on the date of the option grant. In the case of incentive stock options, the exercise price shall not be less than 100% of the fair market value of the Company’s common stock at the time the option is granted, unless the option is granted pursuant to an assumption of or substitution for another option. For holders of more than 10% of the Company’s total combined voting power of all classes of stock, incentive stock options may not be granted at less than 110% of the fair market value of the Company’s stock at the date of grant.

Stock Option Activity

A summary of the Company’s stock option activity under the Plan is as follows (in thousands, except share and per share amounts and years):

	Options Outstanding	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
Balance at December 31, 2021	2,270,079	$ 1.98	8.00	$ 4,174
Options granted	30,000	4.01	—	
Options exercised	—	—	—	
Options cancelled and forfeited	—	—	—	
Balance at June 30, 2022	2,300,079	$ 2.01	7.53	$ 4,605
Vested and exercisable at June 30, 2022	1,754,142	$ 1.91	7.21	$ 3,679

For the six months ended June 30, 2021 and 2022, the total fair value of options that vested during the period was $0.2 million.

There was one option exercised during the six months ended June 30, 2021, with an aggregate intrinsic value of $0.1 million. There were no options exercised during the six months ended June 30, 2022.

There were no options granted to employees or non-employees during the six months ended June 30, 2021. There were 30,000 options granted to non-employees during the six months ended June 30, 2022. The weighted-average grant date fair value of non-employee option grants for the six months ended June 30, 2022 was $2.27 per share.

Stock-Based Compensation Expense

The Company recognized stock-based compensation expense of $0.2 million and $0.3 million for the six months ended June 30, 2021 and 2022, respectively.

As of June 30, 2022, the unrecognized compensation cost related to outstanding employee options was $0.4 million and is expected to be recognized as expense over approximately 3.3 years. Unrecognized compensation cost related to outstanding nonemployee options was $0.4 million as of June 30, 2022 and is expected to be recognized as expense over approximately 1.8 years.

10. Australia Research and Development Tax Incentive

The Company's Australian subsidiary, which conducts core research and development activities, is eligible to receive a 43.5% refundable tax incentive for qualified research and development activities. For the six months ended June 30, 2022, $0.4 million was recorded as a reduction of research and development expenses in the condensed consolidated statements of operations, as the Company determined that it met the eligibility criteria and the amounts claimed are expected to be received shortly after the related tax returns are filed. For the six months ended June 30, 2021, $0.2 million was recorded as a reduction of research and development expenses in the condensed consolidated statements of operations, as the Company determined that it met the eligibility criteria and subsequently collected the tax incentives after filing the related tax returns.

11. Related Party Transactions

Consulting Arrangements

The Company has an advisory consulting agreement with the founding shareholder, who is also a member on the Board of Directors. During the six months ended June 30, 2021 and 2022, the Company incurred and paid $15,000 and $31,000, respectively, which was recoded to research and development expense. As of December 31, 2021 and June 30, 2022, the Company had a $5,000 prepayment relating to the agreement included within other current assets on the condensed consolidated balance sheets.

Other Transactions

As discussed in Note 4, the Company entered into an asset purchase agreement with Impilo, which included several additional license agreements, all of which were paid for with the newly created class of Series C preferred stock, and one of the investors was the Company's founding shareholder. During the six months ended June 30, 2021 and 2022, the Company recorded $0.1 million and $0, respectively, related to this agreement, which was recorded to in-process research and development expense.

As discussed in Note 5, the Company has license agreements with SBP, who owns 715,707 shares of the Company's common stock. During the six months ended June 30, 2021 and 2022, the Company incurred $2.5 million and $41,000, respectively, related to the license agreements, which was recorded to research and development expense. As of December 31, 2021 and June 30, 2022, $27,000 and $17,000, respectively, of these expenses is included in accrued expenses within the condensed consolidated balance sheets. As of December 31, 2021 and June 30, 2022, $0 and $10,000, respectively, of these expenses is included in accounts payable within the condensed consolidated balance sheets. As of December 31, 2021 and June 30, 2022, the Company had a $9,000 and $4,000, respectively, prepayment relating to the agreements included within other current assets on the condensed consolidated balance sheets.

12. Income Taxes

The Company uses an estimated annual effective tax rate, which is based on expected annual income and statutory tax rates in the jurisdictions in which the Company operates, to determine its quarterly provision for income taxes. Certain significant or unusual items are separately recognized in the quarter in which they occur and can be a source of variability in the effective tax rates from quarter to quarter.

The Company's effective tax rates for the six months ended June 30, 2021, and June 30, 2022, were 3.66% and 0%, respectively. The effective tax rate for the six months ended June 30, 2021 differs from the U.S. federal statutory tax rate primarily due to foreign tax credits and research credits offset by nondeductible acquired R&D and the change in the full valuation allowance. The effective tax rate for the six months ended June 30, 2022 differs from the U.S. federal statutory tax rate primarily due to a full valuation allowance related to the Company's deferred tax assets.

The Company's effective tax rates for the three months ended June 30, 2021, and June 30, 2022, were 2.19% and 0%. The effective tax rate for the three months ended June 30, 2021 differs from the U.S. federal statutory tax rate primarily due to foreign tax credits and research credits offset by nondeductible acquired R&D and the change in the full valuation allowance. The effective tax rate for the three months ended June 30, 2022 differs from the U.S. federal statutory tax rate primarily due to a full valuation allowance related to the Company's deferred tax assets.

During 2021, $1.7 million of foreign income tax was withheld related to the Qilu Agreement and the related delivery of the exclusive license and achievement of the first development milestone (Note 6). This foreign income tax expense has been presented as an offset to the revenue on the condensed consolidated statements of operations. As the withholding tax on the foreign revenue is considered an unusual and non-recurring item, it is not included in the above-mentioned effective tax rate for the period ended June 30, 2021.

The mandatory §174 capitalization rules went into effect on January 1, 2022, and were considered as part of the Company's estimated annual effective tax rate. The new rules are not expected to have a material impact on the Company for the year ending December 31, 2022.

The Company is subject to taxation in the United States, California, and Australia. As of June 30, 2022, the Company's tax years are subject to examination by the tax authorities from 2018 and forward for Federal tax purposes and 2017 and forward for California and Australia tax purposes. However, to the extent allowed by law, the tax authorities may have the right to examine the period from inception forward where NOLs and credits were generated and carried forward and make adjustments to the amount of the NOL and credit carryforward amounts. The Company is not currently under examination by any federal, state, or foreign tax authority.

13. Subsequent Events

The Company evaluated subsequent events for recognition and measurement purposes through October 4, 2022, the date the financial statements were issued.

Exhibit 99.4

UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL STATEMENTS

On April 26, 2022, Caladrius Biosciences, Inc. ("Caladrius"), CS Cedar Merger Sub, Inc., a Delaware corporation and wholly owned subsidiary of Caladrius ("Merger Sub"), and Cend Therapeutics, Inc. ("Cend" or the "Company"), a privately-held, clinical-stage biotechnology company, entered into an Agreement and Plan of Merger and Reorganization (the "Merger Agreement"), pursuant to which, among other matters, and subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Merger Sub merged with and into Cend, with Cend continuing as a wholly owned subsidiary of Caladrius (the "Merger"). Upon closing of the Merger on September 15, 2022, the combined company was renamed to Lisata Therapeutics, Inc. ("Lisata") and trades on the Nasdaq under the ticker symbol "LSTA."

Subject to the terms and conditions of the Merger Agreement, at the closing of the Merger, (a) each outstanding share of Cend common stock and Cend preferred stock (except shares of Cend Series D Preferred Stock held by Caladrius) was converted into a number of shares of Caladrius common stock ("Caladrius Common Stock") equal to the exchange ratio described below; and (b) each outstanding Cend stock option that had not previously been exercised prior to the closing of the Merger was assumed by Caladrius. As of immediately after the Merger, Cend's former stockholders owned approximately 48% of the outstanding shares of Caladrius Common Stock and stockholders of Caladrius as of immediately prior to the Merger owned approximately 52% of the outstanding shares of Caladrius Common Stock. The allocation was subject to adjustment based on Caladrius' net cash balance at the time of closing and the amount of any transaction expenses of Cend in excess of $0.3 million at the time of closing. Caladrius' net cash balance at the time of closing was greater than $73,366,000 and as a result, the Caladrius allocation percentage was increased by approximately 2% as the net cash exceeded $73,366,000 by approximately $3,140,000.

Concurrently with the execution of the Merger Agreement and in order to provide Cend with capital for its development programs prior to the closing of the Merger, Caladrius agreed to purchase from Cend shares of Cend Series D Preferred Stock (the "Cend Series D Preferred Stock"), at a purchase price of $10.0 million.

Caladrius submitted to Caladrius' stockholders an amendment to Caladrius' certificate of incorporation to authorize the Caladrius board to effect a reverse stock split of all outstanding shares of Caladrius common stock at a reverse stock split ratio of one new share for every fifteen shares outstanding (the "Caladrius Reverse Stock Split"). The Caladrius Reverse Stock Split was mutually agreed to by Cend and Caladrius and became effective on September 14, 2022, prior to and in connection with the completion of the Merger. All Caladrius historical common stock amounts in the unaudited pro forma condensed combined financial statements have been adjusted for the impact of the Caladrius Reverse Stock Split.

Unaudited Pro Forma Condensed Combined Financial Statements

The following unaudited pro forma condensed combined financial statements have been prepared to illustrate the effects of the Merger. The accompanying unaudited pro forma condensed combined balance sheet as of June 30, 2022 combines the historical consolidated balance sheets of Caladrius and Cend, giving effect to the Merger as if it had been completed on June 30, 2022. The unaudited pro forma condensed combined statements of operations for the six months ended June 30, 2022 and for the year ended December 31, 2021 combine the historical consolidated statements of operations of Caladrius and Cend, giving effect to the Merger as if it had been completed on January 1, 2021.

The unaudited pro forma condensed combined financial statements has been prepared in accordance with Regulation S-X Article 11, Pro Forma Financial Information, as amended by the final rule, Amendments to Financial Disclosures about Acquired and Disposed Businesses, as adopted by the SEC in May 2020 ("Article 11"). The unaudited pro forma condensed combined financial information is provided for illustrative purposes only, does not necessarily reflect what the actual consolidated results of operations would have been had the acquisition occurred on the dates assumed and may not be useful in predicting the future consolidated results of operations or financial position. Cend's results of operations and actual financial position may differ significantly from the pro forma amounts reflected herein due to a variety of factors.

Caladrius acquired Cend and the Merger was accounted for using the asset acquisition method under accounting principles generally accepted in the United States of America ("GAAP"). Caladrius is considered to be the accounting acquirer based on the terms of the Merger Agreement and certain factors including: (i) Caladrius is issuing equity of 3.8 million common shares to shareholders of Cend; (ii) although both entities will contribute to the new management team of Lisata, the Caladrius team will have more individuals on the management team and will hold the CEO, CMO and other senior management roles; (iii) Caladrius paid a premium to acquire Cend's assets; and (iv) Caladrius is significantly larger than Cend regarding total assets, operations, and research and development activities.

The Merger was accounted for as an asset acquisition as substantially all of the fair value is concentrated in intangible assets, primarily, In-Process Research and Development ("IPR&D"). Cend's assets (except for cash) and liabilities were measured and recognized as an allocation of the transaction price based on their relative fair values as of the transaction date with any value associated with IPR&D with no alternative future use being expensed.

The unaudited pro forma condensed combined financial information is based on the assumptions and adjustments that are described in the accompanying notes. Accordingly, the pro forma adjustments are preliminary, subject to further revision as additional information becomes available and additional analyses are performed and have been made solely for the purpose of providing unaudited pro forma condensed combined financial information. Differences between these preliminary estimates and the final accounting, expected to be completed after the closing of the Merger, will occur and these differences could have a material impact on the accompanying unaudited pro forma condensed combined financial information and the combined company's future results of operations and financial position. In addition, differences between the preliminary and final amounts will likely occur as a result of the amount of cash used for Cend's operations, changes in the fair value of Caladrius' common stock, and other changes in Cend's assets and liabilities.

The unaudited pro forma condensed combined financial information does not give effect to the potential impact of current financial conditions, regulatory matters, operating efficiencies or other savings or expenses that may be associated with the integration of the two companies. The unaudited pro forma condensed combined financial information is preliminary and has been prepared for illustrative purposes only and is not necessarily indicative of the financial position or results of operations in future periods or the results that actually would have been realized had Caladrius and Cend been a combined company during the specified periods. The actual results reported in periods following the Merger may differ significantly from those reflected in the unaudited pro forma condensed combined financial information presented herein for a number of reasons, including, but not limited to, differences in the assumptions used to prepare this pro forma financial information.

The unaudited pro forma condensed combined financial statements, including the notes thereto, should be read in conjunction with the separate historical financial statements of Caladrius and Cend, and their respective accompanying notes included elsewhere in this registration statement. Caladrius' condensed consolidated statement of operations and comprehensive loss for the six month period ended June 30, 2022 is derived from Caladrius' Form 10-Q for the six month period ended June 30, 2022 and Caladrius' Form 10-K for the year ended December 31, 2021.

Accounting rules require evaluation of certain assumptions, estimates, or determination of financial statement classifications. The accounting policies of Cend may materially vary from those of Caladrius. During preparation of the unaudited pro forma condensed combined financial information, management has performed a preliminary analysis and is not aware of any material differences, and accordingly, this unaudited pro forma condensed combined financial information assumes no material differences in accounting policies. Following the acquisition, management will conduct a final review of Cend's accounting policies in order to determine if differences in accounting policies require adjustment or reclassification of Cend's results of operations or reclassification of assets or liabilities to conform to Caladrius' accounting policies and classifications. As a result of this review, management may identify differences that, when conformed, could have a material impact on these unaudited pro forma condensed combined financial statements.

Unaudited Pro Forma Condensed Combined Balance Sheet
As of June 30, 2022
(in thousands, except per share data)

	Historical Caladrius	Historical Cend	Transaction Accounting Adjustments	Notes	Pro Forma Combined
ASSETS					
Cash and cash equivalents	$ 33,348	$ 11,202	$ —		$ 44,550
Marketable securities	39,643	—	—		39,643
Tax benefit receivable	—	879	—		879
Prepaid expenses and other current assets	1,956	1,610	—		3,566
Total current assets	74,947	13,691	—		88,638
Property and equipment, net	282	—	—		282
Investment in Cend	10,000	—	(10,000)	**G**	—
Intangible assets	—	—	1,590	**L**	1,590
Other assets	648	—	—		648
Total assets	$ 85,877	$ 13,691	$ (8,410)		$ 91,158
LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK, AND STOCKHOLDERS' EQUITY (DEFICIT)					
Liabilities					
Accounts payable	$ 1,097	$ 303	$ —		$ 1,400
Accrued liabilities	2,260	1,165	4,697	**C,D**	8,122
Other current liabilities	—	210	—		210
Total current liabilities	3,357	1,678	4,697		9,732
Other long-term liabilities	383	22	—		405
Total liabilities	3,740	1,700	4,697		10,137
COMMITMENTS AND CONTINGENCIES					
Redeemable convertible preferred stock					
Series A redeemable convertible preferred stock	—	1,100	(1,100)	**A**	—
Series B redeemable convertible preferred stock	—	3,941	(3,941)	**A**	—
Stockholders' equity (deficit)					
Series C convertible preferred stock	—	—	—	**A**	—
Series D convertible preferred stock	—	—	—	**A,G**	—
Preferred stock, $0.01 par value	—	—	—		—
Common stock, $0.001 par value	61	—	(53)	**B,M**	8
Additional paid-in capital	546,976	21,982	2,093	**A,B,G,K,M**	571,051
Treasury stock	(708)	—	—		(708)
Accumulated deficit	(463,868)	(14,897)	(10,241)	**A,B,C,D,J,K,L**	(489,006)
Accumulated other comprehensive loss	(70)	(135)	135	**A**	(70)
Total stockholders' equity (deficit)	82,391	6,950	(8,066)		81,275
Non-controlling interests	(254)	—	—		(254)
Total stockholders' equity (deficit)	82,137	6,950	(8,066)		81,021
Total liabilities, redeemable convertible preferred stock, and stockholders' equity (deficit)	$ 85,877	$ 13,691	$ (8,410)		$ 91,158

See accompanying notes to unaudited pro forma condensed combined financial information

Unaudited Pro Forma Condensed Combined Financial Statements of Operations
For the Six Months Ended June 30, 2022
(in thousands, except per share data)

	Historical Caladrius	Historical Cend	Transaction Accounting Adjustments	Notes	Pro Forma Combined
Net revenues	$ —	$ 591	$ —		$ 591
Operating Expenses:					
Research and development	6,517	3,572	—		10,089
General and administrative	6,823	1,709	58	L	8,590
Operating expenses	13,340	5,281	58		18,679
Operating loss	(13,340)	(4,690)	(58)		(18,088)
Other income (expense):					
Investment income, net	158	—	—		158
Other expense, net	(149)	—	—		(149)
Total other expense	9	—	—		9
Net loss before benefit from income taxes	(13,331)	(4,690)	(58)		(18,079)
Benefit from income taxes	(2,479)	—	—		(2,479)
Net loss	$ (10,852)	$ (4,690)	$ (58)		$ (15,600)
Net loss per share attributable to common shareholders:					
Basic	$ (2.69)	$ (1.10)			$ (2.00)
Diluted	$ (2.69)	$ (1.10)			$ (2.00)
Weighted average common shares outstanding:					
Basic	4,036	4,280	(507)	I	7,809
Diluted	4,036	4,280	(507)	I	7,809

See accompanying notes to unaudited pro forma condensed combined financial information

Unaudited Pro Forma Condensed Combined Statements of Operations
For the Year Ended December 31, 2021
(in thousands, except per share data)

	Historical Caladrius	Historical Cend	Transaction Accounting Adjustments	Notes	Pro Forma Combined
Net revenues	$ —	$ 14,787	$ —		$ 14,787
Operating Expenses:					
Research and development	17,680	8,148	—		25,828
In-process research and development	—	1,584	23,394	**H**	24,978
General and administrative	11,370	1,150	5,008	**C,D,L**	17,528
Operating expenses	29,050	10,882	28,402		68,334
Operating income (loss)	(29,050)	3,905	(28,402)		(53,547)
Other income (expense):					
Investment income, net	151	—	—		151
Other expense, net	(75)	—	—		(75)
Interest income	—	4	—		4
Total other income	76	4	—		80
Net income (loss) before expense (benefit) from income taxes	(28,974)	3,909	(28,402)		(53,467)
Income tax expense (benefit)	(1,508)	170	—		(1,338)
Net income (loss)	$ (27,466)	$ 3,739	$ (28,402)		$ (52,129)
Income allocable to participating securities	$ —	$ (1,466)	$ —		$ —
Net income (loss) attributable to common shareholders	$ (27,466)	$ 2,273	$ (28,402)		$ (52,129)
Net income (loss) per share attributable to common shareholders:					
Basic	$ (7.45)	$ 0.54			$ (7.02)
Diluted	$ (7.45)	$ 0.48			$ (7.02)
Weighted average common shares outstanding:					
Basic	3,688	4,211	(475)	**I**	7,424
Diluted	3,688	5,076	(1,340)	**I**	7,424

See accompanying notes to unaudited pro forma condensed combined financial information

Note 1 - Description of the Merger

On April 26, 2022, Caladrius Biosciences, Inc. (“Caladrius”), CS Cedar Merger Sub, Inc., a Delaware corporation and wholly owned subsidiary of Caladrius (“Merger Sub”), and Cend Therapeutics, Inc. (“Cend” or the “Company”), a privately-held, clinical-stage biotechnology company, entered into an Agreement and Plan of Merger and Reorganization (the “Merger Agreement”), pursuant to which, among other matters, and subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Merger Sub merged with and into Cend, with Cend continuing as a wholly owned subsidiary of Caladrius (the “Merger”). Upon closing of the Merger on September 15, 2022, the combined company was renamed to Lisata Therapeutics, Inc. (“Lisata”) and trades on the Nasdaq under the ticker symbol “LSTA.”

Subject to the terms and conditions of the Merger Agreement, at the closing of the Merger, (a) each outstanding share of Cend common stock and Cend preferred stock (except shares of Cend Series D Preferred Stock held by Caladrius) was converted into 3,772,768 shares of Caladrius common stock (“Caladrius Common Stock”), based on an exchange ratio of 0.5338; and (b) each outstanding Cend stock option that had not previously been exercised prior to the closing of the Merger was assumed by Caladrius and converted into options to purchase shares of Caladrius Common Stock based on the exchange ratio of 0.5338. As of immediately after the Merger, Cend’s former stockholders owned approximately 48% of the outstanding shares of Caladrius Common Stock and stockholders of Caladrius as of immediately prior to the Merger owned approximately 52% of the outstanding shares of Caladrius Common Stock. At the time of closing, the allocation was adjusted based on Caladrius’ net cash balance and as a result, the Caladrius allocation percentage was increased 2% as the net cash was greater than $73,366,000 by approximately $3,140,000.

Caladrius submitted to Caladrius’ stockholders an amendment to Caladrius’ certificate of incorporation to authorize the Caladrius board to effect a reverse stock split of all outstanding shares of Caladrius common stock at a reverse stock split ratio of one new share for every fifteen shares outstanding (the “Caladrius Reverse Stock Split”). The Caladrius Reverse Stock Split was mutually agreed to by Cend and Caladrius and became effective on September 14, 2022. All Caladrius historical common stock amounts in the unaudited pro forma condensed combined financial statements have been adjusted for the impact of the Caladrius Reverse Stock Split.

Consummation of the Merger was subject to certain closing conditions, including, among other things, approval by the stockholders of Caladrius and Cend, and Caladrius’s satisfaction of a minimum net cash threshold at closing, approximately $76.5 million at closing on September 15, 2022, and as described further in the Merger Agreement. In accordance with the terms of the Merger Agreement, (i) certain executive officers, directors and stockholders of Cend (solely in their respective capacities as Cend stockholders) holding approximately 77.5% of the outstanding Cend capital stock entered into support agreements with Caladrius to vote all of their shares of Cend capital stock in favor of adoption of the Merger Agreement (the “Cend Support Agreements”) and (ii) certain executive officers and directors of Caladrius (solely in their respective capacities as Caladrius stockholders) holding approximately 1.8% of the outstanding Caladrius common stock entered into support agreements with Cend to vote all of their shares of Caladrius common stock in favor of approval of the Merger Agreement (the “Caladrius Support Agreements,” together with the Cend Support Agreements, the “Support Agreements”). The Support Agreements include covenants with respect to the voting of such shares in favor of approving the transactions contemplated by the Merger Agreement and against any competing acquisition proposals and place certain restrictions on the transfer of the shares of Caladrius and Cend held by the respective signatories thereto.

Concurrently with the execution of the Merger Agreement and in order to provide Cend with capital for its development programs prior to the closing of the Merger, Caladrius agreed to purchase from Cend shares of Series D Preferred Stock (the “Cend Series D Preferred Stock”), of Cend at a purchase price of $10.0 million. In addition, Caladrius and Cend entered into a Collaboration Agreement (the “Collaboration Agreement”), pursuant to which Caladrius and Cend agreed to collaborate on certain developmental and clinical activities prior to the closing of the Merger. Under the Collaboration Agreement, Caladrius and Cend will form a joint steering committee (the “Committee”) comprised of individuals from both entities.

Note 2 - Basis of Pro Forma Presentation

The unaudited pro forma condensed combined financial information of the combined company is presented to illustrate the proposed effects of the Merger. The unaudited pro forma condensed combined financial information has been prepared in accordance with Article 11 of Regulation S-X, as amended by Securities and Exchange Commission (“SEC”) Final Rule Release No. 33-10786 “Amendments to Financial Disclosures about Acquired and Disposed Businesses.” Release No. 33-10786 replaced the existing pro forma adjustment criteria with simplified requirements to depict the accounting for the transaction (“Transaction Accounting Adjustments”) and present the reasonably estimable synergies and other transaction effects that have occurred or are reasonably expected to occur (“Management’s Adjustments”). The combined company has elected not to present Management’s Adjustments and will only be presenting Transaction Accounting Adjustments in the unaudited pro forma condensed combined financial information.

The Merger was accounted for by using the cost accumulation and allocation model of accounting in accordance with the asset acquisition accounting guidance set forth in Accounting Standards Codification (ASC) 805, *Business Combinations* ("ASC 805").

The unaudited pro forma condensed combined statements of operations for the six month period ended June 30, 2022 and for the year ended December 31, 2021, give effect to the Merger as if it had been consummated on January 1, 2021. The unaudited pro forma condensed combined balance sheet as of June 30, 2022 gives effect to the Merger as if it had been consummated on June 30, 2022. Based on Caladrius' preliminary review of Cend's summary of significant accounting policies and preliminary discussions between management teams of Caladrius and Cend, the nature and amount of any adjustments to the historical financial statements of Cend to conform its accounting policies to those of Caladrius are not expected to be material. Upon completion of the Merger, further review of Cend's accounting policies may result in additional revisions to Cend's accounting policies and classifications to conform to those of Caladrius.

To determine the accounting for this Merger under GAAP, a company must assess whether an integrated set of assets and activities should be accounted for as an acquisition of a business or an asset acquisition. The initial screen test is met as substantially all of Cend's fair value is concentrated in intangible assets, primarily, In-Process Research & Development ("IPR&D"). As such, the acquisition was treated as an asset acquisition. Cend's assets (except for cash) and liabilities were measured and recognized as an allocation of the transaction price based on their relative fair values as of the transaction date with any value associated with IPR&D with no alternative future use being expensed.

Asset acquisitions are to be accounted for by allocating costs, including transaction costs, of the acquisition to the acquired assets based on their relative fair value basis. For the purpose of measuring the estimated fair value of the assets acquired and liabilities assumed, Caladrius estimated the fair values as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants as of the measurement date. The fair value measurements utilize estimates based on key assumptions of the Merger, including historical and current market data. The unaudited pro forma adjustments included herein are preliminary and will be adjusted as additional information becomes available and as additional analyses are performed. The final purchase price allocation will be determined subsequent to the Merger, and the final amounts of the assets acquired, and liabilities assumed may differ materially from the values recorded in the pro forma financial information.

Pro forma transaction accounting adjustments are included only to the extent they are adjustments that reflect the accounting for the Merger in accordance with GAAP.

Caladrius and Cend expect to incur significant costs associated with integrating the operations of Caladrius and Cend after the Merger is completed. The unaudited pro forma condensed combined financial information does not reflect the costs of any integration activities or benefits that may result from realization of future cost savings from operating efficiencies expected to result from the Merger.

The unaudited pro forma condensed combined financial information may differ from the final purchase accounting for a number of reasons, including the fact that the estimates of fair values of assets and liabilities acquired are preliminary and subject to change when the valuation and other studies are finalized. In addition, the values will be based on the actual values as of the closing date of the Merger. The differences that may occur between the preliminary estimates and the final purchase accounting could have a material impact on the accompanying unaudited pro forma condensed combined financial information.

Note 3 — Preliminary Purchase Price

The accompanying unaudited pro forma condensed combined financial statements reflect a purchase price of approximately $37.1 million (the "Consideration") comprised of equity consideration of approximately $23.6 million, the carrying value of Caladrius' cost method investment in Cend's Series D Preferred Stock of approximately $10.0 million, the incremental fair value of Cend's fully vested stock options of approximately $1.9 million, and estimated transaction costs of approximately $1.6 million.

The Consideration payable by Caladrius takes into account the value of Caladrius' interests in Cend's Series D Preferred Stock. Prior to the closing of the Merger, Caladrius accounted for its interest in Cend using the cost method, and the carrying value was approximately $10.0 million as of June 30, 2022. The Company accounted for the asset acquisition of the interest of Cend as a step acquisition, which required a cost accumulation approach of the Company's ownership interest in Cend which will be valued at its carryover basis of $10.0 million and included in the purchase price.

The table below represents the total purchase price (dollars in thousands, except per share data):

Estimated number of common shares of the combined company owned by Cend stockholders (1)		3,772,768
Multiplied by the fair value per share of Caladrius common stock on September 15, 2022 (2)	$	6.25
Total	**$**	**23,580**
Carrying value of Caladrius' cost method investment in Cend (3)		10,000
Incremental fair value of Cend's fully vested stock options (4)		1,939
Caladrius estimated transaction costs (5)		1,600
Total estimated purchase price	**$**	**37,119**

1. For purposes of this unaudited pro forma combined financial information, 3,772,768 represents the historical 7,068,037 shares of Cend common stock and preferred stock outstanding on June 30, 2022, adjusted for the exchange ratio.

2. The equity portion of the purchase price was based on the closing price of Caladrius as reported on the Nasdaq Capital Market on September 15, 2022.

3. Using cost accumulation accounting, the carrying value of Caladrius' cost method investment in Cend's Series D Preferred Stock is included in the total purchase price as of June 30, 2022. There were no impairment indicators through the Closing of the Merger for the cost method investment. Caladrius will continue to evaluate the cost method investment for impairment indicators each reporting period.

4. Represents the incremental fair value of the Cend replacement options of approximately $1.8 million related to the fully vested replacement options subject to service-based vesting conditions and approximately $0.1 million related to vested replacement options subject to performance-based vesting conditions achieved prior to the Closing Date, assumed by Caladrius upon the consummation of the Merger as described in Note 4 — Shares of Caladrius Common Stock Issued to Cend's Stockholders upon closing of the Merger. In accordance with, and analogous to ASC 805, as no post-Merger services are required for the fully vested replacement awards, and Cend's employees rendered all of the required service for the Cend awards as of the date of the Merger, the incremental fair value is included in the purchase price.

   The amount attributable to post-Merger service is approximately $0.2 million for replacement options subject to service-based vesting conditions which are not subject to accelerated vesting and will not vest upon the change in control, approximately $0.3 million for replacement options subject to performance-based vesting conditions that require a double trigger (change in control and severance) to vest, and $48.9 thousand for unvested replacement options subject to performance-based vesting conditions which will become fully vested upon the closing of the Merger. Replacement options with accelerated vesting at the closing of the Merger were deemed to be for the benefit of the combined entity. Caladrius will recognize the stock-based compensation expense for the replacement options subject to service-based vesting conditions as additional compensation cost on a straight-line basis over the remaining vesting period of the original awards, will recognize the stock-based compensation related to the achievement of the double trigger performance-based vesting conditions in the period during which it becomes probable the conditions will be met, and will recognize the stock-based compensation expense for the unvested replacement options subject to performance-based vesting which will fully vest upon the closing of the Merger as compensation cost on day one following the Closing Date.

   The difference between the total value of the replacement awards of approximately $5.4 million, and the fair value of the original Cend awards of approximately $3.0 million, is approximately $2.4 million.

5. Caladrius transaction costs are approximately $1.6 million. The transaction costs have been reflected as an increase in the purchase price.

For purposes of this pro forma analysis, the above purchase price has been allocated based the relative fair value of the assets and liabilities acquired (in thousands):

Preliminary Purchase Price Allocation:	**June 30, 2022 Pro forma**
Cash and cash equivalents	$ 11,202
Net working capital (excluding cash)	811
Other liabilities	(22)
Acquired in-process research and development	23,394
License	1,734
Net assets acquired	**$ 37,119**

The guidance in ASC 805 requires an initial screen test to determine if substantially all of the fair value of the gross assets acquired is concentrated in a single asset or group of similar assets. If that screen is met, the set is not a business. The initial screen test was met as Caladrius determined that substantially all of the fair value was concentrated in the acquired IPR&D. The fair value of the IPR&D was determined to be approximately $61.7 million before the purchase price was allocated among the assets and liabilities acquired, as shown above.

IPR&D represents the research and development assets of Cend which were in-process, but not yet completed, and which Caladrius has the opportunity to advance. Current accounting standards require that the fair value of IPR&D projects acquired in an asset acquisition with no alternative future use be allocated a portion of the consideration transferred and charged to expense at the acquisition date. The actual purchase price allocated to IPR&D will fluctuate until the closing date of the Merger, and the final valuation of the IPR&D consideration could differ significantly from the current estimate.

License represents the Exclusive License and Collaboration Agreement (the “Qilu Agreement”) in which Cend granted an exclusive license to Qilu for the development and commercialization of CEND-1 in the Territory (defined as the Greater Area of China including China, Macau, Hong Kong, and Taiwan). Under the terms of the agreement, Qilu is solely responsible for the development of CEND-1 in its Territory. In consideration for the license, Qilu made a one-time, non-refundable, non-creditable upfront payment of $10.0 million to Cend. Cend is also eligible to receive developmental and commercial milestone payments up to $100.0 million and $125.0 million, respectively, tiered royalties on net sales ranging from 10% to 15%, and tiered sublicensing revenues ranging from 12% to 35%. To date, Cend has recognized approximately $15.0 million[1] in revenue under the Qilu Agreement resulting from the up-front license fee, a development milestone, as well as through the sale of clinical supply materials.

Note 4 — Shares of Caladrius Common Stock Issued to Cend’s Stockholders upon Closing of the Merger

Pursuant to the Merger Agreement, at the Effective Time, Caladrius issued 3,772,768 shares of Common Stock to the holders of all of the Cend capital stock in exchange for all of the shares of Cend capital stock (including the shares of common stock issuable upon the conversion of all shares of preferred stock, except Series D Preferred Stock), immediately prior to the Effective Time, determined as follows:

	Shares
Cend:	
Cend Series A Preferred Stock outstanding	371,396
Cend Series B Preferred Stock outstanding	1,071,237
Cend Series C Preferred Stock outstanding	1,345,699
Cend shares of common stock outstanding	4,279,705
Total Cend outstanding shares pre-close	7,068,037
Exchange ratio (rounded)	0.5338
Total Cend merger common shares	3,772,768

[1] Cend management to confirm if amount has changed

In addition, in accordance with the Merger Agreement, Caladrius assumed all of the issued and outstanding options to acquire Cend common stock, pursuant to the Cend 2016 Equity Incentive Plan (the "Cend Plan"), with such stock options representing the right to purchase a number of shares of Caladrius Common Stock equal to 0.5338 multiplied by the number of shares of Cend's common stock previously represented by such stock options immediately prior to the closing of the Merger, with a proportional adjustment to the exercise price of such options.

Basic loss per share represents the net loss per share calculated using the historical weighted average shares outstanding, and the issuance of additional shares in connection with the Merger, assuming the shares were outstanding at the beginning of the periods presented. Diluted loss per common share is the same as basic loss per common share for all periods presented because the effects of potentially dilutive items were anti-dilutive. The following common share equivalent securities have been excluded from the calculation of weighted-average common shares outstanding because the effect is anti-dilutive for the periods presented:

	June 30, 2022
Anti-dilutive common share equivalents:	(in thousands)
Stock options of Caladrius	524
Stock options of Cend	1,228
Warrants to purchase Caladrius common stock	1,424
Total anti-dilutive common share equivalents	**3,176**

The information below reflects historical per share information for Caladrius and Cend and unaudited pro forma per share information of the combined company as if Caladrius and Cend had been combined as of or for the periods presented. The net loss per share information reflects the Merger as if the transaction had occurred on January 1, 2021.

Note 5 - Pro Forma Adjustments

Adjustments included in the column under the heading "Transaction Accounting Adjustments" are primarily based on information contained within the analysis will be performed after the completion of the merger to confirm these estimates or make adjustments in the final purchase price allocation, as necessary.

Given Caladrius' history of net losses and valuation allowance, management assumed a statutory tax rate of 0%. Therefore, the pro forma adjustments to the condensed combined statements of operations and comprehensive loss resulted in no additional income tax adjustment to the pro forma financials.

The unaudited pro forma adjustments reflected in the unaudited pro forma condensed combined financial statements as as follows:

A. To eliminate Cend's pre-merger redeemable convertible preferred stock, convertible preferred stock, common stock, paid-in capital, accumulated deficit, and accumulated other comprehensive loss balances.

	June 30, 2022
	(in thousands)
Elimination of Cend's Series A redeemable convertible preferred stock	$ (1,100)
Elimination of Cend's Series B redeemable convertible preferred stock	(3,941)
Elimination of Cend's Series C convertible preferred stock	—
Elimination of Cend's Series D preferred stock	—
Elimination of Cend's common stock	—
Elimination of Cend's additional paid-in capital	(21,982)
Elimination of Cend's historical accumulated deficit	14,897
Elimination of Cend's accumulated other comprehensive loss	135
Elimination of Cend's accumulated deficit for other pro forma adjustments impacting accumulated deficit, such as transaction costs (C)	3,097
Total adjustments to Cend's historical equity	**$ (8,894)**

B. To reflect the asset acquisition Consideration, including the capitalization of the fair value of the number of shares of the combined company owned by Cend's stockholders and Caladrius' transaction costs as well as the adjustment to accumulated deficit for the acquired in-process research and development:

	June 30, 2022
	(in thousands)
Capitalization of the fair value of the estimated number of shares of the combined company to be owned by Cend's stockholders	$ 23,580
Carrying value of Caladrius' cost method investment in Cend	10,000
Caladrius' estimated transaction costs as part of asset acquisition (D)	1,600
Incremental fair value of Cend's fully vested replacement options (Note 3)	1,939
Impact of expensed IPR&D acquired (H) and accumulated amortization of the acquired license (L)	(23,538)
Total adjustment to reflect asset acquisition purchase price	**$ 13,581**

C. To record Cend's transaction costs of approximately $3.1 million, for legal and advisory fees, and transactional fees in addition to $0.1 million included in accrued liabilities as of June 30, 2022.

D. To record Caladrius' transaction costs of approximately $1.6 million, for legal and advisory fees and transactional fees as of June 30, 2022.

E. To record Cend's transaction costs of approximately $3.2 million, for legal and advisory fees, and transactional fees for the year ended December 31, 2021.

F. To record Caladrius' transaction costs of approximately $1.6 million, for legal and advisory fees and transactional fees for the year ended December 31, 2021. Transaction costs directly related to the Merger of $1.6 million will be included in the purchase price (see Note 3).

G. To record the elimination of Caladrius' cost method investment in Cend at the Effective Time of the Merger, as well as the cancellation of the shares of Series D Preferred Stock that were issued to Caladrius. Per the Merger Agreement, the Series D Preferred Stock was not converted to shares of common stock of Cend at the time of the Merger, rather the Series D Preferred Stock was cancelled and no consideration exchanged.

H. To record the impact of expensing the acquired IPR&D upon consummation of the asset acquisition (Note 3).

I. Calculation of weighted-average shares outstanding:

	June 30, 2022	December 31, 2021
	(in thousands)	
Historical Cend weighted-average shares of common stock outstanding	4,280	4,211
Impact of Cend's convertible preferred stock assuming conversion	2,788	2,788
Total	7,068	6,999
Application of exchange ratio of historical Cend weighted-average shares outstanding	0.5338	0.5338
Adjusted Cend weighted-average shares outstanding	3,773	3,736
Historical Caladrius weighted-average shares outstanding	4,036	3,688
Total weighted average shares outstanding	**7,809**	**7,424**

As Caladrius had a net loss on a pro forma combined basis, stock options to purchase common stock have been excluded from the calculation of diluted net loss per share because all such securities are anti-dilutive for all periods presented.

J. To record the following adjustments to accumulated deficit:

	June 30, 2022
	(in thousands)
Elimination of Cend's accumulated deficit	$ 17,994
Impact of Cend's transaction costs as part of asset acquisition (C)	(3,097)
Impact of expensed IPR&D acquired (H), Caladrius' transaction costs as part of asset acquisition (D), and accumulated amortization of the acquired license (L)	(25,138)
Total adjustment to accumulated deficit	**$ (10,241)**

K. To record the following adjustments to additional paid-in capital:

	June 30, 2022
	(in thousands)
Elimination of Cend's additional paid-in capital and par value	$ (21,982)
To reflect Cend's remaining stock post-Merger	23,576
To reflect the reclassification of Caladrius' historical par value to additional paid-in capital for reverse stock split	57
To reflect the impact of asset acquisition to additional paid-in capital	442
Total adjustment to additional paid-in capital	**$ 2,093**

L. Represents the acquired Qilu Agreement in which Cend granted an exclusive license to Qilu for the development and commercialization of CEND-1 in the amount of approximately $1.7 million, net of accumulated amortization of approximately $0.2 million. The license is a definite lived intangible asset with an estimated remaining useful life of fifteen years. The amortization expense of approximately $0.1 million, and approximately $0.1 million has been included in the pro forma statements of operations for the year ended December 31, 2021 and for the six month period ended June 30, 2022, respectively.

M. To record the reclassification of Caladrius' historical common stock par value to additional paid-in capital of $57.0 thousand due to the effect of the reverse stock split on September 14, 2022.