

As confidentially submitted to the U.S. Securities and Exchange Commission on June 23, 2021.
This draft registration statement has not been publicly filed with the U.S. Securities and Exchange Commission and all information herein remains strictly confidential.

Registration No. 333-

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933**

Cognition Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

2836
(Primary Standard Industrial
Classification Code Number)

13-4365359
(I.R.S. Employer
Identification Number)

**2403 Sidney Street
Pittsburgh, Pennsylvania 15203
(412) 481-2210**

(Address, including zip code, and telephone number, including area code, of Registrant's principal executive offices)

**Lisa Ricciardi
Chief Executive Officer
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2403 Sidney Street
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Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this Registration Statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. ☐

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

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 7(a)(2)(B) of the Securities Act. ☐

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Proposed maximum aggregate offering price ⁽¹⁾	Amount of registration fee ⁽²⁾
Common Stock, \$0.001 par value per share	\$	\$

(1) Estimated solely for the purpose of computing the amount of the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended. Includes the aggregate offering price of additional shares of common stock that the underwriters have the option to purchase.

(2) Calculated pursuant to Rule 457(o) based on an estimate of the proposed maximum aggregate offering price.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

Subject to completion, dated , 2021

Preliminary prospectus

shares



Common stock

This is the initial public offering of shares of common stock of Cognition Therapeutics, Inc.

We are offering shares of our common stock. It is currently estimated that the initial public offering price per share will be between \$ and \$. Prior to this offering, there has been no public market for our common stock.

We intend to apply to list our common stock on the Nasdaq Global Market under the trading symbol “CGTX”.

We are an “emerging growth company” and a “smaller reporting company” as defined under the federal securities laws and, as such, have elected to comply with certain reduced public company reporting requirements for this prospectus and may elect to do so in future filings.

Investing in our common stock involves a high degree of risk. See the section titled “Risk Factors” beginning on page 11 to read about factors you should consider before buying shares of our common stock.

	Per share	Total
Initial public offering price	\$	\$
Underwriting discounts and commissions ⁽¹⁾	\$	\$
Proceeds to us before expenses	\$	\$

(1) See the section titled “Underwriting” beginning on page 172 for additional information regarding compensation payable to the underwriters.

We have granted the underwriters an option for a period of 45 days to purchase up to additional shares of common stock at the initial public offering price, less the underwriting discounts and commissions.

The underwriters expect to deliver the shares against payment in New York, New York on , 2021.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities, or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

B. Riley Securities

Prospectus dated , 2021

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“Cognition Therapeutics, Inc.” the “Cognition Therapeutics” logo and other trademarks, trade names or service marks of Cognition Therapeutics, Inc. appearing in this prospectus are the property of Cognition Therapeutics, Inc. All other trademarks, trade names and service marks appearing in this prospectus are the property of their respective owners. Solely for convenience, the trademarks and trade names in this prospectus may be referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert their rights thereto.

Neither we nor the underwriters have authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectuses prepared by or on behalf of us or to which we have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the shares offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus or in any applicable free writing prospectus is current only as of its date, regardless of its time of delivery or any sale of shares of our common stock. Our business, financial condition and results of operations may have changed since that date.

For investors outside the United States: Neither we nor the underwriters have done anything that would permit this offering or possession or distribution of this prospectus or any free writing prospectus we may provide to you in connection with this offering in any jurisdiction where action for that purpose is required, other than in the United States. You are required to inform yourselves about and to observe any restrictions relating to this offering and the distribution of this prospectus and any such free writing prospectus outside the United States.

Through and including _____, 2021 (25 days after the date of this prospectus), all dealers that effect transactions in our common stock, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to the dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to unsold allotments or subscriptions.

Market and Industry Data

This prospectus contains estimates and other statistical data made by independent parties relating to our industry and the markets in which we operate, including estimates and statistical data about our market position, market opportunity, the incidence of certain medical conditions and other industry data. These data, to the extent they contain estimates or projections, involve a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates or projections. Although we have not independently verified the accuracy or completeness of the data contained in these industry publications and reports, based on our industry experience we believe that the publications are reliable, the conclusions contained in the publications and reports are reasonable and the third-party information included in this prospectus and in our estimates is accurate and complete.

PROSPECTUS SUMMARY

This summary highlights selected information contained in greater detail elsewhere in this prospectus. This summary is not complete and does not contain all of the information you should consider in making your investment decision. Before investing in our common stock, you should carefully read this entire prospectus. You should carefully consider, among other things, the sections titled “Risk Factors,” “Special Note Regarding Forward-Looking Statements” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our consolidated financial statements and the related notes included elsewhere in this prospectus. As used in this prospectus, unless the context otherwise requires, references to “we,” “us,” “our,” the “company,” “Cognition” and similar references refer to Cognition Therapeutics, Inc., and its consolidated subsidiary.

Overview

We are a clinical-stage biopharmaceutical company engaged in the discovery and development of innovative, small molecule therapeutics targeting age-related degenerative diseases and disorders of the central nervous system, or CNS, and retina. Currently available therapies for these diseases are limited, with many diseases having no approved therapies or treatments. Our goal is to develop disease modifying treatments for patients with these degenerative disorders by initially leveraging our expertise in the σ -2 (sigma-2) receptor, or S2R, which is expressed by multiple cell types, including neuronal synapses, and acts as a key regulator of cellular damage commonly associated with certain age-related degenerative diseases of the CNS and retina. We believe that targeting the S2R complex represents a mechanism that is functionally distinct from other current approaches in clinical development for the treatment of degenerative diseases.

Since our inception, we have collaborated and worked closely with key healthcare organizations and thought leading institutions in the field of degenerative diseases to develop and advance our therapeutic candidates. To date we have been awarded approximately \$168.4 million in grants and financial support primarily from the National Institute of Aging, or NIA, a division of the National Institutes of Health to support our clinical trials.

Our lead product candidate, CT1812, is an orally delivered, small molecule antagonist designed to penetrate the blood-brain barrier and bind selectively to the S2R complex. The S2R complex is comprised of transmembrane protein 97, or TMEM97, a four-domain transmembrane protein that forms a complex with progesterone receptor membrane component 1, or PGRMC1. The S2R complex is expressed in the CNS, the retina, as well as peripheral organs, including the pancreas, liver and kidney. Internal and third-party studies suggest that the role of PGRMC1 and TMEM97, the protein components of the S2R complex, regulate cell damage response processes, including cholesterol biosynthesis, vesicle trafficking, progesterone signaling, lipid membrane-bound protein trafficking and receptor stabilization at the cell surface. In addition, the S2R complex regulates autophagy, the cellular process by which altered cellular proteins are degraded and removed. The aberrant activity of these processes, believed to be triggered by cellular stresses, is a hallmark of the dysfunction related to degenerative diseases.

We have initially focused on the development of CT1812 for the treatment of Alzheimer’s disease, or AD, a disease that afflicts approximately 6.2 million people in the United States and disease prevalence is expected to more than double by 2050. The direct healthcare costs to care for patients with AD and other dementias in the United States is currently estimated to exceed \$300 billion. CT1812 targets the accumulation of β -amyloid, or A β , oligomers, which has been linked to AD. By displacing these A β oligomers from neuronal receptors in the S2R complex, we expect to demonstrate that CT1812 can slow the loss of synapses and cognitive decline observed in AD. CT1812 is the first S2R antagonist to reach clinical trials and is currently in Phase 2 development for the treatment of AD.

We are continuing to enroll patients in two ongoing Phase 2 clinical trials (SHINE and SEQUEL) with CT1812 in mild-to-moderate AD. Preliminary results from an interim analysis of the first 24 patients in Part A of our ongoing SHINE Phase 2 clinical trial demonstrated a statistically significant decline in the presence of A β and a positive trend on cognitive function as measured by the Alzheimer’s Disease Assessment Scale-Cognitive Subscale, or ADAS-Cog, in patients receiving CT1812 compared to placebo, and we anticipate top-line data from this study in the first half of 2023. Our ongoing SEQUEL Phase 2 clinical trial is also evaluating changes in brain function, as measured by electroencephalography, or EEG, in mild-to-moderate AD with top-line data expected in 2023. We have treated an estimated 164 subjects with CT1812

in our clinical trials to date including 76 patients with mild-to-moderate AD. CT1812 has continued to be well tolerated and has been granted Fast Track designation by the U.S. Food and Drug Administration, or the FDA, in this indication.












With the support of a grant of approximately \$81.0 million from the NIA, we intend to enroll 540 patients in our COG0203 clinical trial with mild cognitive impairment, or MCI, due to AD or mild AD who have elevated levels of A β as determined by positron emission tomography, or PET, imaging or as measured in cerebral spinal fluid, or CSF. Patients will be randomized to receive CT1812 or a placebo for 18 months. In addition to cognitive and functional measures, such as the Clinical Dementia Rating Scale, or CDR, Sum of Boxes, or SOB, and ADAS-Cog, we intend to use a variety of biomarkers to measure target and/or pathway engagement and assess changes in neurodegeneration and disease progression. We will conduct this clinical trial in collaboration with the Alzheimer's Clinical Trial Consortium, or ACTC, an NIA-funded clinical trials network designed to accelerate studies for therapeutics for AD and related dementias. We expect to begin enrollment for this trial in the first half of 2022.

We intend to expand our CT1812 pipeline to include additional indications such as dry age-related macular degeneration, or dry AMD, a disease that results in the deterioration of the macula, causing visual distortion, loss of central vision and eventual blindness, for which there are currently no FDA approved treatments. The S2R complex is expressed in the retina in several cell types including the retinal pigment epithelial cells, or RPE, photoreceptors and retinal ganglion cells. We believe that an S2R antagonist, such as CT1812, may help to regulate the damage-response processes related to these cells that are impaired in dry AMD. After the completion of our ongoing preclinical studies, and subject to discussion with the FDA, we intend to advance directly into a Phase 2 clinical trial in the second half of 2021, leveraging our knowledge of CT1812's preclinical and clinical profile to date. We have initiated discussions with the FDA regarding our plan.

We also intend to develop and advance other product candidates in the area of synucleinopathies. Synucleinopathies are a group of degenerative diseases characterized by the abnormal accumulation of the alpha-synuclein protein in neural cell bodies, including Parkinson's disease, or PD, and dementia with Lewy bodies, or DLB.

Our Pipeline

We are developing a pipeline of innovative, small molecule product candidates that are designed to target the S2R complex, a key regulator of the cellular damage response for diseases such as AD, dry AMD, geographic atrophy (an advanced form of dry AMD), or GA, and other conditions for which there is significant unmet medical need. Our current pipeline is summarized below:

Product Candidate	Target Indication	Preclinical	Phase 1	Phase 2	Phase 3	Next Anticipated Milestone	Funding
CT1812	Mild-moderate AD					SHINE Topline 1H2023 (Enrolling final cohort 2H2021)	\$30M 
CT1812	Early-stage AD					ACTC Phase 2 COG0203 initiation (1H2022)	\$81M 
CT1812	DLB					Phase 2 initiation* (2H2021)	\$30M 
CT1812	Dry AMD					Phase 2 initiation* (2H2021)	
undisclosed	Synucleinopathies †					IND enabling studies	
undisclosed	Dry AMD					IND enabling studies	

* Provided the FDA agrees, we intend to proceed with Phase 2 studies supported by the Phase 1 AD studies

† including Parkinson's disease and DLB

Our Strategy

Our objectives are to develop and advance our portfolio, beginning with our lead product candidate, CT1812, through clinical development for the treatment of age-related degenerative diseases and disorders of the CNS and retina and to leverage our understanding of the S2R complex and its regulation of pathways to pursue indications in other degenerative disorders. The key elements of our strategy include:

- **Advance clinical development of our lead product candidate, CT1812, in mild-to-moderate AD and earlier stages of the disease.** Our lead product candidate, CT1812, has progressed through Phase 1 and into Phase 2 clinical trials. Funding of the Phase 1 and Phase 2 trials is primarily through the NIA. We plan to evaluate CT1812 in other AD populations as well and develop CT1812 for patients with earlier symptomatic stages of AD and Mild Cognitive Impairment, which is a slight and noticeable measurable decline in cognitive abilities due to AD. We plan to initiate the COG0203 clinical trial in patients with mild dementia associated with early-stage AD in the first half of 2022, which has been funded by a grant award of approximately \$81.0 million from the NIA.
- **Pursue the development of CT1812 for dry AMD.** We plan to evaluate CT1812 as a potential therapy for dry AMD, a common eye disease that results in the deterioration of the macula, causing visual distortion, loss of central vision and eventual blindness. We believe that an S2R antagonist, such as CT1812, may help to regulate the damage-response processes related to these cells that are impaired in dry AMD. After the completion of our ongoing preclinical studies, and subject to discussion with the FDA, we intend to advance directly into a Phase 2 clinical trial in the second half of 2021, leveraging our knowledge of CT1812's preclinical and clinical profile to date. We have initiated discussions with the FDA regarding our plan.
- **Leverage our understanding of the S2R complex to develop product candidates for other CNS and degenerative diseases, including synucleinopathies.** We intend to develop and advance other product candidates to treat synucleinopathies, which include PD and DLB. In the second half of 2021, we anticipate initiating a study of CT1812 in patients with DLB subject to discussion with FDA. Data published in February 2021 showed that the S2R complex may play an integral role in the pathology of PD and we believe these results merit further study.
- **Expand our pipeline through internal development, in-licensing and acquisitions.** We intend to leverage our expertise in drug development and business development to evaluate additional product candidates as well as bring forward novel chemical matter using our library generation and Novel Improved Conditioned Extraction, or NICE, screening platform. To achieve this objective, we may supplement our internal development initiatives through selective in-licensing arrangements, as well as investments in strategic collaborations or partnerships which complement our initiatives.
- **Optimize the value of CT1812 and other product candidates in major markets.** We currently retain all worldwide rights to CT1812 for all indications. We plan to develop and pursue approval of CT1812 and other future product candidates in major markets. Where appropriate, we may use strategic collaborations or partnerships to accelerate development and maximize the commercial potential of our programs. We and our key opinion leaders believe CT1812 also can be used in combination with other therapeutics targeting AD biologies and which may provide us with additional partnering opportunities.
- **Continue to pursue non-dilutive funding opportunities.** The majority of our clinical trials have been funded by approximately \$168.4 million in cumulative grants awarded primarily by the NIA, which includes a grant award of approximately \$81.0 million from the NIA to fund our upcoming Phase 2 (COG0203) study of CT1812 in patients with early-stage AD. These grants are non-dilutive and allow us to collaborate with research institutions in pursuing the development of our product candidates for age-related degenerative diseases. We intend to continue our work with these research institutions and plan to seek additional non-dilutive funding for our clinical development when possible.

Our Team

We have assembled a management team with extensive experience with CNS and degenerative diseases, significant expertise in the S2R biology domain, as well as drug discovery, clinical development, general management and business development. Collectively, our management team has a track record of managing drug development programs that have received regulatory approval and been successfully commercialized. These include programs at Bristol-Myers Squibb Company, Pfizer Inc. and Roche Holding AG. We augment the strengths of our management team with an experienced board of directors and scientific and medical advisory boards.

Risks Associated with our Business

Our business is subject to a number of risks of which you should be aware before making a decision to invest in our common stock. These risks are more fully described in the section titled “Risk Factors” immediately following this prospectus summary. These risks include, among others, the following:

- we are a clinical-stage biopharmaceutical company with no products approved for commercial sale and have incurred significant losses since our inception in 2007. We expect to incur significant losses over for the foreseeable future and may never achieve or maintain profitability;
- we have not yet completed Phase 2 clinical trials and have no history of commercializing products, which may make it difficult for an investor to evaluate the success of our business to date and to assess our future viability;
- even if this offering is successful, we will need substantial additional financing to meet our financial obligations and to pursue our business objectives;
- to date, we have partially relied on non-dilutive grants to cover certain of our capital requirements for our clinical trials, and we may fail to continue to receive non-dilutive funding;
- our business has been and could continue to be adversely affected by the evolving and ongoing COVID-19 global pandemic in regions where we or third parties on which we rely have significant manufacturing facilities, concentrations of clinical trial sites or other business operations;
- our business is heavily dependent on the successful development, regulatory approval and commercialization of CT1812 and any future product candidates that we may develop or acquire;
- we may not successfully expand our pipeline of product candidates, including by pursuing additional indications for CT1812 or by in-licensing or acquiring additional product candidates for other diseases;
- preclinical and clinical development involves a lengthy and expensive process with an uncertain outcome, and the results of preclinical studies and early clinical trials are not necessarily predictive of future results;
- we have not tested any of our product candidates in pivotal clinical trials and our product candidates may not have favorable results in future clinical trials;
- we have conducted, and in the future plan to conduct, clinical trials for product candidates outside the United States, and the FDA and comparable foreign regulatory authorities may not accept data from such trials;
- even if our current or future product candidates obtain regulatory approval, they may fail to achieve the broad degree of adoption and use by physicians, patients, hospitals, healthcare payors and others in the medical community necessary for commercial success; and
- if we are unable to obtain and maintain patent protection for our technology and product candidates including our lead product candidate, CT1812, or if the scope of the patent protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets.

SAFE Offering

In March 2021, we entered into simple agreements for future equity, or SAFEs, with various investors, pursuant to which we received gross proceeds in an aggregate amount equal to \$8.94 million. The amount invested by the investors in the SAFEs is automatically convertible into shares of our common stock upon the closing of this offering at a conversion price equal to 80% of the initial public offering price of our common stock in this offering.

Recent Developments**Notes Conversion**

From March 2018 to July 2020, we issued convertible promissory notes in the aggregate principal amount of \$13.0 million with an interest rate of 8.0% per annum, pursuant to note purchase agreements entered into with certain holders of our capital stock. On May 1, 2021, the holders of all of our outstanding convertible promissory notes agreed to an acceleration of the date of the automatic conversion from June 30, 2021 to May 1, 2021 for all convertible promissory notes. Accordingly, on May 1, 2021, all of our outstanding convertible promissory notes were converted into 10,926,089 shares of our Series B-1 convertible preferred stock, at a conversion price equal to \$1.385 per share. As of the date of this prospectus, no notes are outstanding. Pursuant to the terms of our Series B-1 convertible preferred stock, all shares will automatically convert into shares of our common stock upon the closing of this offering on a one-for-one basis.

Our Corporate Information

We were incorporated under the laws of the State of Delaware on August 21, 2007. Our principal executive offices are located at 2403 Sidney Street, Pittsburgh, Pennsylvania 15203, and our telephone number is (412) 481-2210. Our corporate website address is www.cogrx.com. Information contained on, or accessible through, our website shall not be deemed incorporated into and is not a part of this prospectus or the registration statement of which it forms a part. We have included our website in this prospectus solely as an inactive textual reference.

Implications of Being an Emerging Growth Company

As a company with less than \$1.07 billion in revenue during our last fiscal year, we qualify as an “emerging growth company” as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. An emerging growth company may take advantage of specified reduced reporting requirements that are otherwise generally applicable to public companies. As such, we may take advantage of reduced disclosure and other requirements otherwise generally applicable to public companies, including:

- presenting only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced “Management’s Discussion and Analysis of Financial Condition and Results of Operations” disclosure in this prospectus;
- not being required to have our registered independent public accounting firm attest to management’s assessment of our internal control over financial reporting;
- presenting reduced disclosure about our executive compensation arrangements;
- not being required to hold non-binding advisory votes on executive compensation or golden parachute arrangements; and
- extended transition periods for complying with new or revised accounting standards.

We have taken advantage of some of these reduced disclosure and other requirements in this prospectus. Accordingly, the information contained herein may be different than the information you receive from our competitors that are public companies or other public companies in which you hold stock.

The JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This provision allows an emerging growth company to delay the adoption of some accounting standards until those standards would otherwise apply to private companies.

We will remain an emerging growth company until the earliest of (1) the last day of the fiscal year following the fifth anniversary of the closing of this offering, (2) the last day of the fiscal year in which we have total annual gross revenue of at least \$1.07 billion, (3) the last day of the fiscal year in which we are deemed to be a “large accelerated filer” as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended, or the Exchange Act, which would occur if the market value of our common stock held by non-affiliates exceeded \$700.0 million as of the last business day of the second fiscal quarter of such year or (4) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during the prior three-year period.

We are also a “smaller reporting company,” meaning that the market value of our stock held by non-affiliates plus the proposed aggregate amount of gross proceeds to us as a result of this offering is less than \$700.0 million and our annual revenue is less than \$100.0 million during the most recently completed fiscal year. We may continue to be a smaller reporting company after this offering if either (i) the market value of our stock held by non-affiliates is less than \$250.0 million or (ii) our annual revenue is less than \$100.0 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than \$700.0 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

THE OFFERING	
Issuer	Cognition Therapeutics, Inc.
Common stock offered by us	shares (or shares if the underwriters' exercise in full their option to purchase additional shares).
Offering price	\$ per share.
Common stock outstanding before the offering	shares.
Common stock to be outstanding after this offering	shares (or shares if the underwriters exercise in full their option to purchase additional shares).
Over-allotment option	We have granted a 45-day option to the underwriters to purchase up to additional shares of common stock to cover over-allotments, if any.
Use of proceeds	<p>We estimate that the net proceeds from this offering will be approximately \$ million (or approximately \$ million if the underwriters exercise in full their option to purchase up to additional shares of common stock), based on an assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.</p> <p>We intend to use the net proceeds from this offering to fund research and development of our product candidates and development programs, including our planned Phase 2 trials of CT1812 for the treatment of mild-to-moderate AD, our planned Phase 2 proof of concept trials of CT1812 for dry AMD, our IND-enabling studies of compounds in our library for the treatment of neurodegenerative indications such as PD, and the remainder for our other research and development activities, as well as for working capital and other general corporate purposes. See the section titled "Use of Proceeds" for additional information.</p>
Risk factors	Investing in our common stock involves a high degree of risk. You should read the section titled "Risk Factors" for a discussion of factors to consider carefully, together with all the other information included in this prospectus, before deciding to invest in our common stock.
Proposed Nasdaq Global Market trading symbol	"CGTX"
<p>The number of shares of our common stock to be outstanding after this offering is based on shares of common stock outstanding as of March 31, 2021, assuming (i) the automatic conversion of all outstanding shares of our convertible preferred stock into an aggregate of 51,450,435 shares of our common stock, (ii) the issuance of shares of our common stock upon the assumed net exercise of warrants that otherwise expire upon or prior to the closing of this offering (assuming an initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus), and (iii) the issuance of shares of our common stock issuable upon the conversion of the SAFEs upon</p>	

the closing of this offering in the aggregate amount of \$8.94 million (assuming an initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus), and excludes:

- 14,414,342 shares of our common stock issuable upon the exercise of stock options as of March 31, 2021, at a weighted-average exercise price of \$0.31 per share;
- 690,678 shares of our common stock reserved for issuance pursuant to future awards as of March 31, 2021 under our 2017 Equity Incentive Plan, or the 2017 Plan, which will become available under our 2021 Equity Incentive Plan, or the 2021 Plan, after the closing of this offering;
- shares of our common stock reserved for future issuance under the 2021 Plan which will become effective upon the effectiveness of the Registration Statement of which this prospectus forms a part, as well as any future increases in the number of shares of our common stock reserved for future issuance pursuant to the 2021 Plan; and
- shares of our common stock reserved for future issuance under our Employee Stock Purchase Plan, or the ESPP, which will become effective upon the effectiveness of the Registration Statement of which this prospectus forms a part, as well as any future increases in the number of shares of common stock reserved for issuance under the ESPP.

Unless otherwise indicated, all information contained in this prospectus, including the number of our shares of common stock that will be outstanding after this offering, assumes or gives effect to:

- no exercise of the outstanding options described above;
- the filing and effectiveness of our third amended and restated certificate of incorporation immediately prior to the closing of this offering;
- a for reverse stock split of our common stock to be effected prior to the closing of this offering;
- the automatic conversion of all our outstanding preferred stock into an aggregate of 51,450,435 shares of our common stock upon the closing of this offering;
- the issuance of shares of common stock upon the assumed net exercise of warrants that otherwise expire upon the closing of this offering (assuming an initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus);
- the issuance of shares of our common stock issuable upon the conversion of the SAFEs in the aggregate amount of \$8.94 million (assuming an initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus); and
- no exercise by the underwriters of their option to purchase up to additional shares of our common stock.

SUMMARY CONSOLIDATED FINANCIAL DATA

The following tables set forth a summary of our historical consolidated financial data as of, and for the period ended on, the dates indicated. We have derived the consolidated statements of operations data for the years ended December 31, 2019 and 2020 and the consolidated balance sheet data as of December 31, 2019 and 2020 from our audited consolidated financial statements and related notes appearing elsewhere in this prospectus. For interim periods, we have derived our consolidated financial data for the three months ended March 31, 2020 and 2021 and the selected balance sheet data as of March 31, 2021 from our unaudited consolidated financial statements and related notes appearing elsewhere in this prospectus. The unaudited financial statements were prepared on a basis consistent with our audited financial statements and include, in management's opinion, all adjustments, consisting only of normal recurring adjustments that we consider necessary for a fair presentation of the financial information set forth in those statements. Our historical results are not necessarily indicative of the results that may be expected in the future and our interim results are not necessarily indicative of our expected results for the year ending December 31, 2021. You should read the selected financial data below in conjunction with the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes included elsewhere in this prospectus. The summary consolidated financial data in this section are not intended to replace the financial statements and are qualified in their entirety by the financial statements and related notes included elsewhere in this prospectus.

(in thousands, except share and per share data)	Year Ended December 31,		Three Months Ended March 31,	
	2019	2020	2020	2021
Consolidated Statements of Operations Data:				
Operating Expenses:				
Research and development	\$ 14,379	\$ 12,887	\$ 3,446	\$ 4,430
General and administrative	3,452	4,520	1,445	1,153
Total operating expenses	17,831	17,407	4,891	5,583
Loss from operations	(17,831)	(17,407)	(4,891)	(5,583)
Other income (expense):				
Grant income	13,164	10,855	2,273	4,692
Change in the fair value of the derivative liability	(231)	18	345	1,063
Change in the fair value of the warrant liability	(7)	181	30	—
Other income, net	1,087	394	142	145
(Loss) gain on debt extinguishment	—	(129)	(129)	443
Interest expense, net	(1,024)	(1,751)	(276)	(537)
Total other income (expense), net	12,989	9,568	2,385	5,806
Net (loss) income	(4,842)	(7,839)	(2,506)	223
Cumulative preferred stock dividends	(3,920)	(4,234)	(1,053)	(1,128)
Net loss attributable to common stockholders	\$ (8,762)	\$ (12,073)	\$ (3,559)	\$ (905)
Net loss per share attributable to common stockholders, basic and diluted	\$ (5.77)	\$ (7.35)	\$ (2.34)	\$ (0.51)
Weighted-average common shares outstanding, basic and diluted ⁽¹⁾	1,519,285	1,643,514	1,519,431	1,779,573
Pro forma loss per share, basic and diluted ⁽²⁾		\$		\$
Pro forma weighted-average common shares outstanding, basic and diluted ⁽²⁾				

- (1) See Note 2 to our consolidated financial statements included elsewhere in this prospectus for an explanation of the method used to calculate the basic and diluted net loss per share and the number of shares used in the computation of the per share amounts.

- (2) The calculations for the pro forma net loss per share attributable to common stockholders, basic and diluted, and the pro forma weighted-average shares of common stock outstanding, basic and diluted, assume the conversion of all our outstanding shares of preferred stock into common stock, the assumed net exercise of warrants to purchase common stock that otherwise expire upon or prior to the closing of this offering and the conversion of the SAFEs into shares of our common stock, as if the conversion or exercise had occurred at the beginning of the period presented, or the issuance date, if later.

(in thousands)	As of December 31,		As of March 31,
	2019	2020	2021
Consolidated Balance Sheet Data:			
Cash and cash equivalents	\$ 2,890	\$ 5,189	\$ 13,373
Working capital ⁽¹⁾	3,477	3,658	11,614
Total assets	7,459	7,119	16,512
Simple Agreements for Future Equity	—	—	8,942
Derivative liability	1,493	2,209	1,146
Warrant liability	181	—	—
Convertible notes, net	6,897	12,409	12,691
Total liabilities	12,954	19,933	28,996
Convertible preferred stock	52,927	55,370	55,370
Accumulated deficit	(58,239)	(68,220)	(67,997)
Total stockholders' deficit	(58,422)	(68,184)	(67,854)

- (1) We define working capital as total current assets less total current liabilities. See our audited and unaudited consolidated financial statements included elsewhere in this prospectus and related notes for further details regarding our total current assets and total current liabilities.

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this prospectus, including our consolidated financial statements and the related notes and “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” before deciding whether to invest in our common stock. We have listed below (not necessarily in order of importance or probability of occurrence) what we believe to be the most significant risk factors applicable to us. The occurrence of any of the events or developments described below could materially and adversely affect our business, financial condition, results of operations and prospects. In such an event, the market price of our common stock could decline and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations. Some of the statements in the following risk factors constitute forward-looking statements. Please see the section titled “Special Note Regarding Forward-Looking Statements.”

Risks Related to Our Financial Position and Capital Needs

We are a clinical-stage biopharmaceutical company with no products approved for commercial sale and have incurred significant losses since our inception in 2007. We expect to incur significant losses over the foreseeable future and may never achieve or maintain profitability.

Since our inception, we have incurred significant net losses, and we expect to continue to incur significant expenses and operating losses for the foreseeable future. Our net losses were \$4.8 million and \$7.8 million for the years ended December 31, 2019 and 2020, respectively, and \$2.5 million for the three months ended March 31, 2020. As of March 31, 2021, we had an accumulated deficit of \$68.0 million. Our clinical trials have been funded by approximately \$168.4 million in cumulative non-dilutive grants, awarded primarily by the National Institute of Aging, or NIA, a division of the National Institutes of Health. We have also raised \$57.5 million in gross proceeds through our private placements of convertible preferred stock, convertible promissory notes and Simple Agreements for Future Equity, or SAFEs. We have no products approved for commercialization and have never generated any revenue from product sales.

We have devoted substantially all of our financial resources and efforts to the development of our product candidates, including conducting preclinical studies and clinical trials. We expect to continue to incur significant expenses and operating losses over the next several years. We expect that it could be several years, if ever, before we have a commercialized product. Our net losses may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially for the foreseeable future as we:

- conduct our ongoing and planned clinical trials of CT1812, as well as initiate and complete additional clinical trials;
- pursue regulatory approval of CT1812 for the treatment of mild-to-moderate Alzheimer’s disease, or AD, dry age-related macular degeneration, or dry AMD, and Parkinson’s disease, or PD, and dementia with Lewy bodies, or DLB, and other age-related degenerative diseases and disorders of the central nervous system, or CNS, and retina;
- seek to discover and develop additional clinical and preclinical product candidates using Novel Improved Conditioned Extraction, or NICE, screening platform;
- adapt our regulatory compliance efforts to incorporate requirements applicable to marketed products;
- maintain, expand and protect our intellectual property portfolio;
- hire additional clinical, manufacturing and scientific personnel;
- add operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts;
- incur additional legal, accounting and other expenses in operating as a public company;
- scale up our clinical and regulatory capabilities; and

- establish a commercialization infrastructure and scale up external manufacturing and distribution capabilities to commercialize any product candidates for which we may obtain regulatory approval, including CT1812.

To become and remain profitable, we must succeed in developing and eventually commercializing product candidates that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical testing and clinical trials of our product candidates, obtaining regulatory approval, and manufacturing, marketing and selling any product candidates for which we may obtain regulatory approval, as well as discovering and developing additional product candidates. We are only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, may never generate any revenue or revenue that is significant enough to achieve profitability. Even if we achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our development efforts, obtain product approvals, diversify our offerings or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

We have not yet completed Phase 2 clinical trials and have no history of commercializing products, which may make it difficult for an investor to evaluate the success of our business to date and to assess our future viability.

We commenced operations in 2007, and our operations to date have been largely focused on developing our clinical and preclinical product candidates and our Novel, Improved Conditioned Extraction, or NICE, screening platform, or NICE screening platform. To date, we have not yet demonstrated our ability to successfully complete pivotal clinical trials, obtain regulatory approvals, manufacture a product on a commercial scale, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing products.

We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives. We may also need to transition from a company with a research focus to a company capable of supporting commercial activities. Our inability to adequately address these risks and difficulties or successfully make such a transition could adversely affect our business, financial condition, results of operations and growth prospects.

Even if this offering is successful, we will need substantial additional capital to meet our financial obligations and to pursue our business objectives. If we are unable to raise capital when needed, we could be forced to curtail our planned operations and the pursuit of our growth strategy.

Our operations have required substantial amounts of capital since inception, and we expect our expenses to increase significantly in the foreseeable future. Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. We expect to continue to incur significant expenses and operating losses over the next several years as we complete our ongoing clinical trials of our product candidates, initiate future clinical trials of our product candidates, seek marketing approval for CT1812 for the treatment of age-related degenerative diseases and disorders of the CNS and retina, such as AD, dry AMD, PD and DLB, and advance any of our other product candidates we may develop or otherwise acquire. In addition, our product candidates, if approved, may not achieve commercial success. Our revenue, if any, will be derived from sales of products that we do not expect to be commercially available for the foreseeable future, if at all. If we obtain marketing approval for CT1812 or any other product candidates that we develop or otherwise acquire, we expect to incur significant commercialization expenses related to product sales, marketing, distribution and manufacturing. We also expect an increase in our expenses associated with creating additional infrastructure to support operations as a public company.

As of March 31, 2021, we had \$13.4 million in cash and cash equivalents and have not generated positive cash flows from operations. Based on our current business plans, we believe that the net proceeds

from this offering, together with our existing cash and cash equivalents and income from our non-dilutive grants, will be sufficient for us to fund our operating expenses and capital expenditures requirements through at least . We have based these estimates on assumptions that may prove to be incorrect or require adjustment as a result of business decisions, and we could utilize our available capital resources sooner than we currently expect. Our future capital requirements will depend on many factors, including, but not limited to:

- the scope, progress, costs and results of our ongoing and planned clinical trials of CT1812, as well as the associated costs, including any unforeseen costs we may incur as a result of preclinical study or clinical trial delays due to the COVID-19 pandemic or other delays;
- the scope, progress, costs and results of preclinical development, laboratory testing and clinical trials for any future product candidates we may decide to pursue;
- the extent to which we develop, in-license or acquire other product candidates and technologies;
- the costs and timing of process development and manufacturing scale-up activities associated with our product candidates and other programs we advance them through preclinical and clinical development;
- the availability, timing and receipt of any future NIA Grants;
- the number and development requirements of other product candidates that we may pursue;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- our ability to establish collaborations to commercialize CT1812 or any of our other product candidates outside the United States;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims; and
- the additional costs we may incur as a result of operating as a public company, including our efforts to enhance operational systems and hire additional personnel, including enhanced internal controls over financial reporting.

The expected net proceeds from this offering will not be sufficient to fund any of our product candidates through regulatory approval, and we will need to raise substantial additional capital to complete the development and commercialization of C1812 and our product candidates. If we receive regulatory approval for any of these product candidates, we expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution, depending on where we choose to commercialize. Additional funds may not be available on a timely basis, on favorable terms, or at all, and such funds, if raised, may not be sufficient to enable us to continue to implement our long-term business strategy. Further, our ability to raise additional capital may be adversely impacted by recent volatility in the equity markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic. If we are unable to raise sufficient additional capital, we could be forced to curtail our planned operations and the pursuit of our growth strategy.

To date, we have partially relied on non-dilutive grants to cover certain of our capital requirements for our clinical trials, and we may fail to continue to receive non-dilutive funding.

To date, we have partially relied on the availability of non-dilutive grants from the NIA, or NIA Grants. Although we currently anticipate applying for and potentially receiving additional NIA Grants, we cannot be certain that our grant applications will be successful, that additional NIA Grants will be made available to support our clinical trials or that we will continue to satisfy the award criteria of prior NIA Grants that have already been awarded to us. If we fail to continue to receive NIA Grants, our ability to

continue our clinical programs for CT1812 may be impaired and delayed, and we may otherwise need to seek additional financing through dilutive methods, such as through equity or debt financings. For example, while we have partially relied on NIA Grants in the past, we have issued from time to time shares of our preferred stock, warrants to purchase our preferred stock, convertible promissory notes, and common stock, and entered into SAFEs. Upon the closing of this offering, all outstanding shares of our convertible preferred stock will convert into an aggregate of 51,450,435 shares of our common stock,

shares of our common stock will be issued upon the assumed net exercise of warrants (assuming an initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus), and shares of our common stock will be issued issuable upon conversion of the SAFEs in the aggregate amount of \$8.9 million (assuming an initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus).

We could be subject to audit and repayment of our non-dilutive NIA Grants.

In addition, in connection with the NIA Grants, we may be subject to routine audits by government agencies. As part of an audit, these agencies may review our performance, cost structures and compliance with applicable laws, regulations, policies and standards and the terms and conditions of the applicable NIA Grant. If any of our expenditures are found to be unallowable or allocated improperly or if we have otherwise violated terms of such NIA Grant, the expenditures may not be reimbursed and/or we may be required to repay funds already disbursed. Any audit by the NIA could require significant financial and management resources and may result in a material adjustment to our results of operations and financial condition and harm our ability to operate in accordance with our business plan. Additionally, negative results in any of our ongoing and planned clinical trials of CT1812 that are funded with NIA Grants may result in our failure to receive additional NIA Grants to fund future clinical trials.

The NIA recently issued guidance providing extensions and flexibility for certain NIA Grant recipients conducting NIA-funded clinical trials and human subject studies that are impacted by the declared public health emergency for the COVID-19 pandemic. The ultimate impact of the COVID-19 pandemic on our clinical trials is highly uncertain and subject to change. We have not made a formal assessment with respect to the NIA's current and expanded flexibilities in light of the COVID-19 pandemic, but we continue to monitor the situation closely and are prepared to take all necessary steps to ensure the safety of all human participants and research staff involved in our clinical trials.

Due to the significant resources required for the development of our product candidates, we must prioritize development of certain product candidates and/or certain disease indications. We may expend our limited resources on candidates or indications that do not yield a successful product and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

We are currently focused on developing product candidates to address age-related degenerative diseases and disorders of the CNS and retina. We seek to maintain a process of prioritization and resource allocation among our programs to maintain a balance between aggressively advancing our lead product candidate, CT1812, in identified indications and exploring additional indications or mechanisms as well as developing future product candidates. However, due to the significant resources required for the development of our product candidates, we must focus on specific diseases and disease pathways and decide which product candidates to pursue and the amount of resources to allocate to each such product candidate.

Our decisions concerning the allocation of research, development, collaboration, management and financial resources toward particular product candidates or therapeutic areas may not lead to the development of any viable commercial product and may divert resources away from better opportunities. Similarly, any decision to delay, terminate or collaborate with third parties with respect to certain programs may subsequently also prove to be suboptimal and could cause us to miss valuable opportunities. If we make incorrect determinations regarding the viability or market potential of any of our programs or product candidates or misread trends in the market of age-related degenerative diseases and disorders of the CNS and retina or pharmaceutical, biopharmaceutical or biotechnology industry, our business, financial condition and results of operations could be materially adversely affected. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other product candidates or other diseases and disease pathways that may later prove to

have greater commercial potential than those we choose to pursue, or relinquish valuable rights to such product candidates through collaboration, licensing or other royalty arrangements in cases in which it would have been advantageous for us to invest additional resources to retain development and commercialization rights.

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations.

Our quarterly and annual operating results may fluctuate significantly, which makes it difficult for us to predict our future operating results. These fluctuations may occur due to a variety of factors, many of which are outside of our control and may be difficult to predict, including:

- the timing and cost of, and level of investment in, research, development and, if approved, commercialization activities relating to our product candidates, which may change from time to time;
- the timing and status of enrollment for our clinical trials;
- the cost of manufacturing our product candidates, as well as building out our supply chain, which may vary depending on the quantity of production and the terms of our agreements with manufacturers;
- the availability, timing, and receipt of any future NIA grants;
- expenditures that we may incur to acquire, develop or commercialize additional product candidates and technologies;
- timing and amount of any milestone, royalty or other payments due under any collaboration or license agreement;
- future accounting pronouncements or changes in our accounting policies;
- the timing and success or failure of preclinical studies and clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners;
- the timing of receipt of approvals for our product candidates from regulatory authorities in the United States and internationally;
- coverage and reimbursement policies with respect to our product candidates, if approved, and potential future drugs that compete with our products; and
- the level of demand for our product candidates, if approved, which may vary significantly over time.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance.

This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if any forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated revenue or earnings guidance we may provide.

Our business has been and could continue to be adversely affected by the evolving and ongoing COVID-19 global pandemic in regions where we or third parties on which we rely have significant manufacturing facilities, concentrations of clinical trial sites or other business operations. The COVID-19 pandemic could adversely affect our business and our financial results and could cause a disruption to the development of our product candidates, as well as the business or operations of our manufacturers or other third parties with whom we conduct business.

Our business has been and could continue to be adversely affected by the effects of the evolving and ongoing COVID-19 pandemic, which was declared by the World Health Organization as a global pandemic.

As COVID-19 continues to spread, we may experience ongoing disruptions that could severely impact our business and clinical trials, including:

- delays or difficulties in enrolling and retaining patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials, interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns, or stoppages and disruptions in materials and reagents or interruptions in global shipping that may affect the transport of clinical trial materials;
- changes in federal and local regulations as part of a response to the COVID-19 outbreak which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- the diversion of healthcare resources away from the conduct of clinical trials, including the diversion of healthcare professionals and other staff involved in our clinical trials and healthcare facilities serving as clinical trial sites;
- the interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others, or interruption of clinical trial subject visits and study procedures, the occurrence of which could affect the integrity of clinical trial data;
- limitations on employee resources that would otherwise be focused on the conduct of our preclinical studies and clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people, an increased reliance on working from home, school closures, or mass transit disruptions;
- limitations on maintaining our corporate culture that facilitates the transfer of institutional knowledge within our organization and fosters innovation, teamwork, and a focus on execution;
- interruption of or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines;
- delays in necessary interactions with regulators, ethics committees, and other important agencies and contractors due to limitations in employee resources or forced furlough of government or contractor personnel;
- additional delays, difficulties or interruptions as a result of current or future shutdowns due to the COVID-19 pandemic in countries where we or our third-party service providers operate; and
- the risk that participants enrolled in our clinical trials or study staff conducting the clinical trial visits will acquire COVID-19 while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events, or the ability to complete study visits and collect data.

These and other disruptions in our operations and the global economy could negatively impact our business, operating results and financial condition.

Our clinical trials have been, and may in the future be, affected by the COVID-19 pandemic. For example, the COVID-19 pandemic may impact patient enrollment in our ongoing and future clinical trials of CT1812. In particular, some sites have in the past or may in the future pause enrollment to focus on, and direct resources to, COVID-19, while at other sites, patients may choose not to enroll or continue participating in the clinical trial as a result of the pandemic. In addition, patient visits to medical providers in the United States have slowed as a result of the COVID-19 pandemic. Further, according to the Centers for Disease Control and Prevention, people who have serious chronic medical conditions are at higher risk of getting very sick from COVID-19. As a result, potential patients in our ongoing and future clinical trials of CT1812 may choose to not enroll, not participate in follow-up clinical visits or drop out of the trial as a

precaution against contracting COVID-19. Further, some patients may not be able or willing to comply with clinical trial protocols if quarantines impede patient movement or interrupts healthcare services.

We are unable to predict with confidence the duration of such patient enrollment delays and difficulties. If patient enrollment is delayed for an extended period of time, our ongoing or future clinical trials could be delayed or otherwise adversely affected. Similarly, our ability to recruit and retain principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19, may be adversely impacted.

Ongoing or planned clinical trials may also be impacted by interruptions or delays in the operations of the FDA and comparable foreign regulatory authorities. For example, we have made certain adjustments to the operation of our trials in an effort to ensure the monitoring and safety of patients and minimize risks to trial integrity during the pandemic in accordance with the guidance issued by the FDA, and may need to make further adjustments in the future. We have also initiated our clinical trial protocols to enable remote visits to mitigate any potential impacts as a result of the COVID-19 pandemic. Many of these adjustments are new and untested, may not be effective, may affect the integrity of data collected, and may have unforeseen effects on the progress and completion of our clinical trials and the findings from such clinical trials.

In addition, we may encounter a shortage in supplies of, or in delays in shipping, our study drug or other components of the clinical trial vital for successful conduct of the trial. Further, the successful conduct of our ongoing and future clinical trials depends on retrieving laboratory, imaging and other data from patients. Any failure by the vendors with which we work with to send us such data could impair the progress of such clinical trials. These events could delay our clinical trials, increase the cost of completing our clinical trials and negatively impact the integrity, reliability or robustness of the data from our clinical trials.

Furthermore, quarantines, shelter-in-place and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, related to COVID-19 or other infectious diseases, could impact personnel at our study sites or third-party manufacturing facilities upon which we rely, or the availability or cost of materials, which could disrupt the supply chain for our drug and combination therapy candidates. To the extent our suppliers and service providers are unable to comply with their obligations under our agreements with them or they are otherwise unable to deliver or are delayed in delivering goods and services to us due to the COVID-19 pandemic, our ability to continue meeting clinical supply demand for our product candidates or otherwise advancing development of our product candidates may become impaired.

The spread of COVID-19 and actions taken to reduce its spread may also materially affect us economically. While the potential economic impact brought by, and the duration of, the COVID-19 pandemic may be difficult to assess or predict, there could be a significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity and financial position. In addition, the trading prices for other pharmaceutical companies have been highly volatile as a result of the COVID-19 pandemic. As a result, we may face difficulties raising capital through sales of our common stock or such sales may be on unfavorable terms.

COVID-19 and actions taken to reduce its spread continue to rapidly evolve. The extent to which COVID-19 may impede the development of our product candidates, reduce the productivity of our employees, disrupt our supply chains, delay our clinical trials, reduce our access to capital or limit our business development activities, will depend on future developments, which are highly uncertain and cannot be predicted with confidence.

To the extent the ongoing COVID-19 pandemic adversely affects our business and results of operations, it may also have the effect of heightening many of the other risks and uncertainties described in this “Risk Factors” section.

Risks Related to Discovery, Development and Regulatory Approval of Our Product Candidates

Our business is heavily dependent on the successful development, regulatory approval and commercialization of CT1812 and any future product candidates that we may develop or acquire.

We currently have no products approved for sale, and our lead product candidate is in early stages of clinical development. The success of our business, including our ability to finance our company and generate

revenue in the future, will primarily depend on the successful development, regulatory approval and commercialization of our product candidates and, in particular, the advancement of CT1812, currently our only clinical-stage product candidate. However, given our stage of development, it may be many years, if we succeed at all, before we have demonstrated the safety and efficacy of a product candidate sufficient to warrant approval for commercialization. We cannot be certain that our product candidates will receive regulatory approval or be successfully commercialized even if we receive regulatory approval.

The clinical and commercial success of CT1812 and any future product candidates that we may develop or acquire will depend on a number of factors, including the following:

- our ability to raise any additional required capital on acceptable terms, or at all;
- our ability to complete an investigational new drug application, or IND, enabling studies and successfully submit INDs or comparable applications;
- timely completion of our preclinical studies and clinical trials, which may be significantly slower or cost more than we currently anticipate and will depend substantially upon the performance of third-party contractors;
- delays or difficulties in enrolling and retaining patients in our clinical trials;
- whether we are required by the U.S. Food and Drug Administration, or FDA, or similar foreign regulatory agencies to conduct additional clinical trials or other studies beyond those planned to support the approval and commercialization of our product candidates or any future product candidates;
- acceptance of our proposed indications and primary endpoint assessments relating to the proposed indications of our product candidates by the FDA and similar foreign regulatory authorities;
- our ability to demonstrate to the satisfaction of the FDA and similar foreign regulatory authorities the safety, efficacy and acceptable risk to benefit profile of our product candidates or any future product candidates;
- the prevalence, duration and severity of potential side effects or other safety issues experienced with our product candidates or future approved products, if any;
- achieving and maintaining, and, where applicable, ensuring that our third-party contractors achieve and maintain, compliance with our contractual obligations and with all regulatory requirements applicable to our product candidates or any future product candidates or approved products, if any;
- the ability of third parties with whom we contract to manufacture adequate clinical trial and commercial supplies of our product candidates or any future product candidates remain in good standing with regulatory agencies and develop, validate and maintain commercially viable manufacturing processes that are compliant with current good manufacturing practices, or cGMPs;
- the convenience of our treatment or dosing regimen;
- the timely receipt of necessary marketing approvals from the FDA and similar foreign regulatory authorities;
- acceptance by physicians, payors and patients of the benefits, safety and efficacy of our product candidates or any future product candidates, if approved, including relative to alternative and competing treatments;
- the willingness of physicians, operators of clinics and patients to utilize or adopt any of our product candidates or any future product candidates, if approved;
- our ability to achieve sufficient market acceptance, coverage and adequate reimbursement from third-party payors and adequate market share and revenue for any approved products;
- the COVID-19 pandemic, which may result in clinical site closures, delays to patient enrollment, patients discontinuing their treatment or follow up visits or changes to trial protocols;
- our ability to successfully develop a commercial strategy and thereafter commercialize our product candidates or any future product candidates in the United States and internationally, if approved for

marketing, reimbursement, sale and distribution in such countries and territories, whether alone or in collaboration with others;

- patient demand for our product candidates, if approved, including patients' willingness to pay out-of-pocket for any approved products in the absence of coverage and/or adequate reimbursement from third-party payors;
- our ability to establish and enforce intellectual property rights in and to our product candidates or any future product candidates; and
- our ability to avoid third-party patent interference, intellectual property challenges or intellectual property infringement claims.

In addition, the FDA or other regulatory agencies may not agree with our clinical development plan and require that we conduct additional clinical trials to support our regulatory submissions. We have not yet conducted an end of Phase 2 meeting with the FDA to discuss the registration pathway for CT1812, and our current clinical development plans for CT1812 in mild-to-moderate AD may change as a result of future interactions with the FDA. For example, the FDA may not accept the results of the ongoing CT1812 clinical trials and may require that we conduct additional trials, including more than one pivotal trial, in order to gain approval in AD. Furthermore, any approval of CT1812 for AD may be limited to CT1812 in combination with the existing standard of care.

These factors, many of which are beyond our control, could cause us to experience significant delays or an inability to obtain regulatory approvals or commercialize our product candidates. Even if regulatory approvals are obtained, we may never be able to successfully commercialize any of our product candidates. Accordingly, we cannot provide assurances that we will be able to generate sufficient revenue through the sale of our product candidates or any future product candidates to continue our business or achieve profitability.

Our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern.

Our recurring losses from operations raise substantial doubt about our ability to continue as a going concern. As a result, our independent registered public accounting firm included an explanatory paragraph in its report on our financial statements for the years ended December 31, 2020 and 2019 with respect to this uncertainty. While we believe that the net proceeds from this offering, together with our existing cash and cash equivalents and the income from non-dilutive grants, will be sufficient for us to fund our operating expenses and capital expenditures requirements through at least , we have based these estimates on assumptions that may prove to be wrong, and we may need to raise additional funds. If we are unable to raise capital when needed or on acceptable terms, we could be forced to delay, reduce or eliminate the development and commercialization of our product candidates.

We may not successfully expand our pipeline of product candidates, including by pursuing additional indications for CT1812 or by in-licensing or acquiring additional product candidates for other diseases.

A key element of our strategy is to build and expand our pipeline of product candidates, including by developing CT1812 for the treatment of dry AMD and age-related degenerative diseases and disorders of the CNS beyond indications in AD, and by identifying other product candidates using our NICE platform. In addition, we may in-license or acquire additional product candidates for other diseases. We may not be able to identify or develop additional product candidates that are safe, tolerable and effective. Even if we are successful in continuing to build our pipeline, the potential product candidates that we identify, in-license or acquire may not be suitable for clinical development. For example, our research methodology may be unsuccessful in identifying potential drug candidates or those we identify may be shown to have harmful side effects or other characteristics that make them unmarketable or unlikely to receive regulatory approval. We have devoted significant resources to discovery efforts through our proprietary NICE platform, and we cannot guarantee that we will be successful in identifying additional potential drug candidates, or that we will be able to successfully identify and in-license new and valuable product candidates from other parties.

Research and development of pharmaceuticals is inherently risky. We cannot give any assurance that any of our product candidates will receive regulatory approval.

We are at an early stage of clinical development of our only clinical stage product candidate, CT1812. Our future success is dependent on our ability to successfully develop, obtain regulatory approval for and then successfully commercialize our product candidates, and we may fail to do so for many reasons, including the following:

- our product candidates may not successfully complete preclinical studies or clinical trials;
- a product candidate may on further study be shown to have harmful side effects or other characteristics that indicate it does not meet applicable regulatory criteria;
- our competitors may develop therapeutics that render our product candidates obsolete or less attractive;
- the market for a product candidate may change so that the continued development of that product candidate is no longer reasonable or commercially attractive;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all;
- if a product candidate obtains regulatory approval, we may be unable to establish sales and marketing capabilities, or successfully market such approved product candidate; and
- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors.

If any of these events occur, we may be forced to abandon our development efforts for a product candidate or candidates, which would have a material adverse effect on our business and could potentially cause us to cease operations. Failure of a product candidate may occur at any stage of preclinical or clinical development, and we may never succeed in developing marketable products or generating product revenue.

We may not be successful in our efforts to further develop our current and future product candidates. Each of our product candidates will require significant clinical development, management of preclinical, clinical and manufacturing activities, regulatory approval, adequate manufacturing supply, a commercial organization and significant marketing efforts before we generate any revenue from product sales, if at all. Any clinical studies that we may conduct may not be acceptable to the FDA or other regulatory authorities or demonstrate the efficacy and safety necessary to obtain regulatory approval to market our product candidates. If the results of our ongoing or future clinical studies are inconclusive with respect to the efficacy of our product candidates, if we do not meet the clinical endpoints with statistical significance or if there are safety concerns or adverse events associated with our product candidates, we may be prevented or delayed in obtaining marketing approval for our product candidates.

In addition, to obtain regulatory approval in countries outside the United States, we must comply with numerous and varying regulatory requirements of such other countries regarding safety, efficacy, chemistry, manufacturing and controls, clinical trials, commercial sales, pricing and distribution of our product candidates. We may also rely on collaborators or partners to conduct the required activities to support an application for regulatory approval and to seek approval for one or more of our product candidates. We cannot be sure that any such collaborators or partners will conduct these activities successfully or do so within the timeframe we desire. Even if we or any future collaborators or partners are successful in obtaining approval in one jurisdiction, we cannot ensure that we will obtain approval in any other jurisdictions. If we are unable to obtain approval for our product candidates in multiple jurisdictions, our revenue and results of operations could be negatively affected.

We may encounter substantial delays in our preclinical studies and clinical trials or may not be able to conduct or complete our preclinical studies or clinical trials on the timelines we expect, if at all.

Clinical trials are expensive and can take many years to complete, and the outcome is inherently uncertain. We cannot guarantee that any clinical trials will be conducted as planned or completed on

schedule, if at all. A failure of one or more clinical trials can occur at any stage and our future clinical trials may not be successful. Clinical trials can be delayed or terminated for a variety of reasons, including delays or failures related to:

- the COVID-19 pandemic, which may result in clinical site closures, delays to patient enrollment, patients discontinuing their treatment or follow up visits or changes to trial protocols;
- the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical trials;
- delays in obtaining, or failure to obtain, regulatory authorization to commence a trial;
- imposition of a temporary or permanent clinical hold by the FDA or comparable foreign regulatory authorities;
- reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- identifying, recruiting and training suitable clinical investigators;
- obtaining institutional review board, or IRB, approval at each trial site;
- new safety findings that present unreasonable risk to clinical trial participants;
- a negative finding from an inspection of our clinical trial operations or study sites;
- recruiting an adequate number of suitable patients to participate in a trial;
- having subjects complete a trial or return for post-treatment follow-up;
- clinical sites deviating from trial protocol or dropping out of a trial;
- addressing subject safety concerns that arise during the course of a trial;
- adding a sufficient number of clinical trial sites; or
- obtaining sufficient supply of product candidates for use in preclinical studies or clinical trials from third-party suppliers.

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

- we may receive feedback from regulatory authorities that requires us to modify the design of our clinical trials or require that we submit additional data or information before allowing a clinical trial to be initiated or continue;
- clinical studies of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon drug development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements, fail to maintain adequate quality controls or be unable to provide us with sufficient product supply to conduct and complete preclinical studies or clinical trials of our product candidates in a timely manner, or at all;
- we or our investigators might have to suspend or terminate clinical trials of our product candidates for various reasons, including non-compliance with regulatory requirements, a finding that our 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 our product candidates may be greater than we anticipate;

- the quality of our product candidates or other materials necessary to conduct preclinical studies or clinical trials of our product candidates may be insufficient or inadequate;
- regulators may revise the requirements for approving our product candidates or such requirements may not be as we anticipate; and
- any future collaborators may conduct clinical trials in ways they view as advantageous to them but that are suboptimal for us.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our 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, we may:

- incur unplanned costs;
- be delayed in obtaining marketing approval for our product candidates or not obtain marketing approval at all;
- obtain marketing approval in some countries and not in others;
- obtain marketing approval for indications or patient populations that are not as broad as intended or desired;
- obtain marketing approval with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings;
- be subject to additional post-marketing testing requirements; or
- have the product removed from the market after obtaining marketing approval.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

We may not be able to initiate or continue clinical trials on a timely basis or at all for any product candidates we identify or develop if we are unable to locate and enroll a sufficient number of eligible patients to participate in the trials as required by applicable regulations or as needed to provide appropriate statistical power for a given trial. The timely completion of clinical trials in accordance with their protocols depends on, among other things, our ability to enroll a sufficient number of patients who remain in the study until its conclusion. The enrollment of patients depends on many factors, including:

- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating; the severity and difficulty of diagnosing the disease under investigation;
- the patient eligibility and exclusion criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to trial sites;
- competition with other companies for clinical trial sites or patients;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- the existing body of safety and efficacy data with respect to the study drug and safety concerns;
- patient referral practices of physicians;
- risk that enrolled subjects will drop out before completion of the trial, including as a result of contracting COVID-19 or other health conditions or being forced to quarantine;
- ability to monitor patients adequately during and after treatment;

- availability and efficacy of approved medications or therapies, or other clinical trials, for the disease or condition under investigation;
- our ability to obtain and maintain patient consents.

In addition, our clinical trials may compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates.

Our product candidates may cause undesirable and unforeseen side effects or have other properties that could halt their clinical development, delay or prevent their regulatory approval, limit their commercial potential or result in significant negative consequences.

Adverse events or other undesirable side effects caused by our product candidates or related to procedures conducted as part of the clinical trials could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. Results of our planned clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. If unacceptable side effects arise in the development of our product candidates, we, the FDA, the IRBs at the institutions in which our studies are conducted or the Data Safety Monitoring Board, or DSMB, could suspend or terminate our clinical trials or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. Treatment-related side effects may not be appropriately recognized or managed by the treating medical staff. We expect to have to train medical personnel using our product candidates to understand the side effect profiles for our clinical trials and upon any commercialization of any of our product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in patient injury or death. Any of these occurrences may materially and adversely affect our business, financial condition, results of operations and prospects.

In addition, early clinical trials may only include a limited number of subjects and limited duration of exposure to our product candidates. In particular, we are pursuing a new approach to inhibiting the synaptic binding and signaling of soluble A β oligomers through the use of small molecule receptor antagonists, like CT1812. As a result, our product candidates may cause unforeseen safety events when evaluated in larger patient populations. Further, clinical trials may not be sufficient to determine the effect and safety consequences of taking our product candidates over a multi-year period.

If any of our product candidates receives marketing approval, and we or others later identify undesirable and unforeseen side effects caused by such product, a number of potentially significant negative consequences could result, including but not limited to:

- regulatory authorities may suspend, limit or withdraw approvals of such product, or seek an injunction against its manufacture or distribution;
- we may be required to conduct additional clinical trials or post-approval studies;
- we may be required to recall a product or change the way such product is administered to patients;
- additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof;
- regulatory authorities may require the addition of labeling statements, such as a “black box” warning or a contraindication, or issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- we may be required to implement a Risk Evaluation and Mitigation Strategy, or REMS, or create a Medication Guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers and/or other elements to assure safe use;

- we could be sued and held liable for harm caused to patients;
- we may be subject to fines, injunctions or the imposition of criminal penalties;
- the product may become less competitive; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and result in the loss of significant revenues to us, which would materially and adversely affect our business, financial condition, results of operations and prospects.

Preclinical and clinical development involves a lengthy and expensive process with an uncertain outcome, and the results of preclinical studies and early clinical trials are not necessarily predictive of future results. We have not tested any of our product candidates in pivotal clinical trials and our product candidates may not have favorable results in future clinical trials.

Preclinical and clinical development is expensive and can take many years to complete, and its outcome is inherently uncertain. We cannot guarantee that any preclinical studies or clinical trials will be conducted as planned or completed on schedule, if at all, and failure can occur at any time during the preclinical study or clinical trial process. Despite promising preclinical or clinical results, any product candidate can unexpectedly fail at any stage of preclinical or clinical development. The historical failure rate for product candidates in our industry is high.

The results from preclinical studies or clinical trials of a product candidate may not predict the results of later clinical trials of the product candidate, and interim, topline, or preliminary results of a clinical trial are not necessarily indicative of final results. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy characteristics despite having progressed through preclinical studies and initial clinical trials. In particular, while we have conducted certain Phase 2 clinical trials of CT1812 targeting mild-to-moderate AD, we do not know whether CT1812 will perform in future clinical trials as it has performed in these prior trials. The positive results we have observed for CT1812 in past clinical trials may not be predictive of our ongoing and future clinical trials in humans. It is not uncommon to observe results in clinical trials that are unexpected based on preclinical studies and early clinical trials, and many product candidates fail in clinical trials despite very promising early results. Moreover, preclinical and clinical data may be susceptible to varying interpretations and analyses. In addition, changes to the design of our current or future clinical trials may be necessary if there are new developments in the field of Alzheimer's research. A number of companies in the biopharmaceutical, pharmaceutical and biotechnology industries have suffered significant setbacks in clinical development even after achieving promising results in earlier studies.

For the foregoing reasons, we cannot be certain that any of our ongoing and planned preclinical studies or clinical trials will be successful or acceptable to the FDA or other regulatory authorities.

Interim "top-line" and preliminary data from studies or trials that we announce or publish from time to time may change as more data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim "top-line" or preliminary data from preclinical studies or clinical trials. Interim data are subject to the risk that one or more of the outcomes may materially change as more data become available. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data when we publish such data. As a result, the "top-line" results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results once additional data have been received and fully evaluated. Preliminary or "top-line" data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Additionally, interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment

continues and more patient data become available. Adverse differences between preliminary or interim data and final data could significantly harm our business, financial condition, results of operations and prospects.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure. Any information we determine not to disclose may ultimately be deemed significant by you or others with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the top-line data that we report differ from final results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, product candidates may be harmed, which could significantly harm our business, financial condition, results of operations and prospects.

We have initially concentrated our research and development efforts on the treatment of AD, a disease that has seen limited success in drug development.

Efforts by biopharmaceutical and pharmaceutical companies in treating AD have seen limited success in drug development. Only one disease-modifying therapeutic option has been approved by the FDA. Biogen's Aduhelm, a monoclonal antibody administered via infusion, received accelerated approval from the FDA on June 7, 2021. We cannot be certain that our oral, small-molecule approach will lead to the development of approvable or marketable products. With the exception of Aduhelm, the only drugs approved by the FDA to treat patients with AD address the symptoms of the disease. Since 2003, over 500 clinical studies have been completed and only Aduhelm has been approved by the FDA, compared to a success rate of 50% to 80% for all other drug candidates. As a result, the FDA has a limited set of products to rely on in evaluating CT1812. This could result in a longer than expected regulatory review process, increased expected development costs or the delay or prevention of commercialization of CT1812 for the treatment of AD.

We have never conducted pivotal clinical trials, and we may be unable to do so for any product candidates we may develop.

We will need to successfully complete pivotal clinical trials in order to obtain the approval of the FDA, EMA or other regulatory agencies to market CT1812 or any future product candidate. Carrying out pivotal clinical trials is a complicated process that requires significant financial resources. As an organization, we have not previously conducted any later stage or pivotal clinical trials. In order to do so, we will need to expand our clinical development and regulatory capabilities, and we may be unable to recruit and train qualified personnel. We also expect to continue to rely on third parties to conduct our pivotal clinical trials. Consequently, we may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to NDA submission and approval of CT1812 or future product candidates. We may require more time and incur greater costs than our competitors and may not succeed in obtaining regulatory approvals of product candidates that we develop. Failure to commence or complete, or delays in, our planned clinical trials, could prevent us from or delay us in commercializing our product candidates.

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

We may seek a Breakthrough Therapy designation for our product candidates if the clinical data support such a designation for one or more 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, in our case, 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.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our 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 drugs 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 our product candidates qualify as breakthrough therapies, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

A Fast Track designation by the FDA, even if granted for any of our product candidates, may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that our product candidates will receive marketing approval.

The FDA granted CT1812 Fast Track designation in October 2017 for the treatment of mild-to-moderate AD, and, in the future, we may seek Fast Track designation for other of our product candidates. 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 Fast Track designation. The FDA has broad discretion whether or not to grant this designation. Even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Fast Track designation may not result in a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program. Many small molecule product candidates that have received Fast Track designation have failed to obtain marketing approval.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA to review and/or approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

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 our business. On March 18, 2020, the FDA announced its intention to temporarily postpone routine surveillance inspections of domestic manufacturing facilities. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

We have conducted, and in the future plan to conduct, clinical trials for product candidates outside the United States, and the FDA and comparable foreign regulatory authorities may not accept data from such trials.

We have conducted clinical trials of our product candidates outside the United States, and plan to continue to do so in the future. For example, we initially conducted our Phase 1b SNAP clinical trial of CT1812 in collaboration with the Karolinska Institute in Sweden. In addition, the Phase 1 single and multiple ascending dose studies of CT1812 in healthy volunteers (COG0101) as well as the first-in-patient study

(COG0102) were conducted in Australia. The acceptance of study data from clinical trials conducted outside the United States or another jurisdiction by the FDA, any 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:

- the data are applicable to the U.S. population and U.S. medical practice;
- the trials were performed pursuant to good clinical practice, or GCP, requirements; and
- if necessary, the FDA is able to validate the data through an on-site inspection.

Many foreign regulatory authorities have similar requirements. In addition, foreign trials are 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 would be costly and time-consuming and delay aspects of our business plan, and which may result in product candidates that we may develop not receiving approval or clearance for commercialization in the applicable jurisdiction.

If we are not successful in identifying, developing and commercializing additional product candidates, our ability to expand our business and achieve our strategic objectives would be impaired.

Although a substantial amount of our effort will focus on the continued development and potential approval of our current product candidates, a key element of our strategy is to identify, develop and commercialize a portfolio of products that help restore normal cellular damage responses in age-related degenerative diseases and disorders of the CNS and retina. A component of our strategy is to evaluate our product candidates in multiple indications based, in part, on our evaluation of certain biomarkers in a disease area. For example, we intend to evaluate CT1812 and other product candidates discovered through our NICE platform in other diseases beyond indications in AD, such as dry AMD, geographic atrophy, or GA, and synucleinopathies, including PD and DLB. However, we have not yet evaluated CT1812 in these patient populations and we may find that while we have seen promising results in one neurodegenerative disease, that effect is not replicated across other indications with promising similarities. Even if we successfully identify additional product candidates, we may still fail to yield additional product candidates for development and commercialization for many reasons, including the following:

- the research methodology used may not be successful in identifying potential product candidates;
- we may be unable to identify viable product candidates through our NICE platform;
- competitors may develop alternatives that render our additional product candidates obsolete;
- additional product candidates we develop may be covered by third parties' patents or other exclusive rights;
- an additional product candidate may be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- an additional product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- an additional product candidate may not be accepted as safe and effective by physicians and patients.

We therefore cannot provide any assurance that we will be able to successfully identify or acquire additional product candidates, advance any of these additional product candidates through the development process, successfully commercialize any such additional product candidates, if approved, or assemble sufficient resources to identify, acquire, develop or, if approved, commercialize additional product candidates. If we are unable to successfully identify, acquire, develop and commercialize additional product candidates, our commercial opportunities may be limited.

Even if the product candidates that we develop receive regulatory approval in the United States or another jurisdiction, they may never receive approval in other jurisdictions, which would limit market opportunities for our product candidates and adversely affect our business.

Approval of a product candidate in the United States by the FDA or by the requisite regulatory agencies in any other jurisdiction does not ensure approval of such product candidate by regulatory authorities in other countries or jurisdictions. The approval process varies among countries and may limit our or any future collaborators' ability to develop, manufacture, promote and sell product candidates internationally. Failure to obtain marketing approval in international jurisdictions would prevent the product candidates from being marketed outside of the jurisdictions in which regulatory approvals have been received. In order to market and sell product candidates in the European Union, or EU, and many other jurisdictions, we and any future collaborators must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and may involve additional preclinical studies or clinical trials both before and after approval. In many countries, any product candidate for human use must be approved for reimbursement before it can be approved for sale in that country. In some cases, the intended price for such product is also subject to approval. Further, while regulatory approval of a product candidate in one country does not ensure approval in any other country, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in others. If we or any future collaborators fail to comply with the regulatory requirements in international markets or to obtain all required marketing approvals, the target market for a particular potential product will be reduced, which would limit our ability to realize the full market potential for the product and adversely affect our business.

Risks Related to Our Business and Industry

We are heavily dependent on the success of CT1812, our lead product candidate, which is still under clinical development, and if CT1812 does not receive regulatory approval or is not successfully commercialized, our business may be harmed.

The success of our business, including our ability to finance our company and generate revenue in the future, will primarily depend on the successful development, regulatory approval and commercialization of CT1812, currently our only clinical-stage product candidate. To date, we have invested a significant portion of our efforts and financial resources in the development of CT1812 for the treatment of AD. Our future success is substantially dependent on our ability to successfully complete clinical development for, obtain regulatory approval for and successfully commercialize CT1812, which may never occur. We expect that a substantial portion of our efforts and expenditures over the next few years will be devoted to CT1812, which will require additional clinical development, management of clinical and manufacturing activities, regulatory approval in multiple jurisdictions, obtaining manufacturing supply, building of a commercial organization, substantial investment and significant marketing efforts before we can generate any revenues from any commercial sales. We cannot be certain that we will be able to successfully complete any of these activities.

Furthermore, while inhibition of A β oligomers has been validated as a therapeutic approach, the use of small molecule receptor antagonists, such as CT1812, to inhibit the synaptic binding and signaling of soluble A β oligomers is an innovative therapeutic approach, which exposes us to certain risks. For example, we may discover unforeseen safety events or that CT1812 does not possess certain properties required for therapeutic effectiveness. Even if found to be effective in one type of disease, CT1812, or the associated therapeutic approach, may not be effective in other diseases. In addition, given our therapeutic approach, designing preclinical studies and clinical trials to demonstrate its effect is complex and exposes us to risks.

The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of drug products are subject to extensive regulation by the FDA and comparable regulatory authorities in other countries. We are not permitted to market CT1812 in the United States until we receive approval of an NDA from the FDA, or in any foreign countries until we receive the requisite approval from such countries. We have not submitted an NDA to the FDA or comparable applications to other regulatory authorities for CT1812 and may not be in a position to do so for several years, if ever. If we are unable to obtain the necessary regulatory approvals for CT1812, we will not be able to commercialize CT1812 in AD, dry AMD, PD and

DLB or other age-related degenerative diseases and disorders of the CNS and retina, and our financial position will be materially adversely affected and we may not be able to generate sufficient revenue to continue our business.

We will need to increase the size of our organization, and we may experience difficulties in managing growth.

As of March 31, 2021, we had 20 full-time and 2 part-time employees. We will need to continue to expand our managerial, operational, finance and other resources in order to manage our operations and clinical trials, continue our development activities and commercialize CT1812, our lead product candidate, or any future product candidates. Our management and personnel, systems and facilities currently in place may not be adequate to support this future growth. Our need to effectively execute our growth strategy requires that we:

- manage our clinical trials effectively;
- identify, recruit, retain, incentivize and integrate additional employees, including personnel focused on research and development and, if our product candidates receive marketing approval, sales;
- manage our internal development and operational efforts effectively while carrying out our contractual obligations to third parties; and
- continue to improve our operational, financial and management controls, reports systems and procedures.

Our future financial performance and our ability to develop, manufacture and commercialize CT1812 and our product candidates, if approved, will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert financial and other resources, and 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.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize CT1812, if approved, and our product candidates and, accordingly, may not achieve our research, development and commercialization goals.

If we fail to attract and retain senior management and key scientific personnel, our business may be materially and adversely affected.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management and clinical and scientific personnel. We are highly dependent upon members of our senior management, particularly our President and Chief Executive Officer, Lisa Ricciardi, as well as our senior scientists and other members of our management team. The loss of services of any of these individuals could delay or prevent the successful development of our product pipeline, initiation or completion of our planned clinical trials or the commercialization of our product candidates or any future product candidates.

Competition for qualified personnel in the biopharmaceutical field is intense due to the limited number of individuals who possess the skills and experience required by our industry. We will need to hire additional personnel as we expand our clinical development and if we initiate commercial activities. We may not be able to attract and retain quality personnel on acceptable terms, or at all. In addition, to the extent we hire personnel from competitors, we may be subject to allegations that they have been improperly solicited or that they have divulged proprietary or other confidential information, or that their former employers own their research output.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our current or future product candidates.

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during product 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 and breach of warranty. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our current or future product candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- regulatory investigations, product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue; and
- the inability to commercialize our current or any future product candidates.

If we are unable to obtain and maintain sufficient product liability insurance at an acceptable cost and scope of coverage to protect against potential product liability claims, the commercialization of our current or any future product candidates we develop could be inhibited or prevented. We currently carry product liability insurance covering our clinical trials. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions and deductibles, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient funds to pay such amounts. Moreover, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses. If and when we obtain approval for marketing any of our product candidates, we intend to expand our insurance coverage to include the sale of such product candidate; however, we may be unable to obtain this liability insurance on commercially reasonable terms or at all.

We may explore strategic collaborations that may never materialize or may fail.

We may attempt to broaden the global reach of our platform by selectively collaborating with leading therapeutic companies and other organizations. As a result, we may periodically explore a variety of possible additional strategic collaborations in an effort to gain access to additional product candidates or resources. At the current time, we cannot predict what form such a strategic collaboration might take. In the event we do form such collaborations, we intend to retain significant economic and commercial rights to our programs in key geographic areas that are core to our long-term strategy. We are likely to face significant competition in seeking appropriate strategic collaborators, and strategic collaborations can be complicated and time consuming to negotiate and document. We may not be able to negotiate strategic collaborations on acceptable terms, or at all. We are unable to predict when, if ever, we will enter into any additional strategic collaborations because of the numerous risks and uncertainties associated with establishing them.

We may seek to grow our business through acquisitions of complementary businesses, and the failure to manage acquisitions, or the failure to integrate them with our existing business, could harm our financial condition and operating results.

From time to time, we may consider opportunities to acquire other companies, products or technologies that may enhance our manufacturing capabilities, expand the breadth of our markets or customer base, or advance our business strategies. Potential acquisitions involve numerous risks, including: problems assimilating

the acquired service offerings, products or technologies; issues maintaining uniform standards, procedures, quality control and policies; unanticipated costs associated with acquisitions; diversion of management's attention from our existing business; risks associated with entering new markets in which we have limited or no experience; increased legal and accounting costs relating to the acquisitions or compliance with regulatory matters; and unanticipated or undisclosed liabilities of any target.

We have no current commitments with respect to any acquisition. We do not know if we will be able to identify acquisitions we deem suitable, whether we will be able to successfully complete any such acquisitions on favorable terms or at all, or whether we will be able to successfully integrate any acquired service offerings, products or technologies. Our potential inability to integrate any business, products or technologies effectively may adversely affect our business, results of operations and financial condition.

Significant disruptions of information technology systems, breaches of data security and other incidents could materially adversely affect our business, results of operations and financial condition.

We collect and maintain information in digital and other forms that is necessary to conduct our business, and we are increasingly dependent on information technology systems and infrastructure to operate our business. In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information and personal information. It is critical that we do so in a secure manner to maintain the privacy, security, confidentiality and integrity of such confidential information. We have established physical, electronic and organizational measures designed to safeguard and secure our systems to prevent a data compromise, and rely on commercially available systems, software, tools and monitoring to provide security for our information technology systems and the processing, transmission and storage of digital information. We have also outsourced elements of our information technology infrastructure, and as a result a number of third-party vendors may have access to our confidential information. Our internal information technology systems and infrastructure, and those of any future collaborators and our contractors, consultants, vendors and other third parties on which we rely, are vulnerable to damage or unauthorized access or use resulting from computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, cyber-attacks or cyber-intrusions over the Internet, denial or degradation of service attacks, ransomware, hacking, phishing and other social engineering attacks, attachments to emails, persons inside our organization or persons with access to systems inside our organization.

The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. The prevalent use of mobile devices that access confidential information also increases the risk of lost or stolen devices, security incidents and data security breaches, which could lead to the loss of confidential information or other intellectual property. As a result of the COVID-19 pandemic, we may face increased risks of a security breach or disruption due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. The costs to us to investigate, mitigate and remediate security incidents, breaches, disruptions, network security problems, bugs, viruses, worms, malicious software programs and security vulnerabilities could be significant, and while we have implemented security measures to protect our data security and information technology systems, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, delays, cessation of service, negative publicity and other harm to our business and our competitive position. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Any security compromise affecting us, our partners or our industry, whether real or perceived, could harm our reputation, erode confidence in the effectiveness of our security measures and lead to regulatory scrutiny. Moreover, if a computer security breach affects our systems or results in the unauthorized access to or unauthorized use, disclosure, release or other processing of personally identifiable information or clinical trial data, it may be necessary to notify individuals, governmental authorities, supervisory bodies, the media and other parties pursuant to privacy and security laws, and our reputation could be materially damaged. We would also be exposed to a risk of loss, governmental

investigations or enforcement, or litigation and potential liability, which could materially adversely affect our business, results of operations and financial condition.

Failure to comply with health and data protection laws and regulations could lead to government enforcement actions and civil or criminal penalties, private litigation or adverse publicity and could negatively affect our operating results and business.

We are subject to or affected by federal, state and foreign data protection laws and regulations which address privacy and data security. In the United States, numerous federal and state laws and regulations, including the U.S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and its implementing regulations, or HITECH, state data breach notification laws, state health information privacy laws and federal and state consumer protection laws, including Section 5 of the Federal Trade Commission Act, which govern the collection, use, disclosure and protection of health-related and other personal information, may apply to our operations and the operations of any future collaborators. In addition, we may obtain health information from third parties, including research institutions from which we obtain clinical trial data, that are subject to privacy and security requirements under HIPAA, as amended by HITECH, and other privacy and data security laws. Depending on the facts and circumstances, we could be subject to significant administrative, civil and criminal penalties if we obtain, use or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA. Further, various states have implemented similar privacy laws and regulations. For example, California also recently enacted the California Consumer Privacy Act of 2018, or CCPA. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing and receive detailed information about how their personal information is used. The CCPA also provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA went into effect on January 1, 2020 and grants the California Attorney General the power to bring enforcement actions for violations beginning July 1, 2020. The CCPA has been amended from time to time, 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 our business activities and as a result may increase our compliance costs and potential liability. Many similar privacy laws have been proposed at the federal level and in other states.

Foreign data protection laws, including Regulation 2016/679, known as the General Data Protection Regulation, or GDPR, may also apply to health-related and other personal information data subjects in the EU or the United Kingdom, or UK. The GDPR went into effect on May 25, 2018. Companies that must comply with the GDPR face increased compliance obligations and risk, including robust regulatory enforcement of data protection requirements as well as potential fines for noncompliance of up to €20 million or 4% of annual global revenue of the noncompliance company, whichever is greater. The GDPR imposes numerous requirements for the collection, use, storage and disclosure of personal information of EU or UK data subjects, including requirements relating to providing notice to and obtaining consent from data subjects, personal data breach notification, cross-border transfers of personal information, and honoring and providing for the rights of EU or UK individuals in relation to their personal information, including the right to access, correct and delete their data.

Compliance with U.S. and foreign data protection laws and regulations could require us to take on more onerous obligations in our contracts, require us to engage in costly compliance exercises, restrict our ability to collect, use and disclose data, or in some cases, impact our or our partners' or suppliers' ability to operate in certain jurisdictions. Failure to comply with U.S. and foreign data protection laws and regulations could result in government investigations and/or enforcement actions, fines, civil or criminal penalties, private litigation or adverse publicity and could negatively affect our operating results and business.

Moreover, clinical trial subjects about whom we or any of our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend and could result in adverse publicity that could materially and adversely affect our business, financial condition, results of operations and prospects.

Our employees and independent contractors, including principal investigators, consultants, any future commercial collaborators, service providers and other vendors, may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have an adverse effect on our results of operations.

We are exposed to the risk that our employees and independent contractors, including principal investigators, consultants, any future commercial collaborators, service providers and other vendors may engage in misconduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or other unauthorized activities that violate the laws and regulations of the FDA and other similar regulatory bodies, including those laws that require the reporting of true, complete and accurate information to such regulatory bodies; manufacturing standards; U.S. federal and state healthcare fraud and abuse, data privacy laws and other similar non-U.S. laws; or laws that require the true, complete and accurate reporting of financial information or data. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, the creation of fraudulent data in our preclinical studies or clinical trials, or illegal misappropriation of product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. In addition, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and financial results, including, without limitation, the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid and other U.S. healthcare programs, other sanctions, imprisonment, contractual damages, reputational harm, diminished profits and future earnings and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent protection for our technology and product candidates including our lead product candidate, CT1812, or if the scope of the patent protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets.

We rely, and will continue to rely, upon a combination of patents, trademarks, trade secret protection and confidentiality agreements with employees, consultants, collaborators, advisors and other third parties to protect the intellectual property related to our current and future drug development programs and product candidates. Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our technology and product candidates. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our current and future drug development programs and product candidates, successfully defend our intellectual property rights against third-party challenges and successfully enforce our intellectual property rights to prevent third-party infringement. The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner.

It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. We may choose not to seek patent protection for certain innovations or products and may choose not to pursue patent protection in certain jurisdictions, and under the laws of certain jurisdictions, patents or other intellectual property rights may be unavailable or limited in scope and, in any event, any patent protection we obtain may be limited. As a result, some of our product candidates are not, and in the future may not be, protected by patents. We generally apply for patents in those countries where we intend to make, have made, use, offer for sale, or sell products and where we assess the risk of infringement to justify the cost of seeking patent protection. However, we do not seek protection in all countries where we intend to sell products and we may not accurately predict all the countries where patent protection would ultimately be desirable. If we fail to timely file a patent application in any such country, we may be precluded from doing so at a later date. The patent applications that we own may

fail to result in issued patents with claims that cover any of our product candidates in the United States or in other foreign countries. We may also inadvertently make statements to regulatory agencies during the regulatory approval process that may be inconsistent with positions that have been taken during prosecution of our patents, which may result in such patents being narrowed, invalidated or held unenforceable, and vice versa that may affect the regulatory approval process.

The patents and patent applications that we own may fail to result in issued patents with claims that protect any of our product candidates in the United States or in other foreign countries. We cannot guarantee any current or future patents will provide us with any meaningful protection or competitive advantage. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which can prevent a patent from issuing from a pending patent application, or be used to invalidate a patent. The examination process may require us to narrow our claims, which may limit the scope of patent protection that we may obtain. Even if patents do successfully issue based on our patent applications, and even if such patents cover our product candidates, uses of our product candidates, or other aspects related to our product candidates, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, invalidated or held unenforceable, any of which could limit our ability to prevent competitors and other third parties from developing and marketing similar products or limit the length of terms of patent protection we may have for our products and technologies. Other companies may also design around technologies we have patented or developed. Any successful opposition to these patents or any other patents owned by us in the future could deprive us of rights necessary for the successful commercialization of any of our product candidates, if approved. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced. If any of our patents are challenged, invalidated, circumvented by third parties or otherwise limited or expire prior to the commercialization of our products, and if we do not own or have exclusive rights to other enforceable patents protecting our products or other technologies, competitors and other third parties could market products and use processes that are substantially similar to, or superior to, ours and our business would suffer.

If the patent applications we hold with respect to our development programs and product candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for any of our product candidates, it could dissuade companies from collaborating with us to develop product candidates, and threaten our ability to commercialize, future products. Our pending applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Any such outcome could harm our business.

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. The standards that the USPTO and its foreign counterparts use to grant patents are not always applied predictably or uniformly. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States, and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions. For example, European patent law restricts the patentability of methods of treatment of the human body more than U.S. law does. Publications of discoveries in scientific literature often lag behind 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, we cannot know with certainty whether we were the first to make the inventions claimed in our owned patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or product candidates, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

Patent reform legislation in the United States, including the Leahy-Smith America Invents Act, or the Leahy-Smith Act, could increase those uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. The Leahy-Smith Act was signed into law on September 16, 2011 and 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 and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. These include allowing 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. After March 15, 2013, under the Leahy-Smith Act, the United States transitioned to a first inventor to file system in which, assuming that the other statutory requirements are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications, our ability to obtain future patents, and the enforcement or defense of our issued patents, all of which could harm our business, financial condition, results of operations and prospects.

Moreover, we may be subject to a third-party pre-issuance submission of prior art to the USPTO or become involved in opposition, derivation, reexamination, *inter partes* review, post-grant review or interference proceedings challenging our owned patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our 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, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Moreover, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Without patent protection for our current or future product candidates, we may be open to competition from generic versions of such products. 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, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on our product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. The requirements for patentability may differ in certain countries, particularly developing countries, and the breadth of patent claims allowed can be inconsistent. 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, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may also export infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

We do not have patent rights in certain foreign countries in which a market may exist. Moreover, in foreign jurisdictions where we do have patent rights, proceedings to enforce such rights could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, and our patent applications at risk of not issuing. Additionally, such proceedings could provoke third parties to assert claims against us. We may not prevail in

any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Thus, we may not be able to stop a competitor from marketing and selling in foreign countries products and services that are the same as or similar to our products and services, and our competitive position in the international market would be harmed.

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 biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop.

Patent terms may be inadequate to protect our competitive position on our product candidates including our lead product candidate, CT1812 for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. In the United States, a patent's term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the U.S. Patent and Trademark Office, or USPTO, in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over an earlier filed patent. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including generics or biosimilars.

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, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. We expect to seek extensions of patent terms in the United States and, if available, in other countries where we are prosecuting patents.

Depending upon the timing, duration and specifics of FDA marketing approval of our drug candidates, one or more of our U.S. patents may be eligible for limited patent term extension, or PTE, under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years beyond the normal expiration of the patent as compensation for patent term lost during development and the FDA regulatory review process, which is limited to the approved indication (and potentially additional indications approved during the period of extension) covered by the patent. This extension is limited to only one patent that covers the approved product, the approved use of the product, or a method of manufacturing the product. However, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. We may not be granted an extension because of, for example, 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 we request. Even if we are able to obtain an extension, the patent term may still expire before or shortly after we receive FDA marketing approval.

If we are unable to extend the expiration date of our existing patents or obtain new patents with longer expiry dates, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data to obtain approval of competing products following our patent expiration and launch their product earlier than might otherwise be the case.

If we do not obtain protection under the Hatch-Waxman Amendments by obtaining data exclusivity, our business may be harmed.

Our commercial success will largely depend on our ability to obtain market exclusivity in the United States and other countries with respect to our drug candidates and their target indications. Depending upon the timing, duration and specifics of FDA marketing approval of our drug candidates, certain of our product candidates may be eligible for marketing exclusivity. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to obtain approval of an NDA for a new chemical entity, or NCE. A drug is an NCE if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. If market exclusivity is granted for an NCE, during the exclusivity period, the FDA may not accept for review or approve an abbreviated new drug application, or ANDA, or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed in the FDA's publication *Approved Drug Products with Therapeutic Equivalence Evaluations*, which we refer to as the Orange Book, with the FDA by the innovator NDA holder. The FDCA also provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages, dosage forms or strengths of an existing drug. This three-year exclusivity covers only the conditions associated with the new clinical investigations and prohibits the FDA from approving an ANDA, or a 505(b)(2) NDA submitted by another company with overlapping conditions associated with the new clinical investigations for the three-year period. Clinical investigation exclusivity does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. Five-year and three-year exclusivity will not delay the submission or approval of an NDA for the same drug. However, an applicant submitting an NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

If we are unable to obtain such marketing exclusivity for our product candidates, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data to obtain approval of competing products and launch their product earlier than might otherwise be the case.

The validity, scope and enforceability of any patents listed in the Orange Book that cover our product candidates including our lead product candidate CT1812 can be challenged by third parties.

If one of our product candidates is approved by the FDA, one or more third parties may challenge the current patents, or patents that may issue in the future, within our portfolio which could result in the invalidation of, or render unenforceable, some or all of the relevant patent claims or a finding of non-infringement. For example, if a third party files an application under Section 505(b)(2) or an ANDA for a generic drug containing any of our product candidates, and relies in whole or in part on studies conducted by or for us, the third party will be required to certify to the FDA that either: (1) there is no patent information listed in the Orange Book with respect to our NDA for the applicable approved drug candidate; (2) the patents listed in the Orange Book have expired; (3) the listed patents have not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patents are invalid or will not be infringed by the manufacture, use or sale of the third party's generic drug. A certification that the new drug will not infringe the Orange Book-listed patents for the applicable approved drug candidate, or that such patents are invalid, is called a paragraph IV certification. If the third party submits a paragraph IV certification to the FDA, a notice of the paragraph IV certification must also be sent to us once the third party's ANDA is accepted for filing by the FDA. We may then initiate a lawsuit to defend the patents identified in the notice. The filing of a patent infringement lawsuit within 45 days of receipt of the notice automatically prevents the FDA from approving the third party's ANDA until the earliest of 30 months or the date on which the patent expires, the lawsuit is settled, or the court reaches a decision in the infringement lawsuit in favor of the third party. If we do not file a patent infringement lawsuit within the required 45-day period, the third party's ANDA will not be subject to the 30-month stay of FDA approval.

Moreover, a third party may challenge the current patents, or patents that may issue in the future, within our portfolio which could result in the invalidation of some or all of the patents that might otherwise be eligible for listing in the Orange Book for one of our products. If a third party successfully challenges all of the patents that might otherwise be eligible for listing in the Orange Book for one of our products, we will not be entitled to the 30-month stay of FDA approval upon the filing of an ANDA for a generic drug containing any of our product candidates, and relies in whole or in part on studies conducted by or for us.

Litigation or other proceedings to enforce or defend intellectual property rights are often very complex in nature, may be very expensive and time-consuming, may divert our management's attention from our core business, and may result in unfavorable results that could limit our ability to prevent third parties from competing with our drug candidates.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for noncompliance with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and other foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign national or international patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance 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. Noncompliance events that could result in abandonment or lapse of patent rights include, but are not limited to, failure to timely file national and regional stage patent applications based on our international patent application, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering any of our product candidates, our competitors might be able to enter the market earlier than anticipated, which would harm our business.

We may need to license intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.

The issuance of a patent does not give us the right to practice the patented invention. A third party may hold intellectual property, including patent rights, that are important or necessary to the development of our product candidates. Third parties may also have blocking patents that could prevent us from marketing our products or practicing our own patented technology. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our drug candidates, in which case we would be required to obtain a license from these third parties on commercially reasonable terms. Such a license may not be available, or it may not be available on commercially reasonable terms, in which case our business would be harmed.

The risks described elsewhere pertaining to our intellectual property rights also apply to any intellectual property rights that we may in-license, and any failure by us or our potential licensors to obtain, maintain, defend and enforce these rights could harm our business. In some cases we may not have control over the prosecution, maintenance or enforcement of the patents that we may license, and may not have sufficient ability to provide input into the patent prosecution, maintenance and defense process with respect to such patents, and our potential licensors may fail to take the steps that we believe are necessary or desirable in order to obtain, maintain, defend and enforce the licensed patents.

Third-party claims or litigation alleging infringement of patents or other proprietary rights, or seeking to invalidate patents or other proprietary rights, may delay or prevent the development and commercialization of any of our product candidates including our lead product candidate, CT1812.

Our commercial success depends in part on our avoiding infringement and other violations of the patents and proprietary rights of third parties. However, while certain research, development and commercialization activities may be protected by the safe harbor provision of the Hatch Waxman Act, other activities may subject to claims that we infringe or otherwise violate patents or other intellectual

property rights owned or controlled by third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, derivation and administrative law proceedings, *inter partes* review and post-grant review before the USPTO, as well as oppositions and similar processes in foreign jurisdictions. Numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we and our collaborators are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, and as we gain greater visibility and market exposure as a public company, the risk increases that our product candidates or other business activities may be subject to claims of infringement of the patent and other proprietary rights of third parties. Third parties may assert that we are infringing their patents or employing their proprietary technology without authorization.

There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire. Similarly, if any third-party patent was to be held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy, the holders of any such patent may be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all. In addition, we may be subject to claims that we are infringing other intellectual property rights, such as trademarks or copyrights, or misappropriating the trade secrets of others, and to the extent that our employees, consultants or contractors use intellectual property or proprietary information owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful infringement or other intellectual property claim against us, we 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 our affected products, which may be impossible or require substantial time and monetary expenditure. We 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, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates, and we have done so from time to time. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

Some of our competitors may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they have substantially greater resources. In addition, intellectual property litigation, regardless of its outcome, may cause negative publicity, adversely impact prospective customers, cause product shipment delays, or prohibit us from manufacturing, marketing or otherwise commercializing our products, services and technology. Any uncertainties resulting from the initiation and continuation of any litigation could adversely impact our ability to raise additional funds or otherwise harm our business, results of operation, financial condition or cash flows.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by

disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments, which could adversely impact the price of our common shares. If securities analysts or investors perceive these results to be negative, it could adversely impact the price of our common shares. The occurrence of any of these events may harm our business, results of operation, financial condition or cash flows.

We cannot provide any assurances that third-party patents do not exist which might be enforced against our drugs or product candidates, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties or other forms of compensation to third parties.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might harm our ability to develop and market our products.

We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is or may be relevant to or necessary for the commercialization of our product candidates in any jurisdiction. Patent applications in the United States and elsewhere are not published until approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. In addition, U.S. patent applications filed before November 29, 2000 and certain U.S. patent applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Therefore, patent applications covering our products could have been filed by others without our knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our product candidates or the use of our products.

The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our products. We may incorrectly determine that our products are not covered by a third-party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, and our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products.

If we fail to identify and correctly interpret relevant patents, we may be subject to infringement claims. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being forced to pay damages, we may be temporarily or permanently prohibited from commercializing any of our products that are held to be infringing. We might, if possible, also be forced to redesign products or services so that we no longer infringe the third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

We may become involved in lawsuits to protect or enforce our patents or our other intellectual property rights, which could be expensive, time consuming and unsuccessful.

Competitors may infringe or otherwise violate our patents or our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file legal claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. As a result, we cannot predict with certainty how much protection, if any, will be given to our patents if we attempt to enforce them and they are challenged in court. Further, even if we prevail against an infringer in U.S. district court, there is always the risk that the infringer will file an appeal and the district court judgment will be overturned at the appeals court and/or that an adverse decision will be issued by the appeals court relating to the validity or enforceability of our patents. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications

at risk of not issuing. The initiation of a claim against a third party may also cause the third party to bring counter claims against us such as claims asserting that our patents are invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement or lack of written description or statutory subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant material information from the USPTO, or made a materially misleading statement, during prosecution. Third parties may also raise similar validity claims before the USPTO in post-grant proceedings such as ex parte reexaminations, *inter partes* review, or post-grant review, or oppositions or similar proceedings outside the United States, in parallel with litigation or even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. We cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of any future patent protection on our current or future product candidates.

We may not be able to detect or prevent misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Our business could be harmed if in litigation the prevailing party does not offer us a license on commercially reasonable terms. Any litigation or other proceedings to enforce our intellectual property rights may fail, and even if successful, may result in substantial costs and distract our management and other employees.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could harm the price of our common shares.

Because of the expense and uncertainty of litigation, we may not be in a position to enforce our intellectual property rights against third parties.

Because of the expense and uncertainty of litigation, we may conclude that even if a third party is infringing our issued patent, any patents that may be issued as a result of our pending or future patent applications or other intellectual property rights, the risk-adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of our company or our shareholders. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution.

Changes in U.S. patent law or the patent law of other countries or jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our product including our lead product candidate, CT1812.

The United States has recently enacted and implemented wide-ranging patent reform legislation. In addition, patent reform legislation may pass in the future that could lead to additional uncertainties and increased costs surrounding the prosecution, enforcement and defense of our patents and pending patent applications. The United States Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our 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 actions by the United States Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we own or that we might obtain in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we own or that we may

obtain in the future. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by United States and foreign legislative bodies. Those changes may materially affect our patents or patent applications and our ability to obtain additional patent protection in the future. The United States federal government retains certain rights in inventions produced with its financial assistance under the Bayh-Dole Act. The federal government retains a “nonexclusive, nontransferable, irrevocable, paid-up license” for its own benefit. The Bayh-Dole Act also provides federal agencies with “march-in rights.” March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a “nonexclusive, partially exclusive, or exclusive license” to a “responsible applicant or applicants.” If the patent owner refuses to do so, the government may grant the license itself.

We may not be able to protect our intellectual property rights throughout the world, which could impair our business.

Filing, prosecuting and defending patents covering any of our product candidates throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we may obtain patent protection, but where patent enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued patents and any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing. We do not have patent rights in certain foreign countries in which a market may exist. Moreover, many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of some countries do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. Additionally, such proceedings could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Thus, we may not be able to stop a competitor from marketing and selling in foreign countries products and services that are the same as or similar to our products and services, and our competitive position in the international market would be harmed.

Many countries, including European Union countries, India, Japan and China, have compulsory licensing laws under which a patent owner may be compelled under specified circumstances to grant licenses to third parties. In those countries, we may have limited remedies if patents are infringed or if we are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Because we expect to rely on third parties to manufacture our product candidates, and we expect to continue to collaborate with third parties on the development of our product candidates, we must, at times, share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Any disclosure, either intentional or unintentional, by our employees, the employees of third parties with whom we share our facilities or third-party consultants and vendors that we engage to perform research,

clinical trials or manufacturing activities, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market. Further, adequate remedies may not exist in the event of unauthorized use or disclosure. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may harm our business and results of operations.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. Policing unauthorized use of our intellectual property is difficult, expensive and time-consuming, and we may be unable to determine the extent of any unauthorized use. Moreover, enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third-party collaborators. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

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

We do and may employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, competitors or potential competitors. Although we seek to protect our ownership of intellectual property rights by ensuring that our agreements with our employees, collaborators and other third parties with whom we do business include provisions requiring such parties to assign rights in inventions to us and to not use the confidential information of their former employer, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or product candidates. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees. Moreover, any such litigation or the threat thereof may harm our reputation, our ability to form strategic alliances or sublicense our rights to collaborators, engage with scientific advisors or hire employees or consultants, each of which would harm our business, results of operations and financial condition.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We may be subject to claims that former employees, collaborators or other third parties have an interest in our patents, trade secrets, or other intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or our ownership of our patents, trade secrets or other intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our product candidates. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could harm our business, financial condition, results of operations and prospects.

In addition, while it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we

may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Our and their assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to management.

Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities, and have a harmful effect on the success of our business.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, 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 adversely impact the price of our common shares. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property. In addition, the uncertainties associated with litigation could compromise our ability to raise the funds necessary to continue our clinical trials and internal research programs. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace, including compromising our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties, or enter into development collaborations that would help us commercialize our product candidates, if approved.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patents for our product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect our trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. In addition, we may not be able to obtain adequate remedies for any such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

Any trademarks we have obtained or may obtain may be infringed or successfully challenged, resulting in harm to our business.

We expect to rely on trademarks as one means to distinguish any of our drug candidates that are approved for marketing from the products of our competitors. Once we select new trademarks and apply to register them, our trademark applications may not be approved. Third parties may oppose or attempt to

cancel our trademark applications or trademarks, or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our drugs, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks and we may not have adequate resources to enforce our trademarks. If we attempt to enforce our trademarks and assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

Our intellectual property agreements with third parties may be subject to disagreements over contract interpretation, which could narrow the scope of our rights to the relevant intellectual property or technology.

Certain provisions in our intellectual property agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could affect the scope of our rights to the relevant intellectual property or technology, or affect financial or other obligations under the relevant agreement, either of which could harm our business, financial condition, results of operations and prospects. For example, the NIA has provided grants to fund certain of our preclinical activities and clinical trials. If the United States or another jurisdiction decides that the NIA grant bestows rights to our patent applications, that could affect our ability to obtain valid and enforceable patent claims protecting our rights as they relate to our lead product candidate, CT1812, our other product candidates and our NICE platform. As a consequence of these and other factors, our patent applications may fail to result in issued patents with claims that cover our product candidates in the United States or in other countries. Such a loss of patent protection could harm our business.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

Once granted, patents may remain open to invalidity challenges including opposition, interference, re-examination, post-grant review, *inter partes* review, nullification or derivation action in court or before patent offices or similar proceedings for a given period after allowance or grant, during which time third parties can raise objections against such grant. In the course of such proceedings, which may continue for a protracted period of time, the patent owner may be compelled to limit the scope of the allowed or granted claims thus attacked, or may lose the allowed or granted claims altogether.

In addition, the degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, provide a barrier to entry against our competitors or potential competitors, or permit us to maintain our competitive advantage. Moreover, if a third party has intellectual property rights that cover the practice of our technology, we may not be able to fully exercise or extract value from our intellectual property rights. The following examples are illustrative:

- others may be able to make product that is similar to product candidates we intend to commercialize that is not covered by the patents that we own;
- we, or any collaborators might not have been the first to make or reduce to practice the inventions covered by the issued patents or pending patent applications that we own;
- we or any collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges;
- our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights, and then use the

information learned from such activities to develop competitive products for sale in our major commercial markets; and we may not develop additional proprietary technologies that are patentable;

- third parties performing manufacturing or testing for us using our products or technologies could use the intellectual property of others without obtaining a proper license;
- parties may assert an ownership interest in our intellectual property and, if successful, such disputes may preclude us from exercising exclusive rights over that intellectual property;
- we may not develop additional proprietary technologies that are patentable;
- we may not be able to obtain and maintain necessary licenses on commercially reasonable terms, or at all; and
- the patents of others may harm our business.

Should any of these events occur, they could significantly harm our business and results of operations.

Risks Related to Commercialization, Manufacturing and Reliance on Third Parties

Even if our current or future product candidates obtain regulatory approval, they may fail to achieve the broad degree of adoption and use by physicians, patients, hospitals, healthcare payors and others in the medical community necessary for commercial success.

Even if one or more of our product candidates receive FDA or other regulatory approvals, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, healthcare payors and others in the medical community. Most of our product candidates target mechanisms for which there are limited or no currently approved products, which may result in slower adoption by physicians, patients and payors. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant product revenue and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the clinical indications for which the product is approved and patient demand for approved products that treat those indications;
- the safety and efficacy of our product as compared to other available therapies;
- the availability of coverage and adequate reimbursement from governmental healthcare plans or third party payors for any of our product candidates that may be approved;
- acceptance by physicians, operators of clinics and patients of the product as a safe and effective treatment;
- physician and patient willingness to adopt a new therapy over other available therapies to treat approved indications;
- overcoming any biases physicians or patients may have toward particular therapies for the treatment of approved indications;
- proper training and administration of our product candidates by physicians and medical staff;
- public misperception regarding the use of our therapies, if approved for commercial sale;
- patient satisfaction with the results and administration of our product candidates and overall treatment experience, including, for example, the convenience of any dosing regimen;
- the cost of treatment with our product candidates in relation to alternative treatments and reimbursement levels, if any, and willingness to pay for the product, if approved, on the part of insurance companies and other third-party payors, physicians and patients;
- the revenue and profitability that our products may offer a physician as compared to alternative therapies;
- limitations or warnings contained in the FDA-approved labeling for our products;
- any FDA requirement to undertake a REMS;

- the effectiveness of our sales, marketing and distribution efforts;
- adverse publicity about our products or favorable publicity about competitive products; and
- potential product liability claims.

We cannot assure you that our current or future product candidates, if approved, will achieve broad market acceptance among physicians, patients, healthcare payors and others in the medical community. Even if we receive regulatory approval to market any of our product candidates, we cannot assure you that any such product candidate will be more effective than other commercially available alternatives or successfully commercialized. Any approval we may obtain could be for indications or patient populations that are not as broad as intended or desired or may require labeling that includes significant use or distribution restrictions or safety warnings. We may also be required to perform additional or unanticipated clinical trials to obtain approval or be subject to additional post-marketing testing requirements to maintain approval. In addition, regulatory authorities may withdraw their approval of a product or impose restrictions on its distribution, such as in the form of a REMS. Any failure by our product candidates to obtain regulatory approval to achieve market acceptance or commercial success would adversely affect our reputation, ability to raise additional capital, financial condition, results of operations and business prospects.

The market opportunities for CT1812, if approved, may be smaller than we anticipate.

We expect to initially seek approval for CT1812 for AD, dry AMD, PD and DLB and other age-related degenerative diseases and disorders of the CNS and retina. Our estimates of market potential have been derived from a variety of sources, including scientific literature, patient foundations and market research and may prove to be incorrect. Even if we obtain significant market share for CT1812 after FDA approval, the potential target populations may be too small to consistently generate revenue, and we may never achieve profitability without obtaining marketing approval for additional indications.

We rely on third-party suppliers to manufacture our product candidates, and we intend to rely on third parties to produce commercial supplies of any approved product. The loss of these suppliers, or their failure to comply with applicable regulatory requirements or to provide us with sufficient quantities at acceptable quality levels or prices, or at all, would materially and adversely affect our business, financial condition, results of operations and prospects.

We do not currently have nor do we plan to build or acquire the infrastructure or capability internally to manufacture supplies of our product candidates or the materials necessary to produce our product candidates for use in the conduct of our preclinical studies or clinical trials, and we lack the internal resources and the capability to manufacture any of our product candidates on a preclinical, clinical or commercial scale. The facilities used by our contract manufacturers to manufacture our product candidates are subject to various regulatory requirements and may be subject to the inspection of the FDA or other regulatory authorities. We do not control the manufacturing processes of, and are completely dependent on, our contract manufacturing partners for compliance with the regulatory requirements, known as cGMPs. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or comparable regulatory authorities in foreign jurisdictions, we may not be able to rely on their manufacturing facilities for the manufacture of our product candidates. In addition, we have limited control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority finds these facilities inadequate for the manufacture of our product candidates or if such facilities are subject to enforcement action in the future or are otherwise inadequate, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates.

We currently rely on third parties at key stages in our supply chain. For instance, the supply chains for our lead product candidate involves several manufacturers that specialize in specific operations of the manufacturing process, specifically, raw materials manufacturing, drug substance manufacturing and drug product manufacturing. As a result, the supply chain for the manufacturing of our product candidates is complicated, and we expect the logistical challenges associated with our supply chain to grow more complex as our product candidates are further developed.

We do not have any control over the process or timing of the acquisition or manufacture of materials by our manufacturers. We generally do not begin preclinical or clinical trials unless we believe we have access to a sufficient supply of a product candidate to complete such study. In addition, any significant delay in, or quality control problems with respect to, the supply of a product candidate, or the raw material components thereof, for an ongoing study could considerably delay completion of our preclinical or clinical trials, product testing and potential regulatory approval of our product candidates.

We have not yet engaged any manufacturers for the commercial supply of our product candidates. Although we intend to enter into such agreements prior to commercial launch of any of our product candidates, we may be unable to enter into any such agreement or do so on commercially reasonable terms, which could have a material adverse impact upon our business. Moreover, if there is a disruption to one or more of our third-party manufacturers' or suppliers' relevant operations, or if we are unable to enter into arrangements for the commercial supply of our product candidates, we will have no other means of producing our product candidates until they restore the affected facilities or we or they procure alternative manufacturing facilities or sources of supply. Our ability to progress our preclinical and clinical programs could be materially and adversely impacted if any of the third-party suppliers upon which we rely were to experience a significant business challenge, disruption or failure due to issues such as financial difficulties or bankruptcy, issues relating to other customers such as regulatory or quality compliance issues, or other financial, legal, regulatory or reputational issues. Additionally, any damage to or destruction of our third-party manufacturers' or suppliers' facilities or equipment may significantly impair our ability to manufacture our product candidates on a timely basis.

In addition, to manufacture our product candidates in the quantities which we believe would be required to meet anticipated market demand, our third-party manufacturers would likely need to increase manufacturing capacity and we may need to secure alternative sources of commercial supply, which could involve significant challenges and may require additional regulatory approvals. In addition, the development of commercial-scale manufacturing capabilities may require us and our third-party manufacturers to invest substantial additional funds and hire and retain the technical personnel who have the necessary manufacturing experience. Neither we nor our third-party manufacturers may successfully complete any required increase to existing manufacturing capacity in a timely manner, or at all. If our manufacturers or we are unable to purchase the raw materials necessary for the manufacture of our product candidates on acceptable terms, at sufficient quality levels or in adequate quantities, if at all, the commercial launch of our product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of such product candidates, if approved.

Our product candidates have never been manufactured on a commercial scale, and there are risks associated with scaling up manufacturing to commercial scale. In particular, we will need to develop a larger scale manufacturing process that is more efficient and cost-effective to commercialize our potential products, which may not be successful.

Our product candidates have never been manufactured on a commercial scale, and there are risks associated with scaling up manufacturing to commercial scale including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, lot consistency and timely availability of raw materials. There is no assurance that our third-party manufacturers will be successful in establishing a larger-scale commercial manufacturing process for our product candidates which achieves our objectives for manufacturing capacity and cost of goods. In addition, there is no assurance that our third-party manufacturers will be able to manufacture our product candidates to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of such products or to meet potential future demand. Our failure to properly or adequately scale scaling up manufacturing for commercial scale would adversely affect our business, results of operations and financial condition.

We rely on third parties in the conduct of all of our clinical trials. If these third parties do not successfully carry out their contractual duties, fail to comply with applicable regulatory requirements or meet expected deadlines, we may be unable to obtain regulatory approval for our product candidates.

We currently do not have the ability to independently conduct clinical trials that comply with the regulatory requirements known as good laboratory practice, or GLP, requirements or GCP requirements,

respectively. The FDA and regulatory authorities in other jurisdictions require us to comply with GCP requirements for conducting, monitoring, recording and reporting the results of clinical trials, in order to ensure that the data and results are scientifically credible and accurate and that the trial subjects are adequately informed of the potential risks of participating in clinical trials. We rely on medical institutions, clinical investigators, contract laboratories and other third parties, such as CROs, to conduct GLP-compliant preclinical studies and GCP-compliant clinical trials on our product candidates properly and on time. While we have agreements governing their activities, we control only certain aspects of their activities and have limited influence over their actual performance. The third parties with whom we contract for execution of our GLP-compliant preclinical studies and our GCP-compliant clinical trials play a significant role in the conduct of these studies and the subsequent collection and analysis of data. These third parties are not our employees and, except for restrictions imposed by our contracts with such third parties, we have limited ability to control the amount or timing of resources that they devote to our programs. Although we rely on these third parties to conduct our GLP-compliant preclinical studies and GCP-compliant clinical trials, we remain responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with its investigational plan and protocol and applicable laws and regulations, and our reliance on the CROs does not relieve us of our regulatory responsibilities.

Many of the third parties with whom we contract may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting preclinical studies, clinical trials or other drug development activities that could harm our competitive position. If the third parties conducting our preclinical studies or our clinical trials do not adequately perform their contractual duties or obligations, experience significant business challenges, disruptions or failures, do not meet expected deadlines, terminate their agreements with us or need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to their failure to adhere to our protocols or to GLPs or GCPs, or for any other reason, we may need to enter into new arrangements with alternative third parties. This could be difficult, costly or impossible, and our preclinical studies or clinical trials may need to be extended, delayed, terminated or repeated. As a result we may not be able to obtain regulatory approval in a timely fashion, or at all, for the applicable product candidate, our business, financial results and the commercial prospects for our product candidates would be harmed, our costs could increase, and our ability to generate revenues could be delayed.

We face significant competition in an environment of rapid technological and scientific change, and there is a possibility that our competitors may achieve regulatory approval before us or develop therapies that are safer, more advanced or more effective than ours, which may negatively impact our ability to successfully market or commercialize any product candidates we may develop and ultimately harm our financial condition.

The development and commercialization of new drug products is highly competitive. Moreover, the neurodegenerative field is characterized by strong and increasing competition, and a strong emphasis on intellectual property. We may face competition with respect to any of our product candidates that we seek to develop or commercialize in the future from major pharmaceutical companies, specialty pharmaceutical companies, and biotechnology companies worldwide. Potential competitors also include academic institutions, government agencies, and other public and private research organizations that conduct research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing, and commercialization.

There are a number of large pharmaceutical and biotechnology companies that are currently pursuing the development of product candidates for the treatment of the diseases and disorders for which we have research programs, including AD, dry AMD, PD and DLB. Companies developing therapeutics for similar indications include large companies with significant financial resources, such as AbbVie, AstraZeneca, Biogen, Celgene, Eli Lilly, GlaxoSmithKline, Johnson & Johnson, Novartis, Pfizer, Roche, Sanofi and Takeda. In addition to competition from other companies targeting neurodegenerative indications, any products we may develop may also face competition from other types of therapies.

Many of our current or potential competitors, either alone or with their strategic partners, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may

result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any products that we may develop. Furthermore, currently approved products could be discovered to have application for treatment of age-related degenerative diseases and disorders, which could give such products significant regulatory and market timing advantages over any of our product candidates. Our competitors also may obtain FDA, EMA or other regulatory approval for their products more rapidly than we may obtain approval for ours and may obtain orphan product exclusivity from the FDA for indications our product candidates are targeting, which could result in our competitors establishing a strong market position before we are able to enter the market. Additionally, products or technologies developed by our competitors may render our potential product candidates uneconomical or obsolete, and we may not be successful in marketing any product candidates we may develop against competitors.

In addition, we could face litigation or other proceedings with respect to the scope, ownership, validity and/or enforceability of our patents relating to our competitors' products and our competitors may allege that our products infringe, misappropriate or otherwise violate their intellectual property. The availability of our competitors' products could limit the demand, and the price we are able to charge, for any products that we may develop and commercialize. See "Risks Related to Our Intellectual Property." The successful commercialization of our product candidates will depend in part on the extent to which governmental authorities and health insurers establish adequate coverage, reimbursement levels and pricing policies. Failure to obtain or maintain coverage and adequate reimbursement for our product candidates, if approved, could limit our ability to market those products and decrease our ability to generate revenue.

The successful commercialization of our product candidates will depend in part on the extent to which governmental authorities and health insurers establish adequate coverage, reimbursement levels and pricing policies. Failure to obtain or maintain coverage and adequate reimbursement for our product candidates, if approved, could limit our ability to market those drugs and decrease our ability to generate revenue.

The availability and adequacy of coverage and reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third-party payors are essential for most patients to be able to afford prescription medications such as our product candidates, if approved. Our ability to achieve acceptable levels of coverage and reimbursement for products by governmental authorities, private health insurers and other organizations will have an effect on our ability to successfully commercialize our product candidates. Even if we obtain coverage for our product candidates by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. We cannot be sure that coverage and reimbursement in the United States, the European Union or elsewhere will be available for our product candidates or any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

Third-party payors increasingly are challenging prices charged for biopharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs or biologics when an equivalent generic drug, biosimilar or a less expensive therapy is available. It is possible that a third-party payor may consider our product candidates as substitutable and only offer to reimburse patients for the cost of the less expensive product. Even if we show improved efficacy or improved convenience of administration with our product candidates, pricing of existing third-party therapeutics may limit the amounts we will be able to charge for our product candidates. These payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in our product candidates. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our product candidates and may not be able to obtain a satisfactory financial return on our investment in the development of product candidates.

There is significant uncertainty related to the insurance coverage and reimbursement of newly-approved products. In the United States, third-party payors, and governmental healthcare plans, such as the

Medicare and Medicaid programs, play an important role in determining the extent to which new drugs and biologics will be covered. The Medicare and Medicaid programs increasingly are used as models in the United States for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs and biologics. Some third-party payors may require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers who use such therapies. We cannot predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates.

No uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement 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 will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases on short notice, and we believe that changes in these rules and regulations are likely.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe and other foreign jurisdictions have and will continue to put pressure on the pricing and usage of our product candidates. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amounts that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our product candidates may be reduced compared with the United States and may be insufficient to generate commercially-reasonable revenue and profits.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products, and, as a result, they may not cover or provide adequate payment for our product candidates. We expect to experience pricing pressures in connection with the sale of our product candidates due to the trend toward managed health care, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and biologics and surgical procedures and other treatments, has become intense. As a result, increasingly high barriers are being erected to the entry of new products.

We currently have no sales organization. If we are unable to establish sales capabilities on our own or through third parties, we may not be able to market and sell our product candidates, if approved, effectively in the United States and foreign jurisdictions or generate product revenue.

We currently do not have a marketing or sales organization. In order to commercialize our product candidates in the United States and foreign jurisdictions, we must build our marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. If any of our product candidates receive regulatory approval, we expect to establish a sales organization with technical expertise and supporting distribution capabilities to commercialize each such product candidate, which will be expensive and time consuming. We have no prior experience in the marketing, sale and distribution of biopharmaceutical products, and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. We may choose to collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize our product candidates. If we are not successful in commercializing our product candidates or any future product candidates, either on our own or through arrangements with one or more third parties, we may not be able to generate any future product revenue and we would incur significant additional losses.

Risks Related to Government Regulation

Even if we obtain regulatory approval for a product candidate, our products will remain subject to regulatory scrutiny.

If our product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies and submission of safety, efficacy and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities.

Manufacturers and manufacturers' facilities are required to comply with extensive FDA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMPs and adherence to commitments made in any approved marketing application. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

We will have to comply with requirements concerning advertising and promotion for any future products. Promotional communications with respect to prescription drugs and biologics are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. We may not promote products for indications or uses for which they do not have approval. The holder of an approved application must submit new or supplemental applications and obtain approval for certain changes to the approved product, product labeling or manufacturing process. We could also be asked to conduct post-marketing clinical trials to verify the safety and efficacy of our products in general or in specific patient subsets. An unsuccessful post-marketing study or failure to complete such a study could result in the withdrawal of marketing approval.

If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, such regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things:

- issue warning letters;
- impose civil or criminal penalties;
- suspend or withdraw regulatory approval;
- suspend any of our clinical trials;
- refuse to approve pending applications or supplements to approved applications submitted by us;
- impose restrictions on our operations, including closing our contract manufacturers' facilities; or
- seize or detain products, or require a product recall.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response, and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from any future products. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected.

Healthcare legislation, including potentially unfavorable pricing regulations or other healthcare reform initiatives, may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates.

We operate in a highly regulated industry. The commercial potential for our approved products, if any, could be affected by changes in healthcare spending and policy in the United States and abroad. New laws,

regulations or judicial decisions or new interpretations of existing laws, regulations or decisions, related to healthcare availability, the method of delivery or payment for healthcare products and services could adversely affect our business, operations and financial condition. The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that may affect our ability to profitably sell our product and product candidates, if approved. The United States government, state legislatures and foreign governments also have shown significant interest in implementing cost-containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs and biologics.

The Affordable Care Act was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. There have been significant ongoing administrative, executive and legislative efforts to modify or eliminate the Affordable Care Act. For example, the Tax Act enacted on December 22, 2017 repealed the shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Internal Revenue Code, commonly referred to as the individual mandate. The Trump administration issued executive orders which sought to reduce burdens associated with the Affordable Care Act and modified how it was implemented. Other legislative changes have been proposed and adopted since passage of the Affordable Care Act. The Affordable Care Act has also been subject to challenges in the courts. On December 14, 2018, a Texas U.S. District Court Judge ruled that the Affordable Care Act is unconstitutional in its entirety because the “individual mandate” was repealed by Congress. On December 18, 2019, the Fifth Circuit U.S. Court of Appeals held that the individual mandate is unconstitutional and remanded the case to the Texas District Court to reconsider its earlier invalidation of the entire Affordable Care Act. An appeal was taken to the U.S. Supreme Court which heard oral arguments in the case on November 10, 2020. On June 17, 2021, the Supreme Court ruled that the plaintiffs lacked standing to challenge the law as they had not alleged personal injury traceable to the allegedly unlawful conduct. As a result, the Supreme Court did not rule on the constitutionality of the ACA or any of its provisions.

Further changes to and under the Affordable Care Act remain possible, although the new Biden administration has signaled that it plans to build on the Affordable Care Act and expand the number of people who are eligible for subsidies under it. President Biden indicated that he intends to use executive orders to undo changes to the Affordable Care Act made by the Trump administration and would advocate for legislation to build on the Affordable Care Act. It is unknown what form any such changes or any law proposed to replace the Affordable Care Act would take, and how or whether it may affect our business in the future. We expect that changes to the Affordable Care Act, the Medicare and Medicaid programs, changes allowing the federal government to directly negotiate drug and biologic prices and changes stemming from other healthcare reform measures, especially with regard to healthcare access, financing or other legislation in individual states, could have a material adverse effect on the healthcare industry.

The Budget Control Act of 2011 has resulted in reductions in spending on certain government programs, including aggregate reductions to Medicare payments to healthcare providers of up to 2.0% per fiscal year. These reductions have been extended until 2030 unless additional Congressional action is taken.

Any reduction in reimbursement from Medicare, Medicaid, or other government programs may result in a similar reduction in payments from private payers. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain and maintain profitability of our product and product candidates, if approved.

We 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 we or any related third parties are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or any related third parties are not able to maintain regulatory compliance, CT1812 or any future product candidates may lose any marketing approval that may have been obtained and we may not achieve or sustain profitability, which would materially affect our business, financial condition and results of operations.

If we develop a small molecule product candidate that obtains regulatory approval, additional competitors could enter the market with generic versions of such drugs, which may result in a material decline in sales of affected products.

Under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, a pharmaceutical manufacturer may file an abbreviated new drug application, or ANDA, seeking approval of a generic version of an approved, small molecule innovator product. Under the Hatch-Waxman Act, a manufacturer may also submit an NDA, under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act that references the FDA's prior approval of the small molecule innovator product. A 505(b)(2) NDA product may be for a new or improved version of the original innovator product. The Hatch-Waxman Act also provides for certain periods of regulatory exclusivity, which preclude FDA approval (or in some circumstances, FDA filing and review) of an ANDA or 505(b)(2) NDA. In addition to the benefits of regulatory exclusivity, an innovator NDA holder may have patents claiming the active ingredient, product formulation or an approved use of the drug, which would be listed with the product in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," known as the Orange Book. If there are patents listed in the Orange Book for a product, a generic or 505(b)(2) applicant that seeks to market its product before expiration of the patents must include in their applications what is known as a "Paragraph IV" certification, challenging the validity or enforceability of, or claiming non-infringement of, the listed patent or patents. Notice of the certification must be given to the patent owner and NDA holder and if, within 45 days of receiving notice, either the patent owner or NDA holder sues for patent infringement, approval of the ANDA or 505(b)(2) NDA is stayed for up to 30 months.

Accordingly, if we choose to develop a small molecule product candidate, and the product is approved, competitors could file ANDAs for generic versions of our small molecule drug products or 505(b)(2) NDAs that reference our small molecule drug products. If there are patents listed for our small molecule drug products in the Orange Book, those ANDAs and 505(b)(2) NDAs would be required to include a certification as to each listed patent indicating whether the ANDA applicant does or does not intend to challenge the patent. We cannot predict which, if any, patents in our current portfolio or patents we may obtain in the future will be eligible for listing in the Orange Book, how any generic competitor would address such patents, whether we would sue on any such patents, or the outcome of any such suit.

We may not be successful in securing or maintaining proprietary patent protection for products and technologies we develop or license. Moreover, if any of our owned or in-licensed patents that are listed in the Orange Book are successfully challenged by way of a Paragraph IV certification and subsequent litigation, the affected product could immediately face generic competition and its sales would likely decline rapidly and materially.

Our business operations and current and future relationships with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our product candidates, if approved. Such laws include, without limitation:

- the U.S. federal civil and criminal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or providing any remuneration (including any kickback, bribe, or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, 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 U.S. federal and state healthcare programs such as Medicare and Medicaid. 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;
- the U.S. federal false claims laws, including the False Claims Act, which can be enforced through whistleblower actions, and civil monetary penalties laws, which, among other things, impose criminal

and civil penalties against individuals or entities for knowingly presenting, or causing to be presented, to the U.S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;

- HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services; similar to the U.S. federal Anti-Kickback Statute, 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;
- HIPAA, as amended by the HITECH and its implementing regulations, which also imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by covered entities, such as health plans, healthcare clearinghouses and healthcare providers, as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- the U.S. Physician Payments Sunshine Act and its implementing regulations, which require certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid or the Children’s Health Insurance Program to report annually to the government information related to certain payments and other transfers of value to physicians, as defined by such law, and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members. Effective January 1, 2022, the U.S. federal physician transparency reporting requirements will extend to include transfers of value made during the previous year to certain non-physician providers such as physician assistants and nurse practitioners;
- analogous U.S. state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private 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 U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state and local laws that require the registration of pharmaceutical sales representatives; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; and state laws governing the privacy, security and disposal of personal information and health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts;
- the U.S. Foreign Corrupt Practices Act of 1977, as amended, which prohibits, among other things, U.S. companies and their employees and agents from authorizing, promising, offering or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public international organizations and foreign government owned or affiliated entities, candidates for foreign political office and foreign political parties or officials thereof; and
- similar data protection and healthcare laws and regulations in the European Union and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers and laws governing the privacy and security of personal data, including the GDPR,

which imposes obligations and restrictions on the collection and use of personal data relating to individuals located in the European Union and European Economic Area (including with regard to health data).

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, such as Medicare and Medicaid or similar programs in other countries or jurisdictions, disgorgement, imprisonment, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of our operations. Further, defending against any such actions can be costly and time-consuming and may require significant personnel resources. Even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

Changes in tax laws and regulations may have a material adverse effect on our business, financial condition and results of operations.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could affect the tax treatment of any of our future domestic and foreign earnings. Any new taxes could adversely affect our domestic and international business operations, and our business and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, the U.S. government enacted significant tax reforms in the past, and certain provisions of any new laws may adversely affect us. Changes in recent years include, but are not limited to, a federal corporate tax rate decrease to 21% for tax years beginning after December 31, 2017, a reduction to the maximum deduction allowed for net operating losses generated in tax years after December 31, 2017, eliminating carrybacks of net operating losses, and providing for indefinite carryforwards for losses generated in tax years after December 31, 2017. The legislation is unclear in many respects and could be subject to potential amendments and technical corrections, and will be subject to interpretations and implementing regulations by the Treasury and Internal Revenue Service, any of which could mitigate or increase certain adverse effects of the legislation. In addition, it is unclear how these U.S. federal income tax changes will affect state and local taxation. Generally, future changes in applicable U.S. tax laws and regulations, or their interpretation and application could have an adverse effect on our business, financial conditions and results of operations.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations, which can harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, or FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors and other collaborators from authorizing, promising, offering or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties to sell our products outside the United States, to conduct clinical trials and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors and other collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties,

imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences.

Risks Related to Our Common Stock and this Offering

Our stock price may be volatile and you may not be able to resell shares of our common stock at or above the price you paid.

The trading price of our common stock following this offering could be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. In particular, the trading prices for biopharmaceutical companies have been highly volatile as a result of the COVID-19 pandemic. These factors include those discussed in this “Risk Factors” section of this prospectus and others such as:

- results from, and any delays in, our current and future clinical trials with CT1812 or any other future clinical development programs, including any delays related to the COVID-19 pandemic;
- announcements of regulatory approval or disapproval of CT1812 or any future product candidates;
- failure or discontinuation of any of our research and development programs;
- the termination of any future collaborations or license agreements;
- delays in the commercialization of CT1812 or any future product candidates;
- public misperception regarding the use of our product candidates;
- acquisitions and sales of new products or product candidates, technologies or businesses;
- manufacturing and supply issues related to our product candidates for clinical trials or future product candidates for commercialization;
- quarterly variations in our results of operations or those of our competitors;
- changes in coverage and recommendations by securities analysts;
- announcements by us or our competitors of new products or product candidates, significant contracts, commercial relationships, acquisitions or capital commitments;
- developments with respect to intellectual property rights;
- our commencement of, or involvement in, litigation;
- changes in financial estimates or guidance;
- any major changes in our board of directors or management;
- new legislation or regulation in the United States relating to the sale or pricing of pharmaceuticals;
- FDA or other U.S. or foreign regulatory actions affecting us or our industry;
- product liability claims or other litigation or public concern about the safety of our product candidates;
- market conditions in the biopharmaceutical sectors; and
- general economic conditions in the United States and abroad.

In addition, the stock markets in general, and the markets for biopharmaceutical stocks in particular, have experienced extreme volatility that may have been unrelated to the operating performance of the issuer. These broad market fluctuations may adversely affect the trading price or liquidity of our common stock.

An active, liquid and orderly market for our common stock may not develop, and you may not be able to resell your common stock at or above the public offering price.

Prior to this offering, there has been no public market for shares of our common stock. Although we intend to apply to have our common stock listed on the Nasdaq Global Market, an active public market for

our shares may not develop or be sustained after this offering. We and the representatives of the underwriters will determine the initial public offering price of our common stock through negotiation. This price will not necessarily reflect the price at which investors in the market will be willing to buy and sell our shares following this offering. In addition, an active trading market may not develop following the consummation of this offering or, if it is developed, may not be sustained. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. An inactive market may also impair our ability to raise capital by selling shares and may impair our ability to acquire other product candidates, businesses or technologies using our shares as consideration.

We are an “emerging growth company” and a “smaller reporting company” and, as a result of the reduced disclosure and governance requirements applicable to emerging growth companies and smaller reporting companies, our common stock may be less attractive to investors.

We are an “emerging growth company” as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and we intend to take advantage of some of the exemptions from reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements; and
- not being required to hold a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the closing of our initial public offering, (b) in which we have total annual gross revenue of at least \$1.07 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds \$700 million as of the prior June 30th, and (2) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period.

Under Section 107(b) of the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. Even after we no longer qualify as an emerging growth company, we may, under certain circumstances, still qualify as a “smaller reporting company,” which would allow us to take advantage of many of the same exemptions from disclosure requirements, including reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements.

Purchasers in this offering will experience immediate and substantial dilution in the book value of their investment.

The initial public offering price of our common stock is substantially higher than the pro forma net tangible book value per share of our common stock before giving effect to this offering. Accordingly, if you purchase our common stock in this offering, you will incur immediate substantial dilution of approximately \$ per share, based on an assumed initial public offering price of \$ per share, the midpoint of the estimated price range set forth on the cover of this prospectus, and our pro forma as adjusted net tangible book value as of March 31, 2021. In addition, following this offering, purchasers in this offering will have contributed approximately % of the total gross consideration paid by stockholders to us to purchase shares of our common stock through March 31, 2021, but will own only approximately % of the shares of common stock outstanding immediately after this offering. Furthermore, if the underwriters

exercise their option to purchase additional shares or outstanding options are exercised, you could experience further dilution. For a further description of the dilution that you will experience immediately after this offering, see the section titled “Dilution.”

If we sell shares of our common stock in future financings, stockholders may experience immediate dilution and, as a result, our stock price may decline.

Because we expect our expenses to increase significantly in the foreseeable future and because, based on our current business plans, we believe that the net proceeds from this offering, together with our existing cash, cash equivalents and marketable securities, will be insufficient for us to fund our operating and capital expenditures beyond the date that is months after the date of this offering, we may from time to time issue additional shares of common stock. These issuances may be at a discount from the current trading price of our common stock. As a result, our stockholders would experience immediate dilution upon the purchase of any shares of our common stock sold at such discount. In addition, as opportunities present themselves, we may enter into financing or similar arrangements in the future, including the issuance of debt securities, preferred stock or common stock. If we issue common stock or securities convertible into common stock, our common stockholders will experience additional dilution and, as a result, our stock price may decline.

Concentration of ownership of our common stock among our existing executive officers, directors and principal stockholders may prevent new investors from influencing significant corporate decisions.

Our executive officers, directors and current beneficial owners of 5% or more of our common stock and their respective affiliates are expected to beneficially own % of our outstanding common stock following the consummation of this offering. As a result, these persons, acting together, would be able to significantly influence all matters requiring stockholder approval, including the election and removal of directors, any merger, consolidation, sale of all or substantially all of our assets, or other significant corporate transactions.

Some of these persons or entities may have interests different than yours. For example, because many of these stockholders purchased their shares at prices substantially below the current market price of our common stock and have held their shares for a longer period, they may be more interested in selling our company to an acquirer than other investors, or they may want us to pursue strategies that deviate from the interests of other stockholders.

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

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after the lock-up and other legal restrictions on resale discussed in this prospectus lapse, the trading price of our common stock could decline. Based upon the number of shares outstanding as of March 31, 2021, including 51,450,435 shares of our common stock issuable upon conversion of our preferred stock, _____ shares of common stock upon the assumed net exercise of warrants (assuming an initial public offering price of \$ _____ per share, the midpoint of the price range set forth on the cover page of this prospectus), _____ shares of our common stock issuable upon the conversion of the SAFEs upon the closing of in the aggregate amount of \$8.9 million (assuming an initial public offering price of \$ _____ per share, the midpoint of the price range set forth on the cover page of this prospectus), we will have outstanding a total of shares of common stock, assuming no exercise of the underwriters’ option to purchase additional shares. Of these shares, substantially all of the shares of our common stock sold in this offering (excluding any shares sold to our director or officers in the directed share program), plus any shares sold upon exercise of the underwriters’ option to purchase additional shares, will be freely tradable, without restriction, in the public market immediately following this offering.

The lock-up agreements pertaining to this offering will expire 180 days from the date of this prospectus. Based upon the number of shares outstanding as of March 31, 2021, plus 51,450,435 shares of our common stock issuable upon conversion of our preferred stock, _____ shares of common stock upon the assumed net exercise of warrants (assuming an initial public offering price of \$ _____ per share, the midpoint of the price range set forth on the cover page of this prospectus); _____ shares of our common stock issuable upon the conversion of the SAFEs upon the closing of in the aggregate amount of \$8.9 million

(assuming an initial public offering price of \$ _____ per share, the midpoint of the price range set forth on the cover page of this prospectus), after the lock-up agreements expire, up to approximately _____ additional shares of common stock will be eligible for sale in the public market, approximately _____ of which shares are held by directors, executive officers and other affiliates and will be subject to Rule 144 under the Securities Act of 1933, as amended, or the Securities Act. National Securities Corporation may, however, in their sole discretion, permit our officers, directors and other stockholders who are subject to these lock-up agreements to sell shares prior to the expiration of the lock-up agreements.

In addition, promptly following the closing of this offering, we intend to file one or more registration statements on Form S-8 under the Securities Act of 1933, as amended, or the Securities Act, registering the issuance of _____ shares of common stock subject to options or other equity awards issued or reserved for future issuance under our equity incentive plans. Shares registered under these registration statements on Form S-8 will be available for sale in the public market subject to vesting arrangements and exercise of options, the lock-up agreements described above and the restrictions of Rule 144 in the case of our affiliates.

After this offering, the holders of approximately _____ shares of our common stock, or approximately _____ % of our total outstanding shares of common stock, will be entitled to rights with respect to the registration of their shares under the Securities Act, subject to the lock-up agreements described above. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares purchased by affiliates. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

We have broad discretion to determine how to use the funds raised in this offering, and may use them in ways that may not enhance our operating results or the price of our common stock.

Our management will have broad discretion over the use of proceeds from this offering, and we could spend the proceeds from this offering in ways our stockholders may not agree with or that do not yield a favorable return, if at all. We currently expect to use the net proceeds from this offering to fund research and development of our product candidates and development programs, including our planned Phase 2 trials of CT1812 for the treatment of mild-to-moderate AD, our planned Phase 2 proof of concept trials of CT1812 for the dry AMD, our IND-enabling studies of compounds in our library for the treatment of neurodegenerative indications such as PD, and the remainder for our other research and development activities, as well as for working capital and other general corporate purposes, including costs and expenses associated with being a public company. However, our use of these proceeds may differ substantially from our current plans. If we do not invest or apply the proceeds of this offering in ways that improve our operating results, we may fail to achieve expected financial results, which could cause our stock price to decline.

Our ability to use net operating loss carryforwards and other tax attributes may be limited.

As of December 31, 2020, we had federal net operating loss, or NOL, carryforwards of approximately \$37.9 million and state NOL carryforwards of approximately \$37.9 million available to offset future taxable income. If not utilized, the federal and state NOL carryforwards will begin to expire in various years beginning in 2027. As of December 31, 2020, we also had \$3.7 million of federal research and development tax credit carryforwards available to reduce future income taxes. The federal research and development tax credits will begin to expire in 2027, if not utilized. The state research and development tax credits have no expiration date. Utilization of NOL carryforwards and credits may be subject to an annual limitation due to the “ownership change” provisions under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended. An “ownership change” is generally defined as a cumulative change in the ownership interest of significant stockholders over a rolling three-year period in excess of 50 percentage points. Similar provisions under state tax law may also apply. If finalized, Treasury Regulations currently proposed under Section 382 of the Code may further limit our ability to utilize our pre-change NOLs or credits if we undergo a future ownership change. We may experience an ownership change in the future as a result of subsequent shifts in our stock ownership, some of which changes are outside our control. Such ownership changes could result in the expiration of our NOL carryforwards and other tax attributes before they can be utilized and, if we are profitable, our future cash flows could be adversely affected due to our increased tax liability.

Additionally, under the Tax Cut and Jobs Act, the Tax Act, as modified by the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act”, NOL carryforwards arising in tax years beginning after December 31, 2020 are limited to 80% of taxable income. Under the Tax Act, federal NOL carryforwards arising in tax years beginning after December 31, 2017 may be carried forward indefinitely. Under the CARES Act, federal NOL carryforwards arising in tax years beginning after December 31, 2017 and before January 1, 2021 may be carried back to each of the five tax years preceding the tax year of such loss. The changes in the carryforward and carryback periods as well as the limitation on use of NOL carryforwards may significantly impact our ability to use NOL carryforwards, particularly for tax years beginning after December 31, 2020, as well as the timing of any such use, and could adversely affect our results of operations.

Provisions in our charter documents and under Delaware law could discourage a takeover that stockholders may consider favorable and may lead to entrenchment of management.

Our amended and restated certificate of incorporation and amended and restated bylaws, both of which will become effective immediately prior to the completion of this offering, will contain provisions that could delay or prevent changes in control or changes in our management without the consent of our board of directors. These provisions will include the following:

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of our board of directors to elect a director to fill a vacancy, however occurring, including by an expansion of the board of directors, which prevents stockholders from being able to fill vacancies on our board of directors;
- the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the price and other terms of those shares, including voting or other rights or preferences, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquiror;
- the ability of our board of directors to alter our amended and restated bylaws without obtaining stockholder approval;
- the required approval of at least 66 2/3% of the shares entitled to vote at an election of directors to adopt, amend or repeal our amended and restated bylaws or repeal the provisions of our amended and restated certificate of incorporation regarding the election and removal of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- the requirement that a special meeting of stockholders may be called only by the board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and
- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders’ meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror’s own slate of directors or otherwise attempting to obtain control of us.

We are also subject to the anti-takeover provisions contained in Section 203 of the Delaware General Corporation Law. Under Section 203, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other exceptions, the board of directors has approved the transaction. For a description of our capital stock, see the section titled “Description of Capital Stock.”

Our third amended and restated certificate of incorporation and amended and restated bylaws will provide that the Court of Chancery of the State of Delaware will be the exclusive forum for certain disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our third amended and restated certificate of incorporation and amended and restated bylaws will provide that the Court of Chancery of the State of Delaware (or, in the event that the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware or other state courts of the State of Delaware) is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a claim of breach of fiduciary duty, any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our third amended and restated certificate of incorporation or our amended and restated bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine; provided that, the exclusive forum provision will not apply to suits brought to enforce any liability or duty created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction; and provided further that, if and only if the Court of Chancery of the State of Delaware dismisses any such action for lack of subject matter jurisdiction, such action may be brought in another state or federal court sitting in the State of Delaware. Our third amended and restated certificate of incorporation and amended and restated bylaws will also provide that the federal district courts of the United States of America will be the exclusive forum for the resolution of any complaint asserting a cause of action against us or any of our directors, officers, employees or agents and arising under the Securities Act. Nothing in our third amended and restated certificate of incorporation and amended and restated bylaws precludes stockholders that assert claims under the Exchange Act from bringing such claims in state or federal court, subject to applicable law.

This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, other employees or stockholders, which may discourage lawsuits with respect to such claims, although our stockholders will not be deemed to have waived our compliance with federal securities laws and the rules and regulations thereunder. Furthermore, the enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions, and there can be no assurance that such provisions will be enforced by a court in those other jurisdictions. If a court were to find the choice of forum provision that will be contained in our amended and restated certificate of incorporation and amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition.

We do not currently intend to pay dividends on our common stock, and, consequently, your ability to achieve a return on your investment will depend on appreciation in the price of our common stock.

We do not currently intend to pay any cash dividends on our common stock for the foreseeable future. We currently intend to invest our future earnings, if any, to fund our growth. Therefore, you are not likely to receive any dividends on your common stock for the foreseeable future. Since we do not intend to pay dividends, your ability to receive a return on your investment will depend on any future appreciation in the market value of our common stock. There is no guarantee that our common stock will appreciate or even maintain the price at which our holders have purchased it.

Participation in this offering by our existing stockholders and/or their affiliated entities may reduce the public float for our common stock.

To the extent certain of our existing stockholders and their affiliated entities participate in this offering, such purchases would reduce the non-affiliate public float of our shares, meaning the number of shares of our common stock that are not held by officers, directors and controlling stockholders. A reduction in the public float could reduce the number of shares that are available to be traded at any given time, thereby adversely impacting the liquidity of our common stock and depressing the price at which you may be able to sell shares of common stock purchased in this offering.

General Risk Factors

Unfavorable global economic or political conditions could adversely affect our business, financial condition or results of operations.

Our business is susceptible to general conditions in the global economy and in the global financial markets. A global financial crisis or a global or regional political disruption could cause extreme volatility in the capital and credit markets. A severe or prolonged economic downturn, including a recession or depression resulting from the current COVID-19 pandemic, or political disruption could result in a variety of risks to our business, including weakened demand for our product candidates or any future product candidates, if approved, and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy or political disruption could also strain our manufacturers or suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our potential products. Any of the foregoing could materially and adversely affect our business, financial condition, results of operations and prospects, and we cannot anticipate all of the ways in which the political or economic climate and financial market conditions could adversely impact our business.

If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our stock, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. We do not currently have and may never obtain research coverage by securities and industry analysts. If no or few securities or industry analysts commence coverage of us, the trading price for our stock would be negatively impacted. In the event we obtain securities or industry analyst coverage, if any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our clinical trials and operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

We may be subject to securities litigation, which is expensive and could divert our management's attention.

In the past, companies that have experienced volatility in the market price of their securities have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Regardless of the merits or the ultimate results of such litigation, securities litigation brought against us could result in substantial costs and divert our management's attention from other business concerns.

We will incur significant costs as a result of operating as a public company, and our management will devote substantial time to new compliance initiatives. We may fail to comply with the rules that apply to public companies, including Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, which could result in sanctions or other penalties that could materially and adversely affect our business, financial condition, results of operations and prospects.

We will incur significant legal, accounting and other expenses as a public company, including costs resulting from public company reporting obligations under the Exchange Act and regulations regarding corporate governance practices. The listing requirements of the Nasdaq Global Market and the rules of the Securities and Exchange Commission, or SEC, require that we satisfy certain corporate governance requirements relating to director independence, filing annual and interim reports, stockholder meetings, approvals and voting, soliciting proxies, conflicts of interest and a code of conduct. Our management and other personnel will need to devote a substantial amount of time to ensure that we comply with all of these requirements. Moreover, the reporting requirements, rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. Any changes we make to comply with these obligations may not be sufficient to allow us to satisfy our obligations as a public company on a timely basis, or at all. These reporting requirements, rules and regulations, coupled with the increase in potential litigation exposure associated with being a public company, could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors or board

committees or to serve as executive officers, or to obtain certain types of insurance, including directors' and officers' insurance, on acceptable terms.

After this offering, we will be subject to Section 404 and the related rules of the SEC, which generally require our management and independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting. Beginning with the second annual report that we will be required to file with the SEC, Section 404 requires an annual management assessment of the effectiveness of our internal control over financial reporting. However, for so long as we remain an emerging growth company as defined in the JOBS Act, we intend to take advantage of certain exemptions from various reporting requirements that are applicable to public companies that are not emerging growth companies, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404. Once we are no longer an emerging growth company or, if prior to such date, we opt to no longer take advantage of the applicable exemption, we will be required to include an opinion from our independent registered public accounting firm on the effectiveness of our internal control over financial reporting.

During the course of our review and testing, we may identify deficiencies and be unable to remediate them before we must provide the required reports. Furthermore, if we identify any material weaknesses, we may not detect errors on a timely basis and our financial statements may be materially misstated. We or our independent registered public accounting firm may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting, which could materially and adversely affect our business, financial condition, results of operations and prospects, cause investors to lose confidence in our reported financial information and cause the trading price of our stock to fall. In addition, as a public company we will be required to file accurate and timely quarterly and annual reports with the SEC under the Exchange Act. In order to report our results of operations and financial statements on an accurate and timely basis, we will depend in part on CROs and other third parties to provide timely and accurate notice of their costs to us. Any failure to report our financial results on an accurate and timely basis could result in sanctions, lawsuits, delisting of our shares from the Nasdaq Global Market or other adverse consequences that would materially and adversely affect our business, financial condition, results of operations and prospects.

We will incur increased costs and demands upon management as a result of being a public company.

As a public company listed in the United States, we will incur significant additional legal, accounting and other costs. These additional costs could negatively affect our financial results. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including regulations implemented by the SEC and The Nasdaq Stock Market LLC, may increase legal and financial compliance costs and make some activities more time-consuming. These laws, regulations and standards are subject to varying interpretations and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If notwithstanding our efforts to comply with new laws, regulations and standards, we fail to comply, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

Failure to comply with these rules might also make it more difficult for us to obtain some types of insurance, including director and officer liability insurance, and we might be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, on committees of our board of directors or as members of senior management.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements concerning our business, operations and financial performance, as well as our plans, objectives and expectations for our business operations and financial performance and condition. All statements other than statements of historical or current facts included in this prospectus are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “aim,” “anticipate,” “assume,” “believe,” “contemplate,” “continue,” “could,” “design,” “due,” “estimate,” “expect,” “goal,” “intend,” “may,” “objective,” “plan,” “positioned,” “potential,” “predict,” “seek,” “should,” “target,” “will,” “would” and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology. In addition, statements that “we believe” or similar statements reflect our beliefs and opinions on the relevant subject. All forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those expressed in, or implied by these, forward-looking statements and therefore, you should not unduly rely on such statements, including, but not limited to:

- our ability to raise additional capital to fund our operations and continue the development of our current and future product candidates;
- the clinical nature of our business and our ability to successfully advance our current and future product candidates through our ongoing and future clinical trials, preclinical studies and development activities;
- our ability to generate revenue from future product sales and our ability to achieve and maintain profitability;
- the accuracy of our projections and estimates regarding our expenses, capital requirements, cash utilization, and need for additional financing;
- the expected uses of the net proceeds from this offering;
- the extent to which the COVID-19 pandemic and measures taken to contain its spread ultimately impact our business, including our ongoing and future clinical trials, preclinical studies and development activities;
- our dependence on the success of CT1812, our lead product candidate;
- the novelty of our approach to targeting the S2R complex to treat age-related degenerative diseases and disorders, and the challenges we will face due to the novel nature of such approach;
- the success of competing therapies that are or become available;
- the initiation, progress, success, cost, and timing of our ongoing and future clinical trials, preclinical studies and development activities;
- our ability to obtain and maintain regulatory clearance of CT1812 for approved IND applications and any future IND applications for any of our other product candidates;
- the timing, scope and likelihood of regulatory filings and approvals, including final regulatory approval of our product candidates;
- the performance of third parties in connection with the development of our product candidates, including third parties conducting our future clinical trials as well as third-party suppliers and manufacturers;
- our ability to attract and retain strategic collaborators with development, regulatory, and commercialization expertise;
- our ability to successfully commercialize our product candidates and develop sales and marketing capabilities, if our product candidates are approved;
- the size and growth of the potential markets for our product candidates and our ability to serve those markets;
- regulatory developments and approval pathways in the United States and foreign countries for our product candidates;

- the potential scope and value of our intellectual property and proprietary rights;
- our ability, and the ability of any future licensors, to obtain, maintain, defend, and enforce intellectual property and proprietary rights protecting our product candidates, and our ability to develop and commercialize our product candidates without infringing, misappropriating, or otherwise violating the intellectual property or proprietary rights of third parties;
- our ability to recruit and retain key members of management and other clinical and scientific personnel;
- developments relating to our competitors and our industry; and
- other risks and uncertainties, including those described under the caption “Risk Factors” in this prospectus.

We have based these forward-looking statements largely on our current expectations, estimates, forecasts and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. In light of the significant uncertainties in these forward-looking statements, you should not rely upon forward-looking statements as predictions of future events. Although we believe that we have a reasonable basis for each forward-looking statement contained in this prospectus, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur at all. You should refer to the section titled “Risk Factors” and elsewhere in this prospectus for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. Except as required by law, we undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise.

You should read this prospectus and the documents that we reference in this prospectus and have filed as exhibits to the registration statement, of which this prospectus is a part, completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of the forward-looking statements in this prospectus by these cautionary statements.

USE OF PROCEEDS

We estimate that the net proceeds from this offering will be approximately \$ million (or \$ million if the underwriters exercise their option to purchase additional shares in full), assuming an initial offering price of \$ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting underwriting discounts and commissions and offering expenses payable by us.

Each \$1.00 increase or decrease in the assumed initial public offering price of \$ per share would increase or decrease, as applicable, the net proceeds to us from this offering by \$ million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the number of shares we are offering. Each increase or decrease of 1.0 million shares in the number of shares offered by us would increase or decrease, as applicable, the net proceeds to us from this offering by \$ million, assuming that the assumed initial public offering price remains the same and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We do not expect that a change in the initial public offering price or the number of shares by these amounts would have a material effect on our uses of the proceeds from this offering, although it may accelerate the time when we need to seek additional capital.

The principal purposes of this offering are to increase our capitalization and financial flexibility, establish a public market for our common stock and to facilitate future access to the public equity markets by us, our employees and our stockholders, obtain additional capital to support our operations and increase our visibility in the marketplace. We currently intend to use the net proceeds from this offering together with our existing cash and cash equivalents as follows:

- approximately \$ million to fund our planned Phase 2 trials of CT1812 for the treatment of mild-to-moderate AD;
- approximately \$ million to fund our planned Phase 2 proof of concept trials of CT1812 for the dry AMD;
- approximately \$ million to fund our IND-enabling studies of compounds in our library for the treatment of neurodegenerative indications such as PD; and
- the remainder for our other research and development activities, as well as for working capital and other general corporate purposes.

The expected use of the net proceeds from this offering represents our intentions based on our current plans and business conditions, which could change in the future as our plans and business conditions evolve. Further, due to the uncertainties inherent in the small molecule development process, it is difficult to estimate with certainty the exact amounts of the net proceeds from this offering that may be used for the above purposes. We may also use a portion of our net proceeds to acquire or invest in complementary products, technologies, or businesses. However, we currently have no agreements or commitments to do so. As a result, our management will have broad discretion over the use of the net proceeds from this offering, and our investors will be relying on the judgment of our management regarding the application of the net proceeds of this offering. The amounts and timing of our expenditures will depend upon numerous factors including the results of our research and development efforts, the timing, number, scope and success of our nonclinical studies and clinical trials, and the timing and success of any regulatory submissions.

Based on our current business plans, we believe that the net proceeds from this offering, together with our existing cash and cash equivalents and the income from non-dilutive grants, will be sufficient for us to fund our operating expenses and capital expenditures requirements through at least . In particular, we expect that the net proceeds from this offering will fund us through receipt of topline data readouts for our planned Phase 2 trials of CT1812 for the treatment of mild-to-moderate AD, Phase 2 proof of concept trials or CT1812 for dry AMD as well as IND-enabling studies and IND applications for compounds in our library for the treatment of neurodegenerative indications such as PD. The expected net proceeds from this offering will not be sufficient for us to fund any of our product candidates through regulatory approval and commercialization, and we will need to raise substantial additional capital to complete the development and commercialization of our product candidates. We have based these estimates on assumptions that may

prove to be incorrect or require adjustment as a result of business decisions, and we could utilize our available capital resources sooner than we currently expect. For additional information regarding our potential capital requirements, including factors that could cause actual costs to vary from the estimates set forth above, see the section of this prospectus titled “Risk Factors.”

As of the date of this prospectus, we intend to invest the net proceeds in short-term interest-bearing investment-grade securities, certificates of deposit or government securities. The goal with respect to the investment of these net proceeds is capital preservation and liquidity so that such funds are readily available to fund our operations.

DIVIDEND POLICY

We have never declared or paid any cash dividends on our common stock, and we do not currently intend to pay any cash dividends on our common stock in the foreseeable future. We currently intend to retain all available funds and any future earnings to support operations and to finance the growth and development of our business. Any future determination to pay dividends will be made at the discretion of our board of directors subject to applicable laws and will depend upon, among other factors, our results of operations, financial condition, contractual restrictions and capital requirements. Our future ability to pay cash dividends on our common stock may be limited by any future debt instruments or preferred securities.

CAPITALIZATION

The following table sets forth our cash, cash equivalents, short term investments and our capitalization as of March 31, 2021:

- on an actual basis;
- on a pro forma basis to give effect to (i) the filing and effectiveness of our third amended and restated certificate of incorporation immediately prior to the closing of this offering, (ii) the automatic conversion of all outstanding shares of our convertible preferred stock into an aggregate of 51,450,435 shares of our common stock upon the closing of this offering, (iii) the issuance of _____ shares of our common stock upon the assumed net exercise of warrants that otherwise expire upon or prior to the closing of this offering (assuming an initial public offering price of \$ _____ per share, the midpoint of the price range set forth on the cover page of this prospectus), and (iv) the issuance of _____ shares of our common stock issuable upon conversion of the SAFEs upon the closing of this offering in the aggregate amount of \$8.9 million (assuming an initial public offering price of \$ _____ per share, the midpoint of the price range set forth on the cover page of this prospectus); and
- on a pro forma as adjusted basis to give effect to (i) the pro forma adjustments described above and (ii) the issuance and sale of _____ shares of our common stock in this offering at an assumed initial public offering price of \$ _____ per share, the midpoint of the price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The pro forma as adjusted information set forth in the table below is illustrative only and will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing. You should read this table together with the sections of this prospectus captioned “Selected Consolidated Financial Data,” “Use of Proceeds,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” “Description of Capital Stock” and our financial statements and related notes included elsewhere in this prospectus.

	As of March 31, 2021		
	Actual	Pro Forma ⁽¹⁾	Pro Forma as Adjusted ⁽²⁾
	(in thousands except share and per share data)		
Cash and cash equivalents	\$ 13,373	\$	\$
Convertible notes	12,691		
Accrued interest	1,879		
Derivative liability	1,146		
Simple Agreements for Future Equity	8,942		
Series A convertible preferred stock, par value \$0.001 per share, 3,067,519 shares authorized at March 31, 2021, 2,819,027 shares issued and outstanding as of March 31, 2021; liquidation preference of \$4,860 as of March 31, 2021	4,616		
Series A-1 convertible preferred stock, par value \$0.001 per share, 3,970,776 shares authorized at March 31, 2021, 3,730,366 shares issued and outstanding as of March 31, 2021; liquidation preference of \$5,682 as of March 31, 2021	5,398		
Series A-2 convertible preferred stock, par value \$0.001 per share, 3,565,063 shares authorized at March 31, 2021, 3,565,063 shares issued and outstanding as of March 31, 2021; liquidation preference of \$6,115 as of March 31, 2021	5,809		
Series B convertible preferred stock, par value \$0.001 per share, 30,450,000 shares authorized at March 31, 2021, 30,409,890 shares issued and outstanding as of March 31, 2021; liquidation preference of \$41,632 as of March 31, 2021	39,547		
Series B-1 convertible preferred stock, par value \$0.001 per share, 0 shares authorized at March 31, 2021, 0 shares issued and outstanding as of March 31, 2021; liquidation preference of \$0 as of March 31, 2021	—		
Stockholders' equity (deficit):			
Common stock, \$0.001 par value, 58,000,000 shares authorized at March 31, 2021; 1,809,998 shares issued and outstanding at March 31, 2021	2		
Additional paid-in capital	333		
Accumulated deficit	(67,997)		
Accumulated other comprehensive loss	(192)		
Total stockholders' deficit	(67,854)		
Total capitalization	\$ 12,174		

- (1) The pro forma and pro forma as adjusted information set forth above is illustrative only, and our cash and cash equivalents and capitalization following the completion of this offering will depend on the actual initial public offering price and other terms of the offering determined at the pricing of this offering. Each \$1.00 increase (decrease) in the assumed initial public offering price of \$ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash and cash equivalents, additional paid-in capital, total stockholders' equity and total capitalization by \$ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase (decrease) of 1,000,000 shares in the number of shares offered by us would increase (decrease) the pro forma as adjusted amounts of each of cash and cash equivalents,

additional paid-in capital, total stockholders' equity and total capitalization by \$ million, assuming that the assumed initial public offering price remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

- (2) If the underwriters exercise in full their option to purchase additional shares of our common stock, (i) an additional shares of common stock would be issued and we would receive approximately \$ in additional net proceeds, based on the assumed initial offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us; and (ii) cash and cash equivalents, additional paid-in-capital, total stockholders' equity and total capitalization would each increase by \$.

The number of shares of our common stock to be outstanding after this offering reflected in the table above is based on shares of our common stock outstanding as of March 31, 2021, which gives effect to the pro forma transactions described above and excludes:

- 14,414,342 shares of our common stock issuable upon the exercise of stock options as of March 31, 2021, at a weighted-average exercise price of \$0.31 per share;
- 690,678 shares of our common stock reserved for issuance pursuant to future awards as of March 31, 2021 under our 2017 Plan, which will become available under our 2021 Plan, after the closing of this offering;
- shares of our common stock reserved for future issuance under the 2021 Plan which will become effective upon the effectiveness of the Registration Statement of which this prospectus forms a part, as well as any future increases in the number of shares of our common stock reserved for future issuance pursuant to the 2021 Plan; and
- shares of our common stock reserved for future issuance under our ESPP, which will become effective upon the effectiveness of the Registration Statement of which this prospectus forms a part, as well as any future increases in the number of shares of common stock reserved for issuance under the ESPP.

DILUTION

If you invest in our common stock in this offering, your ownership interest will be diluted to the extent of the difference between the initial public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock after this offering.

Our historical net tangible book deficit as of March 31, 2021 was \$(67.9) million, or \$(37.49) per share of our common stock. Our historical net tangible book deficit is the amount of our total tangible assets less our total liabilities and preferred stock, which is not included within stockholders' deficit. Historical net tangible book deficit per share represents historical net tangible book deficit divided by the number of shares of our common stock outstanding as of March 31, 2021.

Our pro forma net tangible book value as of March 31, 2021, before giving effect to this offering, was \$ million, or \$ per share. Pro forma net tangible book value, before the issuance and sale of shares in this offering, gives effect to:

- the automatic conversion of all outstanding shares of convertible preferred stock into an aggregate of 51,450,435 shares of our common stock upon the closing of this offering;
- the issuance of shares of common stock upon the assumed net exercise of warrants that otherwise expire upon or prior to the closing of this offering (assuming an initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus); and
- the issuance of shares of our common stock issuable upon the conversion of the SAFEs upon the closing of this offering in the aggregate amount of \$8.9 million (assuming an initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus).

Pro forma net tangible book value per share represents pro forma net tangible book value divided by the total number of shares outstanding as of March 31, 2021 after giving effect to the pro forma adjustments described above.

Net tangible book value dilution per share to new investors represents the difference between the amount per share paid by purchasers of common stock in this offering and the pro forma as adjusted net tangible book value per share of our common stock immediately following the closing of this offering. After giving effect to the pro forma transactions described above and the sale of shares of common stock in this offering at an assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of March 31, 2021 would have been \$ million, or \$ per share. This represents an immediate increase in pro forma as adjusted net tangible book value of \$ per share to our existing stockholders and an immediate dilution of \$ per share to new investors participating in this offering. The following table illustrates this dilution on a per share basis:

Assumed initial public offering price per share	\$
Historical net tangible book value per share as of March 31, 2021	\$(37.49)
Increase per share attributable to the pro forma adjustments described above	
Pro forma net tangible book value per share as of March 31, 2021	
Increase in pro forma net tangible book value per share attributed to new investors purchasing shares of common stock in this offering	
Pro forma as adjusted net tangible book value per share immediately after this offering	
Dilution per share to new investors purchasing shares of common stock in this offering	\$

Each \$1.00 increase or decrease in the assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease, as applicable, our pro forma as adjusted net tangible book value per share after this offering by \$ per share

and the dilution per share to new investors participating in this offering by \$ _____ per share, assuming that the number of shares of common stock offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, an increase of 1.0 million in the number of shares of common stock offered by us would increase the pro forma as adjusted net tangible book value after this offering by \$ _____ per share and decrease the dilution per share to new investors participating in this offering by \$ _____ per share, and a decrease of 1.0 million shares of common stock offered by us would decrease the pro forma as adjusted net tangible book value by \$ _____ per share, and increase the dilution per share to new investors in this offering by \$ _____ per share, assuming that the assumed initial public offering price of \$ _____ per share, the midpoint of the price range set forth on the cover page of this prospectus, remains the same and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

If the underwriters exercise in full their option to purchase additional shares of common stock from us, the pro forma as adjusted net tangible book value per share after giving effect to this offering at an assumed initial public offering price of \$ _____ per share, the midpoint of the price range set forth on the cover page of this prospectus, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, would be \$ _____ per share, representing an immediate increase to existing stockholders of \$ _____ per share, and dilution to new investors participating in this offering of \$ _____ per share.

The following table summarizes, as of March 31, 2021, on the pro forma as adjusted basis described above, the total number of shares of common stock purchased from us on an as converted to common stock basis, the total consideration paid or to be paid, and the weighted-average price per share paid or to be paid by existing stockholders and by new investors in this offering at an assumed initial public offering price of \$ _____ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, before deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. As the table shows, new investors purchasing common stock in this offering will pay an average price per share substantially higher than our existing stockholders paid.

	Shares purchased	Percentage	Amount	Percentage	Average price per share
Existing stockholders					\$ _____
Public stockholders					\$ _____
Total	_____	100.0%	_____	100.0%	

The table above assumes no exercise of the underwriters' option to purchase _____ additional shares in this offering. If the underwriters' option to purchase additional shares is exercised in full, the number of shares of our common stock held by existing stockholders would be reduced to approximately _____ % of the total number of shares of our common stock outstanding after this offering, and the number of shares of common stock held by new investors purchasing shares of common stock in this offering would be increased to approximately _____ % of the total number of shares of our common stock outstanding after this offering.

A \$1.00 increase or decrease in the assumed initial public offering price of \$ _____ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease the total consideration paid by new investors by \$ _____ million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same. An increase or decrease of 1,000,000 shares in the number of shares offered by us would increase or decrease the total consideration paid by new investors by \$ _____ million, assuming that the assumed initial public offering price remains the same.

The number of shares of our common stock to be outstanding after this offering is based on _____ shares of our common stock outstanding as of March 31, 2021, which gives effect to the pro forma transactions described above and excludes:

- 14,414,342 shares of our common stock issuable upon the exercise of stock options as of March 31, 2021, at a weighted-average exercise price of \$0.31 per share;

- 690,678 shares of our common stock reserved for issuance pursuant to future awards as of March 31, 2021 under our 2017 Plan, which will become available under our 2021 Plan, after the closing of this offering;
- shares of our common stock reserved for future issuance under the 2021 Plan which will become effective upon the effectiveness of the Registration Statement of which this prospectus forms a part, as well any future increases in the number of shares of our common stock reserved for future issuance pursuant to the 2021 Plan; and
- shares of our common stock reserved for future issuance under our ESPP, which will become effective upon the effectiveness of the Registration Statement of which this prospectus forms a part, as well as any future increases in the number of shares of common stock reserved for issuance under the ESPP.

To the extent that any outstanding stock options or warrants are exercised, new stock options are issued, or we issue additional shares of common stock in the future at per share prices below the price per share to the public in this offering, there will be further dilution to new investors. In addition, we may choose to raise additional capital because of market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. If we raise additional capital through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

SELECTED CONSOLIDATED FINANCIAL DATA

The following tables summarize our selected financial data for the periods and as of the dates indicated. We have derived our selected statements of operations data for the years ended December 31, 2019 and 2020 and the selected balance sheet data as of December 31, 2019 and 2020 from our audited financial statements and related notes included elsewhere in this prospectus. For interim periods, we have derived our selected statements of operations data for the three months ended March 31, 2020 and 2021 and the selected balance sheet data as of March 31, 2021 from our unaudited financial statements and related notes included elsewhere in this prospectus. The unaudited financial statements were prepared on a basis consistent with our audited financial statements and include, in management's opinion, all adjustments, consisting only of normal recurring adjustments that we consider necessary for a fair presentation of the financial information set forth in those statements. Our historical results are not necessarily indicative of the results that may be expected in the future and our interim results are not necessarily indicative of our expected results for the year ending December 31, 2021. You should read the selected financial data below in conjunction with the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes included elsewhere in this prospectus. The selected financial data in this section are not intended to replace the financial statements and are qualified in their entirety by the financial statements and related notes included elsewhere in this prospectus.

(in thousands, except share and per share data)	Year Ended December 31,		Three Months Ended March 31,	
	2019	2020	2020	2021
Consolidated Statements of Operations Data:				
Operating Expenses:				
Research and development	\$ 14,379	\$ 12,887	\$ 3,446	\$ 4,430
General and administrative	3,452	4,520	1,445	1,153
Total operating expenses	17,831	17,407	4,891	5,583
Loss from operations	(17,831)	(17,407)	(4,891)	(5,583)
Other income (expense):				
Grant income	13,164	10,855	2,273	4,692
Change in the fair value of the derivative liability	(231)	18	345	1,063
Change in the fair value of the warrant liability	(7)	181	30	—
Other income, net	1,087	394	142	145
(Loss) gain on debt extinguishment	—	(129)	(129)	443
Interest expense, net	(1,024)	(1,751)	(276)	(537)
Total other income (expense), net	12,989	9,568	2,385	5,806
Net (loss) income	(4,842)	(7,839)	(2,506)	223
Cumulative preferred stock dividends	(3,920)	(4,234)	(1,053)	(1,128)
Net loss attributable to common stockholders	\$ (8,762)	\$ (12,073)	\$ (3,559)	\$ (905)
Net loss per share attributable to common stockholders, basic and diluted	\$ (5.77)	\$ (7.35)	\$ (2.34)	\$ (0.51)
Weighted-average common shares outstanding, basic and diluted ⁽¹⁾	1,519,285	1,643,514	1,519,431	1,779,573
Pro forma loss per share, basic and diluted ⁽²⁾		\$		\$
Pro forma weighted-average common shares outstanding, basic and diluted ⁽²⁾				

- (1) See Note 2 to our consolidated financial statements included elsewhere in this prospectus for an explanation of the method used to calculate the basic and diluted net loss per share and the number of shares used in the computation of the per share amounts.

- (2) The calculations for the pro forma net loss per share attributable to common stockholders, basic and diluted, and the pro forma weighted-average shares of common stock outstanding, basic and diluted, assume the conversion of all our outstanding shares of preferred stock into common stock, the assumed net exercise of warrants to purchase common stock that otherwise expire upon or prior to the closing of this offering and the conversion of the SAFEs into shares of our common stock, as if the conversion or exercise had occurred at the beginning of the period presented, or the issuance date, if later.

(in thousands)	As of December 31,		As of March 31,
	2019	2020	2021
Consolidated Balance Sheet Data:			
Cash and cash equivalents	\$ 2,890	\$ 5,189	\$ 13,373
Working capital	3,477	3,658	11,614
Total assets	7,459	7,119	16,512
Simple Agreements for Future Equity	—	—	8,942
Derivative liability	1,493	2,209	1,146
Warrant liability	181	—	—
Convertible notes, net	6,897	12,409	12,691
Total liabilities	12,954	19,933	28,996
Convertible preferred stock	52,927	55,370	55,370
Accumulated deficit	(58,239)	(68,220)	(67,997)
Total stockholders' deficit	(58,422)	(68,184)	(67,854)

- (1) We define working capital as total current assets less total current liabilities. See our audited and unaudited consolidated financial statements included elsewhere in this prospectus and related notes for further details regarding our total current assets and total current liabilities.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with the section entitled "Summary Financial Data" and our financial statements and related notes appearing elsewhere in this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the section entitled "Risk Factors," our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. You should carefully read the sections entitled "Risk Factors" and "Special Note Regarding Forward-Looking Statements" to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements.

Overview

We are a clinical-stage biopharmaceutical company engaged in the discovery and development of innovative, small molecule therapeutics targeting age-related degenerative diseases and disorders of the central nervous system, or CNS, and retina. Currently available therapies for these diseases are limited, with many diseases having no approved therapies or treatments. Our goal is to develop disease modifying treatments for patients with these degenerative disorders by initially leveraging our expertise in the σ -2 (sigma-2) receptor, or S2R, which is expressed by multiple cell types, including neuronal synapses, and acts as a key regulator of cellular damage commonly associated with certain age-related degenerative diseases of the CNS and retina. We believe that targeting the S2R complex represents a mechanism that is functionally distinct from other current approaches in clinical development for the treatment of degenerative diseases.

Since our inception in 2007, we have incurred significant operating losses and devoted substantially all of our time and resources to developing our lead product candidate, CT1812, building our intellectual property portfolio, raising capital and recruiting management and technical staff to support these operations. As of March 31, 2021, we had an accumulated deficit of \$68.0 million and we incurred a net loss of \$2.5 million for the three months ended March 31, 2020 and we had net income of \$0.2 million for the three months ended March 31, 2021. We incurred net losses of \$4.8 million and \$7.8 million for the years ended December 31, 2019 and 2020, respectively.

To date, we have funded our operations primarily with proceeds from grants awarded by the National Institute of Aging, or NIA, a division of the National Institutes of Health and proceeds from the sales of our convertible promissory notes, convertible preferred stock, Simple Agreements for Future Equity, or SAFEs, and stock option exercises. Since our inception, we have received approximately \$168.4 million in cumulative grant awards to fund our clinical trials, primarily from the NIA, and we have raised approximately \$57.5 million in net proceeds from sales of our equity securities, convertible notes, SAFEs and stock option exercises. On March 25, 2021, we entered into SAFEs, with various investors, pursuant to which we received gross proceeds in an aggregate amount equal to \$8.9 million. As of March 31, 2021, we had cash and cash equivalents of \$13.4 million. We expect to continue to incur significant and increasing expenses and net losses for the foreseeable future, as we advance our current and future product candidates through preclinical and clinical development, manufacture drug product and drug supply, seek regulatory approval for our current and future product candidates, maintain and expand our intellectual property portfolio, hire additional research and development and business personnel and operate as a public company. We will not generate revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for our product candidates. In addition, if we obtain regulatory approval for our product candidates and do not enter into a third-party commercialization partnership, we expect to incur significant expenses related to developing our commercialization capability to support product sales, marketing, manufacturing and distribution activities.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of public or private equity offerings, debt financings or other sources, such as potential collaboration agreements and strategic alliances, licensing or similar arrangements with third parties. To the extent available, we expect to continue our pursuit of non-dilutive

research contributions, or grants, including additional NIA grant funding. However, we may fail to receive additional NIA grants, or we may be unable to raise additional funds or enter into such other agreements or arrangements when needed on acceptable terms, or at all. Our failure to obtain additional NIA grants or raise capital or enter into such agreements as and when needed could have a material adverse effect on our business, results of operations and financial condition.

Because of the numerous risks and uncertainties associated with product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to raise capital, maintain our research and development efforts, expand our business or continue our operations at planned levels, and as a result we may be forced to substantially reduce or terminate our operations.

We do not own or operate manufacturing facilities. We rely, and expect to continue to rely, on third parties for the manufacture of CT1812 for preclinical studies and clinical trials, as well as for commercial manufacture if CT1812 obtains marketing approval. We also rely, and expect to continue to rely, on third parties to manufacture, package, label, store, and distribute CT1812, if marketing approval is obtained. We believe that this strategy allows us to maintain a more efficient infrastructure by eliminating the need for us to invest in our own manufacturing facilities, equipment, and personnel while also enabling us to focus our expertise and resources on the development of CT1812.

Impact of COVID-19 on Our Business

Our business has been and could continue to be adversely affected by the effects of the recent and evolving COVID-19 pandemic, which was declared by the World Health Organization as a global pandemic. Our clinical trials have been, and may in the future be, affected by the COVID-19 pandemic. For example, the COVID-19 pandemic may impact patient enrollment in our ongoing and future clinical trials of CT1812. In particular, some sites have in the past or may in the future pause enrollment to focus on, and direct resources to, COVID-19, while at other sites, patients may choose not to enroll or continue participating in the clinical trial as a result of the pandemic. In addition, patient visits to medical providers in the United States have slowed as a result of the COVID-19 pandemic. Further, according to the Centers for Disease Control and Prevention, people who have serious chronic medical conditions are at higher risk of getting very sick from COVID-19. As a result, potential patients in our ongoing and future clinical trials of CT1812 may choose to not enroll, not participate in follow-up clinical visits or drop out of the trial as a precaution against contracting COVID-19. Further, some patients may not be able or willing to comply with clinical trial protocols if quarantines impede patient movement or interrupts healthcare services.

Our ongoing or planned clinical trials may also be impacted by interruptions or delays in the operations of the FDA and comparable foreign regulatory authorities. For example, we have made certain adjustments to the operation of our trials in an effort to ensure the monitoring and safety of patients and minimize risks to trial integrity during the pandemic in accordance with the guidance issued by the FDA and may need to make further adjustments in the future. We have also initiated our clinical trial protocols to enable remote visits to mitigate any potential impacts as a result of the COVID-19 pandemic. Many of these adjustments are new and untested, may not be effective, may affect the integrity of data collected, and may have unforeseen effects on the progress and completion of our clinical trials and the findings from such clinical trials.

The spread of COVID-19 and actions taken to reduce its spread may also materially affect us economically. While the potential economic impact brought by, and the duration of, the COVID-19 pandemic may be difficult to assess or predict, there could be a significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity and financial position. In addition, the trading prices for other pharmaceutical companies have been highly volatile as a result of the COVID-19 pandemic. As a result, we may face difficulties raising capital through sales of our common stock or such sales may be on unfavorable terms.

SAFE Offering

In March 2021, we entered SAFEs with various investors, pursuant to which we received gross proceeds in an aggregate amount equal to \$8.9 million. The amount invested by the investors in the SAFEs is automatically convertible into shares of our common stock upon the closing of this offering at a conversion price equal to 80.0% of the initial public offering price of our common stock in this offering.

Recent Developments***Notes Conversion***

From March 2018 to July 2020, we issued convertible promissory notes in the aggregate principal amount of \$13.0 million with an interest rate of 8.0% per annum, pursuant to note purchase agreements entered into with certain holders of our capital stock. On May 1, 2021, the holders of all of our outstanding convertible promissory notes agreed to an acceleration of the date of the automatic conversion from June 30, 2021 to May 1, 2021 for all convertible promissory notes. Accordingly, on May 1, 2021, all of our outstanding convertible promissory notes were converted into 10,926,089 shares of our Series B-1 convertible preferred stock, at a conversion price equal to \$1.385 per share. As of the date of this prospectus, no notes are outstanding. Pursuant to the terms of our Series B-1 convertible preferred stock, all shares will automatically convert into shares of our common stock upon the closing of this offering on a one-for-one basis.

Components of Our Results of Operations***Operating Expenses******Research and Development Expenses***

Research and development expenses consist primarily of direct and indirect costs incurred for our research activities, including development of our drug discovery efforts and the development of our product candidates. Direct costs include laboratory materials and supplies, contracted research and manufacturing, clinical trial costs, consulting fees, and other expenses incurred to sustain our research and development program. Indirect costs include personnel-related expenses, consisting of employee salaries, related benefits, and stock-based compensation expense for employees engaged in research and development activities, facilities, and other expenses consisting of direct and allocated expenses for rent and depreciation, and lab consumables.

We expense research and development costs as incurred. Non-refundable advance payments for goods and services that will be used over time for research and development are capitalized and recognized as goods are delivered or as the related services are performed. In-licensing fees and other costs to acquire technologies used in research and development that have not yet received regulatory approval and that are not expected to have an alternative future use are expensed when incurred. We track direct costs by stage of program, clinical or preclinical. However, we do not track indirect costs on a program specific basis because these costs are deployed across multiple programs and, as such, are not separately classified.

We cannot reasonably determine the nature, timing, and estimated costs of the efforts that will be necessary to complete the development of, and obtain regulatory approval for, any of our product candidates. Product candidates in later stages of development generally have higher development costs than those in earlier stages. We expect that our research and development expenses will increase substantially for the foreseeable future as we continue to invest in research and development activities related to developing our product candidates, as our product candidates advance into later stages of development, as we begin to conduct larger clinical trials, as we seek regulatory approvals for any product candidates that successfully complete clinical trials, as we expand our product pipeline, as we maintain, expand, protect and enforce our intellectual property portfolio, and as we incur expenses associated with hiring additional personnel to support our research and development efforts.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel-related costs, including employee salaries, related benefits, and stock-based compensation expense for our employees in the executive, finance and accounting, and other administrative functions. General and administrative expenses also include third-party costs such as legal costs, insurance costs, accounting, auditing and tax related fees, consulting fees and facilities and other expenses not otherwise included as research and development expenses. We expense general and administrative costs as incurred.

We expect that our general and administrative expenses will increase substantially for the foreseeable future as we increase our headcount to support our continued research activities and development of our programs. Following the completion of this offering, we also anticipate that we will incur substantially increased expenses as a result of operating as a public company, including expenses related to compliance with the rules and regulations of the Securities and Exchange Commission, and those of any national securities exchange on which our securities are traded, legal, auditing, additional insurance expenses, investor relations activities, and other administrative and professional services.

*Other Income (Expense)**Grant Income*

Grant income relates to the grants awarded from governmental bodies that are conditional cost reimbursement grants and are recognized as grant income as allowable costs are incurred and the right to payment is realized. The grants awarded relate to agreed upon direct and indirect costs for specific studies or clinical trials, which may include personnel and consulting costs, costs paid to contract research organizations, or CROs, research institutions and /or consortiums involved in the grant , as well as facilities and administrative costs. These grants are cost plus fixed fee arrangements in which we are reimbursed for eligible direct and indirect costs over time, up to the maximum amount of each specific grant award. Only costs that are allowable under the grant award, certain government regulations and the NIH's supplemental policy and procedure manual may be claimed for reimbursement, and the reimbursements are subject to routine audits from governmental agencies from time to time. Our clinical trials have been funded by approximately \$168.4 million in cumulative grants awarded primarily by the NIA, which includes an approximately \$81.0 million grant from the NIA to fund our upcoming Phase 2 (COG0203) study of CT1812 in patients with early-stage AD.

Change in fair value of derivative liability

Change in fair value of our derivative liability consists of changes in the fair value of certain conversion and redemption features associated with our convertible notes that are required to be bifurcated and accounted for as free-standing derivative financial instruments.

Change in fair value of warrant liability

Change in fair value of our warrant liability consists primarily of the change in fair value of our unexercised Series A-1 preferred stock warrants during the applicable periods. These warrants expired unexercised in October 2020 and were derecognized at that time.

Interest expense, net

Interest expense, net primarily consists of interest expense from our convertible notes, partially offset by interest income from interest-bearing cash equivalents.

Other income, net

Other income, net consists primarily of research and development tax credits earned in the applicable period, as well as foreign currency transaction gains or losses.

Results of Operations*Comparison of the Years Ended December 31, 2019 and 2020*

The following table summarizes our results of operations (in thousands):

	Year Ended December 31,		Change
	2019	2020	
Operating Expenses:			
Research and development	\$ 14,379	\$ 12,887	\$(1,492)
General and administrative	3,452	4,520	1,068
Total operating expenses	17,831	17,407	(424)
Loss from operations	(17,831)	(17,407)	(424)
Other income (expense):			
Grant income	13,164	10,855	(2,309)
Change in the fair value of the derivative liability	(231)	18	249
Change in the fair value of the warrant liability	(7)	181	188
Other income, net	1,087	394	(693)
Loss on debt extinguishment	—	(129)	(129)
Interest expense, net	(1,024)	(1,751)	(727)
Total other income (expense), net	12,989	9,568	(3,421)
Net loss	\$ (4,842)	\$ (7,839)	\$(2,997)

Research and Development Expenses

The following table summarizes our research and development expenses (in thousands):

	Year Ended December 31,		Change
	2019	2020	
Clinical programs	\$ 8,398	\$ 5,263	\$(3,135)
Personnel	3,039	4,026	987
Manufacturing	1,426	1,798	372
Preclinical programs	1,400	1,693	293
Facilities and other costs	116	107	(9)
	\$14,379	\$12,887	\$(1,492)

Research and development expenses were \$14.4 million for the year ended December 31, 2019, compared to \$12.9 million for the year ended December 31, 2020. The decrease of \$1.5 million was primarily due to the following:

- a decrease of \$3.1 million in clinical programs related to delays due to COVID 19, resulting in timing and scope changes to clinical studies;
- an increase of \$1.0 million in personnel costs due to increased salaries and bonus expense and increased headcount associated with expanded research and development activities; and
- an increase of \$0.4 million in manufacturing expense related to costs incurred with contract manufacturing organizations for production of pre-clinical and future clinical trial materials associated with our most advanced product candidates; and
- an increase of \$0.3 million in preclinical programs due to increased sponsored research spend under grants.

General and Administrative Expenses

General and administrative expenses were \$3.5 million for the year ended December 31, 2019, compared to \$4.5 million for the year ended December 31, 2020. The increase of \$1.0 million was primarily due to the following:

- an increase of \$0.6 million in salaries and bonus expense associated with increased headcount to develop our financial and administrative staff;
- an increase of \$0.2 million in professional fees driven by increased audit, tax, valuation and legal services; and
- an increase of \$0.2 million associated equity-based compensation.

*Other Income (Expense)**Grant Income*

Grant income was \$13.2 million for the year ended December 31, 2019, compared to \$10.9 million for the year ended December 31, 2020. The change in grant income is correlated with the decrease in eligible reimbursable costs incurred during 2020 as compared to 2019.

Change in Fair Value of the Derivative Liability

Changes in the fair value derivative liability resulted in a loss of \$0.2 million for the year ended December 31, 2019, compared to \$.02 million gain for the year ended December 31, 2020. Overall, the change in fair value of these derivative liabilities was not significant in either period.

Change in Fair Value of the Warrant Liability

Changes in the fair value of warrant liabilities resulted in an expense of \$0.01 million for the year ended December 31, 2019, compared to a gain of \$0.2 million for the year ended December 31, 2020. The increase of \$0.2 million was due primarily to the expiration of warrants to purchase Series A-1 preferred stock in October 2020.

Other Income, Net

Other income, net was \$1.1 million for the year ended December 31, 2019, compared to \$0.4 million for the year ended December 31, 2020. The decrease was primarily the result of a decrease in research and development incentive income of \$0.5 million.

Loss on Debt Extinguishment

Loss on debt extinguishment was \$0.1 million for the year ended December 31, 2020. The loss was the result of the execution of the second amendment to the convertible notes on February 27, 2020, which resulted in an extinguishment of the existing notes for accounting purposes. There was no such amendment in the prior year.

Interest Expense, Net

Interest expense, net was \$1.0 million for the year ended December 31, 2019 compared to interest expense, net of \$1.8 million for the year ended December 31, 2020. The change of \$0.8 million in interest expense, net was the result of a higher overall convertible note balance during 2020.

Comparison of the Three Months Ended March 31, 2020 and 2021

The following table summarizes our results of operations (in thousands):

	Three Months Ended March 31,		Change
	2020	2021	
Operating Expenses:			
Research and development	\$ 3,446	\$ 4,430	\$ 984
General and administrative	1,445	1,153	(292)
Total operating expenses	4,891	5,583	692
Loss from operations	(4,891)	(5,583)	(692)
Other income (expense):			
Grant income	2,273	4,692	2,419
Change in the fair value of the derivative liability	345	1,063	718
Change in the fair value of the warrant liability	30	—	(30)
Other income, net	142	145	3
(Loss) gain on debt extinguishment	(129)	443	572
Interest expense, net	(276)	(537)	(261)
Total other income (expense), net	2,385	5,806	3,421
Net (loss) income	<u><u>\$(2,506)</u></u>	<u><u>\$ 223</u></u>	<u><u>\$2,729</u></u>

Research and Development Expenses

The following table summarizes our research and development expenses (in thousands):

	Three Months Ended March 31,		Change
	2020	2021	
Clinical programs	\$1,989	\$ 926	\$(1,063)
Personnel	974	840	(134)
Manufacturing	131	2,308	2,177
Preclinical programs	325	327	2
Facilities and other costs	27	29	2
	<u><u>\$3,446</u></u>	<u><u>\$4,430</u></u>	<u><u>\$ 984</u></u>

Research and development expenses were \$3.4 million for the three months ended March 31, 2020, compared to \$4.4 million for the three months ended March 31, 2021. The increase of \$1.0 million was primarily due to the following:

- an increase of \$2.1 million in manufacturing expense related to costs incurred with contract manufacturing organizations for production of pre-clinical and future clinical trial materials associated with our most advanced product candidates; and
- a decrease of \$1.1 million in spending on clinical programs related to delays due to COVID 19, resulting in timing and scope changes to clinical studies.

General and Administrative Expenses

General and administrative expenses were \$1.4 million for the three months ended March 31, 2020, compared to \$1.2 million for the three months ended March 31, 2021. The decrease of \$0.2 million was primarily due to the following:

- a decrease of \$0.4 million in personnel-related costs as a result of severance liabilities incurred in 2020; partially offset by

- an increase of \$0.2 million in professional fees and consulting services.

Other Income (Expense)

Grant Income

Grant income was \$2.3 million for the three months ended March 31, 2020, compared to \$4.7 million for the three months ended March 31, 2021. The change in grant income is correlated with the increase in eligible reimbursable costs incurred during the three months ended March 31, 2021 as compared to the three months ended March 31, 2020.

Change in Fair Value of the Derivative Liability

Changes in the fair value derivative liability resulted in a gain of \$0.3 million for the three months ended March 31, 2020, compared to a gain of \$1.1 million for the three months ended March 31, 2021. The change was primarily driven by the change in the probability of occurrence of future event inputs in the derivative valuation models during these periods.

Change in Fair Value of the Warrant Liability

Changes in the fair value of warrant liabilities resulted in a gain of \$.03 million for the three months ended March 31, 2020. There was no gain or loss for the three months ended March 31, 2021 as the warrants to purchase Series A-1 preferred stock expired in October 2020.

Other Income, Net

Other income, net was less than \$0.2 million for the three months ended March 31, 2020 and 2021. Overall, the change in income was not significant in either period.

(Loss) gain on Debt Extinguishment

Loss on debt extinguishment was \$0.1 million for the three months ended March 31, 2020. Gain on debt extinguishment was \$0.4 million for the three months ended March 31, 2021. The loss was the result of the execution of the second amendment to the convertible notes on February 27, 2020, which resulted in an extinguishment of the existing notes for accounting purposes. The gain was the result of the forgiveness of the Paycheck Protection Program loan on January 21, 2021.

Interest Expense, Net

Interest expense, net was \$0.3 million for the three months ended March 31, 2020 compared to interest expense, net of \$0.5 million for the three months ended March 31, 2021. The change of \$0.2 million in interest expense, net was the result of a higher overall convertible note balance during the three months ended March 31, 2021.

Liquidity and Capital Resources

Sources of Liquidity

To date, we have funded our operations primarily with proceeds from grants awarded by the NIA, and proceeds from the sales of our convertible promissory notes, convertible preferred stock, and SAFEs, and stock option exercises. Since our inception, we have received grant awards primarily from the NIA in the aggregate amount of approximately \$168.4 million and have raised approximately \$57.5 million in net proceeds from sales of our equity securities, convertible notes and SAFEs, and stock option exercises. On March 25, 2021, we completed a SAFE offering with various investors, pursuant to which we received gross proceeds in an aggregate amount equal to \$8.9 million. As of March 31, 2021, we had \$13.4 million in cash and cash equivalents and have not generated positive cash flows from operations. Based on our current business plans, we believe that the net proceeds from this offering, together with our existing cash and cash equivalents and income from non-dilutive grants, will be sufficient for us to fund our operating expenses and capital

expenditures requirements through at least . We have based these estimates on assumptions that may prove to be incorrect or require adjustment as a result of business decisions, and we could utilize our available capital resources sooner than we currently expect.

Future Funding Requirements

We expect to continue to incur significant and increasing expenses and net losses for the foreseeable future, as we advance our current and future product candidates through preclinical and clinical development, manufacture drug product and drug supply, seek regulatory approval for our current and future product candidates, maintain and expand our intellectual property portfolio, hire additional research and development and business personnel and operate as a public company. We anticipate that we will need to raise additional funding in the future to fund our operations, including the commercialization of any approved product candidates. We are subject to the risks typically related to the development of new products, and we may encounter unforeseen expenses, difficulties, complications, delays, and other unknown factors that may adversely affect our business. Even after this offering, we will need to raise substantial additional capital to fund the development of our product candidates.

Our future funding requirements will depend on many factors, including, but not limited to:

- the scope, progress, costs and results of our ongoing and planned clinical trials of CT1812, as well as the associated costs, including any unforeseen costs we may incur as a result of preclinical study or clinical trial delays due to the COVID-19 pandemic or other delays;
- the scope, progress, costs and results of preclinical development, laboratory testing and clinical trials for any future product candidates we may decide to pursue;
- the extent to which we develop, in-license or acquire other product candidates and technologies;
- the costs and timing of process development and manufacturing scale-up activities associated with our product candidates and other programs as we advance them through preclinical and clinical development;
- the availability, timing, and receipt of any future NIA grants;
- the number and development requirements of other product candidates that we may pursue;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- our ability to establish collaborations to commercialize CT1812 or any of our other product candidates outside the United States;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims; and
- the additional costs we may incur as a result of operating as a public company, including our efforts to enhance operational systems and hire additional personnel, including enhanced internal controls over financial reporting.

Until such time as we can generate significant revenue from product sales, we expect to finance our operations through a combination of public or private equity offerings, debt financings or other sources, such as potential collaboration agreements and strategic alliances, licensing or similar arrangements with third parties. To the extent available, we expect to continue our pursuit of non-dilutive research contributions, or grants, including additional NIA grant funding. However, we may fail to receive additional NIA grants, or we may be unable to raise additional funds or enter into such other agreements or arrangements when needed on acceptable terms, or at all. Our failure to obtain additional NIA grants or raise capital or enter

into such agreements as and when needed could have a material adverse effect on our business, results of operations and financial condition.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through collaborations, licenses and other similar arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us and/or may reduce the value of our common stock. Adequate funding may not be available when needed or on terms acceptable to us, or at all. Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic and otherwise. If we fail to obtain necessary capital when needed on acceptable terms, or at all, it could force us to delay, limit, reduce or terminate our product development programs, commercialization efforts or other operations. Insufficient liquidity may also require us to relinquish rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose. We cannot assure you that we will ever be profitable or generate positive cash flows from operating activities.

Going Concern Assessment

Our consolidated financial statements included elsewhere in this prospectus have been prepared on a basis which assumes we are a going concern. As discussed in Note 1 to those financial statements, we have suffered recurring losses from operations, do not expect to generate revenues or operating cash flows for the foreseeable future, and have stated that substantial doubt exists about our ability to continue as a going concern. Our ability to continue as a going concern may be viewed unfavorably by current and prospective investors, as well as by analysts and creditors. This may in turn make it more difficult for us to raise the additional financing necessary to continue to operate our business and we may be forced to significantly alter our business strategy, substantially curtail our current operations, or cease operations altogether. Based on our current business plans, we believe that the net proceeds from this offering, together with our existing cash and cash equivalents and the income from non-dilutive grants, will be sufficient for us to fund our operating expenses and capital expenditures requirements through at least . This estimate is based on certain significant assumptions, which are uncertain and may turn out to be incorrect.

Cash Flows

The following table summarizes our cash flows for the periods indicated (in thousands):

	Year Ended December 31,		Three Months Ended March 31,	
	2019	2020	2020 (unaudited)	2021 (unaudited)
Cash flows (used in) provided by operating activities	\$(3,098)	\$(3,433)	\$ 530	\$ (772)
Cash flows used in investing activities	(144)	(10)	(10)	—
Cash flows provided by financing activities	2,794	5,765	3,782	8,956
Effect of exchange rate changes on cash and cash equivalents	(60)	(23)	(34)	—
Net increase (decrease) in cash and cash equivalents	<u>\$ (508)</u>	<u>\$ 2,299</u>	<u>\$4,268</u>	<u>\$8,184</u>

Operating Activities

Net cash used in operating activities for the year ended December 31, 2019 was \$3.1 million, which consisted primarily of our net loss of \$4.8 million partially offset by net non-cash charges of \$1.1 million and a net change of \$0.6 million in our operating assets and liabilities. The non-cash charges primarily

consisted of depreciation and amortization of \$0.1 million, amortization of debt discounts of \$0.5 million, change in derivative liabilities of \$0.2 million, and equity-based compensation of \$0.4 million. The net change in our operating assets and liabilities was primarily due to a net increase in other receivables of \$1.1 million, an increase in accounts payable of \$0.9 million, an increase in accrued expenses of \$0.9 million, and a decrease in other current liabilities of \$0.1 million.

Net cash used in operating activities for the year ended December 31, 2020 was \$3.4 million, which consisted primarily of our net loss of \$7.8 million partially offset by net non-cash charges of \$1.3 million and a net decrease of \$3.1 million in our operating assets. The non-cash charges primarily consisted of depreciation and amortization of \$0.1 million, amortization of debt issuances costs of \$0.1 million, amortization of debt discounts of \$0.8 million, change in warrant liabilities of \$0.2 million, loss on debt extinguishment of \$0.1 million, and equity-based compensation of \$0.5 million. The net decrease in our net operating assets was primarily due to a net decrease in other receivables of \$0.9 million, a decrease in accounts payable of \$0.4 million, an increase in accrued expenses of \$0.6 million, a decrease in grant receivables of \$2.1 million, and an increase in other current liabilities of \$0.3 million.

Net cash provided by operating activities for the three months ended March 31, 2020 was \$0.5 million, which consisted primarily of our net loss of \$2.5 million, offset by the net change of \$3.0 million in our operating assets and liabilities. The net change in our operating assets and liabilities was primarily due to a decrease in grant receivables of \$2.0 million, net decrease in other receivables of \$0.2 million, an increase in accounts payable of \$0.3 million, and an increase in accrued expenses of \$0.5 million.

Net cash used in operating activities for the three months ended March 31, 2021 was \$0.8 million, which consisted primarily of our net income of \$0.2 million partially offset by the net non-cash gains of \$1.1 million and a net change of \$0.1 million in our operating assets and liabilities. The non-cash gains primarily consisted of the change in derivative liabilities of \$1.1 million and a gain on debt extinguishment of \$0.4 million. The net change in our operating assets and liabilities was primarily due to an increase in grant receivables of \$1.1 million, a decrease in prepaid expenses and other current assets of \$0.3 million, a net increase in other receivables of \$0.1 million, an increase in accounts payable of \$1.0 million, an increase in accrued expenses of \$0.3 million, and a decrease in other current liabilities of \$0.3 million.

Investing Activities

During the years ended December 31, 2019 and 2020, we used \$0.1 million and \$0.01 million of cash, respectively, for investing activities related to purchases of property and equipment.

During the three months ended March 31, 2020 we used \$0.01 million of cash for investing activities related to purchases of property and equipment. We did not use any cash for investing activities for the three months ended March 31, 2021.

Financing Activities

Net cash provided by financing activities was \$2.8 million and \$5.8 million for the years ended December 31, 2019 and 2020, respectively. The increase in cash provided by financing activities in 2020 relates primarily to a higher level of convertible notes issued during 2020 as compared to 2019 and the paycheck protection program loan. During the first quarter of 2021, we received forgiveness of the paycheck protection program loan in full.

Net cash provided by financing activities was \$3.8 million and \$9.0 million for the three months ended March 31, 2020 and 2021, respectively. The increase in cash provided by financing activities in 2021 relates primarily to the \$8.9 million of SAFEs issued during the three months ended March 31, 2021, as compared to \$3.8 million of convertible notes issued in the three months ended March 31, 2020.

Off-Balance Sheet Arrangements

We have not entered into any off-balance sheet arrangements.

Contractual Obligations

The following table summarizes our contractual obligations as of March 31, 2021 (in thousands):

	Less than 1 Year	1 to 3 Years	3 to 5 Years	More than 5 Years	Total
Operating lease obligations	\$89	\$177	\$—	\$—	\$266
Total	\$89	\$177	\$—	\$—	\$266

We have entered into an operating lease for office and laboratory facilities under agreements that run through June 30, 2023. The amounts reflected in the table above consist of the future minimum lease payments under the non-cancelable lease arrangement.

We enter into contracts in the normal course of business with contract research organizations and other vendors to assist in the performance of our research and development and other services and products for operating purposes. These contracts typically do not contain minimum purchase commitments and generally provide for termination on notice, and therefore are cancelable contracts and not included in the table of contractual obligations.

Critical Accounting Policies and Use of Estimates

We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

Research and Development Costs, Accrued Research and Development Costs and Related Prepaid Expenses

Research and development costs are expensed as incurred. Research and development expenses consist principally of personnel costs, including salaries, stock-based compensation, and benefits for employees, third-party license fees and other operational costs related to our research and development activities, including allocated facility-related expenses and external costs of outside vendors, and other direct and indirect costs. Non-refundable advance payments for research and development costs are deferred and expensed as the related goods are delivered or services are performed. Costs for external development activities are recognized based on an evaluation of the progress to completion of specific tasks. Costs for certain research and development activities are recognized based on the pattern of performance of the individual arrangements, which may differ from the pattern of billings incurred, and are reflected in the consolidated financial statements as prepaid expenses or as accrued research and development expenses.

Equity-Based Compensation

We maintain an equity-based compensation plan as a long-term incentive for employees, non-employee directors and consultants. The plan allows for the issuance of incentive stock options, non-qualified stock options, restricted stock units, and other forms of equity awards.

We recognize equity-based compensation expense for stock options subject to time-based vesting on a straight-line basis over the requisite service period and account for forfeitures as they occur. To the extent any stock option grants are made subject to the achievement of a performance condition, management evaluates when the achievement of any such performance-based milestone is probable based on the relative satisfaction of the performance conditions as of the reporting date. Our stock-based compensation costs are based upon the grant date fair value of options estimated using the Black-Scholes option pricing model.

The Black-Scholes option pricing model utilizes inputs which are highly subjective assumptions and generally require significant judgment. These assumptions include:

- *Expected Term.* The expected term represents the period that the stock-based awards are expected to be outstanding. As we do not have sufficient historical experience for determining the expected term of the stock option awards granted, expected term has been calculated using the simplified method.

- *Risk-Free Interest Rate.* The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the date of grant for zero-coupon U.S. Treasury constant maturity notes with terms approximately equal to the stock-based awards' expected term.
- *Expected Volatility.* Because we have been privately held and do not have a trading history of common stock, the expected volatility was derived from the average historical stock volatilities of the common stock of several public companies within the industry that we consider to be comparable to our business over a period equivalent to the expected term of the stock-based awards.
- *Expected Dividend Yield.* The expected dividend yield is zero as we have not paid and do not anticipate paying any dividends in the foreseeable future.
- *Fair Value of Common Stock.* — The fair value of the shares of common stock underlying the stock-based awards has historically been determined by the Board of Directors with input from management. Because there has been no public market for the common stock, the Board of Directors has determined the fair value of the common stock at the time of grant of the stock-based award by considering a number of objective and subjective factors, including having contemporaneous valuations of the common stock performed by a third-party valuation specialist.

See Note 13 to our audited financial statements for more information concerning certain of the specific assumptions we used in applying the Black-Scholes option pricing model to determine the estimated fair value of our stock options. Certain of such assumptions involve inherent uncertainties and the application of significant judgment.

As of March 31, 2021, the total unrecognized compensation expense related to unvested time-based vesting awards was \$1.1 million, which is expected to be recognized over weighted-average remaining vesting period of approximately 3.1 years. As of March 31, 2021, total unrecognized compensation expense related to un-vested performance-based awards was \$0.3 million, which would be recognized commencing with the period in which the performance condition is deemed probable of achievement.

Based upon the assumed initial public offering price of \$ _____ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, the aggregate intrinsic value of options outstanding as of March 31, 2021 was \$ _____ million, of which \$ _____ million related to vested options and \$ _____ million related to unvested options.

Common Stock Valuations

Historically, for all periods prior to this offering, since there has been no public market of our common stock to date, the fair value of the shares of common stock underlying our share-based awards was estimated on each grant date by our board of directors. To determine the fair value of our common stock underlying option grants, our board of directors considered, among other things, input from management, valuations of our common stock prepared by unrelated third-party valuation firms in accordance with the guidance provided by the American Institute of Certified Public Accountants 2013 Practice Aid, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*, and our board of directors' assessment of additional objective and subjective factors that it believed were relevant, and factors that may have changed from the date of the most recent valuation through the date of the grant. These factors include, but are not limited to:

- our results of operations and financial position, including our levels of available capital resources;
- our stage of development and material risks related to our business;
- progress of our research and development activities;
- our business conditions and projections;
- the valuation of publicly traded companies in the life sciences and biotechnology sectors, as well as recently completed mergers and acquisitions of peer companies;
- the lack of marketability of our common stock as a private company;
- the rights, preferences, and privileges of our convertible preferred stock relative to those of our common stock;

- the likelihood of achieving a liquidity event for our securityholders, such as an initial public offering or a sale of our company, given prevailing market conditions;
- the hiring of key personnel and the experience of management;
- trends and developments in our industry

In valuing our common stock as of December 31, 2019 we utilized a hybrid method of the option pricing model, or OPM, and the probability weighted expected return method, PWERM, for determining the fair value of our common stock based on our stage of development and other relevant factors. Under this method, the per share value calculated on the OPM and PWERM are weighted based on expected exit outcomes to arrive and a final estimated fair value per share of the common stock before a discount for marketability is applied. The calculation of the grant date fair values of share based payments awarded in 2020 utilized the December 31, 2019 common stock value, as there had been no significant changes in our stage of development or other relevant factors impacting the common stock value as of any of the grant dates.

Following the closing of this offering, our board of directors will determine the fair market value of our common stock based on its closing price as reported on the date of grant on the primary stock exchange on which our common stock is traded.

Convertible Instruments

We account for hybrid contracts with embedded conversion features in accordance with GAAP. ASC 815 — Derivatives and Hedging Activities, requires companies to bifurcate certain conversion options and redemption features from their host instruments and account for them as free-standing derivative financial instruments should certain criteria be met. The features requiring bifurcation were initially recorded at fair value, with gains and losses arising from changes in fair value recognized as a component of other income (expense) in the consolidated statement of operations and comprehensive loss.

Recent Accounting Pronouncements

For a description of recent accounting pronouncements, see Note 2 of the notes to our audited financial statements for the year ended December 31, 2020 included elsewhere in this prospectus.

Quantitative and Qualitative Disclosures about Market Risk

Interest Rate Risk

We are exposed to market risk related to changes in interest rates. We had cash and cash equivalents of \$13.4 million as of March 31, 2021. Our exposure to interest rate risk is not significant and a hypothetical 1% change in interest rates during any of the periods presented would not have had a material impact on our financial statements included elsewhere in this prospectus.

Foreign Currency

Our functional currency is the U.S. dollar. As of the date of this prospectus, we are exposed to foreign currency rate risk related to various third-party service contracts denominated in foreign currencies. On July 14, 2015 we established an Australian subsidiary to facilitate for the purpose of conducting research and development efforts. Transaction gains and losses are included in other income (expense), net on our statements of operations and comprehensive loss and were not material for any of the periods presented. A hypothetical 10% change in exchange rates during any of the periods presented would not have had a material impact on our financial statements included elsewhere in this prospectus.

Effects of Inflation

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We believe that inflation has not had a material effect on our financial statements included elsewhere in this prospectus.

Emerging Growth Company Status

We are an emerging growth company, as defined in the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that we (1) are no longer an emerging growth company or (2) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

We will remain an emerging growth company until the earliest to occur of: (1) the last day of the fiscal year in which we have at least \$1.07 billion in annual revenue; (2) the last day of the fiscal year in which we are deemed to be a “large accelerated filer,” as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended, or the Exchange Act, which would occur if the market value of our common stock held by non-affiliates exceeded \$700.0 million as of the last business day of the second fiscal quarter of such year; (3) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during the prior three-year period; and (4) the last day of the fiscal year ending after the fifth anniversary of this offering.

BUSINESS

Overview

We are a clinical-stage biopharmaceutical company engaged in the discovery and development of innovative, small molecule therapeutics targeting age-related degenerative diseases and disorders of the central nervous system, or CNS, and retina. Currently available therapies for these diseases are limited, with many diseases having no approved therapies or treatments. Our goal is to develop disease modifying treatments for patients with these degenerative disorders by initially leveraging our expertise in the σ -2 (sigma-2) receptor, or S2R, which is expressed by multiple cell types, including neuronal synapses, and acts as a key regulator of cellular damage commonly associated with certain age-related degenerative diseases of the CNS and retina. We believe that targeting the S2R complex represents a mechanism that is functionally distinct from other current approaches in clinical development for the treatment of degenerative diseases.

Our lead product candidate, CT1812, is an orally delivered, small molecule antagonist designed to penetrate the blood-brain barrier and bind selectively to the S2R complex. We have initially focused on the development of CT1812 for the treatment of Alzheimer's disease, or AD, by targeting the accumulation of β -amyloid, or A β , oligomers, which has been linked to the disease. By displacing these A β oligomers from neuronal receptors in the S2R complex, we expect to demonstrate that CT1812 can slow the loss of synapses and cognitive decline observed in AD. CT1812 is the first S2R antagonist to reach clinical trials and is currently in Phase 2 development for the treatment of AD. The direct healthcare costs to care for patients with AD and other dementias in the United States is currently estimated to exceed \$300 billion. Approximately 5.8 million people in the U.S. have been diagnosed with AD, and the World Health Organization estimates that AD affects as many as 35 million people globally. Among people with AD, approximately 50% have mild disease, 30% have moderate disease and 20% have severe disease.

We are continuing to enroll patients in two ongoing Phase 2 clinical trials (SHINE and SEQUEL) with CT1812 in mild-to-moderate AD. Preliminary results from an interim analysis of the first 24 patients in Part A of our ongoing SHINE Phase 2 clinical trial demonstrated a statistically significant decline in the presence of A β and a positive trend on cognitive function as measured by the Alzheimer's Disease Assessment Scale-Cognitive Subscale, or ADAS-Cog, in patients receiving CT1812 compared to placebo. We anticipate top-line data in 2023. Our ongoing SEQUEL Phase 2 clinical trial is also evaluating changes in brain function, as measured by electroencephalography, or EEG, in mild-to-moderate AD with top-line data expected in 2023. We have treated 164 subjects with CT1812 in our clinical trials to date including 76 patients with mild-to-moderate AD. CT1812 has continued to be well tolerated and has been granted Fast Track designation by the U.S. Food and Drug Administration, or FDA, in this indication.

Our clinical trials have been funded by approximately \$168.4 million in cumulative grants awarded primarily by the National Institute of Aging, or NIA, a division of the National Institutes of Health, which includes a grant award of approximately \$81.0 million from the NIA to fund our upcoming Phase 2 (COG0203) study of CT1812 in patients with early-stage AD. We intend to enroll 540 patients in our COG0203 clinical trial with mild cognitive impairment, or MCI, due to AD or mild AD who have elevated levels of A β as determined by positron emission tomography, or PET, imaging or as measured in cerebral spinal fluid, or CSF. Patients will be randomized to receive CT1812 or a placebo for 18 months. In addition to cognitive and functional measures, such as the Clinical Dementia Rating Scale, or CDR, Sum of Boxes, or SOB, and ADAS-Cog, we intend to use a variety of biomarkers to measure target and/or pathway engagement and assess changes in neurodegeneration and disease progression. We will conduct this clinical trial in collaboration with the Alzheimer's Clinical Trial Consortium, or ACTC, an NIA-funded clinical trials network designed to accelerate studies for therapeutics for AD and related dementias, and we expect to begin enrollment in the first half of 2022.












We intend to expand our CT1812 pipeline to include additional indications such as dry age-related macular degeneration, or dry AMD, a disease that results in the deterioration of the macula, causing distortion, loss of central vision and eventual blindness, for which there are currently no FDA approved treatments. The S2R complex is expressed in the retina in several cell types including the retinal pigment epithelial cells, or RPE, photoreceptors and retinal ganglion cells. We believe that an S2R antagonist, such as CT1812, may help to regulate the damage-response processes related to these cells that are impaired in dry AMD. After the completion of our ongoing preclinical studies and subject to discussion with the FDA, we

intend to advance directly into a Phase 2 clinical trial in the second half of 2021, leveraging our knowledge of CT1812's preclinical and clinical profile to date. We have initiated discussions with the FDA regarding our plan.

In addition, we intend to develop and advance other product candidates in the area of synucleinopathies. Synucleinopathies are a group of degenerative diseases characterized by the abnormal accumulation of the alpha-synuclein protein in neural cell bodies, including Parkinson's disease, or PD, and dementia with Lewy bodies, or DLB.

Our Pipeline

We are developing a pipeline of innovative, small molecule product candidates that are designed to target the S2R complex, a key regulator of the cellular damage response for diseases such as AD, dry AMD, geographic atrophy (an advanced form of dry AMD), or GA, and other conditions for which there is significant unmet medical need. Our current pipeline is summarized below:

Product Candidate	Target Indication	Preclinical	Phase 1	Phase 2	Phase 3	Next Anticipated Milestone	Funding
CT1812	Mild-moderate AD					SHINE Topline 1H2023 (Enrolling final cohort 2H2021)	\$30M 
CT1812	Early-stage AD					ACTC Phase 2 COG0203 initiation (1H2022)	\$81M 
CT1812	DLB					Phase 2 initiation* (2H2021)	\$30M 
CT1812	Dry AMD					Phase 2 initiation* (2H2021)	
undisclosed	Synucleinopathies †					IND enabling studies	
undisclosed	Dry AMD					IND enabling studies	

* Provided the FDA agrees, we intend to proceed with Phase 2 studies supported by the Phase 1 AD studies
† including Parkinson's disease and DLB

Mild to Moderate AD

We are currently engaged in two ongoing Phase 2 clinical trials, designed to evaluate safety, dosing and potential efficacy for CT1812 as a treatment for mild-to-moderate AD. These trials include evaluations of CT1812's ability to engage with the S2R complex enabling the displacement of A β oligomers, its impact in synaptic density and its restoration of synaptic function. In the largest of these trials, our COG0201 SHINE study, we are assessing CT1812's ability to alter disease progression and cognition, with a target enrollment of 120 participants.

Early-stage AD

We plan to evaluate CT1812 in a 540-patient Phase 2 COG0203 clinical trial to investigate the potential for CT1812's use at an earlier stage of AD. In addition to cognitive and functional measures, such as CDR-SOB, ADAS-Cog and volumetric magnetic resonance imaging, or vMRI, we intend to use a variety of biomarkers to measure target and/or pathway engagement and assess changes in neurodegeneration and disease progression. We plan to initiate this clinical trial in the first half of 2022, which has been funded by a grant of approximately \$81.0 million from the NIA.

DLB

We plan to evaluate CT1812 in a 120-patient Phase 2 COG1201 clinical trial to investigate the potential for CT1812's use as a disease-modifying agent in DLB. We intend to assess cognitive and functional measures

such as Montreal Cognitive Assessment (MoCA), Cognitive Drug Research Battery (CDR), Clinician Assessment of Fluctuation (CAF), Epworth Sleepiness Scale (ESS), Unified Parkinson's Disease Rating Scale — Part III (MDS-UPDRS3), Clinical Global Impression of Change (ADCS-CGIC), ADCS-Activities of Daily Living (ADCS-ADL) and Neuropsychiatric Inventory (NPI). We plan to initiate this clinical trial in the second half of 2021, subject to discussion with FDA. The trial has been funded by a grant of approximately \$30 million from the NIA.

Dry AMD

We are also evaluating the use of CT1812 to treat dry AMD. We believe that human genetic and internal proteomic pathway analyses obtained through our AD trials provides evidence of a relationship between the S2R complex and dry AMD. We are currently engaged in preclinical development activities for this indication, including studies to elucidate the key mechanisms by which CT1812 and the S2R complex alter the biological processes that contribute to dry AMD. We believe that an S2R antagonist, such as CT1812, may help to regulate the damage-response processes related to these cells that are impaired in dry AMD. After the completion of our ongoing preclinical studies and subject to discussion with the FDA, we intend to advance directly into a Phase 2 clinical trial in the second half of 2021, leveraging our knowledge of CT1812's preclinical and clinical profile to date. We have initiated discussions with the FDA regarding our plan.

Discovery Initiatives

We are actively engaged in a number of early-stage discovery programs which are built upon our identification of five structurally distinct chemical series. We believe we have identified several structurally distinct compounds that possess advantages for specific disease indications and patient populations. Two of these next-generation S2R modulators have been identified for synucleinopathies and dry AMD and are being assessed as potential IND candidates.

One of our S2R modulators has shown potential disease modification in synucleinopathies such as DLB and PD. Data indicate that this next-generation S2R modulator has activity in α -synuclein assays, indicating the potential to alleviate α -synuclein oligomer-induced neurotoxicity.

Another of our next-generation S2R modulators has shown activity in cell-based dry AMD assays suggesting the potential to maintain homeostatic functions of RPEs, ameliorate lysosomal dysfunction, and prevent RPE cell death. It has further demonstrated retinal exposures above 80% receptor occupancy with oral administration and favorable PK properties, including high degree of bioavailability and high retina-to-plasma ratio, which we believe may provide us with a suitable next-gen molecule to advance for this indication. Therefore, we believe S2R modulators may present a novel therapeutic approach for these indications and intend to pursue development as described below.

Our Strategy

Our objectives are to develop and advance our portfolio, beginning with our lead product candidate, CT1812, through clinical development for the treatment of age-related degenerative diseases and disorders of the CNS and retina and to leverage our understanding of the S2R complex and its regulation of pathways to pursue indications in other degenerative disorders. The key elements of our strategy include:

- **Advance clinical development of our lead product candidate, CT1812, in mild-to-moderate AD and earlier stages of the disease.** Our lead product candidate, CT1812, has progressed through Phase 1 and into Phase 2 clinical trials. Funding of the Phase 1 and into Phase 2 trials is primarily through the NIA. We plan to evaluate CT1812 in other AD populations as well and develop CT1812 for patients with earlier symptomatic stages of AD and Mild Cognitive Impairment, which is a slight and noticeable measurable decline in cognitive abilities due to AD. We plan to initiate this clinical trial for COG0203 in patients with mild dementia associated with early-stage AD in the first half of 2022, which has been funded by a grant of approximately \$81.0 million awarded from the NIA.
- **Pursue the development of CT1812 for dry AMD.** We plan to evaluate CT1812 as a potential therapy for dry AMD, a common eye disease that results in the deterioration of the macula, causing visual distortion, loss of central vision and eventual blindness. We believe that an S2R antagonist,

such as CT1812, may help to regulate the damage-response processes related to these cells that are impaired in dry AMD. After the completion of our ongoing preclinical studies and subject to discussion with the FDA, we intend to advance directly into a Phase 2 clinical trial in the second half of 2021, leveraging our knowledge of CT1812's preclinical and clinical profile to date. We have initiated discussions with the FDA regarding our plan.

- **Leverage our understanding of the S2R complex to develop product candidates for other CNS and degenerative diseases, including synucleinopathies.** We intend to develop and advance other product candidates to treat synucleinopathies, which include PD and DLB. In the second half of 2021, we anticipate initiating a study of CT1812 in patients with DLB, subject to discussion with the FDA. Data published in February 2021 showed that the S2R complex may play an integral role in the pathology of PD and we believe these results merit further study.
- **Expand our pipeline through internal development, in-licensing and acquisitions.** We intend to leverage our expertise in drug development and business development to evaluate additional product candidates as well as bring forward novel chemical matter using our library generation and Novel Improved Conditioned Extraction, or NICE, screening platform. To achieve this objective, we may supplement our internal development initiatives through selective in-licensing arrangements, as well as investments in strategic collaborations, and partnerships which complement our initiatives.
- **Optimize the value of CT1812 and other product candidates in major markets.** We currently retain all worldwide rights to CT1812 for all indications. We plan to develop and pursue approval of CT1812 and other future product candidates in major markets. Where appropriate, we may use strategic collaborations or partnerships to accelerate development and maximize the commercial potential of our programs. We and our key opinion leaders believe CT1812 also can be used in combination with other therapeutics targeting AD biologies and thus may have many partnering opportunities.
- **Continue to pursue non-dilutive funding opportunities.** The majority of our clinical trials have been funded by approximately \$168.4 million in cumulative grants awarded primarily by the NIA, which includes an approximately \$81.0 million grant award from the NIA to fund our upcoming Phase 2 (COG0203) study of CT1812 in patients with early-stage AD. These grants are non-dilutive and allow us to collaborate with research institutions in pursuing the development of our product candidates for age-related degenerative diseases. We intend to continue our work with these research institutions and plan to seek additional non-dilutive funding for our clinical development when possible.

Our Team and Collaborators

We have assembled a management team with extensive experience with CNS and degenerative diseases, significant expertise in the S2R biology domain, as well as drug discovery, clinical development, general management and business development. Collectively, our management team has a track record of managing drug development programs that have received regulatory approval and been successfully commercialized. These include programs at Bristol-Myers Squibb Company, Pfizer Inc. and Roche Holding AG. In addition, our management team has built companies that have initiated innovative technologies and investigational new drug programs. We augment the strengths of our management team with an experienced board of directors and scientific and medical advisory boards. We believe our team, with its deep scientific and drug development background, positions us to become a leader in the development of therapies for age-related degenerative diseases and disorders.

Since our inception, we have collaborated and worked closely with key healthcare organizations and thought leading institutions in the field of degenerative diseases to develop and advance our therapeutic candidates. To date we have received approximately \$168.4 million in grants and financial support primarily from the NIA to support our clinical trials.

Our Approach to Treating Age-Related Degenerative Diseases of the CNS and Retina

Age-related degenerative diseases are defined by an age-related decline of cellular function often resulting in cell death. Neurodegenerative diseases, perhaps the most prominent of these degenerative disorders, are a variety of conditions defined by progressive degeneration of nerve cells, or neurons, which

often leads to neuronal death, causing decline in cognition or other functions, resulting in decreased quality of life and shorter life span. The two most common neurodegenerative diseases are AD and PD.

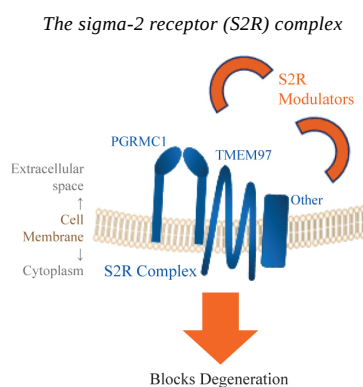
To our knowledge, no other biopharmaceutical company has focused solely on stopping the synaptic binding and signaling of soluble A β oligomers through the use of small molecule receptor antagonists, such as CT1812. We believe our deep expertise in oligomer and synaptic biology provides us with a competitive advantage and led to the creation of (1) proprietary assays that target the critical molecular step causing memory loss and (2) proprietary chemical libraries yielding highly brain penetrant small molecule drugs.

Based on this expertise, we are able to discover and optimize small molecule receptor antagonists like CT1812 that we believe represent a functionally distinct and promising approach to synaptorestorative AD therapeutics where neurons remain viable and functional. These molecules were designed to displace A β oligomers bound to neuronal receptors at synapses by selectively targeting and clearing A β oligomers from the brain into the CSF.

In addition to neurodegenerative diseases, other degenerative diseases include AMD. AMD is a common eye disease that results in the deterioration of the macula, causing visual distortion, loss of central vision and eventual blindness. It is the leading cause of blindness in people over 60 years of age and afflicts approximately 11 million Americans, including an estimated 12% of all U.S. adults over 80 years of age. We believe that human genetic and internal proteomic pathway analyses obtained through our AD trials provides evidence of a relationship between the S2R complex and dry AMD. We are currently engaged in preclinical development activities for this indication, including studies to elucidate the key mechanisms by which CT1812 and the S2R complex alter the biological processes that contribute to dry AMD. We believe that an S2R antagonist, such as CT1812, may help to regulate the damage-response processes related to these cells that are impaired in dry AMD. After the completion of our ongoing preclinical studies and subject to discussion with the FDA, we intend to advance directly into a Phase 2 clinical trial in the second half of 2021, leveraging our knowledge of CT1812's preclinical and clinical profile to date. We have initiated discussions with the FDA regarding our plan. Other S2R modulators are being explored, currently in lead identification studies, prior to lead optimization and candidate selection for IND-enabling studies.

The Sigma-2 Receptor Complex

The S2R complex is comprised of transmembrane protein 97, or TMEM97, a four-domain transmembrane protein that forms a complex with progesterone receptor membrane component 1, or PGRMC1. The S2R complex is expressed in the CNS, the retina, as well as peripheral organs, including the pancreas, liver and kidney. Within the brain, the S2R complex is found in several areas, including the cerebellum, cortex, hippocampus and substantia nigra, and is enriched in neurons as compared to glial cells in the adult brain. In the retina, the S2R complex is expressed in several cell types including the RPE cells, photoreceptors and retinal ganglion cells.



Internal and third-party studies suggest that the role of PGRMC1 and TMEM97, the protein components of the S2R complex, regulate cell damage response processes, including cholesterol biosynthesis, vesicle trafficking, progesterone signaling, lipid membrane-bound protein trafficking and receptor stabilization at the cell surface. In addition, the S2R complex regulates autophagy, the cellular process by which altered cellular proteins are degraded and removed. The aberrant activity of these processes, believed to be triggered by cellular stresses, is a hallmark of the dysfunction related to degenerative diseases. The S2R complex is a key regulator of processes that have been implicated in several age-related degenerative diseases and disorders including AD, retinal diseases, such as dry AMD, and synucleinopathies, such as PD and DLB.

We believe the array of degenerative disorders which involve protein components of the S2R complex allows for the potential therapeutic use of proprietary S2R antagonists in numerous indications. While a fuller understanding of the molecular mechanisms involving the S2R complex remains to be elucidated, evidence suggests that targeting the S2R complex may provide therapeutic benefit to a wide range of age-related degenerative diseases and disorders. We believe modulating the S2R complex to normalize cellular function may provide a restoration of normal cellular processes.

Biomarker and Imaging-Driven Evidence

Biomarkers have become increasingly important in the development of treatments for neurodegenerative diseases for a number of reasons, including monitoring drug activity in patients, assessing changes in disease pathology during treatment and identifying responder populations for clinical studies. Given that biomarker-enabled therapeutics have a higher rate of success at gaining product approval, we elected to employ biomarkers in our programs to mitigate clinical development risk. To that end, in addition to a number of cognitive tests, our clinical trials use a variety of biomarkers to measure target and/or pathway engagement and assess changes in disease progression. For example, in AD, changes in cerebrospinal fluid, or CSF, concentrations of neurogranin and synaptotagmin-1 can be indicative of damage to synapses. In PD and other synucleinopathies, changes in markers such as α -synuclein species, lysosomal enzymes, markers of amyloid and tau pathology, and neurofilament light chain can indicate dysfunction in membrane trafficking and autophagy processes. Quantitative EEG and PET imaging agents as well as vMRI may have utility in several neurodegenerative disorders to measure synaptic function, synaptic density and brain atrophy, respectively.

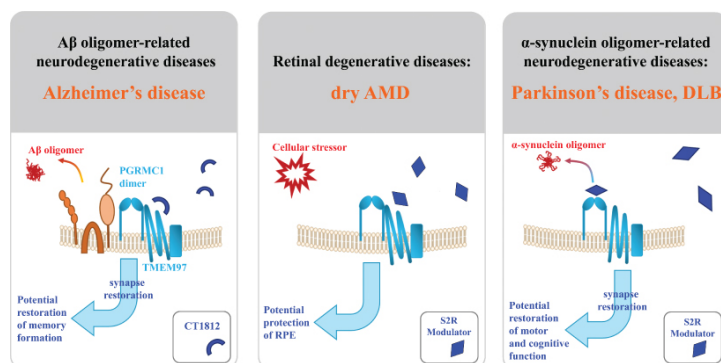
Our Novel, Improved Conditioned Extracts (NICE) Screening Platform

Chemical structures that we are currently evaluating as potential therapeutics for degenerative diseases originate from our NICE screening platform. The NICE screening platform allows us to generate proprietary small molecule libraries derived from natural chemical scaffolds through a proprietary process which we refer to as conditioned extraction. Conditioned extraction, a process pioneered by our cofounder, allows us to eliminate undesirable properties of well characterized, biologically active compounds sourced from natural products, while retaining their biological activity. The resulting molecular configurations are then subjected to proprietary functional *in vitro* screening assays designed to replicate the mature brain and its intricate connections and patterns of electrical signaling. Unlike most other screening assays, such as cells lines derived from immortalized neuronal tumor cells, our use of mature primary neuronal cultures provides us with information-rich measurements more indicative of normal brain function and predictive of functional benefit. We have utilized our NICE screening platform in conjunction with these mature primary neuronal cultures to develop product candidates for our proprietary Early Alzheimer's Screening System, or EASSY.

The candidate library produced by the NICE screening platform is predisposed to compounds with attractive drug-like properties such as low molecular weight, low number of reactive hydrogen bonds, lipophilicity and relatively neutral chemistry properties. These characteristics reduce the reactivity of the molecules and related toxicities, while also enhancing their ability to cross the blood-brain and blood-retina barriers. As a result, the NICE screening platform is designed to accelerate drug development time while reducing development risk. We believe these characteristics provide us with a screening platform that is differentiated from other discovery strategies.

Our Product Candidates

We are leveraging our expertise in the biology of the S2R complex, synaptic function and plasticity, and our understanding of the role of toxic age-related soluble proteins, to construct a pipeline of innovative, differentiated small molecule product candidates that are intended to restore normal cellular damage responses. We intend to develop therapeutics with the potential to overcome diseases associated with age-related toxic protein buildups that disrupt key cellular processes. Our initial product candidates target diseases characterized by dysfunction or dysregulation of the S2R complex that leads to cellular degeneration, as observed in age-related degenerative diseases and disorders, such as AD, dry AMD, PD and DLB as depicted in the illustration below.



Our Lead Product Candidate: CT1812

Our lead product candidate, CT1812, is an orally delivered, small molecule antagonist that penetrates the blood-brain and blood-retina barriers and binds selectively to the S2R complex; and through its modulation restores normal function of synapses, as well as critical cellular processes such as autophagy, cholesterol biosynthesis, vesicle trafficking, progesterone signaling, lipid membrane-bound protein trafficking and receptor stabilization at the cell surface. CT1812 originated from our initial efforts with our NICE screening platform which enables the generation of innovative leads. Leads identified through NICE were then evaluated using proprietary *in vitro* assays designed to better emulate *in vivo* synaptic activity. We believe the use of these assays allows us to identify functionally active structures which may impact neuronal behavior significantly faster than alternate screening approaches. We currently retain worldwide rights to CT1812 for all indications and are developing CT1812 as a potential treatment for a range of diseases including AD, dry AMD and synucleinopathies, such as DLB.

CT1812 for the Treatment of Alzheimer's Disease (AD)

CT1812 was designed to selectively target and displace Aβ oligomers bound to neuronal receptors at synapses by a new and differentiated mechanism of action. CT1812 allosterically modulates, changing the conformation of a key multiprotein regulator of oligomer receptors, the sigma-2 receptor complex. This destabilizes the Aβ oligomer binding site, increasing the off-rate and thereby displacing bound Aβ oligomers, which are then cleared from synapses. In our preclinical studies, CT1812 has demonstrated the potential to protect synapses, facilitate their restoration and improve cognitive performance. These preclinical results are currently being validated in our ongoing Phase 2 clinical trials.

Overview of the Disease

AD is a progressive neurodegenerative disorder characterized by cognitive dysfunction, memory loss, dementia and the impairment of daily living activities, along with numerous behavioral and neuropsychiatric symptoms. In the advanced stages of the disease, an AD patient is unable to recognize faces, use or

understand language and displays a lack of awareness for their surroundings. Continued functional decline ultimately results in the patient's death.

Due to the size of the affected population and the current lack of effective disease modifying therapies, we believe that AD is one of the most significant unmet medical needs of our time. Nearly six million Americans have been diagnosed with AD and disease prevalence is expected to more than double by 2050. The direct healthcare costs to care for patients with AD and other dementias in the United States is currently estimated to exceed \$300 billion and projected to increase to \$1 trillion by 2050. Absent the development of meaningful intervention in the course of the disease, the number of people diagnosed with, and dying from, AD is anticipated to escalate appreciably as lifespans lengthen, since prevalence increases significantly with age. The Centers for Disease Control listed AD as the primary cause of death for more than 121,000 Americans in 2019. The disease is equally devastating worldwide, with the World Health Organization estimating that AD affects as many as 35 million people globally.

Currently Approved AD Therapeutics

Only one disease-modifying therapeutic option has been approved by the FDA. Specifically, Biogen's Aduhelm received accelerated approval on June 7, 2021. The FDA allows accelerated approval for drugs to treat serious conditions that fill an unmet medical need based on a surrogate endpoint. A surrogate endpoint is a marker thought to predict clinical benefit but is not itself a measure of clinical benefit. After receiving accelerated approval, drug companies are still required to conduct studies to confirm the clinical benefit. If the required studies confirm the drug's benefit, then the FDA grants traditional approval of the drug. Aduhelm is a monoclonal antibody administered via infusion reported to reduce A β plaques, which is distinct from our small molecule approach to modulate the S2R, thereby blocking A β oligomers from binding to synapses. The only other therapies approved for AD are indicated to treat the symptoms of AD: acetylcholinesterase inhibitors, or AChEIs, and glutamatergic modulators and an orexin receptor antagonist. AChEIs are designed to slow the degradation of the neurotransmitter acetylcholine, helping to preserve neuronal communication and function temporarily. Glutamatergic modulators are designed to block sustained, low-level activation of the N-methyl-D-aspartate, or NMDA, receptor without inhibiting the normal function of the receptor in memory and cognition. Namenda (memantine), an NMDA receptor antagonist was approved in the United States in 2003. These therapeutic products do not modify or alter the progression of the underlying disease and provide only modest efficacy in treating the symptoms.

Therapeutic Approaches in Development to Treat the Underlying Disease Have Shown Little Success

Numerous therapeutic approaches have been evaluated to remedy the causes of AD. Those focused on reducing the aberrant production, or removal, of intraneuronal neurofibrillary tangles of tau protein have yielded limited clinical benefit. Development initiatives intended to inhibit hyperphosphorylation of the tau protein and related kinase activity, enhance microtubule stability or block tau aggregation have largely been discontinued due to toxicity or a lack of efficacy. Microglial activation and its role in AD-induced neuroinflammation has emerged as another potential target for therapeutic development as has the proper functioning of processes dictating synaptic plasticity, believed to be of central importance to neuronal activity and continued viability. These efforts have also not yielded meaningful clinical advances.

Among the more prevalent and targeted mechanisms implicated in AD, is the accumulation of A β aggregates in the neuronal synapse where disease progression leads to synaptic dysfunction and dysregulation. The accompanying deterioration in neuronal activity ultimately results in neuronal death. As a result, the reduction in the levels of A β aggregates at the synapse has been a prominent objective of a significant number of therapeutic candidates, including active and passive immunotherapies, designed specifically to target A β aggregates. As with other treatment strategies, with the exception of Aduhelm, these approaches have likewise yielded few meaningful treatment advances.

We believe the overarching issue with therapeutic interventions intended to limit A β aggregate concentrations in the brain is that they fail to discriminate between different forms of A β aggregates: fibrils, plaques and oligomers. Accordingly, these efforts may demonstrate success clearing fibrils and the largely inert plaques, but fail to address the specific neurotoxic effects of A β oligomers. We believe that unlike

previously pursued approaches, our strategy of targeting the S2R has the potential to prevent A β oligomer toxicity by acting directly at the synapse, thereby preventing synaptotoxicity, a mechanism we are testing in the clinic currently.

The Role of A β Oligomers on Synapses and the Downstream Impact to Brain Function and AD

Synapses are specialized points of contact between neurons, where electrical signaling and communication takes place. It is well established that synapses are routinely sprouted and resorbed as part of the normal process of learning and memory. Each neuron is covered with an estimated 10,000 synapses and these synapses participate in a complex electrical circuit with other neurons. Neurons do not divide or reproduce as part of normal physiological function.

Emerging scientific evidence suggests that A β oligomers, formed over time through the buildup of A β and its aggregates, bind to specific parts of the synaptic structure and interfere with the normal process of memory formation. This ligand-like activity confers to A β oligomers potent synaptotoxic activity. In response, the neuron dismantles and resorbs the synaptic structure to prevent its abnormal function from interfering with what remains of the normal circuit behavior. If a large enough number of synapses are lost, the neuron dies.

Synaptic loss, however, is not necessarily permanent and synapses can be regained or sprout again once the oligomers are removed. We have observed this process in our research involving preclinical AD models. This observation leads us to believe that displacement of synaptotoxic A β oligomers may enable synapses to recover and potentially slow cognitive decline. We are further encouraged by the numerous precedents which exist that demonstrate the therapeutic utility of blocking ligand-receptor interactions in the brain with small molecule drugs capable of crossing the blood-brain barrier.

CT1812 Uses a Differentiated Mechanism of Action to Selectively Target A β Oligomers

Our proprietary CT1812 clinical candidate employs a novel and fundamentally different mechanism which through alteration of S2R activity selectively facilitates removal of neurotoxic A β oligomers. Experimental evidence suggests that A β oligomers likely occupy binding sites contiguous to the S2R complex. Binding at these locations is believed to produce structural distortions which inhibit the proper functioning of the S2R complex including its role in regulating critical signaling pathways. The preferential binding of CT1812 to the S2R complex produces conformational changes that alters the binding affinity of A β oligomers. CT1812 binding to the S2R complex likely modulates the conformation of the S2R complex, which in turn allosterically alters the conformation of the oligomer binding pocket on the oligomer receptors. Binding pocket destabilization leads to displacement of A β oligomers from the neurons and neuronal synapse. Once displaced, A β oligomers are unable to rebind as long as threshold concentrations of CT1812 are present and are rapidly removed from the synapse. Based on our preclinical studies, we believe that CT1812 not only prevents binding of A β oligomers, displacing them from the S2R complex sites at neuronal synapses, but also slows A β oligomer-induced loss of synapses and restores synaptic activity, which may reverse downstream alterations related to membrane trafficking.

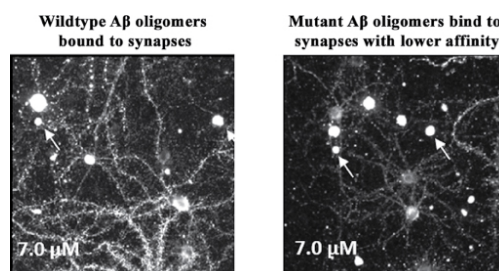
The Use of an S2R Targeted Approach is Supported by the A673T Mutation

We believe the benefit of the mechanism by which CT1812 stops the toxic impact of A β oligomers on cellular function is further supported by an analysis of the A β sequence variant, A673T, which is commonly referred to as the “Icelandic” mutation. The A673T mutation is the first variant associated with a mutation in the protein structure of A β , first identified through a genomic analysis of the Icelandic population, and is notable in that carriers of the mutation are four-fold less likely to develop AD. The A673T mutation, which involves the substitution of the amino acid alanine for threonine at position 673 of the precursor molecule, not only produces fewer A β monomers, but our research indicated that the toxic A β oligomers generated have four-fold lower affinity for brain cell synapses. This reduced binding is evidenced in the results of *in vitro* experiments, which are presented below. Whereas wildtype A β oligomer binding is pronounced, the binding of the A673T variant is much lower.

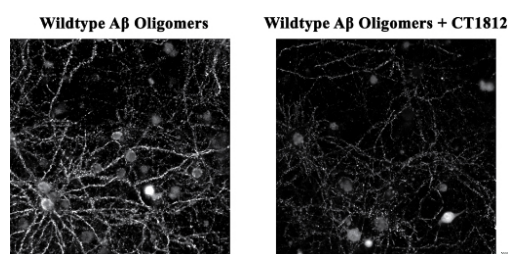
Binding affinities of wildtype versus mutant A β oligomers to synapses
(intensity in arbitrary fluorescent units)

	K_d (nM)	B_{max}^a
wt A β (1 – 42) oligomers	Site 1:442 \pm 70	$7.98 \times 10^5 \pm 0.29 \times 10^5$
A673T mutant A β (1 – 42) oligomers	Site 1:1,955 \pm 502	$5.98 \times 10^5 \pm 0.50 \times 10^5$

K_d is a constant used to evaluate and rank the strengths of interactions for ligands and their receptors. The smaller the K_d value, the greater the binding affinity. B_{max} refers to the maximum amount of a ligand that can bind specifically to a receptors. Intensity is measured in arbitrary fluorescent units.



We believe that CT1812 is the only drug currently in clinical trials that mimics the effects of the A673T mutation. As the images presented below suggest, both CT1812 and the A673T mutation similarly reduce the binding of toxic A β oligomers to synapses. We believe that drugs like CT1812 that mimic the protective effects of the A673T mutation are more likely to succeed in the clinical setting in patients with mild-to-moderate AD.



CT1812 Clinical Results in AD

We have completed four clinical trial evaluations of CT1812, in both healthy volunteers and patients with mild-to-moderate AD, with two clinical trials ongoing and one additional trial with topline results currently available and final results expected in the second half of 2021. The clinical trials we have conducted

to date have enabled us to ascertain the safety of CT1812, as well as validate its mechanism through proof-of-concept trials and conduct initial assessments of its clinical disease modifying efficacy. The following is the status of our completed and ongoing clinical trials.

Overview of our completed, ongoing and planned clinical studies

	FIH / Safety		Proof of Concept / Mechanism				Impact on Disease Pathology	
Study	SAD/MAD COG0101 (N=93)	DDI COG0103 (N=15)	COG0102 (n=19)	SNAP COG0104 (n=3)	SPARC COG0105 (n=23)	SEQUEL COG0202 (n=16)	SHINE COG0201 (n=120)	ACTC COG0203 (n=540)
Population	Healthy Volunteers		Mild-to-Moderate Alzheimer's				Mild-to-Moderate Alzheimer's	Early Alzheimer's
Status	Completed 2015	Completed 2016	Completed 2018	Completed 1H2021	Topline results 1H2021	Ongoing	Ongoing	Enrollment expected to commence in 1H2022
Results	well tolerated	No clinically significant DDI	well tolerated	Evidence of target engagement	Final results 2H2021	Topline 2023	Interim: trend in cognitive improvement Topline 1H2023	~2026

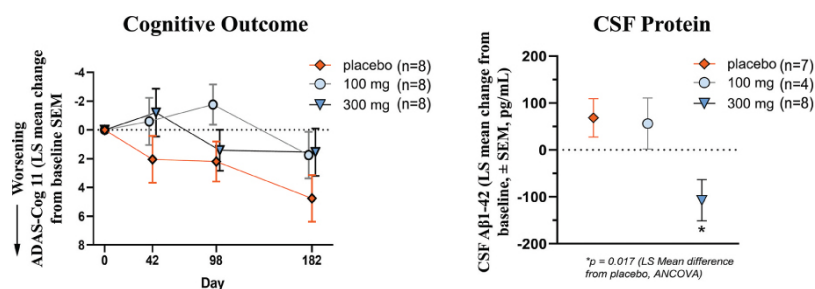
COG0201 — Phase 2 (SHINE) Clinical Trial

Our COG0201 SHINE study is a randomized, double-blind, placebo-controlled Phase 2 clinical trial designed to enroll up to a total of 120 patients with mild-to-moderate AD to evaluate the safety and potential efficacy of CT1812. Participants are divided in two CT1812 dose groups (100 mg or 300 mg) and one placebo group, dosed daily for six months. Endpoints include safety and biomarker evidence of disease modification as well as cognitive function, as measured by the ADAS-Cog 11-item version, or ADAS-Cog 11. ADAS-Cog 11 is a globally recognized cognitive scale that is used to assess cognition in patients with AD.

Preliminary results from an interim analysis of the first 24 patients from the COG0201 study demonstrated that CT1812 continued to be generally well tolerated. There were four serious adverse events, or SAEs, which were not drug-related and occurred in a single placebo patient. The patient was discontinued due to one of the SAEs. Treatment emergent adverse events, or TEAEs, were well balanced across all treatment groups. We observed mild and transient elevations of liver enzymes in three patients without any other indications of liver injury. These results were consistent with findings from earlier clinical studies.

The preliminary results also demonstrated a significant decline in the presence of A β and a three-point mean improvement in the rate of cognitive decline as measured by ADAS-Cog 11, in patients receiving CT1812 when compared to placebo. These results were observed in patients receiving CT1812 or placebo in addition to background therapies they may have already been receiving for AD. We believe these preliminary results provide promising evidence of CT1812's cognitive and biological impact on the 24 patients included in the interim analysis of the SHINE study. These results indicate that patients treated with CT1812 showed relative stability on a measure of cognitive performance compared to the placebo group. A mean difference in the rate of decline of approximately three points was observed between the CT1812 dose groups receiving either 100 mg or 300 mg versus the placebo group based on the ADAS-Cog 11 measurements. After review of these results, which are presented in the graph below, we decided to continue trial enrollment, and anticipate enrolling the remaining patients in the second half of 2021.

Results indicate a three-point improvement in cognitive decline in CT1812-treated patients.



Proteomic measurements were also performed of CSF and plasma from these patients, from which we have comprehensive datasets of whole proteome changes observed in AD patients given CT1812 versus placebo for six months. From this, we identified product candidate pharmacodynamic biomarkers that could reflect processes of target engagement, pathway engagement and/or early disease modification.

The SHINE trial was not powered to detect statistically significant treatment differences. Nevertheless, p-values were calculated at the time of the interim analysis with respect to the clinical and biomarker outcomes to help inform on the potential importance of observed numerical treatment differences. For these interim analyses, p-values < 0.05 were considered “significant” while p values > 0.05 were considered “non-significant.” The approximately three point treatment difference relative to placebo observed for the pooled dose groups that was observed on the ADAS-Cog 11 was non-significant ($p > 0.05$; $p = 0.1295$), while the treatment difference relative to placebo that observed for the reduction in CSF Aβ 42 protein at the 300mg dose was significant ($p < 0.05$; $p = 0.0178$).

Proof-of-Concept Clinical Trials for the Mechanism of CT1812

We have conducted and are continuing to conduct a series of clinical proof-of-concept trials intended to assess target engagement and the impact of CT1812 on synaptic activity. These proof-of-concept trials are presented in more detail below.

COG0202 — Phase 2 (SEQUEL) Trial

Our COG0202 SEQUEL study is a randomized, double-blind, placebo-controlled Phase 2 clinical trial of 16 patients with mild-to-moderate AD to evaluate the potential efficacy of CT1812 in restoring synaptic function in patients through quantitative EEG measurement, as reflected by relative theta power. The trial is configured as a two-arm crossover trial, in which half of the participants will receive 300 mg of CT1812 daily for 29 days. After a 14-day wash out period, these participants will receive placebo for an additional 29 days. The other half of the participants receive placebo daily for 29 days. After a 14-day wash out period, these participants will receive CT1812 treatment for an additional 29 days. CSF and EEG evaluations are taken periodically throughout the duration of the trial. We anticipate reporting topline data from this trial in 2023.

COG0105 — Phase 1 (SPARC) Trial

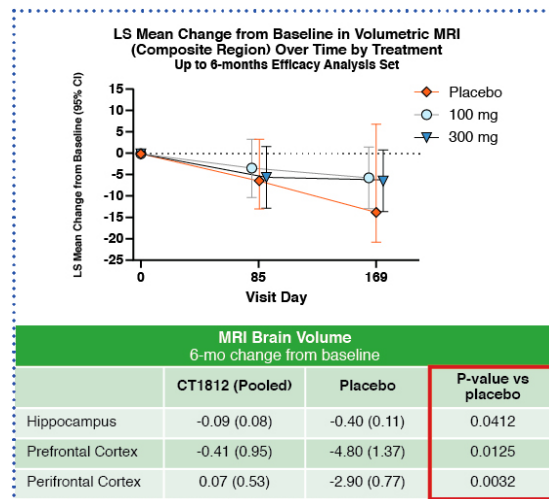
The COG0105 SPARC study is a randomized, double-blind, placebo-controlled Phase 1 clinical trial of 23 patients with mild-to-moderate AD. The primary objectives of the study were to evaluate CT1812 for safety and tolerability. The secondary objectives were to evaluate potential effects of CT1812 on biologically relevant endpoints using various imaging modalities, including PET imaging and vMRI as well as CSF biomarkers, and cognitive and clinical endpoints.

Participants were randomized to receive treatment with 100 mg or 300 mg of CT1812 or placebo once daily for 24 weeks. A preliminary analysis has been made of safety, clinical laboratory measurements, PET

imaging, functional MRI and vMRI, CSF biomarkers and clinical outcomes in patients treated with CT1812 compared to those in patients receiving placebo.

Seventeen patients completed the study protocol, eleven in the CT1812 arm (six in the 100mg cohort; five in the 300mg cohort) and six in the placebo arm. CT1812 was well-tolerated with similar adverse event rates across treatment arms. Most adverse events were mild-to-moderate in severity with no deaths and no treatment-related SAEs reported. We observed mild and transient elevations of liver enzymes without any other indications of liver injury in two patients in the 300 milligram group. The patients were discontinued from the study and the liver enzyme levels returned to normal.

Topline results from the analyses of secondary endpoints demonstrated that after 24-weeks of treatment, there were no significant treatment differences on the ADAS-Cog 11 change from baseline. In addition, there were no significant treatment differences on SV2A signal change compared to baseline. However, vMRI showed a trend ($p=0.0641$) towards a significant reduction in the loss of composite brain volume in CT1812-treated patients (pooled) compared to placebo. A statistically significant ($p<0.05$) reduction in loss of brain volume was also observed in three brain regions (hippocampus, prefrontal cortex and pericentral cortex) in treated patients (pooled) compared to placebo, as shown in the table below.



Additional analyses are underway, including examination of CSF biomarkers including A β , tTau, pTau181 and a host of synaptic biomarkers. Results are expected 2H 2021.

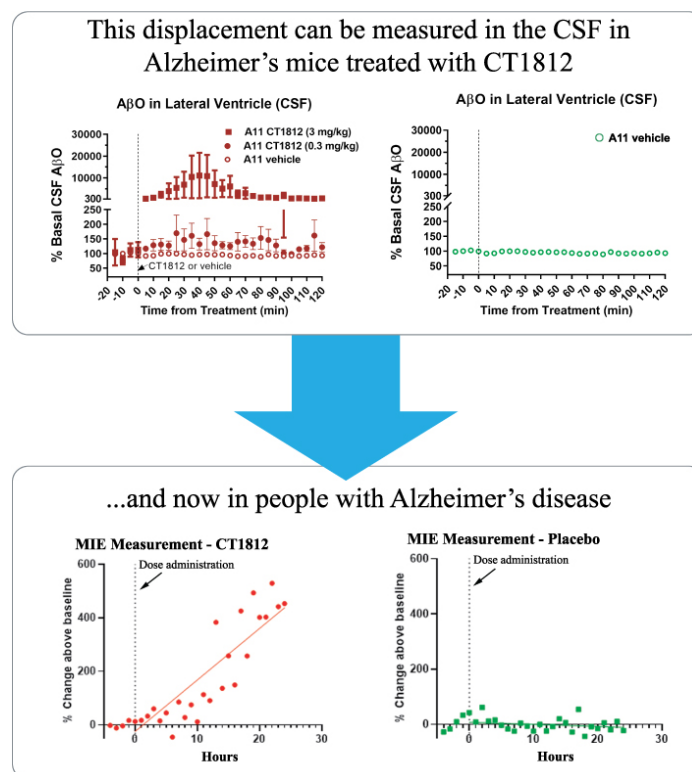
COG0104 — Phase 1 (SNAP) Trial

Our COG0104 SNAP study was a randomized, double-blind, placebo-controlled Phase 1 clinical trial that enrolled three patients with mild-to-moderate AD to measure the effects of CT1812 on displacement of A β oligomers. Patients were randomized 2:1 to receive a single dose of CT1812 or placebo. Patients enrolled in the trial had an indwelling catheter placed in the lumbar CSF space. CSF samples were collected hourly over a 28-hour period. Five CSF samples were collected before and 24 samples collected after administration of a single 560 mg oral dose of CT1812 or placebo. CSF samples from trial participants were analyzed to measure the concentration of A β oligomers over the trial period.

Results of this trial revealed an increase in A β oligomer levels in the CSF over the 24-hour period following treatment with CT1812, but not in the patient administered placebo. These findings were observed using two independent methods, microimmunoelectrode and western blots. This effect of CT1812 was specific to A β oligomers, as no CT1812-related increase in A β 1-40 or 1-42 monomer was observed.

We believe these results provide the early proof of principle of CT1812 target engagement in AD patients. Further, we believe that they corroborate our mechanism of action previously demonstrated in preclinical studies, providing the first evidence that our preclinical studies translate to patients with AD.

First evidence of target engagement in humans, which mirrors that found preclinically; and we believe this reinforces that our mechanism of action extends to patients with AD



COG0102 — Phase 1 Trial

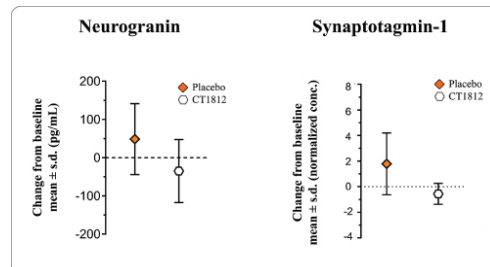
Our COG0102 study was a randomized, double-blind, placebo-controlled, Phase 1 clinical trial of 19 patients with mild-to-moderate AD. Participants were administered one of three oral doses of CT1812, either 90 mg, 280 mg or 560 mg, once daily for 28 days. The primary endpoint of the trial was safety with a secondary objective of establishing the pharmacokinetic, or PK, profile of CT1812. Also included as exploratory endpoints were measurement of CT1812 in CSF, and protein expression changes in CSF and plasma.

In order to gauge the impact of CT1812 on synaptic damage due to AD, we measured concentrations of synaptic proteins, neurogranin and synaptotagmin-1, in CSF samples from these patients using clinically validated standardized assays. Our evaluation of AD protein biomarkers in the CSF revealed that neurogranin levels, shown in the left graph below, in patients treated with CT1812 for 28 days was significantly decreased compared to levels measured in patients administered placebo ($p = 0.05$, analysis of covariance). Neurogranin is a synaptic damage marker that increases in the CSF of AD patients reflecting its decrease in

the brain. The lowering of synaptic damage markers in the CSF is consistent with CT1812's mechanism of action as observed in our preclinical studies and demonstrates the potential of the drug to slow A β oligomer-induced synapse loss.

Another synaptic damage biomarker that is elevated in the CSF of AD patients is synaptotagmin-1. CSF levels of synaptotagmin-1 were similar at baseline and end of study in patients treated with CT1812, whereas its levels in the placebo group displayed a marked increase over the same time period. This analysis of CT1812's impact on synaptotagmin-1 levels is presented in the right graph below. Consistent with our belief that targeting the S2R has the potential to prevent A β oligomer toxicity, we observed a reduction in neurogranin and synaptotagmin in CSF, which are measures of synaptic damage, suggesting that CT1812 may have the ability to protect synapses in AD patients.

Treatment with CT1812 was associated with lower levels of neurogranin and synaptotagmin-1 compared to placebo



CT1812 was well tolerated in the COG0102 study. All AEs were mild-to-moderate. Some of the participants in the highest dose group experienced lymphocytopenia or elevated liver enzymes. These laboratory abnormalities resolved in most patients with continued dosing of CT1812. One trial participant was discontinued from CT1812 prior to study completion because of elevated liver enzymes with subsequent resolution of this abnormality. Lymphocytopenia or elevated liver enzymes were not observed in either the 90 mg or 280 mg dosing cohorts. There were no SAEs.

Our Phase 1 Safety Trials

In addition to Phase 1 clinical trials conducted in our targeted patient population, we also conducted a series of Phase 1 clinical trials in healthy volunteers designed to establish the safety profile of CT1812, as well as determine potential drug-food or drug-drug interactions. These trials and their results, which are summarized below, indicated that CT1812 was generally well-tolerated.

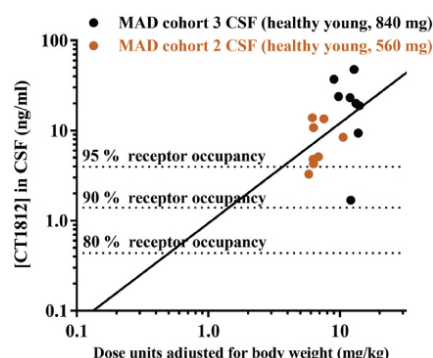
COG0101 — First in human phase 1 clinical trial

Our COG0101 study was a randomized, double-blind, placebo-controlled ascending dose Phase 1 multi-cohort clinical trial of 93 healthy volunteers to assess the safety and potential drug-food interactions of CT1812. The trial was conducted in two segments.

The first segment was structured as an ascending single dose trial, in which participants received one dose of CT1812 with increasing doses given to each of six cohorts. In this segment of the trial, eight participants were enrolled per dosing cohort with six participants receiving CT1812 and two receiving placebo. The doses evaluated were 10 mg, 30 mg, 90 mg, 180 mg, 450 mg and 1,120 mg. A seventh cohort of six patients received a single 90-mg dose after receiving a standardized meal. All doses were administered as scheduled.

The second segment was configured as a multiple ascending dose trial, that enrolled 39 healthy volunteers, divided in three cohorts of ten participants, with one additional cohort consisting of nine healthy elderly volunteers. Each participant in this segment of the trial received a single dose of CT1812 each day for 14 days. The doses evaluated in this second segment were 280 mg, 560 mg and 840 mg.

CT1812 CSF concentrations correlated to a >80% S2R predicted receptor occupancy in brain



Following completion of each trial cohort, bioanalytical evaluation of plasma CT1812 PK was conducted.

This trial demonstrated that administration of CT1812 in single doses of up to 1,120 mg, administered once, as well as up to 840 mg of CT1812 dosed for 14 consecutive days was well tolerated. Significantly, CT1812 concentrations detected in the CSF correlated to an estimated receptor occupancy in the brain of greater than 80%. There was one SAE in the multiple-dose portion of the study that was deemed unrelated to study drug. There were no SAEs related to the product candidate or TEAEs leading to withdrawal from the study.

COG0103 — Phase 1 trial

Our COG0103 study was a Phase 1 clinical trial of 15 healthy volunteers designed to evaluate the potential effects of CT1812 on select CYP isoenzymes: CYP2C19, CYP2C9, CYP2D6 and CYP3A4. This was accomplished by assessing its effects on substrates of these isoenzymes: 20 mg omeprazole, 500 mg tolbutamide, 50 mg dextromethorphan and 4 mg midazolam. The 15 healthy volunteers who participated in the trial received the substrates of these isoenzymes two days prior to the initial dose of CT1812 and PK assessments were performed. A dose of 560 mg of CT1812 was administered to each of the trial participants for the following six consecutive days. The day 6 dose of CT1812 was administered concomitantly with the four-substrate cocktail and PK assessments were repeated.

A weak drug interaction was observed between CT1812 and midazolam and dextromethorphan. A lack of any clinically meaningful interaction was observed with coadministration of omeprazole or tolbutamide. Based on the small magnitude of change in PK parameters of the probe drugs observed in this study for the isoenzymes CYP2D6 and CYP3A4, clinically meaningful interactions are unlikely.

Clinical Development Plans and Future Trials

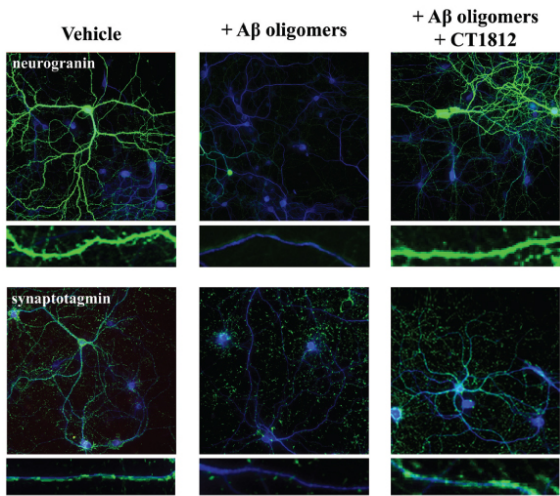
Our Upcoming COG0203 Phase 2 Clinical Trial Fully Funded by NIA Grant of approximately \$81.0 million

Our COG0203 study will be a randomized, double-blind, placebo-controlled Phase 2 clinical trial designed to enroll 540 patients with early-stage AD and powered to show a change in the rate of cognitive and functional decline. We intend to enroll patients with MCI, due to AD or mild AD who have elevated levels of A β as determined by PET imaging or as measured in CSF. The trial will be conducted in collaboration with the ACTC and will utilize up to 35 academic sites associated with the consortium. Patients will be randomized to receive CT1812 or a placebo for 18 months. In addition to a battery of cognitive measures, we intend to use a variety of biomarkers to measure target engagement and assess changes in neurodegeneration and disease progression. We have received a grant of approximately \$81.0 million from the NIA to fully fund this trial.

Preclinical Results

Prior to entering clinical trials, the therapeutic potential of CT1812 was observed in numerous preclinical studies. As is demonstrated in the images below, the addition of A β oligomers to neuronal cell cultures resulted in synaptotoxicity as illustrated by the reduced expression of synaptic markers neurogranin and synaptotagmin. The lack of immunoreactivity of these three synaptic proteins can be seen in the middle column of the image below. However, the presence of CT1812 blocked the A β oligomer-induced loss of synapses, as reflected by the presence of synaptic protein expression displayed in the right-hand column below.

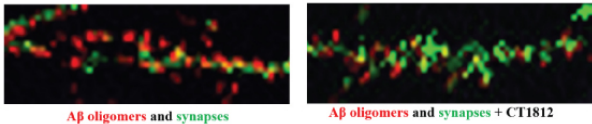
CT1812 prevents A β oligomer-mediated synaptic damage



Immunofluorescent images of cultured brain cells:
green = synaptic markers; blue = neuronal MAP2

Results showed that CT1812 also slowed the loss of synapses that is triggered by A β oligomers. A higher resolution image of the cell culture exposed to A β oligomer is shown below, before the addition of CT1812, which is presented on the left, and after the addition of CT1812, which is presented on the right. A β oligomers shown in red bind to synaptic receptors and reduce numbers of synapses shown in green. The addition of CT1812 displaces A β oligomer binding and appears to block the effects induced by the A β oligomers, with the synapse numbers remaining at levels similar to normal.

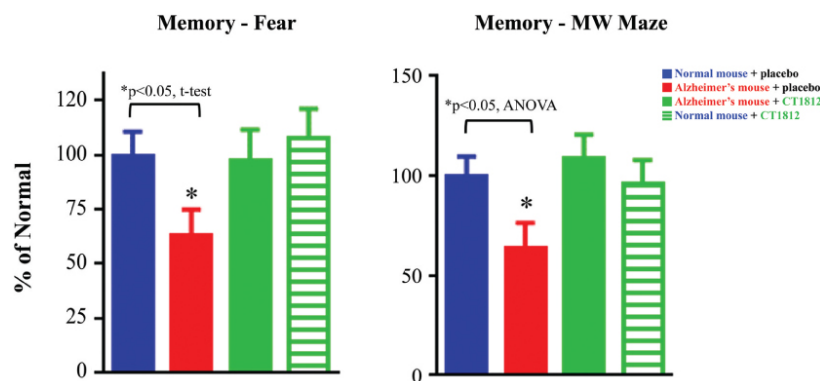
CT1812 slows loss of synapse numbers in the presence of A β oligomers



The protective benefits of CT1812 observed in these *in vitro* assays are supported by functional *in vivo* assessments of CT1812. In one such preclinical study, the memory of mice was tested based on the subject's ability to recall fear-inducing triggers and its performance in a maze. The mice exhibiting symptoms of AD, depicted by the red bars in the image below, performed significantly worse in both the fear and maze tests when compared to normal, non-transgenic mice, represented by the blue bars. However, after

administration of CT1812, the AD mice, represented by the solid green bars, were seen to perform at a level similar to that achieved by normal mice. We believe these results are illustrative of CT1812's ability to restore synaptic proteins and numbers to normal levels and with it, the animal's functional capabilities.

CT1812 restores functional capabilities in a mouse model of AD



CT1812 for the Treatment of Dry Age-Related Macular Degeneration (Dry AMD)

We believe that several lines of evidence suggest that modulation of the S2R complex may provide significant therapeutic utility for the treatment of dry AMD. Human genetics points to TMEM97 as a promising therapeutic target for dry AMD, as indicated via several large-scale, independent genome-wide association, or GWA, studies. In addition, unbiased pathway analysis of AD patient proteomic data obtained during our clinical trials provides independent evidence of a relationship between the S2R complex and dry AMD.

We are currently engaged in preclinical development activities for this indication, including studies to elucidate the key mechanisms by which CT1812 and the S2R complex alter the biological processes that contribute to dry AMD.

Early proof-of-concept studies with CT1812 indicate a role of S2R modulators in rescuing key aspects of dry AMD including maintaining homeostatic functions of RPEs, ameliorating lysosomal dysfunction and preventing RPE cell death. PK assessment indicates that we can achieve therapeutic levels (>80% receptor occupancy) of CT1812 in retinal tissue through oral administration.

We intend to initiate a Phase 2 clinical trial in second half of 2021, subject to discussion with the FDA. We believe that well-characterized clinical endpoints and a defined regulatory path increase the attractiveness of this indication.

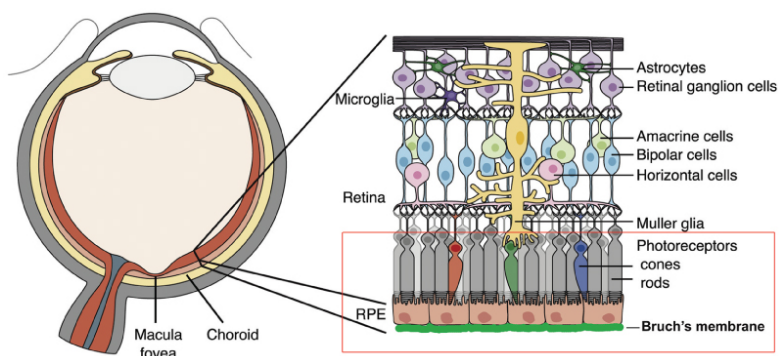
Overview of the Disease

AMD is the leading cause of blindness in people over 50 years of age in the United States, afflicting approximately 11 million people in the U.S., including an estimated 12% of all U.S. adults over 80 years of age. Dry AMD is a progressive condition and accounts for up to 90% of all AMD cases. Advanced dry AMD, or GA, affects approximately 2 million people in the U.S. There are no approved therapeutics available for dry AMD. Other treatments in development are primarily invasive, including intravitreal injections, stem cell replacement and gene therapy approaches. We believe the limited treatment options available for patients with dry AMD, coupled with newly implicated biochemical pathways, make dry AMD an attractive target for the development of therapeutics.

There are two types of AMD, the first of which is neovascular, or wet AMD, and non-neovascular, or dry AMD. Dry AMD, which accounts for approximately 90% of all AMD cases, is a progressive condition

that involves a dysregulation of cellular processes, among which is the accumulation of lipid deposits, known as drusen, that causes a thickening of the Bruch's membrane. This thickening disrupts the cytoarchitecture of the retinal pigment epithelium, or RPE, and this disruption, coupled with oxidative stress and inflammation, leads to the diminished health and function of RPE and photoreceptor cells, with accumulated damage resulting in cell death and visual impairment.

The anatomy of the eye and the regions impacted by AMD



Limitations of Current Treatments

Treatments for dry AMD are currently limited to vitamins and over-the-counter zinc. While there are no therapeutics approved by the FDA to treat dry AMD, there is considerable development activity ongoing involving numerous targets. Among the areas of ongoing interest are efforts targeting the complement pathway and its role in inflammation, as mutations in this pathway have been associated with higher risk of dry AMD. In addition, cell and gene therapy approaches are being evaluated to regenerate RPE cells and rescue the loss of photoreceptors. Small molecule visual cycle modulators are also under evaluation to maintain retinal integrity. Most of these approaches require invasive administrations.

Rationale for S2R Mechanism of Action

Indications of S2R Involvement in Dry AMD

We believe that several lines of evidence suggest that modulation of the S2R complex may provide significant therapeutic utility for the treatment of dry AMD. First, human genetics point to TMEM97 as a promising therapeutic target, as indicated via several large-scale, independent genome-wide association, or GWA, studies. These studies indicate a genetic mutation known as a single nucleotide polymorphism, or SNP, in the TMEM-VTN locus confers decreased risk for dry AMD. It remains unknown if this mutation confers a change in TMEM97 expression levels. However, knockdown of TMEM97 in *in vitro* models of the disease partially rescues RPE cells from oxidative stress-induced cell death. Investigation of the effects of pharmacological perturbation of the S2R complex signaling is currently ongoing to determine if the rescue of cell death mediated by decreasing TMEM97 expression can be replicated by S2R antagonists, such as CT1812.

Unbiased Analysis of Clinical Trial Sample Proteomics Data: Top Disease Ontologies

Unbiased pathway analysis of AD patient proteomic data obtained during the COG0102 and SHINE Part-A clinical trials provides independent evidence of the relationship between the S2R complex and dry AMD. Analyses of CSF were performed to ascertain which predesignated functional disease ontologies may be affected by the administration of CT1812. These analyses identified GA and macular degeneration as two of the top indications affected, with GA presenting the most significant relationship. Subsequent analyses identified several subsets of proteins altered by CT1812 that are involved in dry AMD.

In subsequent analyses examining the overlap of proteins altered in CSF and plasma biofluids of AD patients treated with CT1812 versus placebo, we identified a set of proteins, altered by CT1812 that have been previously shown by other groups to be disrupted in dry AMD or GA, compared to age-matched controls. Subsequent analysis identified several pathways in which these proteins are involved, many of which have known genetic or biological links to processes disrupted in dry AMD. We believe the collective insights provided by these analyses provide early proof of concept that an S2R modulator may be capable of altering AMD relevant proteins and pathways in an aged patient population.

Preclinical Support for Clinical Trials

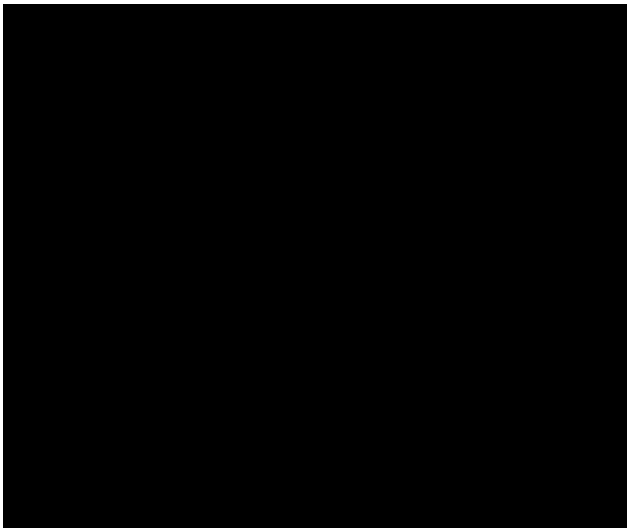
Early proof-of-concept studies indicate a clear role of S2R modulators in rescuing key aspects of dry AMD. Mechanistic studies and pathway analysis suggest a key role of S2R modulators in dry AMD.

Mechanistic Studies Indicate CT1812 Plays a Role in Cell Survival and Inflammatory Pathways in RPE Cells

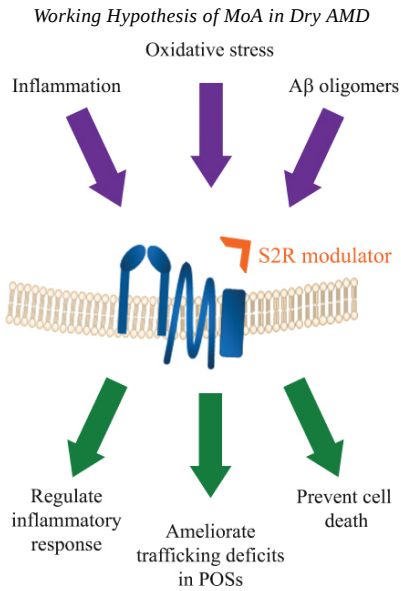
Pathways Altered by CT1812 vs vehicle (p-value < 0.05)
Oxidative stress
Apoptosis and survival APRIL and BAFF signaling
Signaling Transduction Role of MIF as an intracellular mediator
Cell cycle Role of SCF complex in cell cycle regulation
Immune response IFN-alpha/beta signaling via JAK/STAT
Development PEDF signaling
Aβ Oligomers
Immune response BAFF-induced non-canonical NF-kB signaling
Immune response Role of PKR in stress-induced antiviral cell response
Apoptosis and survival APRIL and BAFF signaling
Apoptosis and survival NGF activation of NF-kB
Apoptosis and survival Apoptotic TNF-family pathways
Inflammation
Cytoskeleton remodeling Regulation of actin cytoskeleton nucleation and polymerization by Rho GTPases
Neurophysiological process Activity-dependent synaptic AMPA receptor removal
Cell adhesion Classical cadherin-mediated cell adhesion
Transcription Ligand-dependent activation of the ESR1/SP pathway
Immune response Lysophosphatidic acid signaling via NF-kB

Functional studies support a role of S2R modulators in preventing cell death in a concentration dependent manner, as indicated by the chart below, which suggests that S2R modulators may prevent RPE cell death in dry AMD.

Functional Data Indicates That σ -2 Modulators Rescue Cell Death in RPE Cells



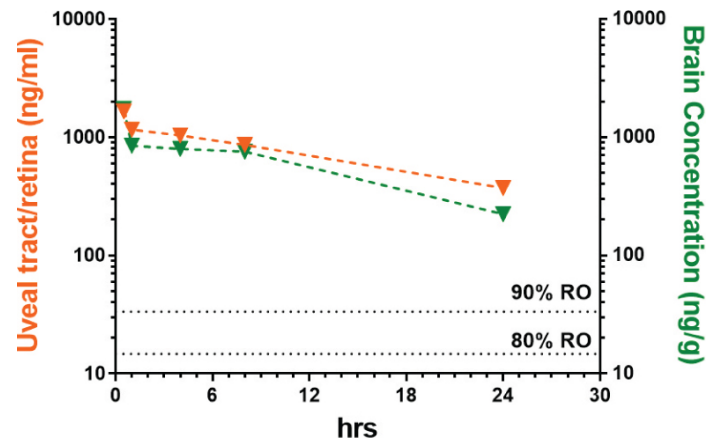
Additional functional studies extend our method of action, or MoA, beyond rescuing cell death, and suggest S2R modulators may ameliorate disruptions in homeostatic functions of RPEs, including ameliorating lysosomal dysfunction and salvaging the ability of RPE cells to recycle photoreceptor outer segments.



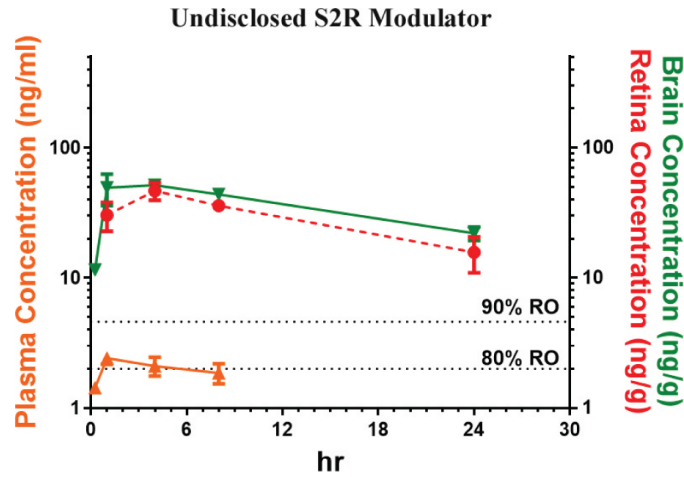
We believe preclinical studies provide further evidence supporting a clinical trial for CT1812 as a potential treatment for dry AMD. PK assessment indicates that we can achieve therapeutic levels (>80%

receptor occupancy) of CT1812 in retinal tissue through oral administration. Moreover, as is illustrated in the graph below, CT1812 levels recorded in the retina were similar to those in the brain, suggesting that the dose(s) used to achieve potential therapeutic levels in the retina needed to achieve efficacy will be similar to the dose(s) for AD.

Similarities in CT1812 concentrations following oral administration in the brain and retina



Another of our next-generation S2R modulator (undisclosed) shows good retinal exposures above 80% receptor occupancy with oral administration. This modulator has favorable PK properties, including high degree of bioavailability and high retina-to-plasma ratio, and shows activity in rescuing deficits in AMD assays.



Additional studies are underway to elucidate the key mechanisms by which CT1812 and the S2R complex alter the biological processes that contribute to dry AMD. *In vitro* and *in vivo* preclinical studies are evaluating the utility of CT1812 to impede the death of retinal ganglion cells. Not only is it anticipated that these proof-of-concept studies will allow us to further elucidate the mechanism by which the S2R

complex modulators act upon the various disease pathologies, but the learnings from this may also inform appropriate patient selection, time of intervention and clinical outcome measurements to enable a successful clinical trial design. We anticipate completing dry AMD preclinical proof-of-concept studies in mid-2021.

Proposed Phase 2 Clinical Trial Design

We believe that an S2R antagonist, such as CT1812, may help to regulate the damage-response processes related to these cells that are impaired in dry AMD. After the completion of our ongoing preclinical studies and subject to discussion with the FDA, we intend to advance directly into a Phase 2 clinical trial in the second half of 2021, leveraging our knowledge of CT1812's preclinical and clinical profile to date. We have initiated discussions with the FDA regarding our plan to leverage results of our previous clinical trials to accelerate clinical development of CT1812 as a treatment for dry AMD.

We anticipate the design of this trial to be a double-blind, placebo-controlled, randomized trial involving three dosing groups, two active treatment dose groups and a placebo group. We plan to enroll 300 patients in this 12-month study, with equal participant numbers in each of the three dose groups, with each trial participant dosed daily. Eligibility requirements are anticipated to include individuals 50 years of age or older that have received a diagnosis of dry AMD, with a best corrected visual acuity, or BCVA, score of 24 letters or more, with GA of between 2.5 mm² and 17.5 mm². The proposed primary endpoint of the trial is change in GA lesion area using fundus autofluorescence imaging. Proposed secondary endpoints are expected to include change in the square root of the GA lesion area, low luminance visual acuity, or LLVA, and BCVA, low luminance visual acuity deficit and drusen volume as measured by optical coherence tomography. We plan on measuring these outcomes at three-month intervals.

S2R Modulators for the Treatment of Synucleinopathies

Substantial cellular and clinical biomarker evidence demonstrate that our S2R modulators, including our clinical drug candidate CT1812, have a beneficial impact on the pathways impaired in synucleinopathies, namely the localization of α -synuclein aggregates in Lewy bodies, which is a chief hallmark of PD and other synucleinopathies. More recently, human genetic evidence has linked SNCA, the gene encoding α -synuclein, to the pathology of synucleinopathies.

We have conducted preclinical studies of S2R ligands in our library, including CT1812, to explore the potential of S2R antagonists to rescue the biological processes that are impaired in synucleinopathies. Subject to discussion with the FDA, we intend to conduct clinical studies in DLB, PD and potentially other synucleinopathies as outlined below.

An Overview of Synucleinopathies

Synucleinopathies are a group of neurodegenerative disorders in which the protein alpha-synuclein accumulates abnormally to form inclusions in the cell bodies or axons of neurons or oligodendrocytes. Two of the primary synucleinopathies are PD and DLB, which each involve motor and cognitive dysfunction. While the cell types and brain structures that are affected in PD and DLB vary markedly between the disorders, synucleinopathies share a characteristic accumulation of α -synuclein aggregates into fibrils, the major constituent of the Lewy bodies that occur inside brain neurons in these diseases.

Increasing evidence suggests that α -synuclein also aggregates into oligomers, and that oligomers are more toxic than fibrils. α -synuclein oligomers contribute to neurodegeneration through a variety of mechanisms including disrupting normal autophagy, and inducing synaptic dysfunction and loss. Synaptic dysfunction and loss contribute to the cognitive and motor symptoms of these diseases.

Synucleinopathies are second only to AD in terms of neurodegenerative disease prevalence. In the United States, as many as one million people suffer from PD and an estimated 1.4 million from DLB. According to the Parkinson's Foundation and the Lewy Body Dementia Association, the direct healthcare costs for patients with PD and DLB are estimated to be approximately \$25 billion and \$31.5 billion per year, respectively. For PD, these direct medical costs include an estimated \$2.5 billion for medications annually in the United States.

Limitations of Current Treatments

Most approved therapeutic products treat the symptoms of the diseases and modulate dopamine. While some existing products provide meaningful symptomatic relief, they have significant side effect risks, fail to address the progression of the disease, and over time gradually lose their effectiveness in treating the symptoms of the disease. There are no currently approved disease-modifying therapeutics for PD or other synucleinopathies.

Rationale for S2R Mechanism of Action for Synucleinopathies

α -synuclein is a protein primarily found in neural tissue that plays a role in neurotransmission. In synucleinopathies such as DLB and PD, α -synuclein builds up in brain cells and forms oligomers that saturably bind to neurons where they impair critical cellular processes, causing synaptic dysfunction and eventual loss. Our decision to pursue the treatment of synucleinopathies with S2R compounds is based on internal and third-party data, indicating that the S2R components PGRMC1 and TMEM97 regulate cell pathways known to be impaired in synucleinopathies, such as autophagy, vesicle trafficking and lipid synthesis; α -synuclein oligomers bind directly to PGRMC1; and synucleinopathies share certain mechanistic similarities with AD, including pathologies related to aberrant oligomeric protein formations.

As summarized below, we believe our preclinical studies provide compelling evidence supporting the use of CT1812 and our next-generation S2R modulators as potential therapeutics to treat synucleinopathies.

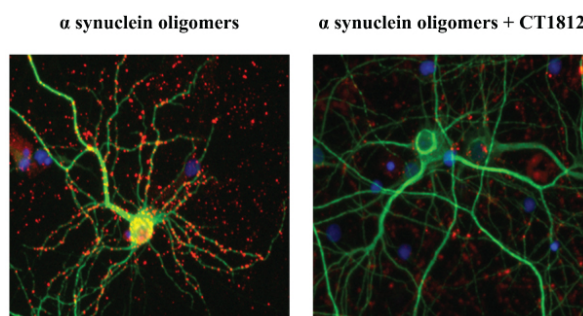
As with oligomers of the A β protein in AD, oligomers of α -synuclein are highly toxic when bound to brains cells and internalized. This binding causes cellular stress, including three major pathway disruptions: upregulation of the autophagy receptor LAMP2A, dysregulation of lipid metabolism and a reduction in membrane trafficking. The S2R complex components, PGRMC1 and TMEM97, directly regulate these processes, activities which are compromised by the binding and internalization of α -synuclein oligomers.

Compounds that bind to S2R and block α -synuclein binding and/or internalization are therefore expected to be disease-modifying.

Preclinical Study Support for Clinical Trials

The results of *in vitro* studies suggest that S2R antagonists, such as CT1812, may have disease modifying effect on the synucleinopathies by reversing pathway disruption and dysregulation caused by α -synuclein oligomers. In work funded by a grant from the Michael J. Fox Foundation, α -synuclein oligomers were found to bind to brain cells in culture and are internalized, indicated by the red dots in the image to the left below. With the addition of S2R antagonist CT1812, the binding and thus internalization of the α -synuclein oligomers is inhibited as indicated in the image to the right below.

CT1812 blocks the binding and internalization of α -synuclein oligomers the neuronal synapses

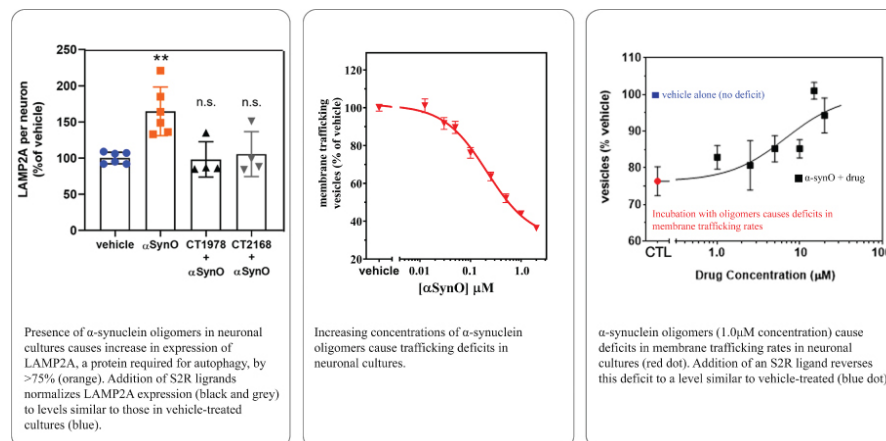


The potential for S2R antagonists to reverse the deleterious cellular effects of α -synuclein oligomers is also reflected in the *in vitro* analysis of LAMP2A expression presented below. LAMP2A is a critical

component of chaperone-mediated autophagy, one of several processes that eliminate damaged cellular proteins. Its expression, noted in orange, is upregulated in the presence of the toxic α -synuclein oligomer, likely a compensatory mechanism in response to the cellular insult. S2R antagonists, which block membrane trafficking deficits caused by α -synuclein oligomers, are observed to inhibit the upregulation of LAMP2A, as evidenced by the dark and light gray in the below chart. As these antagonists are selective for the S2R complex, their ability to reverse the effects of α -synuclein on LAMP2A expression provides compelling evidence of the S2R complex's importance in the regulation of this autophagy pathway.

In vitro analysis further illustrates α -synuclein oligomers' dose-dependent inhibition of membrane trafficking. Importantly, oligomer-related inhibition was noted to be four-fold higher than that observed with high concentrations of monomeric α -synuclein, illustrative of the significantly greater toxicity of α -synuclein oligomers. The addition of CT1812 was observed to reverse the membrane trafficking deficit related to the presence of α -synuclein oligomer, while having no effect on membrane activity when dosed in its absence.

S2R antagonists reverse the effects of α -synuclein oligomers on LAMP2A expression and trafficking



Proposed Phase 2 Clinical Trial in Dementia with Lewy bodies (DLB)

We plan to initiate a Phase 2 clinical trial evaluating the use of CT1812 to treat patients diagnosed with DLB in the second half of 2021, subject to discussion with the FDA. We anticipate the design of this trial to be a double-blind, randomized trial involving three dose groups, two active treatment cohorts and a placebo group. We expect to enroll 120 patients in a six-month study, with equal participant numbers in each of the three dose groups, with daily (QD) dosing. Eligibility requirements will include individuals between 50 and 80 years of age that have received a diagnosis of DLB and have a mini-mental state exam, or MMSE, score of between 18 and 27. Proposed clinical endpoints of the trial include safety and physical activity measurements, cognitive assessments, and PK and pharmacodynamic biomarker analyses compared to baseline measurements recorded at the beginning of the trial. In addition, CSF will be collected and analyzed for α -synuclein content and established patterns of differential protein expression.

Additional Product Candidates

Many degenerative disorders likely involve a dysfunctional cellular damage response mechanism and significant evidence is emerging which highlights the importance of the S2R complex and its components in regulating this response. The complex likely contains a number of relevant binding sites that may allow for multiple disease intervention approaches, making it an attractive therapeutic target. Accordingly, we are actively engaged in a number of earlier-stage discovery programs which are built upon our identification

of five structurally distinct chemical series. From these series we have multiple leads which will be optimize each of our lead series. Each of these leads has demonstrated favorable potency with variable selectivity in early preclinical testing and each of the molecular series possesses distinct bioavailability and PK properties, including differences in half-life and blood-brain and blood-retina permeability.

Proposed Synucleinopathies Clinical Program

Subject to additional funding, we plan to study several next-generation S2R modulators derived from chemically distinct series to measure their ability to rescue cell death in synucleinopathies such as PD and DLB. We would also study α -synuclein pathology and motor deficits in two mechanistically distinct *in vivo* models of synucleinopathies. In parallel, these studies will elucidate the mechanism of action by which S2R modulators are efficacious in PD and DLB and provide essential data to support potential biomarker nomination for PD and DLB.

Grant Funding

Historically, we have sought grant funding to strategically advance our programs. To date, we have secured non-dilutive funds from the NIA, the Michael J Fox Foundation, or MJFF and other groups to pursue our commonly aligned interests of developing therapeutics for neurodegenerative disorders. Taken together, the company has been awarded approximately \$168.4 million in grants for the advancement of our pipeline programs. Of this, approximately \$128.5 million in cumulative non-dilutive grants have been awarded by the NIA to fund development of CT1812 for the treatment of Alzheimer's disease.

Funding Org	Year	Project	Amount
National Institute on Aging (NIH)	2016	COG0101 Ph1b first-in-patient trial for CT1812	\$2,410,669
National Institute on Aging (NIH)	2016	COG0102 Ph1b/2a Clinical Trial for CT1812	\$2,410,669
National Institute on Aging (NIH)	2017	COG0104 Ph1 SNAP Study: CSF Catheter	\$2,527,271
National Institute on Aging (NIH)	2017	COG0105 Ph1 SPARC Study: SV2a PET	\$4,795,774
National Institute on Aging (NIH)	2018	COG0201 Ph2 SHINE Study	\$16,848,329
National Institute on Aging (NIH)	2019	COG0202 Ph2 SEQUEL Study: qEEG	\$3,300,642
National Institute on Aging (NIH)	2020	COG0203 Ph2 Study with ACTC	\$80,974,766
National Institute on Aging (NIH)	2021	COG0108 Study: hAME	\$1,642,783
National Institute on Aging (NIH)	2021	COG0201 Ph2 SHINE Amendment	\$13,634,548
National Institute on Aging (NIH)	2021	COG1201: Study: DLB	\$29,498,048
NIH and others	2010-2018	Ten Preclinical Programs	\$10,359,971
			\$168,403,470

Each of the grants awarded to us relate to agreed upon direct and indirect costs for specific studies or clinical trials, which may include personnel and consulting costs, costs paid to CROs, research institutions and/or consortiums involved in the grant, as well as facilities and administrative costs. These grants are cost plus fixed fee arrangements in which we are reimbursed for our eligible direct and indirect costs over time, up to the maximum amount of each specific grant award. Only costs that are allowable under the grant award, certain government regulations and the NIH's supplemental policy and procedure manual may be claimed for reimbursement, and the reimbursements are subject to routine audits from governmental agencies from time to time. While these NIA grant do not contain payback provisions, the NIA or other government agency may review our performance, cost structures and compliance with applicable laws, regulations, policies and standards and the terms and conditions of the applicable NIA Grant. If any of our expenditures are found to be unallowable or allocated improperly or if we have otherwise violated terms of such NIA grant, the expenditures may not be reimbursed and/or we may be required to repay funds already disbursed. To date, we have not been found to have breached the terms of any NIA grant.

Intellectual Property

We seek to protect and enhance our proprietary technology, inventions, and improvements that are commercially important to the development of our business by seeking, maintaining, and defending patent rights, in the United States and internationally, whether developed internally or licensed from third parties. We will also seek to rely on regulatory protection afforded through inclusion in expedited development and review, data exclusivity, market exclusivity and patent term extensions where available.

Company Owned Intellectual Property

As of May 31, 2021, our intellectual property portfolio contained eight issued U.S. patents, 50 issued foreign patents as well as three pending U.S. provisional applications, three pending U.S. patent applications, one pending PCT application and 22 foreign pending patent applications directed to the composition of matter of, pharmaceutical compositions of, methods of use of, and methods for selecting subsets of patients for treatment with our chemical structures, including our lead CT1812. Our current issued patents relating to CT1812 are projected to begin to expire no earlier than 2035, with the composition of matter patent covering CT1812 set to naturally expire in 2035, subject to adjustment or extension of patent term available in a particular jurisdiction. We will likely be awarded Patent Term Extension, or PTE, when CT1812 is approved as a New Chemical Entity, or NCE, that will extend the term of the CT1812 composition of matter patent by up to five years, and we anticipate pursuing additional patents to further protect CT1812 and to further extend the patent term associated with CT1812. We expect to file additional patent applications in support of current and new product candidates as well as new platform and core technologies.

We are the exclusive owner of six patent families that include several granted U.S. patents and pending U.S. patent applications, as well as granted patents and pending patent applications in numerous foreign jurisdictions, relating to compositions of matter and pharmaceutical compositions of CT1812, analogs of CT1812, and the use of CT1812 for the treatment in certain diseases, disorders and conditions including AD, dry AMD, PD, and synucleinopathies.

The first of these patent families is directed to compositions of matter of CT1812, pharmaceutical compositions of CT1812, methods of using CT1812 for inhibiting amyloid beta effects on a neuronal cell, and methods of using CT1812 to treat AD, and we are the exclusive owner of this patent family in the United States and certain foreign jurisdictions, including Australia, Brazil, Canada, China, the European Union, Hong Kong, India, Israel, Japan, South Korea, Mexico, New Zealand, Russia, and South Africa. As of May 31, 2021, this patent family includes granted patents claiming composition of matter of CT1812, pharmaceutical compositions of CT1812, methods of using CT1812 for inhibiting amyloid beta effects on a neuronal cell, and methods of using CT1812 to treat AD in the United States (three patents), Australia, China, the European Union, Hong Kong, Israel, Japan, Mexico, Russia and South Africa. This patent family also includes a pending U.S. patent application and pending application in certain foreign jurisdictions including Brazil, Canada, the European Union, India, New Zealand, and South Korea. This patent family has a natural expiration date in 2035 subject to any adjustment or extension of patent term that may be available in a particular jurisdiction such as PTE following NDA approval in the United States or extension of patent term via a Supplementary Protection Certificate, or SPC, following EMEA marketing authorization. Upon approval of the NDA for CT1812 in the United States, the patents in this family claiming compositions of matter of CT1812, pharmaceutical compositions of CT1812, and methods of using CT1812 for inhibiting amyloid beta effects on a neuronal cell, and methods of using CT1812 to treat AD will be eligible to be listed in the FDA's publication "*Approved Drug Products with Therapeutic Equivalence Evaluations*," which we refer to as the Orange Book. These patents complement the regulatory exclusivity by providing the basis for an additional waiting periods prior to the FDA's approval of an abbreviated new drug application, or ANDA, or 505(b)(2) applicant. If an ANDA or 505(b)(2) applicant were to file its application referencing the NDA for CT1812 before expiration of our composition of matter, pharmaceutical composition, and method of use patents and the applicant asserted that our patents identified on the Orange Book to be invalid or not be infringed, it may be subject to additional waiting periods prior to the FDA's approval (including a statutory 30-month stay if we sue for infringement, or a shorter period if the patent expires or there are certain settlements or judicial decisions in the patent litigation, starting at the end of the five-year NCE regulatory exclusivity period).

In addition to patent exclusivity, under the provisions of the Hatch-Waxman Act, upon any approval in the United States, we believe that CT1812 will be eligible for five-year NCE regulatory exclusivity, during which time no 505(b)(2) NDA or ANDA can be approved that contains the same active moiety as the chemical entity in the CT1812 NDA. When approved in Europe, CT1812 will also be eligible for 10 years of data and market exclusivity which is extendible for an additional year upon market authorization for one or more new indications during the first eight years of the data and market exclusivity period.

We also own two families of pending patent application directed to methods for selecting subsets of patients with AD for treatment with CT1812 and methods of modulating amyloid beta monomer and oligomer levels using CT1812, as well as three pending provisional patent applications that are directed to radiolabeled forms of CT1812, method of treating dry AMD with CT1812, and methods of treating various neurologic disease including Parkinson's disease and synucleinopathies with CT1812. Any of these applications, if issued, will have a natural expirations between 2038 and 2042, subject to any adjustment or extension of patent term that may be available such as PTE following NDA approval in the United States as well as any term limitations based upon earlier expiring patents.

Additional Product Candidates

We are the exclusive owner of three patent families that include several pending U.S. patent applications, as well as pending patent applications in numerous foreign jurisdictions directed to additional product candidates. These patent families have expirations no earlier than 2038 subject to any adjustment or extension of patent term that may be available such as PTE following NDA approval in the United States as well as any term limitations based upon earlier expiring patents.

Manufacturing Strategy

We oversee and manage third party contract manufacturing organizations to support development and manufacture of product candidates for our clinical trials, and, if we receive marketing approval, we will rely on such manufacturers to meet commercial demand. We expect this strategy will enable us to maintain a more efficient infrastructure, avoiding dependence on our own manufacturing facility and equipment, while simultaneously enabling us to focus our expertise on the clinical development and future commercialization of our products. Currently, we rely on and have agreements with a single third-party contract manufacturer to supply the drug substance for CT1812 and with a single third-party contract manufacturer to manufacture clinical trial supplies of CT1812, and we expect to enter into commercial supply agreements with such manufacturers prior to any potential approval of CT1812. We continue to develop a commercial route for CT1812 API and to meet all requirements for our planned clinical trials. We plan to transfer the API manufacture to a larger third-party manufacturer once the commercial route is developed. The current API manufacturer is able to supply all of our needs for the planned clinical studies.

CT1812 drug product is manufactured via conventional pharmaceutical processing procedures, employing commercially available excipients and packaging materials. The procedure and equipment employed for manufacture and analysis are consistent with standard organic synthesis or pharmaceutical production, and are transferable to a range of manufacturing facilities, if needed. We have selected a larger third-party drug product manufacturer and will be executing technology transfer of drug product manufacture to a larger manufacturer. We will also maintain the current drug substance and product manufacturer as part of our supply chain strategy.

Commercialization Strategy

We currently have no marketing, sales or distribution capabilities. In order to commercialize any products that are approved for commercial sale, we must either develop a sales and marketing infrastructure or collaborate with third parties that have sales and marketing experience.

We may seek third-party support from established pharmaceutical and biotechnology companies for those products that would benefit from the promotional support of a large sales and marketing force. In these cases, we might seek to promote our products in collaboration with marketing partners or rely on relationships with one or more companies with large established sales forces and distribution systems.

We may elect to establish our own sales force to market and sell a product for which we obtain regulatory approval if we expect that the geographic market for a product we develop on our own is limited or that the prescriptions for the product will be written principally by a relatively small number of physicians. If we decide to market and sell any products ourselves, we do not expect to establish direct sales capability until shortly before the products are approved for commercial sale.

Competition

We face substantial competition from multiple sources, including large and specialty biotechnology and pharmaceutical companies, academic research institutions and governmental agencies and public and private research institutions. Our competitors compete with us on the level of the technologies employed, or on the level of development of product candidates. In addition, many small biotechnology companies have formed collaborations with large, established companies to (i) obtain support for their research, development and commercialization of products or (ii) combine several treatment approaches to develop longer lasting or more efficacious treatments that may potentially directly compete with our current or future product candidates. We anticipate that we will continue to face increasing competition as new therapies and combinations thereof, technologies, and data emerge.

In addition to the current standard of care treatments for patients with neurodegenerative diseases, numerous commercial and academic preclinical studies and clinical trials are being undertaken by a large number of parties to assess technologies and product candidates in the CNS field.

Many of our competitors, either alone or in combination with their respective strategic partners, have significantly greater financial resources and expertise in research and development, manufacturing, the regulatory approval process, and marketing than we do. Mergers and acquisition activity in the biopharmaceutical sector is likely to result in greater resource concentration among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through sizeable collaborative arrangements with established companies. These competitors also compete with us in recruiting and retain qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Our commercial opportunity could be reduced or eliminated if one or more of our competitors develop and commercialize products that are safer, more effective, better tolerated, or of greater convenience or economic benefit than our proposed product offering. Our competitors also may be in a position to obtain FDA or other regulatory approval for their products more rapidly, resulting in a stronger or dominant market position before we are able to enter the market. The key competitive factors affecting the success of all of our programs are likely to be product safety, efficacy, convenience and treatment cost.

Employees and Human Capital Resources

As of May 31, 2021, we had 20 employees, 18 of whom were full-time and nine of whom were engaged in research and development activities. Six of our employees hold Ph.D. or M.D. degrees. None of our employees are represented by a labor union. We consider our relationship with our employees to be good.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants. The principal purposes of our equity and cash incentive plans are to attract, retain and reward personnel through the granting of stock-based and cash-based compensation awards, in order to increase stockholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives.

Facilities

Our corporate headquarters is located in the greater New York City area with laboratories in Pittsburgh, PA, where we currently lease approximately 6,068 square feet of laboratory and office space. We believe that our current facilities are adequate to meet our ongoing needs, and that, if we require additional space, we will be able to obtain additional facilities on commercially reasonable terms.

Government Regulation

Government authorities in the United States, at the federal, state, and local level, and other countries extensively regulate, among other things, the research, development, nonclinical and clinical testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing, and export and import of products such as those we are developing. Generally, before a new drug can be marketed, considerable data must be generated, which demonstrate the drug's quality, safety, and efficacy. Such data must then be organized into a format specific for each regulatory authority, submitted for review and approved by the regulatory authority.

U.S. Drug Development Process

In the United States, the FDA regulates drugs under the federal Food, Drug, and Cosmetic Act, or FDCA, and its implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, the approval process or after approval may subject an applicant to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement, or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of nonclinical laboratory tests, animal studies, and formulation studies in accordance with FDA's good laboratory requirements and other applicable regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- approval by an independent IRB ethics committee, either centralized or with respect to each clinical site, before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with GCP requirements to establish the safety and efficacy of the proposed drug for its intended use;
- submission to the FDA of an NDA after completion of all pivotal trials;
- determination by the FDA within 60 days of its receipt of an NDA to accept the filing for substantive review;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with cGMP requirements to ensure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality, and purity, and of selected clinical investigation sites to assess compliance with GCPs;
- FDA review and approval of the NDA to permit commercial marketing of the product for particular indications for use in the United States;
- compliance with any post-approval requirements, including potential requirements to conduct any post-approval studies required by the FDA or the potential requirement to implement a REMS; and
- compliance with the Pediatric Research Equity Act, or PREA, which requires either exemption from the requirements or may require conducting clinical research in a pediatric population.

Prior to beginning the first clinical trial with a product candidate in the United States, we must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical studies. The IND also includes results of animal and *in vitro* studies assessing

the toxicology, PK, pharmacology, and pharmacodynamic characteristics of the product; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. Furthermore, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site and must monitor the study until completed. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the clinical trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which may review data and endpoints at designated check points, make recommendations and/or halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

Phase One: The product candidate is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism, and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing;

Phase Two: The product candidate is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages, and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning;

Phase Three: The product candidate is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk.

Post-approval clinical trials, sometimes referred to as Phase 4 studies, may be conducted after initial marketing approval. These clinical trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA.

The FDA or the sponsor may place a clinical trial on a full or partial clinical hold at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk or concerns related to chemistry, manufacturing and controls. A clinical hold is an order issued by the FDA to delay or suspend an investigation. Following the issuance of a clinical hold or a partial clinical hold, a clinical trial may only proceed after FDA has notified the sponsor that any deficiencies have been corrected and FDA is authorizing the trial to proceed. In addition, an IRB representing each

institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must conduct continuing review and reapprove the study at least annually. The IRB must review and approve, among other things, the study protocol and informed consent information to be provided to study subjects. An IRB must operate in compliance with FDA regulations. An IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB's requirements or if the product candidate has been associated with unexpected serious harm to patients. Finally, some clinical trials are overseen by an independent group of qualified experts organized by the sponsor, known as a data safety monitoring board or committee. Depending on its charter, this group may determine whether a clinical trial may move forward at designated check points based on access to certain data from the clinical trial.

During the development of a new drug, sponsors are given opportunities to meet with the FDA at certain points. These points may be prior to submission of an IND, at the end of Phase 2, and before an NDA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and the FDA to reach agreement on the next phase of development. Sponsors typically use the meetings at the end of the Phase 2 clinical trial to discuss Phase 2 clinical results and present plans for the pivotal Phase 3 clinical trials that they believe will support approval of the new drug.

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

While the IND is active and before approval, progress reports summarizing the results of the clinical trials and nonclinical studies performed since the last progress report must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and investigators for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the same or similar drugs, findings from animal or *in vitro* testing suggesting a significant risk to humans, and any clinically important increased incidence of a serious suspected adverse reaction compared to that listed in the protocol or investigator brochure.

NDA Review and Approval Process

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development nonclinical and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling and other relevant information are submitted to the FDA as part of an NDA requesting approval to market the product. The submission of an NDA is subject to the payment of substantial user fees; a waiver of such fees may be obtained under certain limited circumstances. Additionally, no user fees are assessed on NDAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP-compliant to assure and preserve the product's identity, strength, quality, and purity. Under the Prescription Drug User Fee Act, or PDUFA, guidelines that are currently in effect, the FDA has a goal of ten months from the date of "filing" of a standard NDA for a new molecular entity to review and act on the submission. This review typically takes 12 months from the date the NDA is submitted to FDA because the FDA has approximately two months to make a "filing" decision after the application is submitted. The FDA conducts a preliminary review of all NDAs within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing.

The FDA may refer an application for a novel drug to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCPs. If the FDA determines that the application, manufacturing process, or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates an NDA, it will issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete, and the application will not be approved in its present form. A Complete Response Letter usually describes the specific deficiencies in the NDA identified by the FDA and may require additional clinical data, such as an additional pivotal Phase 3 clinical trial or other significant and time-consuming requirements related to clinical trials, nonclinical studies, or manufacturing. If a Complete Response Letter is issued, the sponsor must resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may decide that the NDA does not satisfy the criteria for approval.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the NDA with a REMS to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a medicine and to enable patients to have continued access to such medicines by managing their safe use. It 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. The FDA also may offer conditional approval subject to, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may also require one or more Phase 4 post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies. In addition, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could impact the timeline for regulatory approval or otherwise impact ongoing development programs.

Expedited Development and Review Programs

The FDA has a fast track designation program that is intended to expedite or facilitate the process for reviewing new drug products that meet certain criteria. Specifically, new drugs are eligible for fast track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. With regard to a fast track product, the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA. CT1812 was awarded Fast Track designation by the FDA in 2016.

Any product submitted to the FDA for approval, including a product with a fast track designation, may also be eligible for other types of FDA programs intended to expedite development and review, such as

priority review and accelerated approval. A product is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the treatment, diagnosis, or prevention of a disease compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug designated for priority review in an effort to facilitate the review. The FDA endeavors to review applications with priority review designations within six months of the filing date as compared to ten months for review of new molecular entity NDAs under its current PDUFA review goals.

In addition, a product may be eligible for accelerated approval. Drug products intended to treat serious or life-threatening diseases or conditions may be eligible for accelerated approval upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. 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. In addition, the FDA currently requires pre-approval of promotional materials as a condition for accelerated approval, which could adversely impact the timing of the commercial launch of the product.

The Food and Drug Administration Safety and Innovation Act established a category of drugs referred to as “breakthrough therapies” that may be eligible to receive breakthrough therapy designation. A sponsor may seek FDA designation of a product candidate as a “breakthrough therapy” if the product is intended, alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the fast track program features, as well as more intensive FDA interaction and guidance. The breakthrough therapy designation is a distinct status from both accelerated approval and priority review, which can also be granted to the same drug if relevant criteria are met. If a product is designated as breakthrough therapy, the FDA will work to expedite the development and review of such drug.

Fast track designation, priority review, accelerated approval, and breakthrough therapy designation do not change the standards for approval, but may expedite the development or approval process. Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. We may explore some of these opportunities for our product candidates as appropriate.

Post-Approval Requirements

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There are continuing, annual program fees for any marketed products. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us and any third-party manufacturers that we 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 compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with

manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters, or untitled letters;
- clinical holds on post-approval or Phase IV clinical studies, if applicable;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment, or exclusion from federal healthcare programs; and
- mandated modification of promotional materials and labeling and the issuance of corrective information.

Under the Pediatric Research Equity Act (PREA) an NDA must contain data to assess the safety and efficacy of the applicant product for indications in applicable pediatric populations. It must also contain information to support dose administration for pediatric populations where the drug may be utilized. FDA has the ability to grant complete waivers, partial waivers, or deferrals for compliance with PREA. PREA requirements may be waived for applications for approval of drug candidates intended to treat, mitigate, prevent, diagnose or cure diseases and other conditions that do not occur in pediatric populations. Generally PREA does not apply for drug candidates which have obtained an orphan designation, unless otherwise regulated by the FDA. Despite this, separate PREA compliance or waivers may still be required for each product indication. Although noncompliance with PREA will generally not be considered for withdrawal of an approval it may be considered by the FDA as the sole basis for enforcement action such as injunction or seizure as non-compliance and may render the drug misbranded.

The FDA closely regulates the marketing, labeling, advertising, and promotion of drug products. A company can make only those claims relating to safety and efficacy that are approved by the FDA 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. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising, and potential civil and criminal penalties. Physicians may prescribe, in their independent professional medical judgment, legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products. The federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined companies from engaging in off-label promotion. The FDA and other regulatory agencies have also required that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA-approved labelling.

Marketing Exclusivity

Market exclusivity provisions authorized under the FDCA can delay the submission and approval of certain marketing applications for products containing the same active ingredient. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to obtain approval of an NDA for a NCE. A drug is an NCE if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. The FDCA also permits patent term restoration of up to five years as compensation for a

patent term lost during product development and FDA regulatory review process to the first applicant to obtain approval of an NDA for a new chemical entity in the United States. Patent-term restoration, however, cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. During the NCE exclusivity period, the FDA may not approve or even accept for review an ANDA or an NDA submitted under Section 505(b)(2) (505(b)(2) NDA), submitted by another company for another drug based on the same active moiety, regardless of whether the drug is intended for the same indication as the original innovative drug or for another indication, where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed in the FDA's publication *Approved Drug Products with Therapeutic Equivalence Evaluations*, which we refer to as the Orange Book, with the FDA by the innovator NDA holder. Upon approval of an NDA, each of the patents listed in the application for the drug is then published in the Orange Book. These products may be cited by potential competitors in support of approval of an ANDA or 505(b)(2) NDA. Any competitor who files an ANDA seeking approval of a generic equivalent version of a drug listed in the Orange Book or a 505(b)(2) NDA referencing a drug listed in the Orange Book must make patent certifications to the FDA that (1) no patent information on the drug or method of use that is the subject of the application has been submitted to the FDA; (2) the patent has expired; (3) the date on which the patent has expired and approval will not be sought until after the patent expiration; or (4) the patent is invalid or will not be infringed upon by the manufacture, use, or sale of the drug product for which the application is submitted. Generally, the ANDA or 505(b)(2) NDA cannot be approved until all listed patents have expired, except where the ANDA or 505(b)(2) NDA applicant challenges a listed patent through the last type of certification, also known as a paragraph IV certification. If the applicant does not challenge the listed patents or indicates that it is not seeking approval of a patented method of use, the ANDA or 505(b)(2) NDA application will not be approved until all of the listed patents claiming the referenced product have expired. If the ANDA or 505(b)(2) NDA applicant has provided a paragraph IV certification the applicant must send notice of the paragraph IV certification to the NDA and patent holders once the application has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the paragraph IV certification. If the paragraph IV certification is challenged by an NDA holder or the patent owner(s) asserts a patent challenge to the paragraph IV certification, the FDA may not approve that application until the earlier of 30 months from the receipt of the notice of the paragraph IV certification, the expiration of the patent, when the infringement case concerning each such patent was favorably decided in the applicant's favor or settled, or such shorter or longer period as may be ordered by a court. This prohibition is generally referred to as the 30-month stay. In instances where an ANDA or 505(b)(2) NDA applicant files a paragraph IV certification, the NDA holder or patent owner(s) regularly take action to trigger the 30-month stay, recognizing that the related patent litigation may take many months or years to resolve. Thus, approval of an ANDA or 505(b)(2) NDA could be delayed for a significant period of time depending on the patent certification the applicant makes and the reference drug sponsor's decision to initiate patent litigation. If the drug has NCE exclusivity and the ANDA is submitted four years after approval, the 30-month stay is extended so that it expires 7 1/2 years after approval of the innovator drug, unless the patent expires or there is a decision in the infringement case that is favorable to the ANDA applicant before then.

The FDCA alternatively provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages, or strengths of an existing drug. This three-year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for drugs containing the active agent for the original indication or condition of use. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to any nonclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Pediatric exclusivity is another type of marketing exclusivity available in the United States. Pediatric exclusivity provides for an additional six months of marketing exclusivity attached to another period of exclusivity if a sponsor conducts clinical trials in children in response to a written request from the FDA. The issuance of a written request does not require the sponsor to undertake the described clinical trials. The

indications the Company is currently pursuing for its product candidates will not be eligible for pediatric exclusivity because they are age-related degenerative diseases and disorders that do not occur in the pediatric population. In addition, orphan drug exclusivity, as described above, may offer a seven-year period of marketing exclusivity, except in certain circumstances.

Other Healthcare Laws

Pharmaceutical manufacturers are subject to additional healthcare laws, regulation, and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business. Such laws include, without limitation, U.S. federal anti-kickback, anti-self-referral, false claims, transparency, including the federal Physician Payments Sunshine Act, consumer fraud, pricing reporting, data privacy, data protection, and security laws and regulations as well as similar foreign laws in the jurisdictions outside the U.S. Similar state and local laws and regulations may also restrict business practices in the pharmaceutical industry, such as state anti-kickback and false claims laws, which may apply to business practices, including but not limited to, research, distribution, sales, and marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, or by patients themselves; 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, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information; state and local laws which require the tracking of gifts and other remuneration and any transfer of value provided to physicians, other healthcare providers and entities; and state and local laws that require the registration of pharmaceutical sales representatives; and state and local laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. For example, California recently enacted the 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 certain 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 took effect on January 1, 2020, and the California Attorney General may bring enforcement actions for violations of the CCPA until January 2023. Further, California voters approved a new privacy law, the California Privacy Rights Act, or CPRA, in the November 3, 2020 election. The final text of the CPRA will be promulgated by July 1, 2022. The CPRA will be fully effective starting on January 1, 2023. The CPRA will significantly modify the CCPA, including by expanding consumers' rights with respect to certain sensitive personal information. The CPRA also creates a new state agency, the California Privacy Protection Agency, that will be vested with authority to implement and enforce the CCPA and the CPRA. New legislation proposed or enacted in various other states will continue to shape the data privacy environment nationally.

The risk of our being found in violation of these or other laws and regulations is increased by the fact that many have not been fully interpreted by the regulatory authorities or the courts and their provisions are open to various interpretations. These laws and regulations are subject to change, which can increase the resources needed for compliance and delay drug approval or commercialization. Any action brought against us for violations of these laws or regulations, even successfully defended, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Also, we may be subject to private "qui tam" actions brought by individual whistleblowers on behalf of the federal or state governments. Actual or alleged violation of any such laws or regulations may lead to investigations and other claims and proceedings by regulatory authorities and in certain cases, private actors, and violation of any of such laws or any other governmental regulations that apply may result in penalties, including, without limitation, significant administrative, civil and criminal penalties, damages, fines, additional reporting obligations, and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, the curtailment or restructuring of operations, exclusion from participation in government healthcare programs and imprisonment.

The Office of Inspector General, or OIG, continues to make modifications to existing Anti-Kickback Statute, or AKS, safe harbors which may increase liability and risk as well as adversely impact sales

relationships. On November 20, 2020, OIG issued the final rule for Safe Harbors under the Federal AKS. This new final rule creates additional safe harbors including ones pertaining to patient incentives. OIG is able to modify safe harbors as well as regulatory compliance requirements which could impact our business adversely. The majority of states also have statutes or regulations similar to these federal laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer.

Coverage and Reimbursement

Sales of any pharmaceutical product depend, in part, on the extent to which such product will be covered by third-party payors, such as federal, state, and foreign government healthcare programs, commercial insurance, and managed healthcare organizations, and the level of reimbursement for such product by third-party payors. Significant uncertainty exists as to the coverage and reimbursement status of any newly approved product. Decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. One third-party payor's decision to cover a particular product does not ensure that other payors will also provide coverage for the product. As a result, the coverage determination process can require manufacturers to provide scientific details, information on cost-effectiveness, and clinical support for the use of a product to each payor separately. This can be a time-consuming process, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

In addition, third-party payors are increasingly reducing reimbursements for pharmaceutical products and related services. The U.S. government and state legislatures have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. Third-party payors are increasingly challenging the prices charged, examining the medical necessity and reviewing the cost effectiveness of pharmaceutical products, in addition to questioning their safety and efficacy. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit sales of any product. Decreases in third-party reimbursement for any product or a decision by a third-party payor not to cover a product could reduce physician usage and patient demand for the product.

At the state level, there are also new laws and ongoing ballot initiatives that create additional pressure on drug pricing and may affect how pharmaceutical products are covered and reimbursed. A number of states have adopted or are considering various pricing actions, such as those requiring pharmaceutical manufacturers to publicly report proprietary pricing information, limit price increases or to place a maximum price ceiling or cap on certain products. Existing and proposed state pricing laws have added complexity to the pricing of pharmaceutical drug products.

In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Pharmaceutical products may face competition from lower-priced products in foreign countries that have placed price controls on pharmaceutical products and may also compete with imported foreign products. Furthermore, there is no assurance that a product will be considered medically reasonable and necessary for a specific indication, that it will be considered cost-effective by third-party payors, that an adequate level of reimbursement will be established even if coverage is available, or that the third-party payors' reimbursement policies will not adversely affect the ability for manufacturers to sell products profitably.

Healthcare Reform

In the United States and certain foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system. In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the ACA, was signed into law, which substantially changed the way healthcare is

financed by both governmental and private insurers in the United States. By way of example, the ACA increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs from 15.1% to 23.1%; it required collection of rebates for drugs paid by Medicaid managed care organizations; imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell certain “branded prescription drugs” to specified federal government programs; it implemented a new methodology under which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected; it expanded the eligibility criteria for Medicaid programs; it created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and it established a Center for Medicare Innovation at the Centers for Medicare & Medicaid Services, or CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been executive, judicial and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. Since January 2017, President Trump signed several Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have passed. For example, in 2017, Congress enacted the Tax Act, which eliminated the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year, a process that is commonly referred to as the “individual mandate.” In addition, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated “Cadillac” tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. On December 14, 2018, a Texas U.S. District Court Judge ruled that the individual mandate is a critical and inseparable feature of the ACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. On December 18, 2019, the U.S. Court of Appeals for the 5th Circuit ruled that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. On March 2, 2020, the U.S. Supreme Court granted the petitions for writs of certiorari to review the case and held oral arguments in November 2020. On June 17, 2021, the Supreme Court ruled that the plaintiffs lacked standing to challenge the law as they had not alleged personal injury traceable to the allegedly unlawful conduct. As a result, the Supreme Court did not rule on the constitutionality of the ACA or any of its provisions. There may be other efforts to challenge, repeal, or replace the ACA. If successful, it may potentially impact our business in the future.

President Joseph R. Biden, Jr. signed the Executive Order on Strengthening Medicaid and stating his administration’s intentions to reverse the actions of his predecessor and strengthen the ACA. As part of this Executive Order, the Department of Health and Human Services, United States Treasury, and the Department of Labor are to review all existing regulations, orders, guidance documents, policies, and agency actions to consider if they are consistent with ensuring both coverage under the ACA and if they make high-quality healthcare affordable and accessible to Americans. We are unable to predict the likelihood of changes to the Affordable Care Act or other healthcare laws which may negatively impact our profitability. President Biden intends, as his predecessor did, to take action against drug prices which are considered “high.” The most likely time to address this would be in the reauthorization of the Prescription Drug User Fee Act, or PDUFA, in 2022 as part of a package bill. Drug pricing continues to be a subject of debate at the executive and legislative levels of U.S. government and we expect to see legislation focusing on this in the coming year. The American Rescue Plan Act of 2021 signed into law by President Biden on March 14, 2021 includes a provision that will eliminate the statutory cap on rebates drug manufacturers pay to Medicaid beginning in January 2024. With the elimination of the cap, manufacturers may be required to compensate states in an amount greater than what the state Medicaid programs pay for the drug.

Other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, effective April 1, 2013, which, due to subsequent legislative amendments, will stay in effect through 2030 with the exception of a temporary suspension implemented under various COVID-19 relief legislation from May 1, 2020 through

March 31, 2021, unless additional congressional action is taken. Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted legislation designed, among other things, to bring more transparency to product pricing, to review the relationship between pricing and manufacturer patient programs, and to reform government program reimbursement methodologies for pharmaceutical products. The Prescription Drug Pricing Reduction Act, or PDPRA, which was introduced in Congress in 2019, and again in 2020, proposed to, among other things, penalize pharmaceutical manufacturers for raising prices on drugs covered by Medicare Parts B and D faster than the rate of inflation, cap out-of-pocket expenses for Medicare Part D beneficiaries, and proposes a number of changes to how drugs are reimbursed in Medicare Part B. A similar drug pricing bill, the Elijah E. Cummings Lower Drug Costs Now Act proposes to enable direct price negotiations by the federal government on certain drugs (with the maximum price paid by Medicare capped based on an international index), requires manufacturers to offer these negotiated prices to other payers, and restricts manufacturers from raising prices on drugs covered by Medicare Parts B and D. This Act passed in the House of Representatives when it was introduced in 2019, and it has been introduced again in the 2021 term. We cannot predict whether any proposed legislation will become law and the effect of these possible changes on our business cannot be predicted at this time.

Legal Proceedings

We are not currently a party to any material legal proceedings. From time to time, we may become involved in other litigation or legal proceedings relating to claims arising from the ordinary course of business.

MANAGEMENT

The following table sets forth information regarding our executive officers and directors:

Name	Age	Position(s)
Executive Officers		
Lisa Ricciardi	61	Chief Executive Officer, President and Director
James M. O'Brien	54	Chief Financial Officer
Employee Director		
Susan Catalano, Ph.D.	57	Director and Chief Science Officer
Non-Employee Directors		
Jack A. Khattar	59	Director, Chairman of the Board
Brett P. Monia, Ph.D.	59	Director
Aaron Fletcher, Ph.D.	41	Director
Stephen Sands	64	Director
Peggy Wallace	64	Director
Mark H. Breedlove	64	Director

Executive Officers***Lisa Ricciardi***

Ms. Ricciardi has served as our Chief Executive Officer and President since March 2020 and as a member of our board of directors since March 2019. From July 2018 to October 2019, she served as CEO of Suono Bio, a biotech company based on Langer Labs (MIT) technology. Prior to her position at Suono Bio, Ms. Ricciardi was a retained executive for BioBusiness Links from November 2015 to June 2018 where she performed interim operating executive and advisory board roles. She served as the Senior Vice President, Global Corporate & Business Development of Foundation Medicine from July 2014 to November 2015, and Senior Vice President, US and International Business Development of Express Scripts from October 2010 to October 2012 and in both cases, led deal teams to sell the two companies. Ms. Ricciardi was in the commercial division of Pfizer Inc., taking three drugs to launch before being appointed by the Chairman to run Global Business Development. Ms. Ricciardi previously served on the boards of Contrafect (Nasdaq: CFRX), Chimerix (Nasdaq: CMRX), United Drug Healthcare Group, PLC (LSE: UDG) and Sepracor (Nasdaq: SEPR). She was appointed as the executive in residence at Columbia Technology Ventures in January 2020.

Ms. Ricciardi earned a Bachelor of Arts degree cum laude in English and Religion from Wesleyan University and an MBA from the University of Chicago Booth School of Management.

We believe that Ms. Ricciardi is qualified to serve on our board of directors due to the valuable experience she brings in her capacity as our Chief Executive Officer and President along with her extensive experience and knowledge of our industry.

James M. O'Brien

Mr. O'Brien has served as our Chief Financial Officer since October 2019. From February 2014 to October 2019, Mr. O'Brien served as Executive Vice President of finance for Enzo Biochem, Inc. (NYSE: ENZ), a biotechnology company providing reference laboratory services to the medical community. From November 2010 to June 2013, Mr. O'Brien served as Vice President and Corporate Controller for Allergan, Inc., (formerly known as Actavis plc.) which has now been acquired by Abbvie (NYSE: ABBV), a pharmaceutical company. He also previously served as a Vice President at Takeda Pharmaceuticals (NYSE: TAK) (formerly known as Nycomed) from January 2010 to August 2010, Chief Accounting Officer at USI Holdings from January 2008 to August 2009, and Vice President and Corporate Controller at Aptuit, an Evotec company (Frankfurt Stock Exchange: EVT) and pharmaceutical services provider, from July 2005

to December 2007. Mr. O'Brien also held leadership roles at Purdue Pharma, Bristol-Myers Squibb and PricewaterhouseCoopers in the earlier stages of his career.

Mr. O'Brien is a certified public accountant (CPA) with a Bachelor of Accountancy from George Washington University and an MBA from Fordham University.

Employee Director

Susan Catalano, Ph.D.

Dr. Catalano is a pharmaceutical industry executive with 22 years of experience in strategic and operational scientific leadership of neurobiology and oncology drug discovery and development programs. She is currently our Chief Science Officer and member of our board of directors since co-founding our company in 2007. Dr. Catalano guided the discovery and development of CT1812. She also established the "International Symposium on sigma-2 Receptors (ISS2R): Role in Health and Disease," now in its fifth year, authored numerous publications and patents and continues to serve as principal investigator of several National Institute of Health, or NIH, awards, and has served on various NIH review panels in the areas of drug discovery and clinical development for neurodegenerative diseases and on the editorial Board of Assay and Drug Discovery Technologies for over 10 years. Previously, she held scientific leadership positions at Acumen Pharmaceuticals, Inc. from 2004 to 2007, Rigel Pharmaceuticals, Inc. from 2001 to 2003, and Roche Biosciences from 1999 to 2001.

Dr. Catalano received her Bachelor of Arts from Barnard College and Ph.D. in Neurobiology from U.C. Irvine with postdoctoral training at U.C. Berkeley and Caltech.

We believe that Dr. Catalano is qualified to serve on our board of directors due to her extensive experience leading the company's discovery and development efforts since its inception, scientific expertise on receptor and disease biology, and knowledge of our industry.

Non-employee Directors

Jack A. Khattar

Mr. Khattar has served as member of our board of directors since July 2020 and was appointed chairman in April 2021. Mr. Khattar founded Supernus Pharmaceuticals, Inc., a pharmaceutical company (Nasdaq:SUPN), in 2005 and has served as its President, Chief Executive Officer, Secretary and director since then. Since June 2016, Mr. Khattar has served as a member of the board of directors of scPharmaceuticals Inc., a pharmaceutical company (Nasdaq:SCPH), and has served as its chairperson since June 2016. From 1999 to 2005, Mr. Khattar served in various positions during that time as a board member, President and Chief Executive Officer of Shire Laboratories Inc., the drug delivery subsidiary of Shire plc. From 1999 to 2004, he also served as a member of Shire plc's Executive Committee. Prior to that, Mr. Khattar served as an executive officer and the chairman of the Management Committee at CIMA Labs Inc., a drug delivery company where he was also responsible for business development, corporate alliances and strategic planning. Prior to joining CIMA in 1995, Mr. Khattar held several marketing and business development positions at Merck & Co., Novartis International AG, Playtex and Kodak Company in various locations, including the United States, Europe and the Middle East. Mr. Khattar currently serves on the board of Navitor Pharmaceuticals, Inc., a private company, since 2020 and Supernus Pharmaceuticals (Nasdaq: SUPN) since 2005. He previously served on the board of Rockville Economic Development, Inc. from 2003 to 2013 and Prevacus, Inc., a privately held development stage biotechnology company from 2015 to 2020. Mr. Khattar has also served on the Advisory Board of New Rhein Healthcare, a private equity firm, since 2019.

Mr. Khattar earned his degrees in Marketing with a BBA from American University of Beirut and an MBA from the Wharton School of the University of Pennsylvania.

We believe that Mr. Khattar is qualified to serve on our board of directors due his leadership, executive, managerial, business and pharmaceutical company experience, along with his more than 30 years of industry experience in the development and commercialization of pharmaceutical products.

Brett P. Monia, Ph.D.

Dr. Monia has served as a member of our board of directors since October 2020. Dr. Monia founded Ionis Pharmaceuticals, Inc., a biotechnology company (Nasdaq: IONS), in 1989, and has served as its Chief Executive Officer since January 2020 after serving as the Chief Operating Officer and Senior Vice President since 2018, as a member of its board of directors since March 2019, and in various other positions with the company since its founding. He is also a director of Dynacure LTD, a clinical stage drug development company, since 2016.

Dr. Monia received his Bachelor of Science in Biology, Biological Sciences and Chemistry from Stockton State College and a Ph.D. in Pharmacology from the University of Pennsylvania.

We believe that Dr. Monia is qualified to serve on our board of directors due to his extensive management experience and deep understanding of our industry.

Aaron Fletcher, Ph.D.

Dr. Fletcher has served as a member of our board of directors since July 2015. In 2014, Dr. Fletcher founded Bios Partners, LP, a biotech venture capital firm, and has served as its Managing Partner since then. In 2012, Dr. Fletcher founded Bios Research, LLC, a financial services firm that provides public equity research in the healthcare space tailored to institutional firms and large family offices. He also currently serves as a director of Cue Biopharma (NYSE: CUE) since October 2019, SKW Holdings Corporation (Nasdaq: SWKH) since August 2019, TFF Pharmaceuticals (Nasdaq: TFFP) since March 2018 where he serves as the chairman of the board, AbiliTech Medical, Inc. since November 2016, Actuate Therapeutics, Inc. since January 2015 where he serves as the chairman of the board, and LTI since August 2014. Dr. Fletcher has also served as a professor at Dallas Baptist University since 2008, where he teaches biochemistry, bioethics and cell biology.

Dr. Fletcher holds a BS in Biology from York College and received his Ph.D. in Biochemistry from Colorado State University.

We believe that Dr. Fletcher is qualified to serve on our board of directors due to his extensive business experience and board membership in venture capital and life science companies.

Stephen Sands

Mr. Sands has served as member of our board of directors since June 2017. Mr. Sands has served as Vice Chairman of Investment Banking since March 2014 and Chairman of the Healthcare Group at Lazard Group LLC since May 2016 and has held other positions at Lazard since 1994. From July 1986, Mr. Sands worked at McKinsey & Company, leaving as a Partner in the healthcare practice in October 1994. While on leave from McKinsey from December 1987 to August 1990, he co-founded two life sciences companies: Enzytech (acquired by Alkermes) and Opta Food Ingredients (acquired by Stake Technology and now SunOpta). He currently is a director of Cytosite Biopharma Inc., a private biotechnology company, since February 2019. Mr. Sands has previously served as director on the boards of several life sciences companies, including National Imaging Associates (acquired by Magellan Health), Inc. and Isogen LLC. (acquired by Monsanto).

In addition to his responsibilities at Lazard, Mr. Sands is a member of the Washington University (St. Louis) School of Engineering & Applied Science National Counsel and of the board of trustees of the New York Hall of Science. Mr. Sands earned a Bachelor of Arts in Biology from Oberlin College, a Bachelor of Science and Master of Science in Chemical Engineering from Washington University in St. Louis, and an MBA with a concentration in Finance from New York University.

We believe that Mr. Sands is qualified to serve on our board of directors due to his deep knowledge of the life sciences industry and financial advisory experience in the biopharma sector.

Peggy Wallace

Ms. Wallace has served as member of our board of directors since September 2016. Ms. Wallace has served as Co-Chief Executive Officer and Managing Partner of Golden Seeds, LLC and Golden Seeds

Funds, an investment company, since 2011 and 2008, respectively, prior to which she served as a Managing Director from 2005 to 2008. Ms. Wallace currently is a member of the boards of directors of two private companies: Chromis Fiberoptics, a fiber optic products supplier, since 2006, and ShipperBee, a delivery company, since January 2018.

Ms. Wallace received her Bachelor of Arts from George Washington University.

We believe that Ms. Wallace is qualified to serve on our board of directors due to her extensive business experience and experience in venture capital and the life science industry.

Mark H. Breedlove

Mark H. Breedlove has served as member of our board of directors since January 2011. Since 2010, Mr. Breedlove served as General Partner for the Breedlove Family Limited Partnership, a family investment partnership, where he is responsible for all direct investment activity, including a strategy of investing in life sciences companies. Since 2003, Mr. Breedlove also has served as President and CEO of Keystone Profiles, Ltd., a steel manufacturing company. From 1999 to 2000, Mr. Breedlove served as President, COO and a member of the Board of Directors of Qualitor Inc., an aftermarket vehicle parts company.

Mr. Breedlove has a Bachelor of Science degree in Business Administration, Finance, from the Pennsylvania State University. He also has an MBA with an emphasis in Finance from the University of Michigan.

We believe that Mr. Breedlove is qualified to serve on our board of directors due to his experience as an investor and his experience with financial matters in a variety of businesses.

Family Relationships

There are no family relationships among our directors and executive officers.

Board Composition and Election of Directors

Our board of directors is currently comprised of eight directors. Six of our directors qualify as independent directors in accordance with the independent director guidelines of Nasdaq. The election of the members of our board of directors is currently governed by the third amended and restated voting agreement that we entered into with certain holders of our common stock and convertible preferred stock and the related provisions of our second amended and restated certificate of incorporation. Pursuant to our third amended and restated voting agreement and second amended and restated certificate of incorporation, our current directors were elected as follows:

- Ms. Wallace was elected as the designee of Golden Seeds Cognition Therapeutics LLC, Golden Seeds Fund LP, Golden Seeds Advisors Fund 2 LP and/or Golden Seeds Fund 2 LP and/or any of their affiliates;
- Dr. Fletcher was elected as a designee of BIOS Memory SPV I, LP and/or any of its affiliates;
- Dr. Monia was elected by the holders of our common stock and convertible preferred stock and designated as an industry expert;
- Ms. Ricciardi was elected by the holders of our common stock and convertible preferred stock and designated as our then-serving and current Chief Executive Officer;
- Mr. Breedlove, Mr. Khattar and Mr. Sands were elected by the holders of our common stock and our convertible preferred stock; and
- Dr. Catalano was elected as the designee by certain holders pursuant to a voting agreement that terminates upon closing of this offering.

After this offering, the number of directors will be fixed by our board of directors, subject to the terms of our third amended and restated certificate of incorporation and amended and restated bylaws that will become effective immediately prior to the closing of this offering. Each of our current directors will continue

to serve as a director until the election and qualification of his or her successor, or until his or her earlier death, resignation or removal.

Classified Board of Directors

In accordance with our third amended and restated certificate of incorporation, which will become effective immediately prior to the closing of this offering, our directors will be divided into three classes serving staggered three-year terms. At each annual meeting of stockholders, a class of directors will be subject to re-election for a three-year term. As a result, only one class of directors will be elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms. Our current directors will be divided among the three classes as follows:

- the Class I directors will be _____, _____, and _____, and their terms will expire at the first annual meeting of stockholders held following the closing of this offering;
- the Class II directors will be _____, _____, and _____, and their terms will expire at the second annual meeting of stockholders held following the closing of this offering; and
- the Class III directors will be _____, _____, and _____, and their terms will expire at the third annual meeting of stockholders held following the closing of this offering.

Each director's term continues until the election and qualification of his or her successor, or his or her earlier death, resignation or removal. Our third amended and restated certificate of incorporation and our amended and restated bylaws, which will become effective immediately prior to the closing of this offering, will authorize only our board of directors to fill vacancies on our board of directors. Any increase or decrease in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors. The classification of our board of directors may have the effect of delaying or preventing a change in control or management. See "Description of Capital Stock — Anti-Takeover Provisions of Delaware Law and our Charter Documents" for a discussion of other anti-takeover provisions will be included in our third amended and restated certificate of incorporation.

Board Leadership Structure

Our board of directors is currently led by our Chairman, Mr. Khattar, an independent director. Our board of directors recognizes that it is important to determine an optimal board leadership structure to ensure the independent oversight of management as the company continues to grow. We separate the roles of chief executive officer and chairman of the board of directors in recognition of the differences between the two roles. The chief executive officer is responsible for setting the strategic direction for our company and the day-to-day leadership and performance of our company, while the chairman of the board of directors provides guidance to the chief executive officer and presides over meetings of the full board of directors. We believe that this separation of responsibilities provides a balanced approach to managing the board of directors and overseeing our company.

Our board of directors has concluded that our current leadership structure is appropriate at this time. However, our board of directors will continue to periodically review our leadership structure and may make such changes in the future as it deems appropriate.

Role of Board in Risk Oversight

Risk assessment and oversight are an integral part of our governance and management processes. Our board of directors encourages management to promote a culture that incorporates risk management into our corporate strategy and day-to-day business operations. Management discusses strategic and operational risks at regular management meetings, and conducts specific strategic planning and review sessions during the year that include a focused discussion and analysis of the risks facing us. Throughout the year, senior management reviews these risks with the board of directors at regular board meetings as part of management presentations that focus on particular business functions, operations or strategies, and presents the steps taken by management to mitigate or eliminate such risks.

Our board of directors does not have a standing risk management committee, but rather administers this oversight function directly through our board of directors as a whole, as well as through various standing

committees of our board of directors that address the risks inherent in their respective areas of oversight. While our board of directors is responsible for monitoring strategic risk exposure, our audit committee oversees management of financial reporting, compliance and litigation risks, as well as the steps management has taken to monitor and control such exposures. Our nominating and corporate governance committee manages risks associated with the independence of our board of directors, potential conflicts of interest and the effectiveness of our board of directors and our compensation committee is responsible for overseeing the management of risks relating to our executive compensation policies, plans and arrangements and the extent to which those policies or practices increase or decrease risks for our company.

Director Independence

In connection with this offering, we intend to apply to list our common stock on the Nasdaq Global Market. Under the Nasdaq listing rules, or the Listing Rules, independent directors must comprise a majority of a listed company's board of directors within a specified period following the closing of this offering. In addition, the Nasdaq Listing Rules require that, subject to specified exceptions, each member of a listed company's audit, compensation and nominating and governance committees be independent. Under the Nasdaq Listing Rules, a director will only qualify as an "independent director" if, in the opinion of that company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

Audit committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Securities Exchange Act of 1934, as amended, or the Exchange Act. In order to be considered independent for purposes of Rule 10A-3, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors or any other board committee: (i) accept, directly or indirectly, any consulting, advisory or other compensatory fee from the listed company or any of its subsidiaries; or (ii) be an affiliated person of the listed company or any of its subsidiaries. We intend to satisfy the audit committee independence requirements of Rule 10A-3 as of the closing of this offering.

Additionally, compensation committee members must not have a relationship with us that is material to the director's ability to be independent from management in connection with the duties of a compensation committee member. We intend to satisfy the compensation committee independence requirements as of the closing of this offering.

Our board of directors has undertaken a review of the independence of each director and determined that all of our directors, other than Ms. Ricciardi and Dr. Catalano, qualify as "independent" directors in accordance with the Nasdaq Listing Rules. Ms. Ricciardi and Dr. Catalano are not considered independent by virtue of their position as our Chief Executive Officer and President, and as our Chief Science Officer, respectively. In making these determinations, our board of directors reviewed and discussed information provided by the directors and us with regard to each director's business and personal activities and relationships as they may relate to us and our management.

Board Committees

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee. Our board of directors may establish other committees to facilitate the management of our business, each of which have the composition and responsibilities described below. The composition and functions of each committee are described below. Members serve on these committees until their resignation or until otherwise determined by our board of directors. Each committee intends to adopt a written charter that satisfies the applicable rules and regulations of the SEC and Nasdaq Listing Rules, which we will post on our website at www.cogrx.com upon the closing of this offering.

Audit Committee

Our audit committee consists of _____, _____ and _____. Our board of directors has determined that each member of our audit committee is independent under the Nasdaq Listing Rules and Rule 10A-3(b)(1) of the Exchange Act. The chair of our audit committee is _____. Our board of directors has determined that each member of the audit committee can read and understanding fundamental

consolidated financial statements and that _____ is an “audit committee financial expert” as such term is currently defined in Item 407(d)(5) of Regulation S-K. Our audit committee is directly responsible for, among other things:

- appointing, evaluating, and overseeing a firm to serve as our independent registered public accounting firm to audit our consolidated financial statements;
- ensuring the independence of the independent registered public accounting firm;
- discussing the scope and results of the audit with the independent registered public accounting firm and reviewing, with management and that firm, our interim and year-end operating results;
- establishing procedures for employees to anonymously submit concerns about questionable accounting or audit matters;
- considering the adequacy of our internal controls and internal audit function;
- monitoring and reviewing legal, regulatory, and administrative compliance to the extent affecting our financial results;
- reviewing proposed waivers of the code of business conduct and ethics for directors and executive officers;
- reviewing and recommending changes or amendments to the code of business and conduct and ethics;
- reviewing material related party transactions or those that require disclosure;
- determining and reviewing risk assessment guidelines and policies, including cybersecurity risks, financial risk exposure, and internal controls regarding information security; and
- approving or, as permitted, pre-approving all audit and non-audit services to be performed by the independent registered public accounting firm.

Compensation Committee

Our compensation committee consists of _____, _____ and _____. Our board of directors has determined that each member of this committee is a non-employee director, as defined by Rule 16b-3 promulgated under the Exchange Act and meets the requirements for independence under the Nasdaq Listing Rules. The chair of our compensation committee is _____. The compensation committee is responsible for, among other things:

- reviewing and approving the compensation of our executive officers and recommending that our board of directors approve, the compensation of our Chief Executive Officer;
- reviewing and recommending to our board of directors the compensation of our directors;
- administering our stock and equity incentive plans and overseeing regulatory compliance related to such plans;
- reviewing and approving, or making recommendations to our board of directors with respect to, incentive compensation and equity plans; and
- reviewing our overall compensation philosophy.

Nominating and Corporate Governance Committee

Our nominating and corporate governance committee consists of _____, _____ and _____. Our board of directors has determined that each member of the nominating and corporate governance committee meets the requirements for independence under the Nasdaq Listing Rules. The chair of our nominating and corporate governance committee is _____. The nominating and corporate governance committee is responsible for, among other things:

- developing and recommending selection criteria for new directors for our board of directors;
- identifying and recommending candidates for membership on our board of directors;

- reviewing and determining board director independence annually and, as needed, as potential conflicts of interest arise;
- reviewing and recommending our corporate governance guidelines and policies;
- overseeing the process of evaluating the performance of our board of directors; and
- assisting our board of directors on corporate governance matters.

Compensation Committee Interlocks and Insider Participation

None of the members of our compensation committee is currently, or has been at any time, one of our executive officers or employees. None of our executive officers currently serves, or has served during the last year, as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving as a member of our board of directors or on our compensation committee.

Board Diversity

Upon the closing of this offering, our nominating and corporate governance committee will be responsible for reviewing with the board of directors, on an annual basis, the appropriate characteristics, skills and experience required for the board of directors as a whole and its individual members. In evaluating the suitability of individual candidates (both new candidates and current members), the nominating and corporate governance committee, in recommending candidates for election, and the board of directors, in approving (and, in the case of vacancies, appointing) such candidates, may take into account many factors, including but not limited to the following:

- personal and professional integrity;
- ethics and values;
- experience in corporate management, such as serving as an officer or former officer of a publicly held company;
- professional and academic experience relevant to our industry;
- experience as a board member of another publicly held company;
- strength of leadership skills;
- experience in finance and accounting and/or executive compensation practices;
- ability to devote the time required for preparation, participation and attendance at board of directors' meetings and committee meetings, if applicable;
- background, gender, age and ethnicity;
- conflicts of interest; and
- ability to make mature business judgments.

Following the closing of this offering, our board of directors will evaluate each individual in the context of the board of directors as a whole, with the objective of ensuring that the board of directors, as a whole, has the necessary tools to perform its oversight function effectively in light of our business and structure.

Non-employee Director Compensation

The following table presents the total compensation earned by each of our non-employee directors in the year ended December 31, 2020. Other than as described below, none of our non-employee directors received any other compensation in the year ended December 31, 2020.

Name	Fees earned or paid in cash (\$)	Option awards (\$) ⁽¹⁾	All other compensation (\$)	Total (\$)
Jack A. Khattar	19,000	40,711	—	59,711
Brett P. Monia, Ph.D.	9,625	40,092	—	49,717
Aaron Fletcher, Ph.D.	—	11,543	—	11,543
Stephen Sands	25,000	7,723	—	32,723
Peggy Wallace	—	11,543	—	11,543
Mark H. Breedlove	—	11,543	—	11,543

(1) Amounts in this column represent the aggregate grant date fair value of the stock options awarded to our directors in fiscal year 2020. For a discussion of the assumptions and methodologies used to calculate the amounts referred to above, please see the discussion of option awards contained in Note 13, Stock Based Compensation, to our financial statements included elsewhere in this filing. As of December 31, 2020, each non-employee director held outstanding options to acquire the following number of shares: Mr. Khattar, 135,000; Dr. Monia, 135,000; Dr. Fletcher, 62,500; Mr. Sands, 172,500; Ms. Wallace, 62,500; and Mr. Breedlove, 74,621.

Non-employee Director Compensation Policy

Prior to this offering, we did not have a formal policy to provide any cash or equity compensation to our non-employee directors for their service on our board of directors or committees of our board of directors. The Company has entered into the following agreements, amended certain agreements, and granted the following awards:

- In 2020, in connection with joining our board of directors as independent, non-employee directors, we entered into agreements with Mr. Khattar and Dr. Monia whereby they would be paid \$50,000 per annum, prorated for any partial year of service, plus a one-time option award of 135,000 shares. Mr. Khattar and Dr. Monia are also eligible for annual option awards of 25,000 shares.
- In 2020, the board of directors awarded Mr. Sands 25,000 stock options. In addition, in order to compensate Mr. Sands on terms consistent with other independent, non-employee directors, as outlined in the agreements entered into with Dr. Monia and Mr. Khattar, our board of directors approved payment to Mr. Sands of \$50,000 per annum, prorated for any partial year, effective as of June 30, 2020.
- Non-independent directors generally receive an option award to purchase 12,500 shares of our common stock in respect of each year of service on the board. Accordingly, during 2020, our board of directors awarded Dr. Fletcher, Ms. Wallace and Mr. Breedlove 37,500 stock options each, for prior and current years of service.
- Director stock option awards generally vest in four equal annual installments on the first, second, third and fourth anniversaries from the date of grant or from the date of appointment to the board.

In connection with this offering, our board of directors approved the following annual non-employee director compensation program, which will take effect following the closing of this offering.

Compensation Elements: Non-Employee Director Compensation Policy

Cash	
Annual Retainer	\$
Annual Committee Chair Retainer	
Audit	\$
Compensation	\$
Nominating and Corporate Governance	\$
Annual Committee Member Retainer	
Audit	\$
Compensation	\$
Nominating and Corporate Governance	\$
Equity	
Initial Equity Grant	
Annual Equity Retainer	

Each annual cash retainer will be paid quarterly in arrears. Our board of directors may, in its discretion, permit a non-employee director to elect to receive any portion of the annual cash retainer in the form of fully vested shares of our common stock in lieu of cash.

Code of Business Conduct and Ethics

In connection with this offering, our board of directors will adopt a written code of business conduct and ethics that will apply to all of our directors, officers and employees. The code of business conduct and ethics will cover fundamental ethics and compliance-related principles and practices such as accurate accounting records and financial reporting, avoiding conflicts of interest, the protection and use of our property and information and compliance with legal and regulatory requirements. Our code of business conduct and ethics will be posted on the investor relations section of our website at www.cogrx.com. We intend to disclose any amendments to our code of business conduct and ethics, or waivers of its requirements, on our website to the extent required by the applicable rules and exchange requirements.

Limitation on Liability and Indemnification Matters

Our third amended and restated certificate of incorporation and our amended and restated bylaws, which will each become effective immediately prior to the closing of this offering, will limit our directors' liability and may indemnify our directors and officers to the fullest extent permitted under the Delaware General Corporation Law, or DGCL. The DGCL provides that directors of a corporation will not be personally liable for monetary damages for breach of their fiduciary duties as directors, except for liability for:

- any breach of the director's duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- any unlawful payment of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the DGCL; or
- any transaction from which the director derived an improper benefit.

The DGCL and our amended and restated bylaws provide that we will, in certain situations, indemnify our directors and officers and may indemnify other employees and other agents, to the fullest extent permitted by law.

We have entered or intend to enter into indemnification agreements with each of our directors and officers. These indemnification agreements may require us, among other things, to indemnify our directors and officers for some expenses, including attorneys' fees, judgments, penalties, fines and settlement amounts incurred by a director or officer in any action or proceeding arising out of his or her service as one of our directors or officers, or any of our subsidiaries or any other company or enterprise to which the person provides services at our request. Subject to certain limitations, our indemnification agreements also require us to advance expenses incurred by our directors, officers and key employees for the defense of any action for which indemnification is required or permitted.

We maintain a directors' and officers' insurance policy pursuant to which our directors and officers are insured against liability for actions taken in their capacities as directors and officers. We believe that these provisions in our amended and restated certificate of incorporation and amended and restated bylaws and these indemnification agreements are necessary to attract and retain qualified persons as directors and officers.

The limitation of liability and indemnification provisions in our third amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against our directors and officers for breach of their fiduciary duty. They may also reduce the likelihood of derivative litigation against our directors and officers, even though an action, if successful, might benefit us and our stockholders. Further, a stockholder's investment may be adversely affected to the extent that we pay the costs of settlement and damage awards against directors and officers as required by these indemnification provisions.

At present, there is no pending litigation or proceeding involving any of our directors, officers or employees for which indemnification is sought and we are not aware of any threatened litigation that may result in claims for indemnification.

Insofar as indemnification for liabilities arising under the Securities Act, may be permitted to directors, officers or control persons, in the opinion of the SEC, such indemnification is against public policy, as expressed in the Securities Act and is therefore unenforceable.

EXECUTIVE COMPENSATION

Our named executive officers, or NEOs, for the year ended December 31, 2020, which consist of our current principal executive officer our former principal executive officer, and our other most highly compensated executive officer, are:

- Lisa Ricciardi, our Chief Executive Officer and President;
- Kenneth I. Moch, our former Chief Executive Officer and President; and
- James M. O'Brien, our Chief Financial Officer.

Summary Compensation Table

The following table provides information regarding the compensation earned by our NEOs for the year ended December 31, 2020.

Name and principal position	Year	Salary (\$)	Bonus (\$)	Option awards (\$) ⁽¹⁾	Non-equity incentive plan compensation (\$) ⁽²⁾	All other compensation (\$)	Total (\$)
Lisa Ricciardi ⁽³⁾	2020	287,385	—	901,904	79,893	3,415 ⁽⁴⁾	1,272,597
<i>Chief Executive Officer</i>							
Kenneth I. Moch ⁽⁵⁾	2020	93,591	—	—	—	609,293 ⁽⁶⁾	702,884
<i>Former Chief Executive Officer and President</i>							
James M. O'Brien	2020	340,000	—	—	70,890	7,323 ⁽⁴⁾	418,213
<i>Chief Financial Officer</i>							

- (1) Amounts shown in this column represent the aggregate grant date fair value of the stock options awarded to the NEO in fiscal year 2020. For a discussion of the assumptions and methodologies used to calculate the amounts referred to above, please see the discussion of option awards contained in Note 13, Stock Based Compensation, to our financial statements included elsewhere in this prospectus. The amounts reported in this column reflect the accounting cost for these stock options and do not correspond to the actual economic value that may be received by the NEO upon exercise of the stock options.
- (2) Amounts shown are cash incentive payments earned in respect of 2020 performance and paid in 2021.
- (3) Ms. Ricciardi served as a non-employee director beginning in January 2020, and was appointed our Chief Executive Officer and President in March 2020. The amount shown in the Option Awards column includes an option grant with a grant date fair value of \$7,696, awarded to Ms. Ricciardi at the beginning of 2020 as compensation for her services as a non-employee director.
- (4) Amounts shown are Company 401(k) match payments.
- (5) Mr. Moch resigned as Chief Executive Officer and President in March 2020.
- (6) Amounts shown for Mr. Moch represent severance of \$386,250 (payable over the 12-month period following his termination date of March 17, 2020), a lump sum payment of \$104,288, accrued vacation payment of \$14,856 and payment of \$100,000 in connection with consulting services payable over the 12-month period following his termination date. In addition, Mr. Moch received \$3,899 in Company match 401(k) payments prior to his termination date.

Narrative Disclosure to the Summary Compensation Table

Elements of Compensation

The compensation of our NEOs generally consists of base salary, annual cash bonus opportunities, long term incentive compensation in the form of equity awards and other benefits, as described below.

Base Salary

The base salary payable to each NEO is intended to provide a fixed component of compensation reflecting the executive's skill set, experience, role, responsibilities, and contributions. Each NEO's initial base salary was specified in her or his employment agreement or letter agreement, as described below, and is reviewed (and, if applicable, adjusted) from time to time by our board of directors or compensation committee. For 2020, the NEOs' annual base salary rates were: \$386,000 for Ms. Ricciardi, \$340,000 for Mr. O'Brien and \$386,250 for Mr. Moch. Ms. Ricciardi's and Mr. O'Brien's base salaries remain unchanged for 2021.

Annual Performance-Based Bonus

Each of our NEOs' performance-based cash bonus opportunity is expressed as a percentage of base salary that can be achieved at a target level by meeting predetermined corporate and individual performance objectives. Our compensation committee annually sets each executive's target bonus for the year. The 2020 annual bonus for Ms. Ricciardi and Mr. O'Brien were targeted at 40% and 30% of their respective base salaries. Mr. Moch did not receive a bonus for 2020.

For 2020, all NEOs were eligible to earn their annual bonuses pursuant to the achievement of corporate and/or individual performance goals, including certain clinical milestones, pipeline, platform and manufacturing development, operations, financing, corporate development, human resources, scientific leadership, and intellectual property. Following a review of the corporate goals attained in 2020, our compensation committee recommended, and our board of directors approved, 2020 annual bonus payments to each of Ms. Ricciardi and Mr. O'Brien in an amount equal to 70% of their respective target bonus amounts, totaling \$79,893 and \$70,890, respectively (pro-rated in the case of Ms. Ricciardi, to account for her start date).

Long Term Equity Incentives

Our equity-based incentive awards are designed to align our interests and the interests of our stockholders with those of our employees and consultants, including our NEOs. Our board of directors or compensation committee approves equity grants. Ms. Ricciardi received options to purchase shares of our common stock in 2020. See "— Employment Arrangements with our NEOs" for more information regarding equity awards made in 2020 to Ms. Ricciardi.

Employment Arrangements with our NEOs*Lisa Ricciardi*

In February 2020, in her capacity as a director, we issued to Ms. Ricciardi an option to purchase 25,000 shares of our common stock, at an exercise price of \$0.33. The option will vest over a four-year period, with 25% of the shares of our common stock underlying the option vesting on March 7, 2021, and 75% of the shares of common stock underlying the option vesting in equal annual installments thereafter.

In March 2020, we entered into an interim CEO letter agreement with Ms. Ricciardi, which provided for a six-month term through September 2020 and her continued service as a member of our board. Pursuant to her interim CEO letter agreement, we issued to Ms. Ricciardi a fully vested option to purchase 65,000 shares of our common stock at an exercise price of \$0.37 per share.

In June 2020, we terminated and replaced Ms. Ricciardi's interim CEO letter agreement with a new employment agreement when she assumed her permanent position. Ms. Ricciardi's current employment agreement provides for her at-will employment as our Chief Executive Officer and President and sets her initial annual base salary at \$386,000 and her initial target annual bonus opportunity at 40% of her base salary (pro-rated for 2020). Ms. Ricciardi's annual performance bonus was prorated based on the portion of the fiscal year during which she was actually employed as the Chief Executive Officer, including her time served in an interim capacity.

Ms. Ricciardi's employment agreement also provided for the issuance of an option (the "Initial Stock Option") to purchase 2,898,689 shares of our common stock, or 5% of our fully diluted equity, at an exercise

price of \$0.37 per share. The Initial Stock Option will vest over a four-year period, with 25% of the common stock underlying the Initial Stock Option vesting on June 1, 2021, and 75% of our common stock underlying the Initial Stock Option vesting in 36 equal monthly installments thereafter. We will also issue an option to purchase shares of our common stock upon completion of the next subsequent offering of an additional series of preferred stock at a price per share equal to \$1.15 in an amount necessary to maintain Ms. Ricciardi's fully diluted equity position at a minimum of 5% and at an exercise price per share equal to the fair market of our common stock on the date of issuance. Should Ms. Ricciardi's performance exceed expectation but the additional series of preferred stock offering does not reach the specified price hurdle, our board of directors will not unreasonably withhold the additional stock options.

Additionally, Ms. Ricciardi's employment agreement provides for the issuance of stock options to purchase shares of our common stock representing an aggregate of 2% of our fully diluted equity, in the event that we achieve certain performance targets upon one or more offerings of our equity securities. We expect that these performance metrics will be achieved in connection with the closing of this offering and intend to grant these options to purchase _____ shares of our common stock, at an exercise price per share equal to the initial public offering price of this offering.

If we undergo a change of control at a price per share of our preferred stock of at least \$3.50, and Ms. Ricciardi remains actively employed on the closing of such change of control, any unvested Shares subject to the Additional Options will become fully vested.

Ms. Ricciardi's employment agreement provides for severance benefits upon a termination of her employment by us without "cause" or her resignation for "good reason", subject to Ms. Ricciardi's execution of a form release of claims. The severance benefits include: (i) payment of all accrued and unpaid base salary, (ii) payment of any expenses incurred by not yet reimbursed, (iii) any benefits that have accrued to Ms. Ricciardi under the terms of the employee benefits of the Company, (iv) to the extent unpaid, payment of the cash bonus awarded to Ms. Ricciardi with respect to the fiscal year prior to the fiscal year of termination, (v) continuation of her base salary for 12 months, (vi) COBRA premiums paid by us until the earlier of the date at the end of the 12 month period following the termination date or the date she becomes eligible for group health insurance through another employer, (vii) and with respect to any of her awarded and outstanding options that are subject to time-based vesting, a number of stock options equal to the number of shares of common stock that would have vested if Ms. Ricciardi continued to be employed by the Company for a period equal to nine (9) months following the date of termination will become vested and exercisable. In addition, if such termination without "cause" or for "good reason" occurs within the 12 month period immediately following a "change of control", then in addition to payments in (i)-(iv) and (vii) above, Ms. Ricciardi's base salary and COBRA continuation period will be extended from 12 months to 18 months, she will receive an amount equal to her target cash bonus for the year in which she was terminated, and the shares of our common stock underlying the Initial Stock Option and the Additional Options will become vested and exercisable.

Ms. Ricciardi's employment agreement also contains customary non-competition and non-solicitation provisions that extend for up to one-year following termination of her employment with us. The payment of any severance benefits under Ms. Ricciardi's employment agreement is conditioned on continued compliance with such covenants.

We expect to enter into a new employment agreement with Ms. Ricciardi that will be effective upon closing of this offering.

James M. O'Brien

In October 2019, we entered into a letter agreement with Mr. O'Brien. Mr. O'Brien's letter agreement provides for Mr. O'Brien's at-will employment as our Chief Financial Officer and sets forth his initial annual base salary of \$340,000 and his initial target annual bonus opportunity at 30% of his base salary. Mr. O'Brien's letter agreement also provided for the issuance of an option to purchase 423,978 shares of our common stock, or 0.75% of our outstanding equity on a fully diluted basis, at an exercise price of \$0.33 per share. The option will vest over a four year period, with 25% of the shares of common stock underlying the option vesting on October 7, 2020, and 75% of the shares of common stock underlying the option vesting in equal monthly installments thereafter, in each case if Mr. O'Brien remains employed by the Company

through the applicable vesting dates. See “— Outstanding Equity Awards at Fiscal Year-End” for additional details regarding the stock option granted to Mr. O’Brien in connection with his hire.

Mr. O’Brien’s letter agreement provides for severance benefits upon a termination of his employment by us without “cause”, or his resignation for “good reason”, subject to Mr. O’Brien’s execution of a general release of claims. The severance benefits include: (i) payment of all accrued and unpaid base salary, (ii) payment for any vacation time accrued but not used, (iii) payment of any business expenses incurred by not yet reimbursed, (iv) continuation of his base salary for six (6) months, (v) payment of any bonus to which he would have otherwise been entitled for the prior fiscal year but for the termination of his employment, and (vi) COBRA premiums paid by us for six (6) months. In addition, if such termination without “cause” or for “good reason” occurs within the 12 month period immediately following a “change of control”, then in addition to payments in (i) through (iii) and (v) above, Mr. O’Brien’s base salary continuation period will be extended from six (6) to twelve (12) months and all unvested restricted stock, stock options and other equity incentives awarded to Mr. O’Brien will become immediately and automatically fully vested and exercisable.

Mr. O’Brien is also subject to certain restrictive covenants. The payment of any severance benefits under Mr. O’Brien’s letter agreement is conditioned on continued compliance with such covenants.

We expect to enter into a new employment agreement with Mr. O’Brien that will be effective upon closing of this offering.

Kenneth I. Moch

Mr. Moch was previously party to an employment agreement with us that contained customary non-competition and non-solicitation provisions extending for up to one-year following termination of his employment with us and a customary invention assignment regarding ownership of intellectual property.

Mr. Moch’s employment agreement provided for severance benefits upon a termination of his employment by the Company without “cause” or his resignation for “good reason,” subject to Mr. Moch’s execution of a form release of claims, as follows: (i) payment of all accrued and unpaid base salary, (ii) payment of any expenses incurred but not yet reimbursed, (iii) any benefits that have accrued to Ms. Moch under the terms of the employee benefit programs of the Company, (iv) payment of his base salary for twelve (12) months following termination and (v) COBRA premiums paid by us until the earlier of the date at the end of the twelve (12) month period following termination date or the date the he becomes eligible for group health insurance through another employer. In addition, if such termination without “cause” or for “good reason” had occurred within the 12-month period immediately following a “change of control”, then in addition to payments in (i)-(v) above, Mr. Moch’s base salary and COBRA continuation period would have been extended from 12 months to 18 months and he would have received an amount equal to his target cash bonus for the year in which he was terminated.

In connection with Mr. Moch’s resignation on March 17, 2020, we entered into a separation and release agreement with Mr. Moch. Under the terms of the separation and release agreement, we agreed to provide to Mr. Moch the following payments and benefits, subject to his execution of a release and compliance with restrictive covenants: (i) payment of his base salary of \$386,250 for 12 months, (ii), the making of a lump sum payment to him in the amount of \$104,287.50, (iii) waiving in the entirety the medical insurance premiums under COBRA until the earlier of March 17, 2021 (12 months after his termination of employment date) and the date Mr. Moch becomes eligible for medical benefits through another employer. Mr. Moch also agreed that except as set forth in the immediately preceding sentence, none of the Company or its affiliates have any obligation or liability to Mr. Moch, including under Mr. Moch’s employment agreement. Mr. Moch’s options to purchase 2,339,304 shares of our common stock that were vested on his date of separation remain exercisable for a period of three year plus three months, and all unvested options on the date of separation were forfeited.

In connection with Mr. Moch’s termination of employment, we entered into an advisor services agreement with Mr. Moch. Pursuant to Mr. Moch’s advisor services agreement, Mr. Moch agreed to provide certain transition services and other consulting services to the company for twelve (12) months, including with respect to our business strategy, legal matters and investor relations as our Chief Executive

Officer requests, and Mr. Moch received an aggregate fee of \$100,000, paid in equal monthly installments for the twelve (12) month period following his termination date.

Outstanding Equity Awards at Fiscal Year-End

The following table provides information regarding the outstanding equity awards held by our NEOs as of December 31, 2020. All awards were granted pursuant to the 2017 Plan and 2007 Plan. See “— Equity incentive plans — 2017 Plan and 2007 Plan” below for additional information.

Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Equity incentive awards: number of securities underlying unexercised unearned options (#)	Option Exercise Price (\$)	Option Expiration Date
Lisa Ricciardi	33,750 ⁽¹⁾	101,250 ⁽¹⁾	—	0.33	9/29/2029
	—	25,000 ⁽²⁾	—	0.33	4/30/2030
	65,000	—	—	0.37	4/22/2030
	—	2,898,686 ⁽³⁾	—	0.37	5/31/2030
James M. O’Brien	123,519 ⁽⁴⁾	299,978 ⁽⁴⁾	—	0.33	10/7/2029
Kenneth I. Moch	2,339,204	—	—	0.27	6/17/2023

(1) This option vests in equal, annual installments with 25% vested on March 18, 2020, with the remaining 75% in 3 equal annual installments thereafter, subject generally to continued service.

(2) This option vests in equal, annual installments with 25% vesting on March 7, 2021, with the remaining 75% in 3 equal annual installments thereafter, subject generally to continued service.

(3) This option vests as follows: 25% vesting on June 1, 2021, with the remaining 75% vesting in 36 substantially equal monthly installments thereafter, subject generally to continued service.

(4) This option vests as follows: 25% vested on October 7, 2020, with the remaining 75% vesting in 36 substantially equal monthly installments thereafter, subject generally to continued service.

Equity Incentive Plans

2021 Plan

Our 2021 Plan will become effective upon the effectiveness of the Registration Statement of which this prospectus forms a part. Upon the effectiveness of the 2021 Plan, we will cease granting awards under our 2017 Plan. A summary of the material terms of the 2021 Plan follows below.

The 2021 Plan authorizes the award of both equity-based and cash-based incentive awards, including: (i) stock options (both incentive stock options and nonqualified stock options), (ii) stock appreciation rights, or SARs, (iii) restricted stock awards, or RSAs, (iv) restricted stock units, or RSUs, and (v) cash or other stock based awards. Incentive stock options may be granted only to employees. All other types of awards may be issued to employees, directors, consultants and other service providers.

Shares Subject to 2021 Plan. We will initially reserve _____ shares of our common stock for issuance under our 2021 Plan. The number of shares reserved for issuance under our 2021 Plan will increase automatically on _____ and each anniversary of such date prior to the termination of the 2021 Plan, equal to the lesser of (i) _____ % of our shares of common stock issued and outstanding on the last day of the immediately preceding fiscal year and (ii) such smaller number of shares as determined by our board or compensation committee. No more than _____ shares of our common stock may be issued under the 2021 Plan through incentive stock options.

The following shares will be added (or added back) to the shares available for issuance under the 2021 Plan:

- Shares subject to 2007 Plan or 2017 Plan (collectively, the “Prior Plans”) or 2021 Plan awards that expire, terminate or are cancelled or forfeited for any reason after the effectiveness of the 2021 Plan;

- Shares that after the effectiveness of the 2021 Plan are withheld to satisfy the exercise price of an option issued under a Prior Plan or the 2021 Plan; and
- Shares that after the effectiveness of the 2021 Plan are withheld to satisfy tax withholding obligations related to any award under a Prior Plan or the 2021 Plan.

However, the total number of shares underlying Prior Plan awards that may be recycled into the 2021 Plan pursuant to the above-described rules will not exceed _____ shares underlying 2007 Plan and 2017 Plan awards as of date of 2021 Plan adoption.

Shares of our common stock issued by us through the assumption or substitution of awards in connection with a future acquisition of another entity will not reduce the shares available for issuance under the 2021 Plan.

Administration. We expect that our 2021 Plan will be administered by our compensation committee. The administrator of the plan will have the authority to, among other things, interpret the plan and award agreements, select grantees, determine the vesting, payment and other terms of awards, and modify or amend awards. Our compensation committee may delegate to one or more of our officers the authority to issue awards under the 2021 Plan to grantees who are not executive officers, subject to parameters established by the compensation committee.

Adjustments. In the event of certain corporate events or transactions (such as a merger, consolidation, reorganization, recapitalization, stock split, reverse stock split, spin-off, stock dividend, or similar transaction or change in our capital structure), our compensation committee will make adjustments or substitutions to the number and kind of shares that may be issued under the 2021 Plan, the number and kind of shares subject to outstanding awards, the exercise price or base price of outstanding awards, and/or any other affected terms and conditions of the 2021 Plan or outstanding awards, in each case as it deems appropriate and equitable.

Stock options. The 2021 Plan provides for the grant of both incentive stock options and non-qualified stock options to purchase shares of our common stock at a stated exercise price. The exercise price of stock options granted under the 2021 Plan must be at least equal to the fair market value of our common stock on the date of grant. The maximum term of options granted under our 2021 Plan is ten years.

Our compensation committee may provide in the terms of the applicable award agreement that the participant may exercise an unvested portion in exchange for restricted stock subject to the same vesting terms as the option.

Stock appreciation rights. An SAR provides for a payment, in cash or shares of our common stock or a combination of both, to the holder based upon the difference between the fair market value of our common stock on the date of exercise and a predetermined exercise price, multiplied by the number of shares. The base price of a SAR must be at least the fair market value of a share of our common stock on the date of grant. SARs may not have a term that is longer than ten years from the date of grant.

Restricted stock awards. An RSA is an issuance of shares of our common stock subject to forfeiture restrictions that lapse based on the satisfaction of service and/or performance conditions. The price, if any, of each share subject to an RSA will be determined by the compensation committee. During the vesting period, a participant will have the right to vote and receive any dividends with respect to restricted stock, provided that our compensation committee may specify that any such dividends are subject to the same vesting schedule as the shares to which they relate.

Restricted stock units. RSUs represent the right to receive shares of our common stock (or cash equal to the value of such shares) at a specified time in the future, following the satisfaction of specified service and/or performance conditions.

Cash or other stock based awards. Cash or other stock based awards (including awards to receive unrestricted shares of our common stock or immediate cash payments) may be granted to participants. Our compensation committee will determine the terms and conditions of each such award, including, as applicable, the term, any exercise or purchase price, performance goals, vesting conditions, and other terms

and conditions. Payment in respect of a cash or other stock based award may be made in cash, shares of our common stock, or a combination of both, at the discretion of our compensation committee.

Change in control. Upon or in anticipation of a change in control (which includes certain merger, asset or stock transactions, certain changes in our board composition and any other event deemed by our board of directors to constitute a change in control), our compensation committee may take such actions as it deems appropriate with respect to outstanding awards under the 2021 Plan. Such actions may include (among other things) the acceleration of award vesting, the substitution of awards, the cancellation of unexercised or unvested awards and the redemption or cashout of awards. In the discretion of our compensation committee, any cash or other substitute consideration payable upon redemption or cashout of an award may be subjected to the same vesting terms that applied to the original award, or earn-out, escrow, holdback or similar arrangements comparable to those applicable to stockholders in connection with the change in control. The compensation committee need not treat all outstanding awards in an identical manner.

Repricing. The compensation committee may in its discretion: (i) cancel options or stock appreciation rights outstanding under the 2021 Plan in exchange for new options or stock appreciation rights with a lower exercise or base price per share; (ii) cancel underwater options or stock appreciation rights outstanding under the 2021 Plan in exchange for consideration payable in our equity securities or cash; or (iii) otherwise directly reduce the exercise or base price of options or stock appreciation rights outstanding under the 2021 Plan.

Director Compensation Limits. Beginning with the _____ calendar year, the aggregate amount of equity and cash compensation payable to a non-employee director with respect to a calendar year for his or her service as a director may not exceed \$ _____ (or \$ _____, in the case of a newly appointed or newly elected non-employee director's first year of service with us. This director compensation limit will not apply to (i) compensation earned by a non-employee director solely in his or her capacity as chairman of the Board or lead independent director, (ii) compensation earned by a non-employee director for services he or she performs outside of his or her role as a non-employee director (i.e. as an advisor or consultant), or (iii) compensation awarded by the Board to a non-employee director in extraordinary circumstances, as determined by the Board in its discretion, so long as, in each case, the non-employee director does not participate in the decision to award him- or herself the additional compensation.

Clawback. Awards under the 2021 Plan will be subject to clawback or recoupment pursuant to any applicable policy, law or exchange listing requirement in effect from time to time.

Transferability. Except for certain estate planning transfers authorized by the compensation committee, awards granted under the 2021 Plan are generally nontransferable except by will or by the laws of descent and distribution.

Amendment and termination. Our board of directors may amend our 2021 Plan at any time, subject to stockholder approval if required by applicable law or exchange listing requirement. The 2021 Plan will terminate ten years after it becomes effective.

2017 Plan

Our Cognition Therapeutics, Inc. 2017 Equity Incentive Plan ("2017 Plan") was adopted by our board of directors, approved by shareholders, and made effective as of September 20, 2017. Our 2017 Plan was originally adopted to enable the issuance of stock options and stock awards to our employees, advisors, directors, and consultants.

As noted above, we expect to terminate the 2017 Plan and will cease granting awards thereunder upon the effective date of our 2021 Plan (described above). Any outstanding awards will continue to be subject to the terms of the 2017 Plan and the applicable award agreements, until such awards are exercised or settled, or until they terminate or expire by their terms.

A summary of the material terms of the 2017 Plan follows below.

Administration. We expect that our compensation committee will administer the 2017 Plan and outstanding awards thereunder following the date of this offering.

As of April 30, 2021, there were (i) 1,028,772 shares available for issuance in respect of new awards under the 2017 Plan and (ii) options outstanding under the 2017 Plan with respect to 6,352,864 shares of our common stock.

Share recycling. Shares underlying 2017 Plan awards that are forfeited, expired, canceled, reacquired by the company prior to vesting will become available for grant under the 2021 Plan.

Options. The 2017 Plan provides for the grant of both (i) incentive stock options, which are intended to qualify for tax treatment as set forth under Section 422 of the Code, as amended, or the Code, and (ii) non-qualified stock options to purchase shares of our common stock at a stated exercise price. The exercise price of stock options granted under the 2017 Plan must be at least equal to the fair market value of our common stock on the date of grant. The maximum term of options granted under our 2017 Plan is ten years.

The board of directors may approve certain stock options issued under the 2017 Plan to become exercisable prior to vesting in exchange for restricted shares of common stock subject to a repurchase right in favor of the company during a specified restriction period.

Stock Awards. The 2017 Plan also allows for the grant or sale of stock awards that may be subject to restrictions, as determined by the board of directors. The price, if any, of each share subject to a stock award will be determined by the board of directors/compensation committee. During the restriction period, a participant will have the right to vote and receive any dividends with respect to stock awards.

Change of Control. If we are subject to a “Change of Control” as defined in the 2017 Plan (including certain dissolution, liquidation, asset sale or merger transactions), the board of directors will determine how to treat outstanding awards under our 2017 Plan. This may include one or more of the following: (i) the acceleration of outstanding options or lapse in restrictions on outstanding stock awards, (ii) the termination of outstanding awards, unless exercised prior to the Change of Control; and (iii) the cashout or redemption of outstanding awards. The board of directors need not treat all outstanding awards in an identical manner.

Adjustments. In the event of a stock dividend, reorganization, recapitalization, stock split, reverse stock split, subdivision, combination, reclassification, merger, asset sale, or other similar event or transaction affecting our common stock, proportional adjustments will be made to the number of shares reserved for issuance under our 2017 Plan; the number and class of shares subject to outstanding awards; and the exercise or repurchase price applicable to outstanding awards.

Transferability. Unless otherwise determined by the board of directors and/or specified in the applicable award agreement, awards under the 2017 Plan generally may not be transferred in any manner other than by will, the laws of descent, and distribution or qualified domestic relations order.

Amendment/Termination. The board of directors may amend or terminate the 2017 Plan at any time; provided, however, that the board of directors shall not amend this Plan without stockholder approval if such approval is required in order to comply with the Code or other applicable laws.

2007 Plan

Our Cognition Therapeutics Inc. Amended and Restated 2007 Equity Incentive Plan (“2007 Plan”) was adopted by our board of directors, approved by shareholders, and made effective as of October 1, 2007, and was most recently amended and restated on January 10, 2017. Our 2007 Plan was originally adopted to enable the issuance of stock options and stock awards to our employees, advisors, directors, and consultants. The 2007 Plan was implemented to encourage the participants to contribute materially to the growth of the company and therefore benefit the company’s stockholders.

As of April 30, 2021, there were stock options with respect to 7,907,353 shares outstanding and no additional shares available for issuance in respect of new awards under the 2007 Plan. Any outstanding awards will continue to be subject to the terms of the 2007 Plan and the applicable award agreements, until such awards are exercised or settled, or until they terminate or expire by their terms.

A summary of the material terms of the 2007 Plan follows below.

Administration. We expect that our compensation committee will administer the 2007 Plan and outstanding awards thereunder following the date of this offering.

Share recycling. If and to the extent shares granted are terminated, expired, canceled, forfeited, exchanged or surrendered without having been exercised, the shares subject to such grants will be available for grant under the 2021 Plan.

Options. The 2007 Plan provides for the grant of both (i) incentive stock options, which are intended to qualify for tax treatment as set forth under Section 422 of the Code, as amended, or the Code, and (ii) non-qualified stock options to purchase shares of our common stock at a stated exercise price. The exercise price of stock options granted under the 2007 Plan must be at least equal to the fair market value of our common stock on the date of grant. The maximum term of options granted under our 2007 Plan is ten years.

The board of directors may approve certain stock options issued under the 2007 Plan to become exercisable prior to vesting in exchange for restricted shares of common stock subject to a repurchase right in favor of the company during a specified restriction period.

Stock Awards. The 2007 Plan also allows for the grant or sale of stock awards that may be subject to restrictions, as determined by the board of directors. The price, if any, of each share subject to a stock award will be determined by the board of directors/compensation committee. During the restriction period, a participant will have the right to vote and receive any dividends with respect to stock awards.

Change of Control. If we are subject to a “Change of Control” as defined in the 2007 Plan (including certain dissolution, liquidation, asset sale or merger transactions), the board of directors will determine how to treat outstanding awards under our 2007 Plan. This may include one or more of the following: (i) the acceleration of outstanding options or lapse in restrictions on outstanding stock awards, (ii) the termination of outstanding awards, unless exercised prior to the Change of Control; and (iii) the cashout or redemption of outstanding awards. The board of directors need not treat all outstanding awards in an identical manner.

Adjustments. In the event of a stock dividend, reorganization, recapitalization, stock split, reverse stock split, subdivision, combination, reclassification, merger, asset sale, or other similar event or transaction affecting our common stock, proportional adjustments will be made to the number of shares reserved for issuance under our 2007 Plan; the number and class of shares subject to outstanding awards; and the exercise or repurchase price applicable to outstanding awards.

Transferability. Unless otherwise determined by the board of directors and/or specified in the applicable award agreement, awards under the 2007 Plan generally may not be transferred in any manner other than by will, the laws of descent, and distribution or qualified domestic relations order.

Amendment/Termination. The board of directors may amend or terminate the 2007 Plan at any time; provided, however, that the board of directors shall not amend this Plan without stockholder approval if such approval is required in order to comply with the Code or other applicable laws.

Employee Stock Purchase Plan

Our board of directors intends to adopt the Employee Stock Purchase Plan, or ESPP, prior to closing of this offering, under which we may provide our employees and employees of our subsidiary with an opportunity to purchase shares of our common stock at a discounted purchase price. The ESPP will first become effective on . The material terms of the ESPP are summarized below. The ESPP is intended to qualify as an “employee stock purchase plan” meeting the requirements of Section 423 of the Code.

Administration. Subject to the express provisions of the ESPP, our compensation committee will have the authority to construe and interpret the ESPP, prescribe, amend, and rescind rules relating to the ESPP’s administration and take any other actions necessary or desirable for the administration of the ESPP and to facilitate compliance with Section 423 of the Code and other applicable law.

Stock Subject to the ESPP. Subject to adjustment as provided in the ESPP, a total of shares of our common stock will be authorized and reserved for issuance under the ESPP. In addition, subject to prior approval by our board of directors in each instance, on or about and each anniversary of such date thereafter prior to the termination of the ESPP, the number of shares of our

common stock authorized and reserved for issuance under the ESPP will be increased by a number of shares of our common stock equal to the least of (i) _____ shares of our common stock, (ii) _____ % of the shares of our common stock outstanding on the final day of the immediately preceding calendar year, and (iii) such smaller number of shares of our common stock as determined by our board of directors. Such shares of our common stock may be newly issued shares, treasury shares or shares acquired on the open market. In the event that any dividend or other distribution (whether in the form of cash, our common stock, or other property), recapitalization, stock split, reverse stock split, reorganization, merger, consolidation, split-up, spin-off, or exchange of our common stock or our other securities, or other change in our structure affecting our common stock occurs, then in order to prevent dilution or enlargement of the benefits or potential benefits intended to be made available under the ESPP, our compensation committee will, in such manner as it deems equitable, adjust the number of shares and class of common stock that may be delivered under the ESPP, the purchase price per share and the number of shares covered by each outstanding option under the ESPP, and the numerical limits described above.

Eligibility. Generally, our employees and employees of our subsidiary who customarily are employed for at least twenty (20) hours per week and for more than five (5) months in any calendar year will be eligible to participate in the ESPP. Notwithstanding the foregoing, our compensation committee may exclude from participation in the ESPP or any offering period employees who are (i) “highly compensated employees” within the meaning of Section 414(q) of the Code, or (ii) citizens or residents of a foreign jurisdiction where the grant of an option under the ESPP to such employee would be prohibited under the laws of such foreign jurisdiction or the grant of an option under the ESPP to such employee in compliance with the laws of such foreign jurisdiction would cause the ESPP to violate the requirements of Section 423 of the Code. No employee may be granted options to purchase shares of our common stock under the ESPP if such employee (x) immediately after the grant would own capital stock possessing 5% or more of the total combined voting power or value of all classes of our capital stock, or (y) holds rights to purchase shares of our common stock under all of our employee stock purchase plans (in accordance with Section 423(b)(8) of the Code) that accrue at a rate exceeding \$25,000 (determined as of the option grant date) for each calendar year in which such rights are outstanding.

Grant and exercise of options. The ESPP provides for six (6) month offering periods, commencing on or about January 1st and July 1st of each year, unless specified otherwise by our compensation committee. Eligible employees may elect to become a participant in the ESPP by submitting an enrollment form, pursuant to which an employee may elect to enroll in the ESPP, authorize a new level of payroll deductions, or stop payroll deductions and withdraw from an offering period. However, a participant may not purchase more than shares of our common stock during each offering period.

During each offering period for which a participant has enrolled, the participant may contribute through payroll deductions in an amount equal to (i) between 1% and _____ %, in whole percentages, of his or her compensation, or (ii) a fixed dollar amount, in each case, on each pay day occurring during such offering period. A participant’s compensation for purposes of the ESPP includes base salary and base wages (including overtime). No interest shall accrue on or be payable with respect to the payroll deductions of a participant in the ESPP. Payroll deductions would be made before deduction for any salary deferral contributions made by the employee to any tax-qualified or nonqualified deferred compensation plan, cafeteria plan or similar arrangement.

On the last trading day of each offering period, a participant’s option to purchase shares of our common stock will be exercised automatically. The per-share purchase price will be the lesser of (i) _____ percent (_____ %) of the fair market value of one share of our common stock on the first trading day of the applicable offering period and (ii) _____ percent (_____ %) of the fair market value of one share of our common stock on the last trading day of the applicable offering period. As soon as reasonably practicable after the last day of each offering period, we will arrange for the delivery to each participant of the shares of our common stock purchased upon exercise of his or her option. We may require that the shares of our common stock be deposited and/or retained for a specified period of time with a financial services firm or other agent it designates as broker. Neither payroll deductions nor rights with respect to the exercise of an option or to receive shares of our common stock are transferable, other than by will, by the laws of descent and distribution, or by written designation of a beneficiary with our compensation committee.

Termination of Employment and Withdrawal from the ESPP. Participants may elect to withdraw from the ESPP at any time and receive back any of their contributions, without interest, not used to purchase shares of our common stock; provided that if a participant wishes to withdraw his or her funds prior to purchase, he or she must submit a revised enrollment form to our compensation committee at least fifteen (15) days prior to the end of the then-current offering period. Participants who terminate employment before the end of an offering period will be deemed to have withdrawn from the ESPP and the payroll deductions in the participant's notional account that have not been used to purchase shares of our common stock will be returned to the participant.

Amendment and Termination of the ESPP. Our compensation committee may amend or terminate the ESPP at any time for any reason. If the ESPP is terminated, our compensation committee may elect to terminate the outstanding offering period either immediately, or after shares of our common stock have been purchased on the last trading day of the offering period (which may, in the discretion of our compensation committee, be accelerated) and all amounts that have not been used to purchase shares of our common stock will then be returned to participants as soon as administratively practicable. In the event of a merger, consolidation, acquisition of property or stock, separation, reorganization, or other corporate event described in Section 424 of the Code, each outstanding option will be assumed or an equivalent option substituted by the successor corporation, or a parent, or subsidiary of such successor corporation. If the successor corporation refuses to assume or substitute the option, the offering period with respect to which the option relates will be shortened by setting a new purchase date that occurs before the date of the applicable transaction. Unless terminated earlier pursuant to the terms of the ESPP, the ESPP will have a term of 10 years following the ESPP's effective date.

Other Benefits

We currently provide welfare benefits that are available to all of our employees, including our NEOs, including health, dental, life, vision and disability insurance.

In addition, we maintain, and the NEOs participate in, a 401(k) plan that provides eligible employees with an opportunity to save for retirement on a tax-advantaged basis and under which we are permitted to make safe harbor and discretionary employer contributions. The 401(k) plan also provides for automatic enrollment for eligible employees who do not make a deferral election. Employees' pre-tax contributions are allocated to each participant's individual account and are then invested in selected investment alternatives according to the participants' directions. The 401(k) plan is intended to be qualified under Section 401(a) of the Code, with the related trust intended to be tax exempt under Section 501(a) of the Code. As the 401(k) plan is a safe harbor plan, we are required to make a certain level of matching contributions. We match 100% of a participating employee's deferral contributions up to 4% of annual compensation, and participants are always fully vested in their safe harbor matching employer contributions.

We do not maintain any defined benefit pension plans or nonqualified deferred compensation plans.

Rule 10b5-1 Sales Plans

Our directors and executive officers may adopt written plans, known as Rule 10b5-1 plans, in which they will contract with a broker to buy or sell our common stock on a periodic basis. Under a Rule 10b5-1 plan, a broker executes trades pursuant to parameters established by the director or officer when entering into the plan, without further direction from them. The director or officer may amend or terminate a Rule 10b5-1 plan subject to compliance with our insider trading policy. Our directors and executive officers also may buy or sell additional shares outside of a Rule 10b5-1 plan when they are not in possession of material nonpublic information subject to compliance with our insider trading policy. Prior to 180 days after the date of this offering, subject to early termination, the sale of any shares under such plan would be prohibited by the lock-up agreement that the director or officer has entered into with the underwriters.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following includes a summary of transactions since January 1, 2018 and any currently proposed transactions to which we were or are expected to be a participant in which (1) the amount involved exceeded or will exceed the lesser of \$120,000 or one percent of our average total assets at year-end for the last two completed fiscal years, and (2) any of our directors, executive officers or holders of more than 5% of our capital stock, or any affiliate or member of the immediate family of the foregoing persons, had or will have a direct or indirect material interest, other than compensation and other arrangements that are described under the section titled “Executive compensation” and “Management — Non-employee director compensation.”

We believe the terms obtained or consideration that we paid or received, as applicable, in connection with the transactions described below were comparable to terms available or the amounts that we would pay or receive, as applicable, in arm’s-length transactions.

Convertible Promissory Note Financing and Conversion

From March 2018 to July 2020, we issued convertible promissory notes in the aggregate principal amount of \$13.0 million with an interest rate of 8.0% per annum, pursuant to note purchase agreements entered into with certain holders of our capital stock. On May 1, 2021, the holders of all of our outstanding convertible promissory notes agreed to an acceleration of the date of the automatic conversion from June 30, 2021 to May 1, 2021 for all convertible promissory notes. Accordingly, on May 1, 2021, all of our outstanding convertible promissory notes were converted into 10,926,089 shares of our Series B-1 convertible preferred stock, at a conversion price equal to \$1.385 per share. As of the date of this prospectus, no notes are outstanding. Pursuant to the terms of our Series B-1 convertible preferred stock, all shares will automatically convert into shares of our common stock upon the closing of this offering on a one-for-one basis.

The table below sets forth the principal amount of convertible promissory notes purchased by our directors and holders of more than 5.0% of our capital stock and their affiliated entities, and the number of shares of our Series B-1 convertible preferred stock issued pursuant to the Notes Conversion.

Name	Principal Amount of Convertible Notes	Shares of Series B-1 Convertible Preferred Stock
Entities affiliated with Breedlove Family Limited Partnership ⁽¹⁾	\$ 475,730	343,487
Entities affiliated with Golden Seeds Cognition Therapeutics, LLC ⁽²⁾	\$1,841,258	1,329,428
Entities affiliated with BIOS Memory SPV I, LP ⁽³⁾	\$4,250,000	3,068,592
Ogden CAP Associates, LLC ⁽⁴⁾	\$ 491,127	354,604
Stephen Sands ⁽⁵⁾	\$ 25,000	18,050

- (1) Mr. Breedlove, one of our directors, is the General Partner of the Breedlove Family Limited Partnership.
- (2) Golden Seeds Cognition Therapeutics, LLC is a beneficial owner of more than 5% of our common stock or shares of common stock issuable upon the exercise of stock options or warrants that are exercisable within 60 days of _____, 2021. Ms. Wallace, one of our directors, is the Co-Chief Executive Officer and Managing Partner of Golden Seeds, LLC and Golden Seeds Funds.
- (3) BIOS Memory SPV I, LP is a beneficial owner of more than 5% of our common stock or shares of common stock issuable upon the exercise of stock options or warrants that are exercisable within 60 days of _____, 2021. Dr. Fletcher, one of our directors, is the Managing Partner of Bios Partners, LP and founded Bios Research, LLC.
- (4) Ogden CAP Associates, LLC is a beneficial owner of more than 5% of our common stock or shares of common stock issuable upon the exercise of stock options or warrants that are exercisable within 60 days of _____, 2021 and has been granted a board observer seat in connection with such holdings.
- (5) Mr. Sands is one of our independent directors.

Simple Agreements for Future Equity

In March 2021, we entered into the SAFEs, or the safe offering, with various investors, pursuant to which we received gross proceeds in an aggregate amount equal to \$8.9 million. The amount invested by the investors in the safe offering is automatically convertible into shares of our common stock upon the closing of this offering at a conversion price equal to 80% of the initial public offering price of our common stock in this offering. As a result, upon the closing of this offering, the principal amount invested in the sale offering is convertible into _____ shares of our common stock, based on an assumed initial offering price of \$ _____ per share, the midpoint of the price range set forth on the cover page of this prospectus.

The table below sets forth the amount invested in the safe offering by holders of more than 5% of our capital stock and their affiliated entities and the number of shares of our common stock issuable upon conversion of the principal amount invested in the safe offering upon the closing of this offering.

Name	Amount of SAFEs	Shares of Common Stock
Entities affiliated with Golden Seeds Cognition Therapeutics, LLC ⁽¹⁾	\$3,092,383	
Entities affiliated with BIOS Memory SPV I, LP ⁽²⁾	\$2,000,000	

- (1) Golden Seeds Cognition Therapeutics, LLC is a beneficial owner of more than 5% of our common stock or shares of common stock issuable upon the exercise of stock options or warrants that are exercisable within 60 days of, _____, 2021. Ms. Wallace, one of our directors, is the Co-Chief Executive Officer and Managing Partner of Golden Seeds, LLC and Golden Seeds Funds.
- (2) BIOS Memory SPV I, LP is a beneficial owner of more than 5% of our common stock or shares of common stock issuable upon the exercise of stock options or warrants that are exercisable within 60 days of _____, 2021. Dr. Fletcher, one of our directors, is the Managing Partner of Bios Partners, LP and founded Bios Research, LLC.

Voting Agreement

In connection with the issuance and sale of our shares of preferred stock, we entered into a voting agreement with certain holders of our common stock and each holder of our preferred stock. Each holder of more than 5% of our capital stock, as set forth in the section titled “Principal Stockholders,” is a party to these agreements. Our directors who are parties to these agreements or who are related to parties to these agreements are Dr. Catalano, Ms. Wallace, Dr. Fletcher and Mr. Breedlove. The voting agreement, including all rights thereunder, will automatically terminate immediately prior to the closing of this offering.

Right of First Refusal and Co-Sale Agreement

In connection with the issuance and sale of our shares of preferred stock, we entered into a right of first refusal and co-sale agreement with certain holders of our common stock and each holder of our preferred stock. Each holder of more than 5% of our capital stock, as set forth in the section titled “Principal Stockholders,” is a party to these agreements. Our directors who are parties to these agreements or who are related to parties to these agreements are Dr. Catalano, Ms. Wallace, Dr. Fletcher and Mr. Breedlove.

The right of first refusal and co-sale agreement, including all rights thereunder, will automatically terminate immediately prior to the closing of this offering.

Investors’ Rights Agreement

In connection with the issuance and sale of our shares of preferred stock, we entered into an investors’ rights agreement, as amended, or the investors’ rights agreement, with certain holders of our common stock and each holder of our preferred stock. The holders of more than 5% of our capital stock listed above are parties to these agreements. The investors’ rights agreement imposes certain affirmative obligations on us, including with respect to financial reporting obligations and investor inspections, and also grants certain other rights to certain of the holders of our capital stock party thereto, including rights of first offer, demand and piggyback registration rights and, if we are eligible, Form S-3 registration rights, with respect to the

shares of capital stock held by them. See the section titled “Description of Capital Stock — Registration Rights” for additional information. Certain provisions of the investors’ rights agreement, including our affirmative obligations and the right of first offer rights will terminate immediately prior to the closing of this offering, while the registration rights set forth in the investors’ rights agreement will continue in effect after the closing of this offering until they expire in accordance with their terms.

Executive Officer and Director Compensation

Please see “Executive compensation” and “Management — Non-employee director compensation” for information regarding the compensation of our directors and executive officers.

Employment Agreements

We have entered into employment agreements and letter agreements with certain of our executive officers that, among other things, provide for certain compensatory and change in control benefits, as well as severance benefits. For a description of these agreements with our NEOs, see the section titled “Executive compensation — Employment Arrangements with our NEOs.”

Indemnification Agreements

We have entered and intend to continue to enter into indemnification agreements with each of our directors and officers. These indemnification agreements may require us, among other things, to indemnify our directors and officers for some expenses, including attorneys’ fees, judgments, fines and settlement amounts incurred by a director or officer in any action or proceeding arising out of his or her service as one of our directors or officers, or any of our subsidiaries or any other company or enterprise to which the person provides services at our request. For more information regarding these indemnification agreements, see “Management — Limitation on liability and indemnification matters.”

Policies and Procedures for Related Party Transactions

Our board of directors will adopt a written related party transaction policy, which will become effective upon the closing of this offering, setting forth the policies and procedures for the review and approval or ratification of related-party transactions. This policy will cover any transaction, arrangement or relationship or any series of similar transactions, arrangements or relationships, in which we were or are to be a participant and a related party had or will have a direct or indirect material interest, as determined by the audit committee of our board of directors, including, without limitation, purchases of goods or services by or from the related party or entities in which the related party has a material interest, and indebtedness, guarantees of indebtedness or employment by us of a related party.

All related party transactions described in this section occurred prior to adoption of this policy and as such, these transactions were not subject to the approval and review procedures set forth in the policy. However, these transactions were reviewed and approved by our board of directors.

PRINCIPAL STOCKHOLDERS

The following table sets forth, as of _____, 2021, information regarding beneficial ownership of our capital stock by:

- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our common stock;
- each of our NEOs;
- each of our directors; and
- all of our executive officers and directors as a group.

The percentage ownership information under the column titled “Beneficial ownership prior to this offering” is based on _____ shares of common stock outstanding as of _____, 2021, assuming (i) the automatic conversion of all outstanding shares of our convertible preferred stock into an aggregate of 51,450,435 shares of common stock upon the closing of this offering, (ii) the issuance of _____ shares of common stock upon the exercise of warrants that otherwise expire upon or prior to the closing of this offering (assuming an initial public offering price of \$ _____ per share, the midpoint of the price range set forth on the cover page of this prospectus), and (iii) the issuance of _____ shares of our common stock issuable upon the conversion of the SAFEs in the aggregate amount of \$8.94 million upon the closing of this offering (assuming an initial public offering price of \$ _____ per share, the midpoint of the price range set forth on the cover page of this prospectus). The percentage ownership information under the column titled “Beneficial ownership after this offering” is based on the sale of shares of common stock in this offering (assuming an initial public offering price of \$ _____ per share, the midpoint of the price range set forth on the cover page of this prospectus). The percentage ownership information assumes no exercise of the underwriters’ option to purchase additional shares.

Beneficial ownership is determined according to the rules of the SEC and generally means that a person has beneficial ownership of a security if he, she or it possesses sole or shared voting or investment power over that security. In addition, shares of common stock issuable upon the exercise of stock options or warrants and the conversion of convertible securities that are exercisable or convertible within 60 days of _____, 2021, are included in the following table. These shares are deemed to be outstanding and beneficially owned by the person holding those options or warrants for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person. The information contained in the following table does not necessarily indicate beneficial ownership for any other purpose. Unless otherwise indicated, the persons or entities identified in this table have sole voting and investment power with respect to all shares shown as beneficially owned by them, subject to applicable community property laws.

Unless otherwise noted below, the address for each beneficial owner listed in the table below is c/o Cognition Therapeutics, Inc., 2403 Sidney Street, Pittsburgh, Pennsylvania 15203.

Name of Beneficial Owner	Beneficial ownership prior to this offering		Beneficial ownership after this offering	
	Number of shares beneficially owned	Percentage of beneficial ownership	Number of shares beneficially owned	Percentage of beneficial ownership
5% and Greater Stockholders:				
Golden Seeds Cognition Therapeutics, LLC		%		
Ogden CAP Associates, LLC		%		
BIOS Memory SPV I, LP		%		
Pittsburgh Life Sciences Greenhouse		%		
Named Executive Officers and Directors:				
Lisa Ricciardi		%		
James M. O’Brien		%		

Name of Beneficial Owner	Beneficial ownership prior to this offering		Beneficial ownership after this offering	
	Number of shares beneficially owned	Percentage of beneficial ownership	Number of shares beneficially owned	Percentage of beneficial ownership
Susan Catalano, Ph.D.		%		
Mark H. Breedlove		%		
Aaron Fletcher, Ph.D.		%		
Jack A. Khattar		%		
Brett P. Monia, Ph.D.		%		
Stephen Sands		%		
Peggy Wallace		%		
All current directors and executive officers as a group (13 persons)		%		

DESCRIPTION OF CAPITAL STOCK

The following descriptions are summaries of the material terms of our third amended and restated certificate of incorporation, amended and restated bylaws, the investor rights agreement to which we and certain of our stockholders are parties and of the DGCL. Because the following is only a summary, it does not contain all of the information that may be important to you. For a complete description, you should refer to our form of third amended and restated certificate of incorporation, form of amended and restated bylaws and investors' rights agreement, copies of which have been filed as exhibits to the registration statement of which this prospectus is part.

General

Upon the closing of this offering and the filing of our third amended and restated certificate of incorporation with the Secretary of State for the State of Delaware, our authorized capital stock will consist of _____ shares of common stock, par value \$0.001 per share, and _____ shares of preferred stock, par value \$0.001 per share. All of our outstanding shares of common stock are, and the shares of common stock to be issued in this offering will be, fully paid and nonassessable.

Common Stock

Outstanding Shares

As of _____, 2021, there would have been _____ shares of common stock outstanding, held by _____ stockholders of record, after giving effect to the automatic conversion of all our preferred stock outstanding into an aggregate of 51,450,435 shares of our common stock, the issuance of _____ shares of our common stock issuable upon the exercise of warrants to purchase common stock that otherwise would expire upon or prior to the closing of this offering, and the issuance of _____ shares of our common stock issuable upon the conversion of the SAFEs in the aggregate amount of \$8.9 million, in each case immediately upon the closing of this offering (assuming an initial public offering price of \$ _____ per share, the midpoint of the price range set forth on the cover page of this prospectus).

Voting Rights

Each holder of our common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders, including the election of directors. Our stockholders do not have cumulative voting rights in the election of directors. Accordingly, holders of a majority of the voting shares are able to elect all of the directors. In addition, the affirmative vote of holders of 66⅔% of the voting power of all of the then outstanding voting stock will be required to take certain actions, including amending certain provisions of our third amended and restated certificate of incorporation, such as the provisions relating to amending our amended and restated bylaws, procedures for our stockholder meetings, the classified board, director liability, and exclusive forum for proceedings.

Dividends

Subject to preferences that may be applicable to any then outstanding preferred stock, holders of our common stock are entitled to receive dividends, if any, as may be declared from time to time by our board of directors out of legally available funds.

Liquidation

In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities and the satisfaction of any liquidation preference granted to the holders of any then outstanding shares of preferred stock.

Rights and Preferences

Holders of our common stock have no preemptive, conversion, subscription or other rights, and there are no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and

privileges of the holders of our common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of our preferred stock that we may designate in the future.

Preferred Stock

Upon the closing of this offering, all outstanding shares of our preferred stock will be automatically converted into an aggregate of 51,450,435 shares of common stock. Under the terms of our third amended and restated certificate of incorporation that will become effective immediately prior to the closing of this offering, our board of directors is authorized to direct us to issue _____ shares of preferred stock in one or more series without stockholder approval. Our board of directors has the discretion to determine the rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, of each series of preferred stock.

The purpose of authorizing our board of directors to issue preferred stock and determine its rights and preferences is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions, future financings and other corporate purposes, could have the effect of making it more difficult for a third-party to acquire, or could discourage a third-party from seeking to acquire, a majority of our outstanding voting stock. Upon the closing of this offering, there will be no shares of preferred stock outstanding, and we have no present plans to issue any shares of preferred stock.

Warrants

As of March 31, 2021, the certain intuitional investors held warrants to purchase an aggregate of 650,656 shares of our common stock at a weighted average exercise price of \$0.06 per share, subject to customary adjustments provided in the warrant agreement. The warrants expire upon the closing of the offering.

Stock Options and Grant Plan Shares

As of March 31, 2021, 14,414,342 shares of common stock were issuable upon the exercise of outstanding stock options, at a weighted average exercise price of \$0.31 per share. For additional information regarding terms of our equity incentive plans, see the section titled “Executive compensation — Equity incentive plans.”

Registration Rights

The investors’ rights agreement grants certain of the holders of _____ shares of our capital stock party thereto certain registration rights in respect of the “registrable securities” held by them, which securities include (1) the shares of our common stock issued upon the conversion of shares of our preferred stock, (2) the shares of common stock issued upon the conversion and/or exercise of any other security, and (3) any shares of our common stock issued as a dividend or other distribution with respect to the shares described in the foregoing clause (1) and (2). The registration of the resale of these shares of our common stock pursuant to the exercise of these registration rights would enable the holders thereof to sell such shares without restriction under the Securities Act when the applicable registration statement is declared effective.

Holders of _____ shares of our common stock (including shares issuable upon the conversion of our preferred stock) are entitled to such registration rights pursuant the investors’ rights agreement.

Expenses of Registration

Subject to specified conditions and limitations, we are required to pay all expenses, other than underwriting discounts and commissions and stock transfer taxes incurred in connection with any exercise of these registration rights.

Expiration of Registration Rights

These registration rights will expire on the earlier to occur of (1) such time after the closing of this offering in which all of such holders registrable shares can be sold without limitation during a three-month period without registration, and (2) the four year anniversary of the closing of this offering.

Demand Registration Rights

At any time beginning six months after the closing of this offering, the holders of a majority of the common stock issued or issuable upon conversion of our preferred stock then outstanding may, on not more than two occasions, request that we prepare, file and maintain a registration statement on Form S-1 to register the sale of their registrable securities, provided such registrable securities represent at least 20% of all registrable securities then outstanding. Once we are eligible to use a registration statement on Form S-3, the stockholders party to the investors' rights agreement representing at least 20% of the registrable securities then outstanding may, not more than twice in any twelve-month period, request that we prepare, file and maintain a registration statement on Form S-3 covering the sale of their registrable securities, but only if the anticipated offering price, net of underwriting discounts and commissions, would exceed \$1.0 million.

Piggyback Registration Rights

In the event that we propose to register any of our securities under the Securities Act, either for our own account or for the account of other security holders, the stockholders party to the investors' rights agreement will be entitled to certain "piggyback" registration rights allowing them to include their registrable securities in such registration, subject to certain marketing and other limitations. As a result, whenever we propose to file a registration statement under the Securities Act, other than with respect to a demand registration or a registration statement on Form S-8, these holders will be entitled to notice of the registration and will have the right to include their registrable securities in the registration subject to certain limitations.

Indemnification

The investors' rights agreement contains customary cross-indemnification provisions, pursuant to which we are obligated to indemnify the selling holders of registrable securities in the event of either material misstatements or omissions in the applicable registration statement attributable to us or our violation of the Securities Act, and the selling stockholders are obligated to indemnify us for material misstatements or omission in the registration statement attributable to them, subject to certain limitations.

Anti-Takeover Provisions of Delaware Law and Our Charter Documents

Some provisions of Delaware law and our third amended and restated certificate of incorporation and our amended and restated bylaws that will become effective immediately prior to the closing of this offering contain provisions that could make the following transactions more difficult: acquisition of us by means of a tender offer; acquisition of us by means of a proxy contest or otherwise; or removal of our incumbent officers and directors. It is possible that these provisions could make it more difficult to accomplish or could deter transactions that stockholders may otherwise consider to be in their best interest or in our best interests, including transactions that might result in a premium over the market price for our shares.

These provisions, summarized below, are expected to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe that the benefits of increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging these proposals because negotiation of these proposals could result in an improvement of their terms.

Section 203 of the Delaware General Corporation Law

We are subject to Section 203 of the DGCL, which prohibits persons deemed "interested stockholders" from engaging in a "business combination" with a publicly-held Delaware corporation for three years following the date these persons become interested stockholders unless the business combination is, or the transaction in which the person became an interested stockholder was, approved in a prescribed manner or another prescribed exception applies. Generally, an "interested stockholder" is a person who, together with affiliates and associates, owns, or within three years prior to the determination of interested stockholder status did own, 15% or more of a corporation's voting stock. Generally, a "business combination" includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. The existence of this provision may have an anti-takeover effect with respect to transactions not approved

in advance by the board of directors, such as discouraging takeover attempts that might result in a premium over the market price of our common stock.

Elimination of Stockholder Action by Written Consent

Our third amended and restated certificate of incorporation, which will become effective immediately prior to the closing of this offering, will provide that all stockholder actions must be effected at a duly called meeting of stockholders and not by consent in writing. A special meeting of stockholders may be called only by a majority of our board of directors, the chair of our board of directors, or our chief executive officer.

Undesignated Preferred Stock

The ability to authorize undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change control of us. These and other provisions may have the effect of deterring hostile takeovers or delaying changes in control or management of our company.

Amendment of Charter Provisions

Our third amended and restated certificate of incorporation will further provide that the affirmative vote of holders of at least 66²/₃% of the voting power of all of the then outstanding shares of voting stock, voting as a single class, will be required to amend certain provisions of our third amended and restated certificate of incorporation, including provisions relating to the size of the board, removal of directors, special meetings, actions by written consent and cumulative voting. The affirmative vote of holders of at least 66²/₃% of the voting power of all of the then outstanding shares of voting stock, voting as a single class, will be required to amend or repeal our amended and restated bylaws, although our amended and restated bylaws may be amended by a simple majority vote of our board of directors.

Classified Board; Election and Removal of Directors

Our third amended and restated certificate of incorporation will further provide that our board of directors is divided into three classes, Class I, Class II and Class III, with each class serving staggered terms, and will give our board of directors the exclusive right to expand the size of our board of directors and to elect directors to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director.

Choice of Forum

Our third amended and restated certificate of incorporation will provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, another state court located within the State of Delaware or, if no state court located within the State of Delaware has jurisdiction, the federal district court for the District of Delaware) will be the sole and exclusive forum for (i) any derivative action or proceeding brought on behalf of us, (ii) any action asserting a claim of breach of a fiduciary duty owed by any current or former director, officer, stockholder, employee or agent of ours to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the DGCL, our third amended and restated certificate of incorporation or our amended and restated bylaws (in each case, as may be amended from time to time), (iv) any action asserting a claim governed by the internal affairs doctrine of the State of Delaware, or (v) any other action asserting an “internal corporate claim,” as defined in Section 115 of the DGCL, in all cases subject to the court having personal jurisdiction over all indispensable parties named as defendants.

In addition, our third amended and restated certificate of incorporation will further provide that, unless we consent in writing to the selection of an alternative forum (which consent may be given at any time, including during the pendency of litigation), the federal district courts of the United States of America shall be the sole and exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. Any person or entity purchasing or otherwise acquiring or holding any interest in any of our securities will be deemed to have notice of and consented to this provision.

Limitation on Liability and Indemnification Matters

For a discussion of liability and indemnification, see “Management — Limitation on Liability and Indemnification Matters.”

Listing

We intend to apply to list our common stock on The Nasdaq Global Market under the trading symbol “CGTX”.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is .

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for our common stock, and a liquid trading market for our common stock may not develop or be sustained after this offering. Future sales of our common stock, including shares issued upon the exercise of outstanding options or warrants, in the public market after the closing of this offering, or the perception that those sales may occur, could adversely affect the prevailing market price for our common stock from time to time or impair our ability to raise equity capital in the future.

Based on the number of shares of common stock outstanding as of _____, 2021, upon the closing of this offering and assuming (i) the automatic conversion of all our preferred stock outstanding as of into an aggregate of 51,450,435 shares of our common stock upon the closing of this offering, (ii) the issuance of _____ shares of our common stock issuable upon the exercise of warrants to purchase common stock that otherwise would expire upon the closing of this offering (assuming an initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus), (iii) the issuance of _____ shares of our common stock issuable upon the conversion of the SAFEs upon the closing of this offering in the aggregate amount of \$8.9 million (assuming an initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus), (iv) no exercise of the underwriters' option to purchase additional shares of common stock, and (v) no exercise of outstanding options to purchase _____ shares of our common stock, we will have outstanding an aggregate of approximately _____ shares of common stock. All of the shares sold in this offering will be freely tradable unless purchased by our "affiliates" as such term is defined in Rule 144 under the Securities Act or purchased by existing stockholders and their affiliated entities that are subject to lock-up agreements. All remaining shares of common stock held by existing stockholders immediately prior to the closing of this offering will be "restricted securities," as such term is defined in Rule 144. These restricted securities were issued and sold in private transactions and are eligible for public sale only if registered under the Securities Act or if they qualify for an exemption from registration under the Securities Act, including the exemptions provided by Rule 144 or Rule 701 of the Securities Act, or Rule 701, which rules are summarized below.

As a result of the lock-up agreements referred to below and the provisions of Rule 144 and Rule 701 under the Securities Act, based on the number of shares of our common stock outstanding as of _____, 2021, the remaining shares of our common stock will generally become for sale in the public market are as follows:

Approximate Number of Shares	First Date Available for Sale on the Public Markets
Shares	181 days after the date of this prospectus, upon expiration of the lock-up agreements referred to below, subject in some cases to applicable volume, manner of sale and other limitations under Rule 144 and Rule 701.

We may issue shares of common stock from time to time as consideration for future acquisitions, investments or other corporate purposes.

In the event that any such acquisition, investment or other transaction is significant, the number of shares of common stock that we may issue may in turn be significant. We may also grant registration rights covering those shares of common stock issued in connection with any such acquisition and investment.

In addition, the shares of common stock reserved for future issuance under the 2017 Plan and 2021 Plan will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements, a registration statement under the Securities Act or an exemption from registration, including Rule 144 and Rule 701.

Rule 144

Under Rule 144, as currently in effect, once we have been subject to the public company reporting requirements of the Exchange Act for at least 90 days, and we are current in our Exchange Act reporting at the time of sale, a person (or persons whose shares are required to be aggregated) who is not deemed to have been one of our "affiliates" for purposes of Rule 144 at any time during the three months preceding a

sale and who has beneficially owned restricted securities within the meaning of Rule 144 for at least six months, including the holding period of any prior owner other than one of our “affiliates,” is entitled to sell those shares in the public market (subject to the lock-up agreement referred to below, if applicable) without complying with the manner of sale, volume limitations or notice provisions of Rule 144, but subject to compliance with the public information requirements of Rule 144. If such a person has beneficially owned the shares proposed to be sold for at least one year, including the holding period of any prior owner other than “affiliates,” then such person is entitled to sell such shares in the public market without complying with any of the requirements of Rule 144 (subject to the lock-up agreement referred to below, if applicable).

In general, under Rule 144, as currently in effect, once we have been subject to the public company reporting requirements of the Exchange Act for at least 90 days, our “affiliates,” as defined in Rule 144, who have beneficially owned the shares proposed to be sold for at least six months, are entitled to sell in the public market, upon expiration of any applicable lock-up agreements and within any three-month period, a number of those shares of our common stock that does not exceed the greater of:

- 1% of the number of shares of common stock then outstanding, which will equal approximately _____ shares of common stock immediately upon the closing of this offering (calculated as of _____, 2021 on the basis of the assumptions described above and assuming no exercise of the underwriter’s option to purchase additional shares and no exercise of outstanding options or warrants subsequent to _____, 2021); or
- the average weekly trading volume of our common stock on during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Such sales under Rule 144 by our “affiliates” or persons selling shares on behalf of our “affiliates” are also subject to certain manner of sale provisions, notice requirements and requirements related to the availability of current public information about us. Notwithstanding the availability of Rule 144, the holders of substantially all of our restricted securities have entered into lock-up agreements as referenced above and their restricted securities will become eligible for sale (subject to the above limitations under Rule 144) upon the expiration of the restrictions set forth in those agreements.

Rule 701

In general, under Rule 701 as currently in effect, any of our employees, directors, officers, consultants or advisors who acquired common stock from us in connection with a written compensatory stock or option plan or other written agreement in compliance with Rule 701 before the effective date of the registration statement of which this prospectus is a part (to the extent such common stock is not subject to a lock-up agreement) and who are not our “affiliates” as defined in Rule 144 during the immediately preceding 90 days, is entitled to rely on Rule 701 to resell such shares beginning 90 days after the date of this prospectus in reliance on Rule 144, but without complying with the notice, manner of sale, public information requirements or volume limitation provisions of Rule 144. Persons who are our “affiliates” may resell those shares beginning 90 days after the date of this prospectus without compliance with minimum holding period requirements under Rule 144 (subject to the terms of the lock-up agreement referred to below, if applicable).

Lock-Up Agreements

In connection with this offering, we, our directors, our executive officers and the holders of substantially all of our common stock, stock options and other securities convertible into, exercisable or exchangeable for our common stock, have agreed, subject to certain exceptions, with the underwriters not to directly or indirectly offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, or enter into any hedging, swap or other agreement or transaction that transfers any of the economic consequences of ownership of shares of our common stock or any options to purchase shares of our common stock, or any securities convertible into or exchangeable for shares of common stock, during the period from the date of this prospectus continuing through the date 180 days after the date of this prospectus, except with the prior written consent of the representative of the underwriters, and certain other limited exceptions. These agreements are described in the section titled “Underwriting.”

In addition to the restrictions contained in the lock-up agreements described above, we have entered into agreements with certain security holders, including the amended and restated investors' rights agreement, our standard form of option agreement, our standard form of restricted stock agreement and our standard form of restricted stock purchase agreement, that contain market stand-off provisions or incorporate market stand-off provisions from our equity incentive plan imposing restrictions on the ability of such security holders to offer, sell or transfer our equity securities for a period of 180 days following the date of this prospectus.

Following the lock-up periods set forth in the agreements described above, and assuming that the representative of the underwriters do not release any parties from these agreements, all of the shares of our common stock that are restricted securities or are held by our affiliates as of the date of this prospectus will be eligible for sale in the public market in compliance with Rule 144 under the Securities Act.

Registration Rights

Upon the closing of this offering, the holders of up to approximately million shares of our common stock (which includes all of the shares of common stock issuable upon (i) the automatic conversion of our preferred stock upon the closing of this offering, (ii) the conversion of our convertible notes, and (iii) the exercise of warrants that otherwise would expire upon the closing of this offering), or their transferees will be entitled to rights with respect to the registration of the resale of their shares under the Securities Act, subject to the lock-up agreements described under "Lock-Up Agreements" above. Registration of the resale of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act immediately upon the effectiveness of the registration statement registering such shares, except for shares purchased by affiliates.

Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock. The requisite percentage of these stockholders have waived all such stockholders' rights to notice of this offering and to include their shares of registrable securities in this offering.

See the section titled "Description of Capital Stock — Registration Rights" for additional information. Shares covered by a registration statement will be eligible for sale on the public market upon the expiration or release from the terms of any applicable lock-up agreement.

Equity Incentive Plans

We intend to file with the SEC a registration statement on Form S-8 under the Securities Act covering the shares of common stock reserved for issuance under the 2007 Plan, the 2017 Plan and the 2021 Plan. Such registration statement is expected to be filed and become effective as soon as practicable after the closing of this offering. Accordingly, shares registered under such registration statement will be available for sale in the open market following its effective date, subject to Rule 144 volume limitations for affiliates and the lock-up agreements described above, if applicable.

MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS

The following discussion is a summary of the material U.S. federal income tax consequences to Non-U.S. Holders (as defined below) of the purchase, ownership and disposition of our common stock issued pursuant to this offering, but does not purport to be a complete analysis of all potential tax effects. The effects of other U.S. federal tax laws, such as estate and gift tax laws, and any applicable state, local or non-U.S. tax laws are not discussed. This discussion is based on the Code, Treasury Regulations promulgated thereunder, judicial decisions, and published rulings and administrative pronouncements of the U.S. Internal Revenue Service, or the IRS, in each case in effect as of the date hereof. These authorities may change or be subject to differing interpretations. Any such change or differing interpretation may be applied retroactively in a manner that could adversely affect a Non-U.S. Holder of our common stock. We have not sought and will not seek any rulings from the IRS regarding the matters discussed below. There can be no assurance the IRS or a court will not take a contrary position to that discussed below regarding the tax consequences of the purchase, ownership and disposition of our common stock.

This discussion is limited to Non-U.S. Holders that hold our common stock as a “capital asset” within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all U.S. federal income tax consequences relevant to a Non-U.S. Holder’s particular circumstances, including the impact of the Medicare contribution tax on net investment income. In addition, it does not address consequences relevant to Non-U.S. Holders subject to special rules, including, without limitation:

- U.S. expatriates and former citizens or long-term residents of the United States;
- persons subject to the alternative minimum tax;
- persons holding our common stock as part of a hedge, straddle or other risk reduction strategy or as part of a conversion transaction or other integrated investment;
- banks, insurance companies and other financial institutions;
- brokers, dealers or traders in securities;
- “controlled foreign corporations,” “passive foreign investment companies” and corporations that accumulate earnings to avoid U.S. federal income tax;
- partnerships or other entities or arrangements treated as partnerships for U.S. federal income tax purposes (and investors therein);
- tax-exempt organizations or governmental organizations;
- persons deemed to sell our common stock under the constructive sale provisions of the Code;
- persons who hold or receive our common stock pursuant to the exercise of any employee stock option or otherwise as compensation;
- tax-qualified retirement plans;
- “qualified foreign pension funds” and entities all of the interests of which are held by qualified foreign pension funds; and
- persons subject to special tax accounting rules as a result of any item of gross income with respect to our common stock being taken into account in an applicable financial statement.

If an entity or arrangement treated as a partnership for U.S. federal income tax purposes holds our common stock, the tax treatment of a partner in the partnership will depend on the status of the partner, the activities of the partnership and certain determinations made at the partner level. Accordingly, partnerships holding our common stock and the partners in such partnerships should consult their tax advisors regarding the U.S. federal income tax consequences to them.

THIS DISCUSSION IS FOR INFORMATIONAL PURPOSES ONLY AND IS NOT TAX ADVICE. INVESTORS SHOULD CONSULT THEIR TAX ADVISORS WITH RESPECT TO THE APPLICATION OF THE U.S. FEDERAL INCOME TAX LAWS TO THEIR PARTICULAR SITUATIONS AS WELL AS ANY TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP

AND DISPOSITION OF OUR COMMON STOCK ARISING UNDER THE U.S. FEDERAL ESTATE OR GIFT TAX LAWS OR UNDER THE LAWS OF ANY STATE, LOCAL OR NON-U.S. TAXING JURISDICTION OR UNDER ANY APPLICABLE INCOME TAX TREATY.

Definition of a Non-U.S. Holder

For purposes of this discussion, a “Non-U.S. Holder” is any beneficial owner of our common stock that is neither a “U.S. person” nor an entity treated as a partnership for U.S. federal income tax purposes. A U.S. person is any person that, for U.S. federal income tax purposes, is or is treated as any of the following:

- an individual who is a citizen or resident of the United States;
- a corporation or entity treated as a corporation that is created or organized under the laws of the United States, any state thereof, or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust that (i) is subject to the primary supervision of a U.S. court and the control of one or more “United States persons” (within the meaning of Section 7701(a)(30) of the Code), or (ii) has a valid election in effect to be treated as a United States person for U.S. federal income tax purposes.

Distributions

As described in the section titled “Dividend Policy,” we do not currently intend to pay any cash dividends on our capital stock in the foreseeable future. However, if we make distributions of cash or property on our common stock, such distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and first be applied against and reduce a Non-U.S. Holder’s adjusted tax basis in its common stock, but not below zero. Any excess will be treated as capital gain and will be treated as described below under “— Sale or Other Taxable Disposition.”

Subject to the discussions below on effectively connected income, backup withholding and the Foreign Account Tax Compliance Act, or FATCA, dividends paid to a Non-U.S. Holder of our common stock will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends (or such lower rate specified by an applicable income tax treaty, provided the Non-U.S. Holder furnishes a valid IRS Form W-8BEN or W-8BEN-E (or other applicable documentation) certifying qualification for the lower treaty rate). A Non-U.S. Holder that does not timely furnish the required documentation, but that qualifies for a reduced treaty rate, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. Non-U.S. Holders should consult their tax advisors regarding their entitlement to benefits under any applicable income tax treaty.

If dividends paid to a Non-U.S. Holder are effectively connected with the Non-U.S. Holder’s conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment or fixed base in the United States to which such dividends are attributable), the Non-U.S. Holder will be exempt from the U.S. federal withholding tax described above. To claim the exemption, the Non-U.S. Holder must furnish to the applicable withholding agent a valid IRS Form W-8ECI, certifying that the dividends are effectively connected with the Non-U.S. Holder’s conduct of a trade or business within the United States.

Any such effectively connected dividends generally will be subject to U.S. federal income tax on a net income basis at the regular graduated rates. A Non-U.S. Holder that is a corporation also generally will be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on its effectively connected earnings and profits attributable to such dividends, as adjusted for certain items. Non-U.S. Holders should consult their tax advisors regarding any applicable tax treaties that may provide for different rules.

Sale or Other Taxable Disposition

Subject to the discussions below regarding backup withholding and FATCA, a Non-U.S. Holder will not be subject to U.S. federal income tax on any gain realized upon the sale or other taxable disposition of our common stock unless:

- the gain is effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment or fixed base in the United States to which such gain is attributable);
- the Non-U.S. Holder is a nonresident alien individual present in the United States for 183 days or more during the taxable year of the disposition and certain other requirements are met; or
- our common stock constitutes a U.S. real property interest, or USRPI, by reason of our status as a U.S. real property holding corporation, or USRPHC, for U.S. federal income tax purposes.

Gain described in the first bullet point above generally will be subject to U.S. federal income tax on a net income basis at the regular graduated rates. A Non-U.S. Holder that is a corporation also generally will be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on its effectively connected earnings and profits attributable to such gain, as adjusted for certain items.

Gain described in the third bullet point above will be subject to U.S. federal income tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty), which may be offset by U.S. source capital losses of the Non-U.S. Holder (even though the individual is not considered a resident of the United States), provided the Non-U.S. Holder has timely filed U.S. federal income tax returns with respect to such losses.

With respect to the third bullet point above, we believe we currently are not, and do not anticipate becoming, a USRPHC. However, because the determination of whether we are a USRPHC depends on the fair market value of our USRPIs relative to the fair market value of our non-U.S. real property interests and our other business assets, there can be no assurance we currently are not a USRPHC or will not become one in the future. Even if we are or were to become a USRPHC, gain arising from the sale or other taxable disposition by a Non-U.S. Holder of our common stock will not be subject to U.S. federal income tax if our common stock is "regularly traded," as defined by applicable Treasury Regulations, on an established securities market, and such Non-U.S. Holder owned, actually and constructively, 5% or less of our common stock throughout the shorter of the five-year period ending on the date of the sale or other taxable disposition or the Non-U.S. Holder's holding period. If we are a USRPHC and either our common stock is not regularly traded on an established securities market or a Non-U.S. Holder holds more than 5% of our common stock, actually or constructively, during the applicable testing period, such Non-U.S. Holder will generally be taxed on any gain in the same manner as gain that is effectively connected with the conduct of a U.S. trade or business, except that the branch profits tax generally will not apply.

Non-U.S. Holders should consult their tax advisors regarding any applicable income tax treaties that may provide for different rules.

Information Reporting and Backup Withholding

Payments of dividends on our common stock will not be subject to backup withholding, provided the holder either certifies its non-U.S. status by furnishing a valid IRS Form W-8BEN, W-8BEN-E or W-8ECI or otherwise establishes an exemption. However, information returns are required to be filed with the IRS in connection with any dividends on our common stock paid to the Non-U.S. Holder, regardless of whether any tax was actually withheld. In addition, proceeds of the sale or other taxable disposition of our common stock within the United States or conducted through certain U.S.-related brokers generally will not be subject to backup withholding or information reporting, if the applicable withholding agent receives the certification described above or the holder otherwise establishes an exemption. Proceeds of a disposition of our common stock conducted through a non-U.S. office of a non-U.S. broker that does not have certain enumerated relationships with the United States generally will not be subject to backup withholding or information reporting.

Copies of information returns that are filed with the IRS also may be made available under the provisions of an applicable treaty or agreement to the tax authorities of the country in which the Non-U.S. Holder resides or is established.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against a Non-U.S. Holder's U.S. federal income tax liability, provided the required information is timely furnished to the IRS.

Additional Withholding Tax on Payments Made to Foreign Accounts

Withholding taxes may be imposed under Sections 1471 to 1474 of the Code (commonly referred to as FATCA) on certain types of payments made to non-U.S. financial institutions and certain other non-U.S. entities. Specifically, a 30% withholding tax may be imposed on dividends on, or (subject to the proposed Treasury Regulations discussed below) gross proceeds from the sale or other disposition of, our common stock paid to a "foreign financial institution" or a "non-financial foreign entity" (each as defined in the Code), unless (i) the foreign financial institution undertakes certain diligence and reporting obligations, (ii) the non-financial foreign entity either certifies it does not have any "substantial United States owners" (as defined in the Code) or furnishes identifying information regarding each substantial United States owner or (iii) the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from these rules. If the payee is a foreign financial institution and is subject to the diligence and reporting requirements in clause (i) above, it must enter into an agreement with the U.S. Department of the Treasury requiring, among other things, that it undertakes to identify accounts held by certain "specified United States persons" or "United States-owned foreign entities" (each as defined in the Code), annually report certain information about such accounts, and withhold 30% on certain payments to non-compliant foreign financial institutions and certain other account holders. Foreign financial institutions located in jurisdictions that have an intergovernmental agreement with the United States governing FATCA may be subject to different rules.

Under the applicable Treasury Regulations and administrative guidance, withholding under FATCA generally applies currently to payments of dividends on our common stock. While withholding under FATCA would have applied also to payments of gross proceeds from the sale or other disposition of our common stock on or after January 1, 2021, proposed Treasury Regulations eliminate FATCA withholding on payments of gross proceeds entirely. Taxpayers generally may rely on these proposed Treasury Regulations until final Treasury Regulations are issued.

Prospective investors should consult their tax advisors regarding the potential application of withholding under FATCA to their investment in our common stock.

UNDERWRITING

B. Riley Securities, Inc. is acting as lead managing underwriter of the offering and acting as representative of the underwriters named below. We have entered into an underwriting agreement with the underwriters, dated _____, 2021. Subject to the terms and conditions of the underwriting agreement, we agreed to sell to the underwriters, and the underwriters agreed to purchase shares of our common stock, at the public offering price less the underwriting discounts and commissions set forth on the cover page of this prospectus.

Underwriters	Number of Shares
B. Riley Securities, Inc.	
Total	

The underwriters are committed to purchase all of the shares of common stock offered by us if any are taken, other than those covered by the option to purchase additional shares described below. The underwriting agreement provides that the underwriters' obligations to purchase shares of our common stock are subject to conditions contained in the underwriting agreement. A copy of the underwriting agreement has been filed as an exhibit to the registration statement of which this prospectus forms a part.

We have been advised by B. Riley Securities, Inc. that it proposes to offer shares of our common stock directly to the public at the public offering price set forth on the cover page of this prospectus, and at this price less a concession not in excess of \$ _____ per share of common stock to other dealers. The underwriters may allow, and certain dealers may re-allow, a discount from the concession not in excess of \$ _____ per share of common stock to certain brokers and dealers. After this offering, the offering price, concessions and other selling terms may be changed by the underwriters.

None of our securities included in this offering may be offered or sold, directly or indirectly, nor may this prospectus and any other offering material or advertisements in connection with the offer and sales of any of our common stock be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons who receive this prospectus are advised to inform themselves about and to observe any restrictions relating to this offering of our common stock and the distribution of this prospectus. This prospectus is neither an offer to sell nor a solicitation of any offer to buy any of our common stock included in this offering in any jurisdiction where that would not be permitted or legal.

Each underwriter has advised us that it does not intend to confirm sales to any accounts over which it exercises discretionary authority.

Underwriting Discount and Expenses

The following table summarizes the underwriting discount to the public offering price of the shares offered pursuant to this prospectus.

	Per Share	Total Without Exercise of Over- Allotment	Total With Exercise of Over- Allotment
Public offering price	\$	\$	\$
Underwriting discounts and commissions	\$	\$	\$
Proceeds, before expenses to us	\$	\$	\$

In addition to the discount set forth in the above table, we have agreed to reimburse the underwriters up to \$200,000 for certain of their fees and expenses relating to the offering. These expenses are payable by us.

Over-Allotment Option

In addition to the discount set forth in the above table, we have granted to the underwriters an option, exercisable not later than 45 days after the date of this prospectus, to purchase up to an additional 15% of

the shares of common stock firmly committed in this offering at the public offering price, less the underwriting discount, set forth on the cover page of this prospectus. The underwriters may exercise the option solely to cover over-allotments, if any, made in connection with this offering. If any additional shares of our common stock are purchased pursuant to the over-allotment option, the underwriters will offer these additional shares of our common stock on the same terms as those on which the other shares of common stock are being offered hereby.

Determination of Offering Price Listing

We intend to apply to list our common stock on The Nasdaq Global Market under the symbol “CGTX.” In order to meet the requirements for listing on that exchange, the underwriters have undertaken to sell a minimum number of shares to a minimum number of beneficial owners as required by that exchange.

Before this offering, there has been no public market for our common stock. Our lead managing underwriter, National Securities Corporation, is not obligated to make a market in our securities, and even if it chooses to make a market, can discontinue doing so at any time without notice. Neither we nor any underwriter can provide any assurance that an active and liquid trading market in our securities will develop or, if developed, that the market will continue.

The public offering price of the shares offered by this prospectus has been determined by negotiation between us and the underwriters. Among the factors considered in determining the public offering price of the shares were:

- our history and our prospects;
- the industry in which we operate;
- our past and present operating results;
- the previous experience of our executive officers; and
- the general condition of the securities markets at the time of this offering.

The offering price stated on the cover page of this prospectus should not be considered an indication of the actual value of the shares. Upon the commencement of trading, the price of our shares will be subject to change as a result of market conditions and other factors, and we cannot assure you that the shares can be resold at or above the public offering price.

Lock-Up Agreements

We, our executive officers and directors and each holder of our common stock have agreed not to sell or transfer any common stock or securities convertible into or exchangeable or exercisable for common stock, for 180 days after the date of this prospectus, subject to specified exceptions, without first obtaining the written consent of B. Riley Securities, Inc. Specifically, these persons have agreed, with certain limited exceptions, not to directly or indirectly:

- offer, pledge, sell, contract to sell or lend any common stock;
- sell any option or contract to purchase any common stock;
- purchase any option or contract to sell any common stock;
- grant any option, right or warrant to purchase any common stock;
- otherwise transfer or dispose of any common stock;
- make a demand or exercise any right with respect to the registration of any common stock;
- enter into any swap or any other agreement or any transaction that transfers, in whole or in part, the economic consequences of ownership of common stock, whether any such swap or transaction is to be settled by delivery of common stock or other securities, in cash or otherwise;
- publicly disclose the intention to make any offer, sale, pledge or disposition, or to enter into any transaction, swap hedge or other arrangement relating to any common stock; or

- in the case of the Company, file or cause to be filed any registration statement (other than a registration statement on Form S-8) with the Commission relating to the offering of any shares of our capital stock or any securities convertible into or exercisable or exchangeable for shares of our capital stock.

This lock-up provision applies to common stock and to securities convertible into or exchangeable or exercisable for common stock. It also applies to common stock owned now or acquired later by the person executing the agreement or for which the person executing the agreement later acquires the power of disposition.

Indemnification

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act relating to losses or claims resulting from material misstatements in or omissions from this prospectus, the registration statement of which this prospectus forms a part, certain free writing prospectuses that may be used in the offering and in any marketing materials used in connection with this offering and to contribute to payments the underwriters may be required to make in respect of those liabilities.

Short Positions and Penalty Bids

The underwriters may engage in over-allotment, syndicate covering transactions and penalty bids or purchases for the purpose of pegging, fixing or maintaining the price of the common stock, in accordance with Regulation M under the Exchange Act.

- Over-allotment involves sales by the underwriters of shares in excess of the number of shares the underwriters are obligated to purchase, which creates a syndicate short position. The short position may be either a covered short position or a naked short position. In a covered short position, the number of shares over-allotted by an underwriter is not greater than the number of shares that it may purchase in the over-allotment option. In a naked short position, the number of shares involved is greater than the number of shares in the over-allotment option. The underwriters may close out any short position by either exercising their over-allotment option and/or purchasing shares in the open market.
- Syndicate covering transactions involve purchases of the common stock in the open market after the distribution has been completed in order to cover syndicate short positions. In determining the source of shares to close out the short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which it may purchase shares through the over-allotment option. If the underwriters sell more shares than could be covered by the over-allotment option, a naked short position, the position can only be closed out by buying shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there could be downward pressure on the price of the shares in the open market after pricing that could adversely affect investors who purchase in the offering.
- Penalty bids permit an underwriter to reclaim a selling concession from a syndicate member when the shares originally sold by the syndicate member are purchased in a stabilizing or syndicate covering transaction to cover syndicate short positions.

These syndicate covering transactions and penalty bids may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of the common stock. As a result, the price of the common stock may be higher than the price that might otherwise exist in the open market. These transactions may be effected on the NASDAQ Global Market, and if commenced, they may be discontinued at any time.

Neither we nor the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of the common stock. In addition, neither we nor the underwriters make any representation that the underwriters will engage in these transactions or that any transaction, once commenced, will not be discontinued without notice.

Electronic Distribution

A prospectus in electronic format may be made available on the Internet sites or through other online services maintained by the underwriters, or by their affiliates. In those cases, prospective investors may view offering terms online. Other than the prospectus in electronic format, the information on an underwriter's website and any information contained in any other website maintained by an underwriter is not part of the prospectus or the registration statement of which this prospectus forms a part, has not been approved and/or endorsed by us or the underwriters in their capacity as underwriters and should not be relied upon by investors.

The underwriters' compensation in connection with this offering is limited to the fees and expenses described above under "Underwriting Discount and Expenses."

Other Relationships

The underwriters and certain of their affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. The underwriters and certain of their affiliates may in the future engage in investment banking and other commercial dealings in the ordinary course of business with us and our affiliates, for which it may in the future receive customary fees, commissions and expenses.

In addition, in the ordinary course of its business activities, the underwriters and their affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for its own account and for the accounts of its customers. Such investments and securities activities may involve securities and/or instruments of ours or our affiliates. The underwriters and their affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or financial instruments and may hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

LEGAL MATTERS

The validity of the issuance of our common stock offered in this prospectus will be passed upon for us by Troutman Pepper Hamilton Sanders LLP, Philadelphia, Pennsylvania. Certain legal matters in connection with this offering will be passed upon for the underwriters by McGuireWoods LLP, New York, New York.

EXPERTS

The consolidated financial statements of Cognition Therapeutics, Inc. at December 31, 2020 and 2019, and for each of the two years in the period ended December 31, 2020, appearing in this prospectus and registration statement have been audited by Ernst & Young LLP, independent registered public accounting firm, as set forth in their report thereon (which contains an explanatory paragraph describing conditions that raise substantial doubt about the Company's ability to continue as a going concern as described in Note 1 to the consolidated financial statements) appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the SEC a registration statement on Form S-1, including exhibits and schedules, under the Securities Act, with respect to the shares of common stock being offered by this prospectus. This prospectus, which constitutes part of the registration statement, does not contain all of the information in the registration statement and its exhibits. For further information with respect to us and the common stock offered by this prospectus, we refer you to the registration statement and its exhibits. Statements contained in this prospectus as to the contents of any contract or any other document referred to are not necessarily complete, and in each instance, we refer you to the copy of the contract or other document filed as an exhibit to the registration statement. Each of these statements is qualified in all respects by this reference.

You may read our SEC filings, including this registration statement, over the Internet at the SEC's website at www.sec.gov. Upon the closing of this offering, we will be subject to the information reporting requirements of the Exchange Act and we will file reports, proxy statements and other information with the SEC. These reports, proxy statements and other information will be available for review at the SEC's website referred to above. We also maintain a website at www.cogrx.com, at which, following the closing of this offering, you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. Information contained on or accessible through our website is not a part of this prospectus or the registration statement of which it forms a part, and the inclusion of our website address in this prospectus is an inactive textual reference only. You should not consider the contents of our website in making an investment decision with respect to our common stock.

Index to Consolidated Financial Statements
As of and for the years ended December 31, 2019 and 2020

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and the Board of Directors of Cognition Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Cognition Therapeutics, Inc. and Subsidiary (the Company) as of December 31, 2019 and 2020, the related consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholders' deficit and cash flows for the years then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2019 and 2020, and the results of its operations and its cash flows for the years then ended in conformity with U.S. generally accepted accounting principles.

The Company's Ability to Continue as a Going Concern

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

Basis for Opinion

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

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

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

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2020.

Philadelphia, Pennsylvania

May 7, 2021

COGNITION THERAPEUTICS, INC.

CONSOLIDATED BALANCE SHEETS

Amounts in thousands, except share and per share amounts

	As of December 31,	
	2019	2020
Assets		
Current assets		
Cash and cash equivalents	\$ 2,890	\$ 5,189
Grant receivables	2,662	564
Prepaid expenses	117	544
Other receivables	1,462	588
Other current assets	29	23
Total current assets	7,160	6,908
Property and equipment, net	299	211
Total assets	<u>\$ 7,459</u>	<u>\$ 7,119</u>
Liabilities, Convertible Preferred Stock, and Stockholders' Deficit		
Current liabilities		
Accounts payable	2,357	2,003
Current portion of capital lease obligation	4	—
Accrued expenses	1,321	994
Other current liabilities	1	253
Total current liabilities	3,683	3,250
Paycheck protection program loan	—	443
Derivative liability	1,493	2,209
Warrant liability	181	—
Convertible notes, net	6,897	12,409
Accrued interest	700	1,622
Total liabilities	<u>12,954</u>	<u>19,933</u>
Commitments and contingencies		
Convertible preferred stock:		
Series A convertible preferred stock, par value \$0.001 per share, 3,067,519 shares authorized at December 31, 2019 and 2020, 2,819,027 shares issued and outstanding as of December 31, 2019 and 2020; liquidation preference of \$4,766 as of December 31, 2020	4,413	4,616
Series A-1 convertible preferred stock, par value \$0.001 per share, 3,970,776 shares authorized at December 31, 2019 and 2020, 3,730,366 shares issued and outstanding as of December 31, 2019 and 2020; liquidation preference of \$5,572 as of December 31, 2020	5,160	5,398
Series A-2 convertible preferred stock, par value \$0.001 per share, 3,565,063 shares authorized at December 31, 2019 and 2020, 3,565,063 shares issued and outstanding as of December 31, 2019 and 2020; liquidation preference of \$5,997 as of December 31, 2020	5,552	5,809
Series B convertible preferred stock, par value \$0.001 per share, 30,450,000 shares authorized at December 31, 2019 and 2020, 30,409,890 shares issued and outstanding as of December 31, 2019 and 2020; liquidation preference of \$40,826 as of December 31, 2020	<u>37,802</u>	<u>39,547</u>
Total convertible preferred stock	<u>52,927</u>	<u>55,370</u>
Stockholders' deficit:		
Common stock, \$0.001 par value, 58,000,000 shares authorized at December 31, 2019 and 2020; 1,519,431 and 1,742,756 shares issued and outstanding at December 31, 2019 and 2020, respectively	2	2
Additional paid-in capital	—	221
Accumulated deficit	(58,239)	(68,220)
Accumulated other comprehensive loss	(185)	(187)
Total stockholders' deficit	<u>(58,422)</u>	<u>(68,184)</u>
Total liabilities, convertible preferred stock, and stockholders' deficit	<u>\$ 7,459</u>	<u>\$ 7,119</u>

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

COGNITION THERAPEUTICS, INC.
Consolidated Statements of Operations and Comprehensive Loss
Amounts in thousands, except share and per share amounts

	For the Year Ended December 31,	
	2019	2020
Operating Expenses:		
Research and development	\$ 14,379	\$ 12,887
General and administrative	3,452	4,520
Total operating expenses	17,831	17,407
Loss from operations	(17,831)	(17,407)
Other income (expense):		
Grant income	13,164	10,855
Change in the fair value of the derivative liability	(231)	18
Change in the fair value of the warrant liability	(7)	181
Other income, net	1,087	394
Loss on debt extinguishment	—	(129)
Interest expense, net	(1,024)	(1,751)
Total other income (expense), net	12,989	9,568
Net loss	(4,842)	(7,839)
Cumulative preferred stock dividends	(3,920)	(4,234)
Net loss attributable to common stockholders	\$ (8,762)	\$ (12,073)
Unrealized loss on foreign currency translation	(20)	(2)
Total comprehensive loss	\$ (4,862)	\$ (7,841)
Net loss per share attributable to common stockholders, basic and diluted	\$ (5.77)	\$ (7.35)
Weighted-average common shares outstanding, basic and diluted	1,519,285	1,643,514

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

COGNITION THERAPEUTICS, INC.
Consolidated Statements of Convertible Preferred Stock and Stockholders' Deficit
Amounts in thousands, except share amounts

	Series A Convertible Preferred Stock		Series A-1 Convertible Preferred Stock		Series A-2 Convertible Preferred Stock		Series B Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Balances as of December 31, 2018	2,819,027	\$4,086	3,730,366	\$4,778	3,565,063	\$5,141	30,409,890	\$35,002	1,519,236	\$ 2	\$ —	\$(49,838)	\$(165)	\$(50,001)
Exercise of warrants	—	—	—	—	—	—	—	—	195	—	—	—	—	—
Equity-based compensation	—	—	—	—	—	—	—	—	—	—	361	—	—	361
Accretion of convertible preferred stock to redemption value	—	327	—	382	—	411	—	2,800	—	—	(361)	(3,559)	—	(3,920)
Other comprehensive loss	—	—	—	—	—	—	—	—	—	—	—	—	(20)	(20)
Net loss	—	—	—	—	—	—	—	—	—	—	—	(4,842)	—	(4,842)
Balances as of December 31, 2019	2,819,027	4,413	3,730,366	5,160	3,565,063	5,552	30,409,890	37,802	1,519,431	2	—	(58,239)	(185)	(58,422)
Exercise of common stock warrants	—	—	—	—	—	—	—	—	163,334	—	34	—	—	34
Exercise of stock options	—	—	—	—	—	—	—	—	59,991	—	13	—	—	13
Equity-based compensation	—	—	—	—	—	—	—	—	—	—	475	—	—	475
Accretion of convertible preferred stock to redemption value	—	203	—	238	—	257	—	1,745	—	—	(301)	(2,142)	—	(2,443)
Other comprehensive loss	—	—	—	—	—	—	—	—	—	—	—	—	(2)	(2)
Net loss	—	—	—	—	—	—	—	—	—	—	—	(7,839)	—	(7,839)
Balances as of December 31, 2020	2,819,027	\$4,616	3,730,366	\$5,398	3,565,063	\$5,809	30,409,890	\$39,547	1,742,756	\$ 2	\$ 221	\$(68,220)	\$(187)	\$(68,184)

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

COGNITION THERAPEUTICS, INC.

Consolidated Statements of Cash Flows

Amounts in thousands

	For the Year Ended December 31,	
	2019	2020
Cash flows from operating activities:		
Net loss	\$(4,842)	\$(7,839)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	81	98
Amortization of debt issuance costs	30	54
Amortization of debt discount	464	782
Change in the fair value of the derivative liability	231	(18)
Change in the fair value of the warrant liability	7	(181)
Loss on debt extinguishment	—	129
Equity-based compensation	361	475
Changes in operating assets and liabilities:		
Grant receivables	(43)	2,097
Prepaid expenses and other current assets	(22)	(417)
Other receivables	(1,075)	904
Accounts payable	862	(364)
Accrued expenses and interest	934	595
Other current liabilities	(86)	252
Net cash used in operating activities	<u>(3,098)</u>	<u>(3,433)</u>
Cash flows from investing activities:		
Payments for property and equipment	(144)	(10)
Net cash used in investing activities	<u>(144)</u>	<u>(10)</u>
Cash flows from financing activities:		
Payments on capital lease obligation	(50)	(4)
Proceeds from the exercise of common stock warrants	—	34
Proceeds from the exercise of stock options	—	13
Proceeds from the paycheck protection program loan	—	443
Proceeds from the issuance of convertible notes	2,878	5,372
Debt issuance costs related to convertible notes	(34)	(93)
Net cash provided by financing activities	<u>2,794</u>	<u>5,765</u>
Effect of exchange rate changes on cash and cash equivalents	(60)	(23)
Net (decrease) increase in cash and cash equivalents	<u>(508)</u>	<u>2,299</u>
Cash and cash equivalents – beginning of period	3,398	2,890
Cash and cash equivalents – end of period	<u>\$ 2,980</u>	<u>\$ 5,189</u>
Supplemental disclosures of non-cash investing and financing activities:		
Purchase of property and equipment in accrued expenses	\$ 55	\$ —
Non-cash accretion of convertible preferred stock to redemption value	\$(3,920)	\$(2,443)

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

Cognition Therapeutics, Inc.
Notes to the consolidated financial statements
Amounts in thousands, except share and per share amounts

1. Description of Business and Financial Condition

Cognition Therapeutics, Inc. and Subsidiary (hereafter “the Company”) incorporated as a Delaware corporation on August 21, 2007. The Company is a biopharmaceutical company developing disease-modifying therapies for central nervous system (CNS) disorders. The Company’s pipeline candidates were discovered using proprietary biology and chemistry platforms designed to identify novel drug targets and disease-modifying therapies that address dysregulated pathways specifically associated with neurodegenerative diseases. The Company was founded on the unique combination of biological expertise around these targets, including proprietary assays that emphasize functional responses, and proprietary medicinal chemistry intended to produce novel, high-quality small-molecule drug candidates.

On July 14, 2015, the Company formed Cognition Therapeutics PTY LTD, a wholly owned subsidiary, primarily for the purpose of conducting research and development efforts at facilities located in Australia. Assets and liabilities of the Company’s Australian subsidiary, which uses the Australian dollar as its local functional currency, are translated to United States (U.S.) dollars at year-end exchange rates. Income statement accounts are translated using the average exchange rates prevailing during the month in which income and expenses are generated. Translation adjustments are recorded to accumulated other comprehensive income (loss) (“AOCI”) within stockholders’ deficit. Gains and losses from foreign currency transactions are included in net loss as a part of other income, net.

Liquidity and Going Concern

As of December 31, 2020, the Company had an accumulated deficit of \$68,220 and cash and cash equivalents of \$5,189. The Company incurred net losses of \$4,842 and \$7,839 for the years ended December 31, 2019 and 2020, respectively. The Company has financed its operations to date primarily through government and private philanthropic grants, private placements of its convertible preferred stock, private offerings of convertible notes, and the Simple Agreement for Future Equity, or SAFEs, described in Note 17. It is not anticipated that the Company will generate commercial revenue or operating cash flows in the foreseeable future. The Company’s ability to continue as a going concern in the near term is largely dependent on the Company’s ability to raise additional funds through debt or equity transactions, grant awards or other means. The Company’s forecasted cash required to fund operations, excluding future fundraising efforts and future additional NIH Grants, indicates that the Company does not have sufficient funds to support operations through the one year period from the issuance date of these financial statements. Accordingly, there is substantial doubt about the Company’s ability to continue as a going concern within one year after the date that these financial statements are issued.

Management’s plans to address this going concern uncertainty include raising additional financing through public or private equity offerings, debt financings, collaborations and licensing arrangements, additional grant awards, or other sources to fund its operations, however, there can be no assurance that the Company will be able to obtain such funding on terms acceptable to the Company, on a timely basis or at all. The failure of the Company to obtain sufficient funds on acceptable terms when needed would have a material adverse effect on the Company’s business, results of operations and financial condition.

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying financial statements have been prepared in conformity with U.S. generally accepted accounting principles (“GAAP”). Any reference in these notes to applicable guidance is meant to refer to

Cognition Therapeutics, Inc.
Notes to the consolidated financial statements
Amounts in thousands, except share and per share amounts

the authoritative United States generally accepted accounting principles as found in the Accounting Standards Codification (“ASC”) and Accounting Standards Update (“ASU”) of the Financial Accounting Standards Board (“FASB”).

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosures of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Cash and Cash Equivalents

Cash and cash equivalents consist primarily of interest-bearing deposits at various financial institutions. The Company considers all highly liquid investments with an original maturity of three months or less when purchased to be cash equivalents.

Receivables

Grant Receivables

Grant receivables relate to outstanding amounts due for reimbursable expenditures of awarded grants issued by the National Institute of Health and are carried at their estimated collectible amounts. The Company expects all receivables to be collectible, and accordingly, there is no allowance for doubtful accounts required on these grant receivables.

Other Receivables

Other receivables consist of research and development tax credits from the state of Pennsylvania and the Australian research and development tax credit from the Australian Tax Authority. Historically, the Company has sold the Pennsylvania tax credits to third parties, while the Australian tax refund is paid directly to the Company by the Australian Tax Authority. Research and development tax refunds and credits are carried at their estimated collectible amounts. The Company expects all receivables to be collectible and accordingly, there is no allowance for doubtful accounts required on these other receivables.

Property and Equipment

Property and equipment is recorded at cost, less accumulated depreciation. Depreciation is computed on the straight-line basis over the estimated useful life of the asset. The Company estimates the useful life to be 5 and 6 years for equipment and furniture and fixtures, respectively. The cost of repairs and maintenance is charged to expense as incurred.

Property and equipment is evaluated for impairment whenever events or changes in circumstances indicate the carrying value of an asset may not be recoverable from the estimated future cash flows expected to result from its use and eventual disposition. If expected cash flows are less than the carrying value, an impairment loss is recognized equal to an amount by which the carrying value exceeds the fair value of the assets. There were no indicators of impairment of long-lived assets during the years ended December 31, 2019 or 2020.

Convertible Instruments

ASC 815, *Derivatives and Hedging Activities* (“ASC 815”) requires companies to bifurcate certain conversion options and redemption features from their host instruments and account for them as free-standing derivative financial instruments should certain criteria be met.

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The Company also follows ASC 480-10, *Distinguishing Liabilities from Equity* (“ASC 480-10”) when evaluating the accounting for its hybrid instruments. A financial instrument that embodies an unconditional obligation, or a financial instrument other than an outstanding share that embodies a conditional obligation, that the issuer must or may settle by issuing a variable number of its equity shares shall be classified as a liability (or an asset in some circumstances) if, at inception, the monetary value of the obligation is based solely or predominantly on any one of the following: (a) a fixed monetary amount known at inception; (b) variations in something other than the fair value of the issuer’s equity shares; or (c) variations inversely related to changes in the fair value of the issuer’s equity shares. Hybrid instruments meeting these criteria are not further evaluated for any embedded derivatives and are carried as a liability at fair value at each balance sheet date.

Debt Issuance Costs and Discounts

The Company incurred third-party costs in connection with the convertible notes as described in Note 9. These costs are classified on the balance sheet as a direct deduction from the convertible notes and amortized over the term of the agreement as interest expense using the effective interest rate method.

Discounts related to bifurcated derivatives resulting from the convertible note issuances are recorded as a reduction to the carrying value of the debt and amortized over the life of the debt using the effective interest method.

Warrants Issued in Connection with Financings

The Company generally accounts for warrants issued in connection with debt and equity financings as a component of equity, unless the warrants include specific features, such as if the warrants are exercisable for securities that are considered contingently redeemable. For warrants that are exercisable for securities that are considered contingently redeemable, the Company records the fair value of the warrants as a liability at each balance sheet date and records changes in fair value in other (income) expense in the consolidated statement of operations and comprehensive loss.

Convertible Preferred Stock

The Company has classified convertible preferred stock outside of stockholders’ deficit in the accompanying balance sheets due to the convertible preferred stock’s redemption features. Originally, the convertible preferred stock was eligible to become redeemable at the holders option at any time after March 20, 2021. This right was removed in connection with an amendment to the Company’s articles of incorporation on July 29, 2020. Pre-amendment, the convertible preferred stock was redeemable due to the passage of time, and therefore, the Company recorded changes in the redemption value and accreted the convertible preferred stock immediately to the redemption value during each period presented. These increases were affected through charges against retained earnings, if any, and then to additional paid-in capital. In the absence of additional paid-in capital, the accretion is charged to accumulated deficit. Post-amendment, the convertible preferred stock is considered to be contingently redeemable only upon the occurrence of a deemed liquidation event (Note 10). As a result, the Company ceased accreting the convertible preferred stock on July 29, 2020. To evaluate whether the changes to the terms of the preferred stock should be accounted for as a modification or extinguishment, the Company follows the qualitative approach, in which amendments to preferred shares are analyzed based on the expected economics as well as the business purpose of the amendment. The Company concluded that the amendment did not result in a significant change to the fundamental nature of the preferred stock, and accordingly, the amendment was accounted for as a modification, and there was no accounting impact for the modification.

Grant income

In 2019 and 2020, the Company generated grant income of \$13,164 and \$10,855 from reimbursements from the National Institute of Health (“NIH”) for aging research. The Company records grant income in

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other income (expense) in the period in which the reimbursable research and development services are incurred and the right to payment is realized. The grants awarded relate to agreed upon direct and indirect costs for specific studies or clinical trials, which may include personnel and consulting costs, costs paid to contract research organizations (CROs), research institutions and/or consortiums involved in the grant, as well as facilities and administrative costs. These grants are cost plus fixed fee arrangements in which the Company is reimbursed for its eligible direct and indirect costs over time, up to the maximum amount of each specific grant award. Only costs that are allowable under the grant award, certain government regulations and the NIH's supplemental policy and procedure manual may be claimed for reimbursement, and the reimbursements are subject to routine audits from governmental agencies from time to time.

Research and Development Costs

The Company is involved in research and development aimed at the development of treatments for a variety of diseases related to the central nervous system, with a primary focus on Alzheimer's Disease. Research and development costs are expensed as incurred. Research and development expenses consist principally of personnel costs, including salaries, stock-based compensation, and benefits for employees, third-party license fees and other operational costs related to our research and development activities, including allocated facility-related expenses and external costs of outside vendors, and other direct and indirect costs. Non-refundable research and development costs are deferred and expensed as the related goods are delivered or services are performed. Costs for external development activities are recognized based on an evaluation of the progress to completion of specific tasks. Costs for certain research and development activities are recognized based on the pattern of performance of the individual arrangements, which may differ from the pattern of billings incurred, and are reflected in the consolidated financial statements as prepaid expenses or as accrued research and development expenses.

Income Taxes

The Company accounts for income taxes under the asset and liability method pursuant to authoritative guidance.

Under the asset and liability method, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. Under this authoritative guidance, the effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. If it is more likely than not that some portion or all of a deferred tax asset will not be recognized, a valuation allowance is recognized.

The Company accounts for uncertainty in income taxes using a recognition threshold of more-likely-than-not to be sustained upon examination by the appropriate taxing authority. Measurement of the uncertainty occurs if the recognition threshold is met. The Company has determined that there were no uncertainties as of December 31, 2019 and December 31, 2020 that met the recognition threshold.

Equity-based Compensation

Following the provisions of ASC 718, *Compensation — Stock Compensation*, the Company recognizes compensation expense for equity-based grants using the straight-line attribution method, in which the expense is recognized ratably over the requisite service period within operating expenses based on the grant date fair value. The Company also has granted awards subject to performance-based vesting. The Company would recognize compensation expense for these awards commencing in the period in which the vesting condition becomes probable of achievement. Grant date fair value is estimated on the date of grant using the Black-Scholes option pricing model. Forfeitures are recognized in the period in which they occur.

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Black-Scholes requires inputs based on certain subjective assumptions, including (i) the expected stock price volatility, (ii) the expected term of the award, (iii) the risk-free interest rate and (iv) expected dividends. Due to the lack of a public market for the Company's common stock and lack of company-specific historical and implied volatility data, the Company has based its computation of expected volatility on the historical volatility of a representative group of public companies with similar characteristics to the Company, including stage of product development and life science industry focus. The historical volatility is calculated based on a period of time commensurate with expected term assumption. The Company uses the simplified method to calculate the expected term for stock options granted to employees whereby the expected term equals the arithmetic average of the vesting term and the original contractual term of the stock options due to its lack of sufficient historical data. The risk-free interest rate is based on U.S. Treasury securities with a maturity date commensurate with the expected term of the associated award. The expected dividend yield is assumed to be zero as the Company has never paid dividends and has no current plans to pay any dividends on its common stock.

Due to the absence of an active market for the Company's common stock, the Company utilized methodologies in accordance with the framework of the American Institute of Certified Public Accountants Technical Practice Aid, *Valuation of Privately-Held Company Equity Securities Issued as Compensation*, to estimate the fair value of its common stock. In determining the exercise prices for stock options granted, the Company has considered the estimated fair value of the common stock as of the measurement date. The estimated fair value of the common stock has been determined at each grant date based upon a variety of factors, including the illiquid nature of the common stock, arm's-length sales of the Company's capital stock (including convertible preferred stock), the effect of the rights and preferences of the preferred stockholders and the prospects of a liquidity event. Among other factors are the Company's financial position and historical financial performance, the status of technological developments within the Company's research, the composition and ability of the current research and management team, an evaluation or benchmark of the Company's competition and the current business climate in the marketplace. Significant changes to the key assumptions underlying the factors used could result in different fair values of common stock at each valuation date.

Concentration of Credit Risk

The Company's financial instruments that are exposed to credit risks consist of cash and cash equivalents. The Company maintains its cash and cash equivalents in bank deposit accounts which, at times, may exceed the federally insured limit. The Company has not experienced any losses in these accounts and does not believe it is exposed to any significant credit risk related to these funds.

Fair Value of Financial Instruments

The Company applies ASC 820, *Fair Value Measurement* ("ASC 820"), which establishes a framework for measuring fair value and clarifies the definition of fair value within that framework. ASC 820 defines fair value as an exit price, which is the price that would be received for an asset or paid to transfer a liability in the Company's principal or most advantageous market in an orderly transaction between market participants on the measurement date. The fair value hierarchy established in ASC 820 generally requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. Observable inputs reflect the assumptions that market participants would use in pricing the asset or liability and are developed based on market data obtained from sources independent of the reporting entity. Unobservable inputs reflect the entity's own assumptions based on market data and the entity's judgments about the assumptions that market participants would use in pricing the asset or liability and are to be developed based on the best information available in the circumstances.

The carrying value of the Company's cash and cash equivalents, grants receivable, prepaid expense, other receivables, other current assets, accounts payable, accrued expenses and other current liabilities

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approximate fair value because of the short-term maturity of these financial instruments. In addition, the Company records its warrant liability and derivative liability at fair value.

The valuation hierarchy is composed of three levels. The classification within the valuation hierarchy is based on the lowest level of input that is significant to the fair value measurement. The levels within the valuation hierarchy are described below:

- **Level 1** — Assets and liabilities with unadjusted, quoted prices listed on active market exchanges. Inputs to the fair value measurement are observable inputs, such as quoted prices in active markets for identical assets or liabilities.
- **Level 2** — Inputs to the fair value measurement are determined using prices for recently traded assets and liabilities with similar underlying terms, as well as direct or indirect observable inputs, such as interest rates and yield curves that are observable at commonly quoted intervals.
- **Level 3** — Inputs to the fair value measurement are unobservable inputs, such as estimates, assumptions, and valuation techniques when little or no market data exists for the assets or liabilities.

Comprehensive Loss

The Company recorded \$20 and \$2 in other comprehensive loss related to foreign currency translation for the years ended December 31, 2019 and 2020, respectively. The Company presents comprehensive loss in a single statement within its consolidated financial statements.

Net Loss Per Share Attributable to Common Stockholders

Basic net loss attributable to common shares is computed by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding during each period. Diluted net loss attributable to common shares includes the effect, if any, from the potential exercise or conversion of securities, such as convertible preferred stock and stock options, which would result in the issuance of incremental shares of common stock. For diluted net loss per share, the weighted-average number of shares of common stock is the same for basic net loss per share due to the fact that when a net loss exists, dilutive securities are not included in the calculation as the impact is anti-dilutive. The Company's convertible preferred stock entitles the holder to participate in dividends and earnings of the Company, and, if the Company were to recognize net income, it would have to use the two-class method to calculate earnings per share. The two-class method is not applicable during periods with a net loss, as the holders of the convertible preferred stock have no obligation to fund losses.

Segments

The Company has determined that it operates and manages one operating segment, which is the business of developing and commercializing therapeutics. The Company's chief operating decision maker, its chief executive officer, reviews financial information on an aggregate basis for the purpose of allocating resources.

Emerging Growth Company Status

The Company is an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 ("JOBS Act"). Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. The Company has elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that it is (a) no longer an emerging growth company or (b) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, these

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financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

Recent Accounting Pronouncements

In February 2016, the FASB issued Accounting Standards Update (ASU) No. 2016-02, *Leases* (Topic 842). ASU No. 2016-02 requires lessees to recognize the assets and liabilities that arise from leases on the balance sheet. A lessee should recognize in the statement of financial position a liability to make lease payments (the lease liability) and a right-of-use asset representing its right to use the underlying asset for the lease term. ASU No. 2016-02 is effective for the Company for annual periods beginning after December 15, 2021. Early adoption is permitted. The Company expects to adopt this guidance when effective and is assessing what effect the adoption of ASU 2016-02 will have on its consolidated financial statements and accompanying notes. The Company expects to record right-of-use assets and liabilities upon adoption.

In June 2018, the FASB issued ASU 2018-07, *Compensation — Stock Compensation* (Topic 718) Improvements to Nonemployee Share-Based Payment Accounting. The new ASU simplifies the accounting for share-based payments to non-employees by aligning it with the accounting for share-based payments to employees, with certain exceptions. The Company adopted the standard on January 1, 2020 and it did not have a material impact on the Company's financial condition, results of operations and cash flows.

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement* (Topic 820). This standard modifies disclosure requirements related to fair value measurement and is effective for all entities for fiscal years beginning after December 15, 2019. Among other things, ASU 2018-13 requires public entities to disclose the range and weighted average used to develop significant unobservable inputs for level 3 fair value measurements, while eliminating the requirement for public entities to disclose the amount of and reasons for transfers between level 1 and level 2 of the fair value hierarchy. Implementation on a prospective or retrospective basis varies by specific disclosure requirement. The standard also allows for early adoption of any removed or modified disclosures upon issuance while delaying adoption of the additional disclosures until their effective date. The Company adopted this guidance on January 1, 2020 and the adoption did not have a material impact on its financial statements.

In August 2020, the FASB issued ASU 2020-06, *Debt — Debt with Conversion and Other Options* (Subtopic 470-20) and *Derivatives and Hedging — Contracts in Entity's Own Equity* (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity. This ASU simplifies the accounting for certain convertible instruments. ASU 2020-06 will be effective for fiscal years beginning after December 15, 2021, with early adoption permitted for interim and annual reporting periods beginning after December 15, 2020. The Company is currently evaluating the impact of the pending adoption of the new standard on the Company's consolidated financial statements.

In October 2020, the FASB issued ASU 2020-10, *Codification Improvements*, which updates various codification topics by clarifying or improving disclosure requirements to align with the SEC's regulations. The Company will adopt ASU 2020-10 as of the reporting period beginning January 1, 2021. The adoption of this update is not expected to have a material effect on the Company's financial statements.

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3. Financial Instruments and Fair Value Measurements

Financial assets and liabilities measured at fair value are summarized below:

As of December 31, 2019				
	Quoted Priced in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets:				
Money market funds	\$1,886	\$—	\$ —	\$1,886
Total assets	<u>\$1,886</u>	<u>\$—</u>	<u>\$ —</u>	<u>\$1,886</u>
Liabilities:				
Derivative liability	\$ —	\$—	\$1,493	\$1,493
Warrant liability	—	—	181	181
Total liabilities	<u>\$ —</u>	<u>\$—</u>	<u>\$1,674</u>	<u>\$1,674</u>

As of December 31, 2020				
	Quoted Priced in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets:				
Money market funds	\$2,853	\$—	\$ —	\$2,853
Total assets	<u>\$2,853</u>	<u>\$—</u>	<u>\$ —</u>	<u>\$2,853</u>
Liabilities:				
Derivative liability	\$ —	\$—	\$2,209	\$2,209
Total liabilities	<u>\$ —</u>	<u>\$—</u>	<u>\$2,209</u>	<u>\$2,209</u>

The following table sets forth a summary of the changes in fair value of the Level 3 liabilities for the years ended December 31, 2019 and 2020:

	Warrant Liability	Derivative Liability	Total
Balance at December 31, 2018	\$ 174	\$ 771	\$ 945
Change in the fair value of the warrant liability	7	—	7
Fair value recognized upon the issuance of Convertible Notes	—	491	491
Change in the fair value of the derivative liability	—	231	231
Balance at December 31, 2019	181	1,493	1,674
Change in the fair value of the warrant liability	(181)	—	(181)
Fair value recognized upon the issuance of Convertible Notes	—	734	734
Change in the fair value of the derivative liability	—	(18)	(18)
Total liabilities	<u>\$ —</u>	<u>\$ 2,209</u>	<u>\$ 2,209</u>

Derivative Liability — The Company recognizes derivative liabilities as a result of the issuance of the convertible notes that contain conversion and redemption features that are required to be bifurcated. The fair value measurement of the derivative liability is classified as Level 3 under the fair value hierarchy as it has been valued using certain unobservable inputs. These inputs include: (1) probability of occurrence of

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future events (such as a qualified financing or a sale), and (2) discount rate for implied return required by investor. Significant increases or decreases in any of those inputs in isolation could result in a significantly lower or higher fair value measurement.

The fair value of the derivative liability was determined by calculating the fair value of the notes with the conversion and redemption features as compared to the fair value of the notes without such features, with the difference representing the value of the conversion and redemption features, or the derivative liability. The conversion and redemption features are measured at fair value as of each reporting date and the change in the fair value for the period is recorded in the consolidated statements of operations as a change in the fair value of the derivative liability. The fair value of the derivative liability is based on Level 3 unobservable inputs. Changes in fair value are recognized as a gain or loss within other income (expense) on the consolidated statements of operations and comprehensive loss.

Warrant Liability — As of December 31, 2019 the company had 180,724 of series A-1 preferred stock warrants outstanding. The fair value of the warrant liability was reported as a long-term liability on the consolidated balance sheet. The warrants expired unexercised in October 2020 and the Company recorded a change in fair value adjustment of \$181 in the consolidated statement of operations and comprehensive loss.

4. Property and Equipment

Property and equipment, net, consisted of the following:

	As of December 31,	
	2019	2020
Equipment	\$ 977	\$ 987
Furniture and fixtures	1	1
Property and equipment, gross	978	988
Less: Accumulated depreciation	(679)	(777)
Property and equipment, net	<u>\$ 299</u>	<u>\$ 211</u>

Depreciation expense for the years ended December 31, 2019 and 2020 was \$43 and \$60. Amortization expense was \$38 for the years ended December 31, 2019 and 2020. Equipment cost includes an asset under a capital lease totaling \$190 on December 31, 2019 and December 31, 2020. Accumulated amortization of the leased equipment as of December 31, 2019 and December 31, 2020 was \$114 and \$152.

5. Accrued Expenses

Accrued expense consists of the following:

	As of December 31,	
	2019	2020
Employee compensation, benefits, and related accruals	\$ 532	\$732
Consulting and contracted research	566	143
Professional fees	164	114
Other accrued	59	5
Total	<u>\$1,321</u>	<u>\$994</u>

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6. Other Receivables

Other receivables consist of the following:

	As of December 31,	
	2019	2020
Research and development incentive receivables	\$1,364	\$489
Other receivables	98	99
Total	\$1,462	\$588

7. Other Income Net

Other income net consists of the following:

	Year Ended December 31,	
	2019	2020
Research and development incentive	\$ 982	\$474
Foreign currency loss	—	(88)
Other income, net	105	8
Total	\$1,087	\$394

8. Commitments and Contingencies

The Company has operating leases for its office and laboratory facilities under agreements that run through June 30, 2023. The Company entered into a capital lease agreement on December 9, 2016, as a lessee. The leased equipment has a one-dollar buyout option at the conclusion of the lease term. The agreement requires 36 total monthly lease payments of \$4,338. In 2020, the capital lease has expired.

Minimum lease commitments consisted of the following as of December 31, 2020:

	Operating Leases
2021	\$118
2022	118
2023	59
Total lease commitments	\$295

Rent expense was \$118 and \$179 for the years ended December 31, 2019 and 2020, respectively.

From time to time, the Company may be involved in disputes or regulatory inquiries that arise in the ordinary course of business. When the Company determines that a loss is both probable and reasonably estimable, a liability is recorded and disclosed if the amount is material to the financial statements taken as a whole. When a material loss contingency is only reasonably possible, the Company does not record a liability, but instead discloses the nature and the amount of the claim, and an estimate of the loss or range of loss, if such an estimate can reasonably be made.

As of December 31, 2019 and 2020, there was no litigation or contingency with at least a reasonable possibility of a material loss.

9. Debt

On March 8, 2018, the Company entered into a Convertible Note Purchase Agreement ("the Original Agreement") with existing investors of the Company. Under the terms of the Original Agreement, the

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Company agreed to issue up to \$5,000 in principle Convertible Notes (the “Original Notes”). The Original Notes accrued interest at 4.0% per annum from the date of issuance with a maturity date of February 27, 2020 (subsequently extended — see below). The Company issued \$2,965 in Original Notes in March and April 2018. Under the terms of the Original Agreement, the following features are included:

- i. Automatic conversion into equity securities upon the closing of an equity financing with aggregate gross proceeds of at least \$10,000, at the conversion price equal to 90.0% of the lowest price per share of the equity financing securities sold (a “Automatic Conversion Upon a Qualified Financing”)
- ii. Optional conversion into equity securities upon the closing of an equity financing that does not constitute a Qualified Financing at a conversion price equal to 90.0% of the price per share of the equity financing securities sold (a “Optional Conversion Upon a Non-Qualified Financing”)
- iii. Optional conversion of the unpaid principal balance plus accrued and unpaid interest to into Series B-1 convertible preferred stock at a conversion price of \$1.385 per share or redemption of the unpaid principal balance plus accrued and unpaid interest if (i) a transaction results in any person or group with over 50.0% voting power, (ii) any consolidation or merger transaction, or (iii) a sale or transfer of substantially all of the Company’s assets (“Option Conversion or Redemption”)
- iv. Automatic redemption of unpaid principal and all accrued and unpaid interest upon maturity, liquidation, dissolution, winding up, or event of default (“Automatic Redemption”)

On November 15, 2018, the Company entered into a Convertible Note Purchase Agreement (the “Additional Agreement”) with existing investors of the Company. Under the terms of the Additional Agreement, the Company agreed to issue up to an aggregate of \$8,000 in principle Convertible Notes (the “Additional Notes”). In connection with the Additional Agreement, the Company amended the Original Notes (the “Amendment”). The Amendment resulted in the following changes to the Original Notes:

- i. the interest rate of the Original Notes accrue interest at 4.0% from issuance to November 15, 2018, and accrue interest at 8.0% from November 15, 2018 to maturity or conversion,
- ii. the conversion price was amended to 80.0% of the price per share in connection with conversion of the notes upon a Qualified or Non-Qualified Financing,
- iii. the holder’s option upon a sale event to receive repayment, at two times the principal plus accrued and unpaid interest, (“Optional Redemption Upon a Sales Transaction”) and
- iv. a condition that each holder of \$1,000 in aggregate principal must be included in the 66 2/3% of the holders of the principal amount of the Notes to provide consent to make any further amendments or waivers.

On February 27, 2020, the Company entered into a Convertible Note Purchase Agreement (the “Second Amendment”) with existing investors of the Company. Under the terms of the Second Amendment, the Company agreed to issue up to an aggregate of \$10,035 in principle Convertible Notes (the “Second Amendment Notes”). In connection with the Second Amendment, the Company amended the Original Notes and Additional Notes. The Second Amendment resulted in the following changes:

- i. extend the maturity date to June 30, 2021
- ii. add a cap for a conversion in connection with a Qualified Financing
- iii. provide for mandatory conversion of the Combined Notes into Series B-1 convertible preferred stock of the Company if the Company has not completed a Qualified Financing on or before June 30, 2021

The Company applied extinguishment accounting to the Original Notes upon execution of the Amendment in 2018 on the basis that the present value of the cash flows under the terms of the Amendment

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of the Original notes were determined to be substantially different. The Company applied extinguishment accounting upon execution of the Second Amendment as the addition of the conversion features are substantive and recorded a loss on debt extinguishment of \$129 in the consolidated statement of operations and comprehensive loss during 2020.

Each Additional Note and Second Amendment Note (collectively with the Original Notes, the “Convertible Notes” or the “Notes”) included the features set forth above. The Company issued \$2,965 Original Notes in 2018, \$4,661 Additional Notes in 2018 and 2019, and \$5,372 Second Amendment Notes in 2020.

The total issuance costs incurred in connection with all closings of the Convertible Notes was \$205.

The Convertible Notes were considered to be a hybrid financial instrument consisting of a fixed interest rate host with certain embedded features requiring evaluation for bifurcation and separate accounting. The Company determined that the Automatic Conversion Upon a Qualified Financing, Optional Conversion Upon a Non-Qualified Financing and the Optional Redemption Upon a Sales Transaction were considered freestanding financial instruments which required bifurcation from the host debt instruments.

The resulting debt discount from the derivative liabilities was presented as a direct deduction from the carrying amount of the Convertible Notes and amortized to interest expense using the effective interest rate method.

The Convertible Notes as of December 31, 2019 and 2020 consist of the following:

	2019	2020
Convertible notes principal	\$7,626	\$12,998
Less: unamortized note issuance costs	(44)	(45)
Less: debt discount	(685)	(544)
	\$6,897	\$12,409

Interest expense on the convertible notes, including amortization of debt issuance costs, consisted of the following for the year ended December 31, 2019 and 2020:

	2019	2020
Coupon interest	\$ 574	\$ 922
Issuance costs amortization	30	54
Discount amortization	464	782
	\$1,068	\$1,758

At December 31, 2020 and 2019, the Company has classified the outstanding convertible notes, as well as accrued interest, within long term liabilities, as the convertible notes are not expected to require the use of current assets to settle the obligations within the next twelve months. In May of 2021, the convertible notes and accrued interest thereon were converted in Series B-1 convertible preferred stock (Note 17).

In April 2020, the Company received a \$443 unsecured loan, bearing interest at 1.0%, pursuant to the Paycheck Protection Program (the “PPP”), a program implemented by the U.S. Small Business Administration (the “SBA”) under the Coronavirus Aid, Relief, and Economic Security Act (the “CARES Act”) (the “PPP Loan”). The PPP provides for loans to qualifying businesses for amounts up to 2.5 times of the average monthly payroll expenses of the qualifying business. The loan and accrued interest are forgivable after eight weeks if the borrower uses the loan proceeds for eligible purposes, including payroll, benefits, rent and utilities. The amount of loan forgiveness may be reduced if the borrower terminates employees or reduces salaries during the eight-week period. The unforgiven portion of the PPP loan is payable over two years at an

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interest rate of 1.0%, with a deferral of payments for the first six months. The Company used the proceeds for purposes consistent with the PPP.

10. Preferred Stock

As of December 31, 2020, convertible preferred stock consisted of the following:

Class of Preferred	Preferred Stock Authorized	Preferred Stock Issued and Outstanding	Carrying Value	Liquidation Preference	Common Stock Issuable Upon Conversion
Series A Preferred Stock	3,067,519	2,819,027	\$ 4,616	\$ 4,766	2,819,027
Series A-1 Preferred Stock	3,970,776	3,730,366	5,398	5,572	3,730,366
Series A-2 Preferred Stock	3,565,063	3,565,063	5,809	5,997	3,565,063
Series B Preferred Stock	30,450,000	30,409,890	39,547	40,826	30,409,890
Total	41,053,358	40,524,346	\$55,370	\$ 57,161	40,524,346

Rights, preferences, privileges, and restrictions:

The holders of shares of Series A, A-1, A-2, B and B-1 convertible preferred stock (or collectively, the “Preferred Stock”) have the rights, preferences, privileges, and restrictions as set forth below:

Dividends:

The holders of the Preferred Stock are entitled to receive cumulative dividends when, as and if declared by the Company’s Board of Directors. Accrued dividends shall accrue only on the unreturned amount of the original issue price taking into account the payment of any mandatory dividend. As used herein, “original issue price” means \$0.69 per share with respect to the Series A and A-1 preferred stock, \$0.8415 per share with respect to the Series A-2 preferred Stock, and \$0.923 per share with respect to the Series B preferred stock. After such time the holders receive their full preferred liquidation amount, less any and all mandatory dividends, the holders of preferred stock will not be entitled to any additional accruing dividends; provided that the holders of the preferred stock will share in all dividends and distributions declared by the Board of Directors and paid by the Company with the holders of common stock on an as if converted to common stock basis.

Voting Rights:

The holders of Preferred Stock are entitled to voting rights equal to the number of shares of common stock into which the shares of Preferred Stock can be converted. In addition, as long as there are shares of Preferred Stock outstanding, each of the holders of over 7.5% of the total Preferred Stock outstanding on a converted basis shall be entitled to designate one director of the Company to be elected by the holders of Preferred Stock. The holders of a majority of the then outstanding shares of common stock, voting together as a single class, shall be entitled to elect one director of the Company. If the holders of the Preferred Stock or common stock fail to elect a sufficient number of directors to fulfill directorships for which they are entitled to elect directors, then any directorship shall remain vacant until the holders of the Preferred Stock or common stock elect such person.

Liquidation Rights:

In the event of any liquidation, dissolution or winding up of the Company, whether voluntary or involuntary, the holders of Preferred Stock have liquidation preferences, before any distribution or payment is made to holders of any common stock, in an amount per share equal to the original issue price for such Preferred Stock plus all accruing dividends (the “Preferred Liquidation Amount”). If the assets and funds to

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be distributed among the holders of Preferred Stock are insufficient to permit the payment to such holders, then the entire assets and funds of the Company legally available for distribution will be distributed ratably among the holders of Preferred Stock in proportion to the Preferred Liquidation Amount each such holder is otherwise entitled to receive on each share, less any mandatory dividends.

Upon completion of the payment of the full liquidation preference of Preferred Stock less any and all mandatory dividends previously distributed, the remaining assets of the Company, if any, shall be distributed among the holders of common stock and Preferred Stock, pro rata based on the number of common shares held by each (assuming conversion of all shares of the Preferred Stock into common stock).

Conversion:

Each share of Preferred Stock is convertible into shares of common stock, at the option of the holder, at any time after date of issuance. Each share of Preferred Stock automatically converts to the number of shares of common stock determined in accordance with the conversion rate upon the closing of a public offering, at a price per share of not less than three times the highest, then applicable conversion price, resulting in offering proceeds of at least \$30,000 net of underwriting discounts and commissions ("Mandatory Conversion Time"). The conversion ratio will be adjusted in the case of specified changes to the Company's capitalization as a result of stock splits, combinations, common stock dividends and distributions, reclassifications, exchanges, substitutions, reorganizations, mergers or consolidations.

Redemption:

Prior to the July 29, 2020 amendment to the article of incorporation, Preferred Stockholders had the right to redeem shares of preferred stock on or after March 20, 2021 after receipt of written notice requesting redemption from 60% of the then outstanding shares of the preferred stock voting together as a single class on an as-converted to common stock basis at a price equal to the original issue price plus all accruing dividends. As the Preferred Stock was redeemable due to the passage of time prior to the amendment, the Company recorded changes in the redemption value and accreted the Preferred Stock immediately to its redemption value during each reporting period.

On July 29, 2020, the articles of incorporation were amended resulting in the removal of the redemption right. As the redemption option was removed in connection with the amendment, the only option for redemption is based on the occurrence of a deemed liquidation event. As the events that would trigger a deemed liquidation event are corporate transactions that are not certain to occur, the Company determined that post July 29, 2020, the Preferred Stock is no longer considered probable to become redeemable, and is instead contingently redeemable. As a result, the Company ceased the accretion of the Preferred Stock to redemption value upon execution of the amendment to the articles of incorporation.

Protective Provisions:

At any time when shares of Preferred Stock are outstanding, the Company shall not, either directly, indirectly by amendment, merger, consolidation or otherwise, do any of the following without the written consent or affirmative vote of at least 60% of the then outstanding shares of Preferred Stock, voting together as a single class on an as-converted to Common Stock basis: (i) effect the consummation of a liquidation event or any other merger or consolidation, (ii) amend, alter or repeal any provision of the Company's certificate of incorporation or bylaws in a manner that adversely affects the powers, preferences or rights of the Preferred Stock, (iii) amend, alter, or repeal any provision of the by-laws of the Company, in a manner that affects the powers, preferences, or rights of Preferred Stock, (iv) increase or decrease the authorized number of shares of Preferred Stock or Common Stock, (v) reclassify, alter, or amend any existing security of the Company in respect to the distribution of assets on the liquidation, dissolution, or winding up of the Company or payment of dividends, if such reclassification, alteration, or amendment would render such other security senior to Preferred Stock in respect to any such right, preference, or privilege, (vi) purchase or

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redeem, or declare any dividend, on any shares of capital stock of the Company other than repurchase of stock pursuant to stock restriction agreements approved by the Board of Directors that grant to the Company the right of repurchase upon termination of the service, (vii) borrow or authorize any amount of indebtedness, other than inventory financing in the ordinary course of business and any indebtedness in an amount of up to \$250 in aggregate that is approved by the Board of Directors, (viii) increase or decrease the authorized number of directors of the Board of Directors (ix) effect a change in business from the discovery and development of small molecule therapeutics targeting toxic proteins that cause cognitive decline associated with Alzheimer's disease and other neurodegenerative diseases, (x) enter into any transaction with any person other than in the ordinary course of business on an arm's length basis, (xi) increase the number of shares of common stock reserved for issuance, (xii) make any loan except advances in ordinary course of business or advances up to \$50 in aggregate approved by the Board of Directors, (xiii) hire, terminate, or change compensation in excess of \$100 of any officer, director, or employee, unless approved by the Board of Directors, (xiv) own any stock or securities of any other corporation, unless approved by the Board of Directors, (xv) guarantee any indebtedness except for trade accounts of the Company or any guarantee approved by the Board of Directors, (xvi) make any investment other than investments in prime commercial paper, money market funds, certificates of deposits in any United States bank having a net worth in excess of \$100,000 or obligations issued or guaranteed by the United States of America, unless approved by the Board of Directors.

11. Warrants

In conjunction with both debt and equity investments, the Company issued warrants on each of the following classes of stock: Common and Series A-1.

The following is a summary of the Company's outstanding common stock warrants as of December 31, 2020:

Number of Warrants	Exercise Price	Expiration Date
163,334	\$0.21	May 2021
375,741	\$0.01	March 2023
78,194	\$0.01	May 2023
33,387	\$0.01	August 2023

Series A-1 Preferred Stock Warrants

The Company reviewed the classification of the warrants as liabilities or equity under the guidance of ASC 480-10, Distinguishing Liabilities from Equity, and concluded that the Series A-1 convertible preferred stock warrants should be classified as a liability. The Company re-measures the warrant liability to fair market value at the end of each reporting period. The Series A-1 preferred stock warrants expired in October 2020 and were not exercised. For the year ended December 31, 2020, the Company recorded a fair value adjustment of \$181 in the consolidated statement of operations and comprehensive loss.

Common Stock Warrants

The Company's common stock warrants are equity classified as there are no features within the warrant agreements that require liability treatment. Accordingly, the warrants are recorded as a component of equity when they are issued.

12. Common Stock

Common stockholders are entitled to dividends if and when declared by the Company's Board of Directors subject to the rights of the preferred stockholders. As of December 31, 2020, no dividends on common stock had been declared by the Company.

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The Company has reserved the following shares of common stock for conversion of preferred stock, exercise of warrants and exercise of stock options as of December 31:

	2019	2020
Convertible preferred stock outstanding	40,524,346	40,524,346
Options issued and outstanding	13,245,253	14,839,637
Warrants for series A-1 preferred stock	180,724	—
Warrants for common stock	813,990	650,656
Total	<u>54,764,313</u>	<u>56,014,639</u>

13. Equity-based Compensation

On September 15, 2017, the Company's Board of Directors (the Board) approved the 2017 Amended and Restated Equity Incentive Plan (the "Plan"), which provides for the granting of incentive stock options, non-qualified stock options and stock awards to employees, certain consultants and directors. The Board, or its designated committee, has the sole authority to select the individuals to whom awards are granted and determine the terms of each award, including the number of shares and the schedule upon which the award becomes exercisable.

The aggregate number of shares of common stock of the Company that may be issued under the Plan is 15,288,989 (taking into account shares of common stock that may become issuable pursuant to Section 3(b) of the Plan in respect of shares of common stock reserved under the Company's Amended and Restated 2007 Equity Incentive Plan). The Plan also allows for a provision for shares granted which are cancelled, forfeited, exchanged or surrendered without having been exercised to subsequently be available for reissuance under the Plan.

The Company recorded total equity-based compensation expense in the statement of operations and comprehensive loss related to incentive stock options and nonstatutory stock options as follows:

	Year Ended December 31,	
	2019	2020
Research and development	\$175	\$216
General and administrative	186	259
Total equity-based compensation	<u>\$361</u>	<u>\$475</u>

As of December 31, 2020, total future compensation expense related to unvested awards yet to be recognized by the Company was \$1,182. Total future compensation expense related to unvested awards yet to be recognized by the Company is expected to be recognized over a weighted- average remaining vesting period of approximately 2.2 years.

The fair value of options granted was estimated on the date of grant using the Black-Scholes option pricing model with the following assumptions:

	Year Ended December 31,	
	2019	2020
Fair value of common stock	\$0.33	\$0.37
Expected volatility	88.92% – 97.50%	101.35% – 109.34%
Risk-free interest rate	1.43% – 2.50%	0.27% – 1.60%
Dividend yield	0.00%	0.00%
Expected term (years)	6.00 – 7.00	5.00 – 6.25

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Expected Term — The expected term represents the period that the stock-based awards are expected to be outstanding. As the Company does not have sufficient historical experience for determining the expected term of the stock option awards granted, expected term has been calculated using the simplified method.

Risk-Free Interest Rate — The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the date of grant for zero-coupon U.S. Treasury constant maturity notes with terms approximately equal to the stock-based awards' expected term.

Expected Volatility — Since the Company is privately held and does not have a trading history of common stock, the expected volatility was derived from the average historical stock volatilities of the common stock of several public companies within the industry that the Company considers to be comparable to our business over a period equivalent to the expected term of the stock-based awards.

Dividend Yield — The expected dividend yield is zero as the Company has not paid and does not anticipate paying any dividends in the foreseeable future.

Fair Value of Common Stock — The fair value of the shares of common stock underlying the stock-based awards has historically been determined by the Board of Directors with input from management. Because there has been no public market for the common stock, the Board of Directors has determined the fair value of the common stock at the time of grant of the stock-based award by considering a number of objective and subjective factors, including having contemporaneous valuations of the common stock performed by a third-party valuation specialist.

Activity for options was as follows:

	Options Outstanding			
	Number of Options	Weighted Average Exercise Price	Aggregate Intrinsic Value (in 000's)	Weighted Average Remaining Contractual Life (in Years)
Balance, December 31, 2019	13,245,253	\$0.28		
Options granted	4,029,807	\$0.37		
Options exercised	(59,991)	\$0.22		
Options forfeited	(2,190,110)	\$0.26		
Options expired	(185,322)	\$0.23		
Balance, December 31, 2020	14,839,637	\$0.30	\$3,511	7.8
Exercisable as of December 31, 2020	9,090,089	\$0.27	\$2,423	6.4
Vested and expected to vest as of December 31, 2020	13,710,311	\$0.30	\$3,274	7.7

The weighted-average grant date fair value of stock options granted was \$0.23 and \$0.30 during the years ended December 31, 2019 and 2020, respectively. There were 2,773,107 stock options granted at an aggregate fair value of \$638 for the year ended December 31, 2019 and 4,029,807 stock options granted at an aggregate fair value of \$1,210 for the year ended December 31, 2020. The total grant-date fair value of stock options vested during the years ended December 31, 2019 and 2020 was \$371 and \$335, respectively. There were no stock options exercised during the year ended December 31, 2019. During the year ended December 31, 2020, there were 59,991 stock options exercised with an aggregate grant date fair value of \$11. The intrinsic value of stock options exercised during the year ended December 31, 2020 was \$19.

The Company granted 1,129,326 option awards containing performance conditions to an executive during the year ended December 31, 2019. As of December 31, 2019, and 2020, the Company determined that the achievement of the performance targets was not probable and therefore, there was no expense

Cognition Therapeutics, Inc.
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recognized for these awards during the years ended December 31, 2019 and 2020, respectively. As of December 31, 2020, total unrecognized compensation expense related to un-vested performance based awards was \$254, which would be recognized commencing with the period in which the performance condition is deemed probable of achievement.

14. Net Loss per Share

The following outstanding potentially dilutive common stock equivalents have been excluded from the calculation of diluted net loss per share attributable to common stockholders for the periods presented due to their antidilutive effect:

	December 31, 2019	December 31, 2020
Convertible preferred stock (as converted)	40,524,346	40,524,346
Options issued and outstanding	13,245,253	14,839,637
Warrants for series A-1 preferred stock	180,724	—
Warrants for common stock	813,990	650,656
Total	54,764,313	56,014,639

The basic and diluted net loss per share attributable to common stockholders has been prepared as follows:

	December 31, 2019	December 31, 2020
Net loss	\$ (4,842)	\$ (7,839)
Cumulative preferred stock dividends	(3,920)	(4,234)
Net loss attributable to common stockholders	\$ (8,762)	\$ (12,073)
Weighted-average common shares outstanding-basic and diluted	1,519,285	1,643,514
Total	\$ (5.77)	\$ (7.35)

15. Retirement Plan

The Company has a 401(k) retirement plan to provide retirement and incidental benefits for its employees. Employees may contribute a percentage of their annual compensation to the 401(k) retirement plan, limited to a maximum annual amount as set periodically by the Internal Revenue Service. The Company matches employee contributions dollar for dollar up to a maximum of 4% of the employees' compensation per person per year. All matching contributions vest immediately. Company matching contributions to the 401(k) retirement plan totaled \$83 and \$110 for the year ended December 31, 2019 and 2020, respectively.

16. Income Taxes

The net loss consists of the following components:

	Year Ended December 31,	
	2019	2020
Domestic	\$ (3,489)	\$ (7,268)
Foreign	(1,353)	(571)
Total	\$ (4,842)	\$ (7,839)

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During the years ended December 31, 2019 and 2020, the Company recorded no current or deferred income tax expenses or benefits as the Company has incurred losses since inception and has provided a full valuation allowance against its deferred tax assets.

Global Intangible Low-Taxed Income ("GILTI") is the excess of a U.S. shareholders total net foreign income over a deemed return on tangible assets. In January 2018, in response to inquiries by companies, the FASB issued guidance that allows companies to elect as an accounting policy whether to treat the GILTI tax as a period cost or to recognize deferred tax assets and liabilities when basis differences exist that are expected to affect the amount of GILTI inclusion upon reversal. The Company has elected to treat GILTI as a period expense.

A reconciliation of the expected income tax (benefit) computed using the federal statutory income tax rate to the Company's effective income tax rate is as follows:

	Year Ended December 31,	
	2019	2020
Income tax computed at federal statutory rate	21.0%	21.0%
State taxes, net of federal benefit	6.5%	7.1%
Change in valuation allowance	(34.5%)	(35.8%)
R&D Credit	10.5%	10.7%
Interest expense	(2.0%)	(3.2%)
Equity-based compensation	(1.4%)	(1.0%)
Other	(0.1%)	1.2%
Effective income tax rate	0.0%	0.0%

The Company's deferred tax assets and liabilities consist of the following:

	December 31, 2019	December 31, 2020
Deferred tax assets:		
Net operating loss carryforwards	\$ 9,902	\$ 11,060
Tax credit carryforwards	2,397	3,713
Equity-based compensation	74	291
Other	—	137
Deferred tax assets	12,373	15,201
Less: valuation allowance	(12,365)	(15,179)
Deferred tax assets after valuation allowance	8	22
Deferred tax liabilities		
Fixed assets	(8)	(22)
Deferred tax liabilities	(8)	(22)
Net deferred tax assets	\$ —	\$ —

The Company evaluated the positive and negative evidence bearing upon its ability to realize the deferred tax assets as of December 31, 2019 and 2020. Management considered the Company's cumulative net losses and concluded as of December 31, 2019 and 2020, that it was more likely than not that the Company would not realize the benefits of the deferred tax assets. Accordingly, a full valuation allowance was established against the net deferred tax assets as of December 31, 2019 and 2020. The valuation allowance

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increased by \$1,669 and \$2,814 for the years ended December 31, 2019 and 2020, respectively, primarily as a result of operating losses generated with no corresponding financial statement benefit.

The Company has incurred net operating losses (“NOL”) since inception. As of December 31, 2020, the Company had federal net operating loss carryforwards of \$37,879 that expire at various dates through 2037. Included in the federal net operating loss carryforwards of \$37,879 is \$11,651 that can be carried forward indefinitely. As of December 31, 2020, the Company had state net operating loss carryforwards of \$37,879, available to reduce future state taxable income, which expire at various dates through 2040. As of December 31, 2020, the Company had foreign net operating loss carryforwards of \$389 that can be carried forward indefinitely. As of December 31, 2020, the Company had federal research and development tax credit carryforwards of \$3,713 available to reduce future federal tax liabilities.

Utilization of the Company’s net operating loss carryforwards and research and development tax credit carryforwards may be subject to a substantial annual limitation under Section 382 of the Internal Revenue Code of 1986 due to ownership changes that have occurred previously or that could occur in the future. These ownership changes may limit the amount of carryforwards that can be utilized annually to offset future taxable income. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain shareholders or public groups in the stock of a corporation by more than 50% over a three-year period. The Company has not conducted a study to assess whether a change of control has occurred or whether there have been multiple changes of control since inception due to the significant complexity and cost associated with such a study. If the Company has experienced a change of control, as defined by Section 382, at any time since inception, utilization of the net operating loss carryforwards or research and development tax credit carryforwards would be subject to an annual limitation under Section 382, which is determined by first multiplying the value of the Company’s stock at the time of the ownership change by the applicable long-term tax-exempt rate, and then could be subject to additional adjustments, as required. Any limitation may result in expiration of a portion of the net operating loss carryforwards or research and development tax credit carryforwards before utilization. Further, until a study is completed, and any limitation is known, no amounts are being presented as an uncertain tax position.

The Company files tax returns as prescribed by the tax laws of the jurisdictions in which it operates. In the normal course of business, the Company is subject to examination by federal and state jurisdictions, where applicable. There are currently no pending tax examinations. The Company’s tax years are still open under statute from inception to the present.

17. Subsequent Events

Subsequent events have been evaluated through May 7, 2021, which is the date the financial statements were issued.

On January 21, 2021, the Company received confirmation from the SBA that the PPP Loan had been forgiven in full including all interest incurred. Accordingly, the Company will recognize income for debt extinguishment pursuant to ASC 470-50-15-4 during the quarter ended March 31, 2021.

On March 25, 2021, the Company entered into simple agreements for future equity (“SAFEs”) with existing investors, pursuant to which the Company received gross proceeds in an aggregate amount equal to \$8,942. Pursuant to the arrangement, all of the SAFEs were initially issued with a conversion price equal to 80% of either the common stock price upon the occurrence of an initial public offering, or the price paid for shares of preferred stock by other investors upon a subsequent private financing. Upon a change of control, investors will be entitled to receive a portion of proceeds equal to the greater of the purchase amount or the amount payable on the number of shares of common stock equal to the purchase amount divided by the liquidity price. In a liquidity or dissolution event, the investors’ right to receive cash is junior to payment of outstanding indebtedness and creditor claims, on par for other SAFEs and preferred stock, and senior to common stock. The SAFE agreements have no interest rate or maturity date, and the SAFE investors have no voting right prior to conversion.

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On May 1, 2021, the holders of the convertible promissory notes agreed to an acceleration of the automatic conversion of all convertible promissory notes from June 30, 2021 to May 1, 2021 into 10,926,089 shares of our class B-1 preferred stock, at a conversion price equal to \$1.385 per share.

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As of March 31, 2021 and for the Three Months Ended March 31, 2020 and March 31, 2021

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Cognition Therapeutics, Inc. and Subsidiary
Consolidated Balance Sheets
(in thousands, except share and per share amounts)

	December 31, 2020	March 31, 2021 (Unaudited)
Assets		
Current assets		
Cash and cash equivalents	\$ 5,189	\$ 13,373
Grant receivables	564	1,675
Prepaid expenses	544	235
Other receivables	588	642
Other current assets	23	27
Total current assets	6,908	15,952
Deferred offering costs	—	372
Property and equipment, net	211	188
Total assets	<u>\$ 7,119</u>	<u>\$ 16,512</u>
Liabilities, Convertible Preferred Stock, and Stockholders' Deficit		
Current liabilities		
Accounts payable	2,003	3,187
Accrued expenses	994	1,151
Other current liabilities	253	—
Total current liabilities	3,250	4,338
Simple Agreements for Future Equity	—	8,942
Paycheck protection program loan	443	—
Derivative liability	2,209	1,146
Convertible notes, net	12,409	12,691
Accrued interest	1,622	1,879
Total liabilities	19,933	28,996
Commitments and contingencies		
Convertible preferred stock:		
Series A convertible preferred stock, par value \$0.001 per share, 3,067,519 shares authorized at December 31, 2020 and March 31, 2021; 2,819,027 shares issued and outstanding as of December 31, 2020 and March 31, 2021; liquidation preference of \$4,860 as of March 31, 2021	4,616	4,616
Series A-1 convertible preferred stock, par value \$0.001 per share, 3,970,776 shares authorized at December 31, 2020 and March 31, 2021; 3,730,366 shares issued and outstanding as of December 31, 2020 and March 31, 2021; liquidation preference of \$5,682 as of March 31, 2021	5,398	5,398
Series A-2 convertible preferred stock, par value \$0.001 per share, 3,565,063 shares authorized at December 31, 2020 and March 31, 2021; 3,565,063 shares issued and outstanding as of December 31, 2020 and March 31, 2021; liquidation preference of \$6,115 as of March 31, 2021	5,809	5,809
Series B convertible preferred stock, par value \$0.001 per share, 30,450,000 shares authorized at December 31, 2020 and March 31, 2021; 30,409,890 shares issued and outstanding as of December 31, 2020 and March 31, 2021; liquidation preference of \$41,632 as of March 31, 2021	39,547	39,547
Total convertible preferred stock	55,370	55,370
Stockholders' deficit:		
Common stock, \$0.001 par value, 58,000,000 shares authorized at December 31, 2020 and March 31, 2021; 1,742,756 and 1,809,998 shares issued and outstanding at December 31, 2020 and March 31, 2021, respectively	2	2
Additional paid-in capital	221	333
Accumulated deficit	(68,220)	(67,997)
Accumulated other comprehensive loss	(187)	(192)
Total stockholders' deficit	(68,184)	(67,854)
Total liabilities, convertible preferred stock, and stockholders' deficit	<u>\$ 7,119</u>	<u>\$ 16,512</u>

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

Cognition Therapeutics, Inc. and Subsidiary
Consolidated Statements of Operations and Comprehensive (Loss) Income
(unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2020	2021
Operating Expenses:		
Research and development	\$ 3,446	\$ 4,430
General and administrative	1,445	1,153
Total operating expenses	4,891	5,583
Loss from operations	(4,891)	(5,583)
Other income (expense):		
Grant income	2,273	4,692
Change in the fair value of the derivative liability	345	1,063
Change in the fair value of the warrant liability	30	—
Other income, net	142	145
(Loss) gain on debt extinguishment	(129)	443
Interest expense, net	(276)	(537)
Total other income (expense), net	2,385	5,806
Net (loss) income	(2,506)	223
Cumulative preferred stock dividends	(1,053)	(1,128)
Net loss attributable to common stockholders	\$ (3,559)	\$ (905)
Unrealized loss on foreign currency translation	(114)	(5)
Total comprehensive (loss) income	\$ (2,620)	\$ 218
Net loss per share attributable to common stockholders, basic and diluted	\$ (2.34)	\$ (0.51)
Weighted-average common shares outstanding, basic and diluted	1,519,431	1,779,573

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

Cognition Therapeutics, Inc. and Subsidiary
Consolidated Statements of Convertible Preferred Stock and Stockholders' Deficit
(unaudited)
(in thousands, except share amounts)

	Series A Convertible Preferred Stock		Series A-1 Convertible Preferred Stock		Series A-2 Convertible Preferred Stock		Series B Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Balances as of December 31, 2019	2,819,027	\$4,413	3,730,366	\$5,160	3,565,063	\$5,552	30,409,890	\$37,802	1,519,431	\$ 2	\$ —	\$(58,239)	\$(185)	\$(58,422)
Equity-based compensation	—	—	—	—	—	—	—	—	—	—	125	—	—	125
Accretion of convertible preferred stock to redemption value	—	88	—	102	—	111	—	752	—	—	(125)	(928)	—	(1,053)
Other comprehensive loss	—	—	—	—	—	—	—	—	—	—	—	—	(114)	(114)
Net loss	—	—	—	—	—	—	—	—	—	—	—	(2,506)	—	(2,506)
Balances as of March 31, 2020	<u>2,819,027</u>	<u>\$4,501</u>	<u>3,730,366</u>	<u>\$5,262</u>	<u>3,565,063</u>	<u>\$5,663</u>	<u>30,409,890</u>	<u>\$38,554</u>	<u>1,519,431</u>	<u>\$ 2</u>	<u>\$ —</u>	<u>\$(61,673)</u>	<u>\$(299)</u>	<u>\$(61,970)</u>

	Series A Convertible Preferred Stock		Series A-1 Convertible Preferred Stock		Series A-2 Convertible Preferred Stock		Series B Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Balances as of December 31, 2020	2,819,027	\$4,616	3,730,366	\$5,398	3,565,063	\$5,809	30,409,890	\$39,547	1,742,756	\$ 2	\$221	\$(68,220)	\$(187)	\$(68,184)
Exercise of stock options	—	—	—	—	—	—	—	—	67,242	—	14	—	—	14
Equity-based compensation	—	—	—	—	—	—	—	—	—	—	98	—	—	98
Other comprehensive loss	—	—	—	—	—	—	—	—	—	—	—	—	(5)	(5)
Net income	—	—	—	—	—	—	—	—	—	—	—	223	—	223
Balances as of March 31, 2021	<u>2,819,027</u>	<u>\$4,616</u>	<u>3,730,366</u>	<u>\$5,398</u>	<u>3,565,063</u>	<u>\$5,809</u>	<u>30,409,890</u>	<u>\$39,547</u>	<u>1,809,998</u>	<u>\$ 2</u>	<u>\$333</u>	<u>\$(67,997)</u>	<u>\$(192)</u>	<u>\$(67,854)</u>

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

Cognition Therapeutics, Inc. and Subsidiary
Consolidated Statements of Cash Flows
(unaudited)
(in thousands)

	Three Months Ended March 31,	
	2020	2021
Cash flows from operating activities:		
Net (loss) income	\$(2,506)	\$ 223
Adjustments to reconcile net (loss) income to net cash provided by (used in) operating activities:		
Depreciation and amortization	25	23
Amortization of debt issuance costs	6	22
Amortization of debt discount	121	260
Change in the fair value of the derivative liability	(345)	(1,063)
Change in the fair value of the warrant liability	(30)	—
Loss (gain) on debt extinguishment	129	(443)
Equity-based compensation	125	98
Changes in operating assets and liabilities:		
Grant receivables	2,007	(1,111)
Prepaid expenses and other current assets	(27)	305
Other receivables	219	(63)
Accounts payable	311	953
Accrued expenses and interest	495	277
Other current liabilities	—	(253)
Net cash provided by (used in) operating activities	530	(772)
Cash flows from investing activities:		
Payments for property and equipment	(10)	—
Net cash used in investing activities	(10)	—
Cash flows from financing activities:		
Payments on capital lease obligation	(4)	—
Proceeds from the issuance of Simple Agreements for Future Equity	—	8,942
Proceeds from the exercise of stock options	—	14
Proceeds from the issuance of convertible notes	3,841	—
Debt issuance costs related to convertible notes	(55)	—
Net cash provided by financing activities	3,782	8,956
Effect of exchange rate changes on cash and cash equivalents	(34)	—
Net increase in cash and cash equivalents	4,268	8,184
Cash and cash equivalents, beginning of period	2,890	5,189
Cash and cash equivalents, end of period	<u>\$ 7,158</u>	<u>\$13,373</u>
Supplemental disclosures of non-cash financing activities:		
Non-cash accretion of convertible preferred stock to redemption value	\$ 1,053	\$ —
Accrued issuance costs related to Simple Agreements for Future Equity	\$ —	\$ 31
Deferred offering costs included in accounts payable and accrued expenses	\$ —	\$ 372

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

Cognition Therapeutics, Inc. and Subsidiary
Notes to Consolidated Financial Statements
(unaudited)
(in thousands, except share and per share amounts)

1. Description of Business and Financial Condition

Cognition Therapeutics, Inc. and Subsidiary (hereafter “the Company”) incorporated as a Delaware corporation on August 21, 2007. The Company is a biopharmaceutical company developing disease modifying therapies for central nervous system (CNS) disorders. The Company’s pipeline candidates were discovered using proprietary biology and chemistry platforms designed to identify novel drug targets and disease-modifying therapies that address dysregulated pathways specifically associated with neurodegenerative diseases. The Company was founded on the unique combination of biological expertise around these targets, including proprietary assays that emphasize functional responses, and proprietary medicinal chemistry intended to produce novel, high-quality small-molecule drug candidates.

On July 14, 2015, the Company formed Cognition Therapeutics PTY LTD, a wholly owned subsidiary, primarily for the purpose of conducting research and development efforts at facilities located in Australia. Assets and liabilities of the Company’s Australian subsidiary, which uses the Australian dollar as its local functional currency, are translated to United States (U.S.) dollars at year-end exchange rates. Income statement accounts are translated using the average exchange rates prevailing during the month in which income and expenses are generated. Translation adjustments are recorded to accumulated other comprehensive income (loss) (“AOCI”) within stockholders’ deficit. Gains and losses from foreign currency transactions are included in net loss as a part of other income, net.

Liquidity and Going Concern

As of March 31, 2021, the Company had an accumulated deficit of \$67,997 and cash and cash equivalents of \$13,373. The Company incurred a net loss of \$2,506 for the three months ended March 31, 2020 and had net income of \$223 for the three months ended March 31, 2021. The Company has financed its operations to date primarily through government and private philanthropic grants, private placements of its convertible preferred stock, private offerings of convertible notes, and the Simple Agreement for Future Equity, or SAFEs, described in Note 12. It is not anticipated that the Company will generate commercial revenue or operating cash flows in the foreseeable future. The Company’s ability to continue as a going concern in the near term is largely dependent on the Company’s ability to raise additional funds through debt or equity transactions, grant awards or other means. The Company’s forecasted cash required to fund operations, excluding future fundraising efforts and future additional NIH Grants, indicates that the Company does not have sufficient funds to support operations through the one-year period from the issuance date of these financial statements. Accordingly, there is substantial doubt about the Company’s ability to continue as a going concern within one year after the date that these financial statements are issued.

Management’s plans to address this going concern uncertainty include raising additional financing through public or private equity offerings, debt financings, collaborations and licensing arrangements, additional grant awards, or other sources to fund its operations, however, there can be no assurance that the Company will be able to obtain such funding on terms acceptable to the Company, on a timely basis or at all. The failure of the Company to obtain sufficient funds on acceptable terms when needed would have a material adverse effect on the Company’s business, results of operations and financial condition.

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

2. Summary of Significant Accounting Policies

The Company’s significant accounting policies are disclosed in the audited financial statements for the year ended December 31, 2020, included elsewhere in this prospectus. Since the date of those financial statements, there have been no changes to its significant accounting policies.

Cognition Therapeutics, Inc. and Subsidiary
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Basis of Presentation

The unaudited interim financial statements have been prepared on the same basis as the audited financial statements. In the opinion of the Company's management, the accompanying unaudited interim consolidated financial statements contain all adjustments that are necessary to present fairly the Company's financial position as of March 31, 2021, and the statements of operations and comprehensive (loss) income, convertible preferred stock and stockholders' deficit and cash flows for the three months ended March 31, 2020 and 2021. Such adjustments are of a normal and recurring nature. The results for the three months ended March 31, 2021 are not necessarily indicative of the results for the year ending December 31, 2021, or for any future period. These interim financial statements should be read in conjunction with the audited financial statements as of and for the year ended December 31, 2020, and the notes thereto, which are included elsewhere in this prospectus.

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosures of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Cash and Cash Equivalents

Cash and cash equivalents consist primarily of interest-bearing deposits at various financial institutions. The Company considers all highly liquid investments with an original maturity of three months or less when purchased to be cash equivalents.

Receivables

Grant Receivables

Grant receivables relate to outstanding amounts due for reimbursable expenditures of awarded grants issued by the National Institute of Health and are carried at their estimated collectible amounts. The Company expects all receivables to be collectible, and accordingly, there is no allowance for doubtful accounts required on these grant receivables.

Other Receivables

Other receivables consist of research and development tax credits from the state of Pennsylvania and the Australian research and development tax credit from the Australian Tax Authority. Historically, the Company has sold the Pennsylvania tax credits to third parties, while the Australian tax refund is paid directly to the Company by the Australian Tax Authority. Research and development tax refunds and credits are carried at their estimated collectible amounts. The Company expects all receivables to be collectible and accordingly, there is no allowance for doubtful accounts required on these other receivables.

Deferred Offering Costs

The Company capitalizes certain legal, accounting and other third-party fees that are directly associated with in-process equity financings, including the initial public offering ("IPO"), as deferred costs until such financings are consummated. After consummation of the equity financing, these costs are recorded in stockholders' deficit as a reduction of proceeds generated as a result of the offering. Should an in-process equity financing be abandoned, the deferred offering costs will be expensed immediately in the consolidated

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statement of operations and comprehensive loss. During the three months ended March 31, 2020 and 2021, the Company incurred \$0 and \$372 of deferred offering costs, respectively, in connection with its IPO registration process.

Property and Equipment

Property and equipment is recorded at cost, less accumulated depreciation. Depreciation is computed on the straight-line basis over the estimated useful life of the asset. The Company estimates the useful life to be 5 and 6 years for equipment and furniture and fixtures, respectively. The cost of repairs and maintenance is charged to expense as incurred.

Property and equipment is evaluated for impairment whenever events or changes in circumstances indicate the carrying value of an asset may not be recoverable from the estimated future cash flows expected to result from its use and eventual disposition. If expected cash flows are less than the carrying value, an impairment loss is recognized equal to an amount by which the carrying value exceeds the fair value of the assets. There were no indicators of impairment of long-lived assets during the three months ended March 31, 2020 or 2021.

Convertible Instruments

ASC 815, *Derivatives and Hedging Activities* ("ASC 815") requires companies to bifurcate certain conversion options and redemption features from their host instruments and account for them as freestanding derivative financial instruments should certain criteria be met.

The Company also follows ASC 480-10, *Distinguishing Liabilities from Equity* ("ASC 480-10") when evaluating the accounting for its hybrid instruments. A financial instrument that embodies an unconditional obligation, or a financial instrument other than an outstanding share that embodies a conditional obligation, that the issuer must or may settle by issuing a variable number of its equity shares shall be classified as a liability (or an asset in some circumstances) if, at inception, the monetary value of the obligation is based solely or predominantly on any one of the following: (a) a fixed monetary amount known at inception; (b) variations in something other than the fair value of the issuer's equity shares; or (c) variations inversely related to changes in the fair value of the issuer's equity shares. Hybrid instruments meeting these criteria are not further evaluated for any embedded derivatives and are carried as a liability at fair value at each balance sheet date.

Debt Issuance Costs and Discounts

The Company incurred third-party costs in connection with the convertible notes as described in Note 6. These costs are classified on the balance sheet as a direct deduction from the convertible notes and amortized over the term of the agreement as interest expense using the effective interest rate method.

Discounts related to bifurcated derivatives resulting from the convertible note issuances are recorded as a reduction to the carrying value of the debt and amortized over the life of the debt using the effective interest method.

Warrants Issued in Connection with Financings

The Company generally accounts for warrants issued in connection with debt and equity financings as a component of equity, unless the warrants include specific features, such as if the warrants are exercisable for securities that are considered contingently redeemable. For warrants that are exercisable for securities that are considered contingently redeemable, the Company records the fair value of the warrants as a liability at each balance sheet date and records changes in fair value in other income (expense) in the consolidated statement of operations and comprehensive loss.

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Convertible Preferred Stock

The Company has classified convertible preferred stock outside of stockholders' deficit in the accompanying balance sheets due to the convertible preferred stock's redemption features. Originally, the convertible preferred stock was eligible to become redeemable at the holders' option at any time after March 20, 2021. This right was removed in connection with an amendment to the Company's articles of incorporation on July 29, 2020. Pre-amendment, the convertible preferred stock was redeemable due to the passage of time, and therefore, the Company recorded changes in the redemption value and accreted the convertible preferred stock immediately to the redemption value during each period presented. These increases were affected through charges against retained earnings, if any, and then to additional paid-in capital. In the absence of additional paid-in capital, the accretion is charged to accumulated deficit. Post-amendment, the convertible preferred stock is considered to be contingently redeemable only upon the occurrence of a deemed liquidation event (Note 7). As a result, the Company ceased accreting the convertible preferred stock on July 29, 2020. To evaluate whether the changes to the terms of the preferred stock should be accounted for as a modification or extinguishment, the Company follows the qualitative approach, in which amendments to preferred shares are analyzed based on the expected economics as well as the business purpose of the amendment. The Company concluded that the amendment did not result in a significant change to the fundamental nature of the preferred stock, and accordingly, the amendment was accounted for as a modification, and there was no accounting impact for the modification.

Grant income

For the three months ended March 31, 2020 and 2021, the Company generated grant income of \$2,273 and \$4,692 from reimbursements from the National Institute of Health ("NIH") for aging research. The Company records grant income in other income (expense) in the period in which the reimbursable research and development services are incurred and the right to payment is realized. The grants awarded relate to agreed upon direct and indirect costs for specific studies or clinical trials, which may include personnel and consulting costs, costs paid to contract research organizations ("CROs"), research institutions and/or consortiums involved in the grant, as well as facilities and administrative costs. These grants are cost plus fixed fee arrangements in which the Company is reimbursed for its eligible direct and indirect costs over time, up to the maximum amount of each specific grant award. Only costs that are allowable under the grant award, certain government regulations and the NIH's supplemental policy and procedure manual may be claimed for reimbursement, and the reimbursements are subject to routine audits from governmental agencies from time to time.

Research and Development Costs

The Company is involved in research and development aimed at the development of treatments for a variety of diseases related to the central nervous system, with a primary focus on Alzheimer's Disease. Research and development costs are expensed as incurred. Research and development expenses consist principally of personnel costs, including salaries, stock-based compensation, and benefits for employees, third-party license fees and other operational costs related to our research and development activities, including allocated facility-related expenses and external costs of outside vendors, and other direct and indirect costs. Non-refundable research and development costs are deferred and expensed as the related goods are delivered or services are performed. Costs for external development activities are recognized based on an evaluation of the progress to completion of specific tasks. Costs for certain research and development activities are recognized based on the pattern of performance of the individual arrangements, which may differ from the pattern of billings incurred, and are reflected in the consolidated financial statements as prepaid expenses or as accrued research and development expenses.

Equity-based Compensation

Following the provisions of ASC 718, *Compensation — Stock Compensation*, the Company recognizes compensation expense for equity-based grants using the straight-line attribution method, in which the

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expense is recognized ratably over the requisite service period within operating expenses based on the grant date fair value. The Company also has granted awards subject to performance-based vesting. The Company would recognize compensation expense for these awards commencing in the period in which the vesting condition becomes probable of achievement. Grant date fair value is estimated on the date of grant using the Black-Scholes option pricing model. Forfeitures are recognized in the period in which they occur.

Black-Scholes requires inputs based on certain subjective assumptions, including (i) the expected stock price volatility, (ii) the expected term of the award, (iii) the risk-free interest rate and (iv) expected dividends. Due to the lack of a public market for the Company's common stock and lack of company specific historical and implied volatility data, the Company has based its computation of expected volatility on the historical volatility of a representative group of public companies with similar characteristics to the Company, including stage of product development and life science industry focus. The historical volatility is calculated based on a period of time commensurate with expected term assumption. The Company uses the simplified method to calculate the expected term for stock options granted to employees whereby the expected term equals the arithmetic average of the vesting term and the original contractual term of the stock options due to its lack of sufficient historical data. The risk-free interest rate is based on U.S. Treasury securities with a maturity date commensurate with the expected term of the associated award. The expected dividend yield is assumed to be zero as the Company has never paid dividends and has no current plans to pay any dividends on its common stock.

Due to the absence of an active market for the Company's common stock, the Company utilized methodologies in accordance with the framework of the American Institute of Certified Public Accountants Technical Practice Aid, *Valuation of Privately-Held Company Equity Securities Issued as Compensation*, to estimate the fair value of its common stock. In determining the exercise prices for stock options granted, the Company has considered the estimated fair value of the common stock as of the measurement date. The estimated fair value of the common stock has been determined at each grant date based upon a variety of factors, including the illiquid nature of the common stock, arm's-length sales of the Company's capital stock (including convertible preferred stock), the effect of the rights and preferences of the preferred stockholders and the prospects of a liquidity event. Among other factors are the Company's financial position and historical financial performance, the status of technological developments within the Company's research, the composition and ability of the current research and management team, an evaluation or benchmark of the Company's competition and the current business climate in the marketplace. Significant changes to the key assumptions underlying the factors used could result in different fair values of common stock at each valuation date.

Concentration of Credit Risk

The Company's financial instruments that are exposed to credit risks consist of cash and cash equivalents. The Company maintains its cash and cash equivalents in bank deposit accounts which, at times, may exceed the federally insured limit. The Company has not experienced any losses in these accounts and does not believe it is exposed to any significant credit risk related to these funds.

Fair Value of Financial Instruments

The Company applies ASC 820, *Fair Value Measurement* ("ASC 820"), which establishes a framework for measuring fair value and clarifies the definition of fair value within that framework. ASC 820 defines fair value as an exit price, which is the price that would be received for an asset or paid to transfer a liability in the Company's principal or most advantageous market in an orderly transaction between market participants on the measurement date. The fair value hierarchy established in ASC 820 generally requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. Observable inputs reflect the assumptions that market participants would use in pricing the asset or liability and are developed based on market data obtained from sources independent of

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the reporting entity. Unobservable inputs reflect the entity's own assumptions based on market data and the entity's judgments about the assumptions that market participants would use in pricing the asset or liability and are to be developed based on the best information available in the circumstances.

The carrying value of the Company's cash and cash equivalents, grants receivable, prepaid expense, other receivables, other current assets, accounts payable, accrued expenses and other current liabilities approximate fair value because of the short-term maturity of these financial instruments. In addition, the Company records its warrant liability, derivative liability, and Simple Agreements for Future Equity at fair value.

The valuation hierarchy is composed of three levels. The classification within the valuation hierarchy is based on the lowest level of input that is significant to the fair value measurement. The levels within the valuation hierarchy are described below:

- Level 1 — Assets and liabilities with unadjusted, quoted prices listed on active market exchanges. Inputs to the fair value measurement are observable inputs, such as quoted prices in active markets for identical assets or liabilities.
- Level 2 — Inputs to the fair value measurement are determined using prices for recently traded assets and liabilities with similar underlying terms, as well as direct or indirect observable inputs, such as interest rates and yield curves that are observable at commonly quoted intervals.
- Level 3 — Inputs to the fair value measurement are unobservable inputs, such as estimates, assumptions, and valuation techniques when little or no market data exists for the assets or liabilities.

Comprehensive Loss

The Company recorded \$114 and \$5 in other comprehensive loss related to foreign currency translation for the three months ended March 31, 2020 and 2021, respectively. The Company presents comprehensive loss in a single statement within its consolidated financial statements.

Net Loss Per Share Attributable to Common Stockholders

Basic net loss attributable to common shares is computed by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding during each period. Diluted net loss attributable to common shares includes the effect, if any, from the potential exercise or conversion of securities, such as convertible preferred stock and stock options, which would result in the issuance of incremental shares of common stock. For diluted net loss per share, the weighted-average number of shares of common stock is the same for basic net loss per share due to the fact that when a net loss exists, dilutive securities are not included in the calculation as the impact is anti-dilutive. The Company's convertible preferred stock entitles the holder to participate in dividends and earnings of the Company, and, if the Company were to recognize net income attributable to common stockholders, it would have to use the two-class method to calculate earnings per share. The two-class method is not applicable during periods with a net loss attributable to common stockholders, as the holders of the convertible preferred stock have no obligation to fund losses.

Segments

The Company has determined that it operates and manages one operating segment, which is the business of developing and commercializing therapeutics. The Company's chief operating decision maker, its chief executive officer, reviews financial information on an aggregate basis for the purpose of allocating resources.

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Emerging Growth Company Status

The Company is an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 (“JOBS Act”). Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. The Company has elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that it is (a) no longer an emerging growth company or (b) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, these financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

Recent Accounting Pronouncements

In February 2016, the FASB issued Accounting Standards Update (ASU) No. 2016-02, *Leases* (Topic 842). ASU No. 2016-02 requires lessees to recognize the assets and liabilities that arise from leases on the balance sheet. A lessee should recognize in the statement of financial position a liability to make lease payments (the lease liability) and a right-of-use asset representing its right to use the underlying asset for the lease term. ASU No. 2016-02 is effective for the Company for annual periods beginning after December 15, 2021. Early adoption is permitted. The Company expects to adopt this guidance when effective and is assessing what effect the adoption of ASU 2016-02 will have on its consolidated financial statements and accompanying notes. The Company expects to record right-of-use assets and liabilities upon adoption.

In June 2018, the FASB issued ASU 2018-07, *Compensation — Stock Compensation* (Topic 718) Improvements to Nonemployee Share-Based Payment Accounting. The new ASU simplifies the accounting for share-based payments to non-employees by aligning it with the accounting for share-based payments to employees, with certain exceptions. The Company adopted the standard on January 1, 2020 and it did not have a material impact on the Company’s financial condition, results of operations and cash flows.

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement* (Topic 820). This standard modifies disclosure requirements related to fair value measurement and is effective for all entities for fiscal years beginning after December 15, 2019. Among other things, ASU 2018-13 requires public entities to disclose the range and weighted average used to develop significant unobservable inputs for level 3 fair value measurements, while eliminating the requirement for public entities to disclose the amount of and reasons for transfers between level 1 and level 2 of the fair value hierarchy. Implementation on a prospective or retrospective basis varies by specific disclosure requirement. The standard also allows for early adoption of any removed or modified disclosures upon issuance while delaying adoption of the additional disclosures until their effective date. The Company adopted this guidance on January 1, 2020 and the adoption did not have a material impact on its financial statements.

In August 2020, the FASB issued ASU 2020-06, *Debt — Debt with Conversion and Other Options* (Subtopic 470-20) and *Derivatives and Hedging — Contracts in Entity’s Own Equity* (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity’s Own Equity. This ASU simplifies the accounting for certain convertible instruments. ASU 2020-06 will be effective for fiscal years beginning after December 15, 2021, with early adoption permitted for interim and annual reporting periods beginning after December 15, 2020. The Company adopted ASU 2020-06 on January 1, 2021, and the adoption did not have a material impact on the Company’s consolidated financial statements and related disclosures.

In October 2020, the FASB issued ASU 2020-10, *Codification Improvements*, which updates various codification topics by clarifying or improving disclosure requirements to align with the SEC’s regulations. The Company adopted ASU 2020-10 on January 1, 2021. The adoption of ASU 2020-10 did not have a material impact on the Company’s consolidated financial statements and related disclosures.

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3. Financial Instruments and Fair Value Measurements

Financial assets and liabilities measured at fair value are summarized below:

As of December 31, 2020				
	Quoted Priced in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets:				
Money market funds	\$2,853	\$—	\$ —	\$2,853
Total assets	<u>\$2,853</u>	<u>\$—</u>	<u>\$ —</u>	<u>\$2,853</u>
Liabilities:				
Derivative liability	\$ —	\$—	\$2,209	\$2,209
Total liabilities	<u>\$ —</u>	<u>\$—</u>	<u>\$2,209</u>	<u>\$2,209</u>

As of March 31, 2021				
	Quoted Priced in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets:				
Money market funds	\$11,795	\$—	\$ —	\$11,795
Total assets	<u>\$11,795</u>	<u>\$—</u>	<u>\$ —</u>	<u>\$11,795</u>
Liabilities:				
Derivative liability	\$ —	\$—	\$ 1,146	\$ 1,146
Simple Agreements for Future Equity	—	—	8,942	8,942
Total liabilities	<u>\$ —</u>	<u>\$—</u>	<u>\$10,088</u>	<u>\$10,088</u>

The following table sets forth a summary of the changes in fair value of the Level 3 liabilities for the three months ended March 31, 2020 and 2021:

	Three Months Ended March 31, 2020		
	Warrant Liability	Derivative Liability	Total
Balance at December 31, 2019	\$181	\$1,493	\$1,674
Fair value recognized upon the issuance of Convertible Notes	—	525	525
Change in the fair value of the liability	(30)	(345)	(375)
Total liabilities	<u>\$151</u>	<u>\$1,673</u>	<u>\$1,824</u>
	Three Months Ended March 31, 2021		
	SAFE	Derivative Liability	Total
Balance at December 31, 2020	\$ —	\$ 2,209	\$ 2,209
Fair value recognized upon the issuance of SAFE	8,942	—	8,942
Change in the fair value of the liability	—	(1,063)	(1,063)
Total liabilities	<u>\$8,942</u>	<u>\$ 1,146</u>	<u>\$10,088</u>

Derivative Liability — The Company recognizes derivative liabilities as a result of the issuance of the convertible notes that contain conversion and redemption features that are required to be bifurcated. The

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fair value measurement of the derivative liability is classified as Level 3 under the fair value hierarchy as it has been valued using certain unobservable inputs. These inputs include: (1) probability of occurrence of future events (such as a qualified financing or a sale), and (2) discount rate for implied return required by investor. Significant increases or decreases in any of those inputs in isolation could result in a significantly lower or higher fair value measurement.

The fair value of the derivative liability was determined by calculating the fair value of the notes with the conversion and redemption features as compared to the fair value of the notes without such features, with the difference representing the value of the conversion and redemption features, or the derivative liability. The conversion and redemption features are measured at fair value as of each reporting date and the change in the fair value for the period is recorded in the consolidated statements of operations as a change in the fair value of the derivative liability. The fair value of the derivative liability is based on Level 3 unobservable inputs. Changes in fair value are recognized as a gain or loss within other income (expense) on the consolidated statements of operations and comprehensive loss.

Warrant Liability — The Company issued 180,724 series A-1 preferred stock warrants in December 2010. The Company recorded a change in fair value adjustment of \$30 in the consolidated statement of operations and comprehensive loss for the three months ended March 31, 2020. The warrants expired unexercised in October 2020.

Simple Agreements for Future Equity — On March 25, 2021, the Company entered into simple agreements for future equity (“SAFEs”) with existing investors, pursuant to which the Company received gross proceeds in an aggregate amount equal to \$8,942. As of March 31, 2021, the assumptions used in the valuation for the instrument did not materially change from the date of issuance. The inputs include: (1) probability of occurrence of future events (such as a change of control or public offering), and (2) discount rate for implied return required by investor.

4. Accrued Expenses

Accrued expense consists of the following as of:

	December 31, 2020	March 31, 2021
Employee compensation, benefits, and related accruals	\$732	\$ 722
Consulting and contracted research	143	197
Professional fees	119	232
Total	<u>\$994</u>	<u>\$1,151</u>

5. Commitments and Contingencies

The Company has operating leases for its office and laboratory facilities under agreements that run through June 30, 2023.

Minimum lease commitments consisted of the following as of March 31, 2021:

	Operating Leases
2021	\$ 89
2022	118
2023	59
Total lease commitments	<u>\$266</u>

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Rent expense was \$57 and \$34 for the three months ended March 31, 2020 and 2021, respectively.

From time to time, the Company may be involved in disputes or regulatory inquiries that arise in the ordinary course of business. When the Company determines that a loss is both probable and reasonably estimable, a liability is recorded and disclosed if the amount is material to the financial statements taken as a whole. When a material loss contingency is only reasonably possible, the Company does not record a liability, but instead discloses the nature and the amount of the claim, and an estimate of the loss or range of loss, if such an estimate can reasonably be made.

As of December 31, 2020 and March 31, 2021, there was no litigation or contingency with at least a reasonable possibility of a material loss.

6. Debt

On March 8, 2018, the Company entered into a Convertible Note Purchase Agreement (“the Original Agreement”) with existing investors of the Company. Under the terms of the Original Agreement, the Company agreed to issue up to \$5,000 in principle Convertible Notes (the “Original Notes”). The Original Notes accrued interest at 4.0% per annum from the date of issuance with a maturity date of February 27, 2020 (subsequently extended — see below). The Company issued \$2,965 in Original Notes in March and April 2018. Under the terms of the Original Agreement, the following features are included:

- Automatic conversion into equity securities upon the closing of an equity financing with aggregate gross proceeds of at least \$10,000, at the conversion price equal to 90.0% of the lowest price per share of the equity financing securities sold (a “Automatic Conversion Upon a Qualified Financing”)
- Optional conversion into equity securities upon the closing of an equity financing that does not constitute a Qualified Financing at a conversion price equal to 90.0% of the price per share of the equity financing securities sold (a “Optional Conversion Upon a Non-Qualified Financing”)
- Optional conversion of the unpaid principal balance plus accrued and unpaid interest to into B-1 Convertible Preferred Stock at a conversion price of \$1.385 per share or redemption of the unpaid principal balance plus accrued and unpaid interest if (i) a transaction results in any person or group with over 50.0% voting power, (ii) any consolidation or merger transaction, or (iii) a sale or transfer of substantially all of the Company’s assets (“Option Conversion or Redemption”) Optional conversion of the unpaid principal balance plus accrued and unpaid interest to into Series B-1 convertible preferred stock at a conversion price of \$1.385 per share or redemption of the unpaid principal balance plus accrued and unpaid interest if (i) a transaction results in any person or group with over 50.0% voting power, (ii) any consolidation or merger transaction, or (iii) a sale or transfer of substantially all of the Company’s assets (“Option Conversion or Redemption”)
- Automatic redemption of unpaid principal and all accrued and unpaid interest upon maturity, liquidation, dissolution, winding up, or event of default (“Automatic Redemption”)

On November 15, 2018, the Company entered into a Convertible Note Purchase Agreement (the “Additional Agreement”) with existing investors of the Company. Under the terms of the Additional Agreement, the Company agreed to issue up to an aggregate of \$8,000 in principle Convertible Notes (the “Additional Notes”). In connection with the Additional Agreement, the Company amended the Original Notes (the “Amendment”). The Amendment resulted in the following changes to the Original Notes:

- the interest rate of the Original Notes accrue interest at 4.0% from issuance to November 15, 2018, and accrue interest at 8.0% from November 15, 2018 to maturity or conversion,
- the conversion price was amended to 80.0% of the price per share in connection with conversion of the notes upon a Qualified or Non-Qualified Financing,

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- the holder's option upon a sale event to receive repayment, at two times the principal plus accrued and unpaid interest, ("Optional Redemption Upon a Sales Transaction") and
- a condition that each holder of \$1,000 in aggregate principal must be included in the 66 2/3% of the holders of the principal amount of the Notes to provide consent to make any further amendments or waivers.

On February 27, 2020, the Company entered into a Convertible Note Purchase Agreement (the "Second Amendment") with existing investors of the Company. Under the terms of the Second Amendment, the Company agreed to issue up to an aggregate of \$10,035 in principle Convertible Notes (the "Second Amendment Notes"). In connection with the Second Amendment, the Company amended the Original Notes and Additional Notes. The Second Amendment resulted in the following changes:

- extend the maturity date to June 30, 2021;
- add a cap for a conversion in connection with a Qualified Financing; and
- provide for mandatory conversion of the Combined Notes into Series B-1 Preferred Convertible Stock of the Company if the Company has not completed a Qualified Financing on or before June 30, 2021.

The Company applied extinguishment accounting to the Original Notes upon execution of the Amendment in 2018 on the basis that the present value of the cash flows under the terms of the Amendment of the Original notes were determined to be substantially different. The Company applied extinguishment accounting upon execution of the Second Amendment as the addition of the conversion features are substantive and recorded a loss on debt extinguishment of \$129 in the consolidated statement of operations and comprehensive loss for the three months ended March 31, 2020.

Each Additional Note and Second Amendment Note (collectively with the Original Notes, the "Convertible Notes" or the "Notes") included the features set forth above. The Company issued \$2,965 Original Notes in 2018, \$4,661 Additional Notes in 2018 and 2019, and \$5,372 Second Amendment Notes in 2020.

The total issuance costs incurred in connection with all closings of the Convertible Notes was \$205.

The Convertible Notes were considered to be a hybrid financial instrument consisting of a fixed interest rate host with certain embedded features requiring evaluation for bifurcation and separate accounting. The Company determined that the Automatic Conversion Upon a Qualified Financing, Optional Conversion Upon a Non-Qualified Financing and the Optional Redemption Upon a Sales Transaction were considered freestanding financial instruments which required bifurcation from the host debt instruments.

The resulting debt discount from the derivative liabilities was presented as a direct deduction from the carrying amount of the Convertible Notes and amortized to interest expense using the effective interest rate method.

The Convertible Notes as of December 31, 2020 and March 31, 2021 consist of the following:

	December 31, 2020	March 31, 2021
Convertible notes principal	\$12,998	\$12,998
Less: unamortized note issuance costs	(45)	(23)
Less: debt discount	(544)	(284)
	<u>\$12,409</u>	<u>\$12,691</u>

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Interest expense on the convertible notes, including amortization of debt issuance costs, consisted of the following for the three months ended March 31, 2020 and 2021:

	2020	2021
Coupon interest	\$153	\$257
Issuance costs amortization	6	22
Discount amortization	121	260
	<u>\$280</u>	<u>\$539</u>

At December 31, 2020 and March 31, 2021, the Company has classified the outstanding convertible notes, as well as accrued interest, within long term liabilities, as the convertible notes are not expected to require the use of current assets to settle the obligations within the next twelve months. In May of 2021, the convertible notes and accrued interest thereon were converted in Series B-1 convertible preferred stock (Note 13). The Company determined the Series B-1 convertible preferred stock issued should be excluded from the calculation of diluted net loss per share attributable to common stockholders for the three months ended March 31, 2020 and 2021 due to the antidilutive effect on earnings per share.

In April 2020, the Company received a \$443 unsecured loan, bearing interest at 1.0%, pursuant to the Paycheck Protection Program (the “PPP”), a program implemented by the U.S. Small Business Administration (the “SBA”) under the Coronavirus Aid, Relief, and Economic Security Act (the “CARES Act”) (the “PPP Loan”). The PPP provides for loans to qualifying businesses for amounts up to 2.5 times of the average monthly payroll expenses of the qualifying business. The loan and accrued interest are forgivable after eight weeks if the borrower uses the loan proceeds for eligible purposes, including payroll, benefits, rent and utilities. The amount of loan forgiveness may be reduced if the borrower terminates employees or reduces salaries during the eight-week period. The unforgiven portion of the PPP loan is payable over two years at an interest rate of 1.0%, with a deferral of payments for the first six months. The Company used the proceeds for purposes consistent with the PPP.

On January 21, 2021, the Company received confirmation from the SBA that the PPP Loan had been forgiven in full including all interest incurred. Accordingly, the Company recognized \$443 of income for the debt extinguishment pursuant to ASC 470-50-15-4 for the three months ended March 31, 2021.

7. Preferred Stock

Convertible preferred stock consisted of the following:

As of December 31, 2020:

Class of Preferred	Preferred Stock Authorized	Preferred Stock Issued and Outstanding	Carrying Value	Liquidation Preference	Common Stock Issuable Upon Conversion
Series A Preferred Stock	3,067,519	2,819,027	\$ 4,616	\$ 4,766	2,819,027
Series A-1 Preferred Stock	3,970,776	3,730,366	5,398	5,572	3,730,366
Series A-2 Preferred Stock	3,565,063	3,565,063	5,809	5,997	3,565,063
Series B Preferred Stock	30,450,000	30,409,890	39,547	40,826	30,409,890
Total	<u>41,053,358</u>	<u>40,524,346</u>	<u>\$55,370</u>	<u>\$ 57,161</u>	<u>40,524,346</u>

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As of March 31, 2021:

Class of Preferred	Preferred Stock Authorized	Preferred Stock Issued and Outstanding	Carrying Value	Liquidation Preference	Common Stock Issuable Upon Conversion
Series A Preferred Stock	3,067,519	2,819,027	\$ 4,616	\$ 4,860	2,819,027
Series A-1 Preferred Stock	3,970,776	3,730,366	5,398	5,682	3,730,366
Series A-2 Preferred Stock	3,565,063	3,565,063	5,809	6,115	3,565,063
Series B Preferred Stock	30,450,000	30,409,890	39,547	41,632	30,409,890
Total	41,053,358	40,524,346	\$55,370	\$ 58,289	40,524,346

Rights, preferences, privileges, and restrictions:

The holders of shares of Series A, A-1, A-2, B and B-1 convertible preferred stock (or collectively, the “Preferred Stock”) have the rights, preferences, privileges, and restrictions as set forth below:

Dividends:

The holders of the Preferred Stock are entitled to receive cumulative dividends when, as and if declared by the Company’s Board of Directors. Accrued dividends shall accrue only on the unreturned amount of the original issue price taking into account the payment of any mandatory dividend. As used herein, “original issue price” means \$0.69 per share with respect to the Series A and A-1 preferred stock, \$0.8415 per share with respect to the Series A-2 preferred Stock, and \$0.923 per share with respect to the Series B preferred stock. After such time the holders receive their full preferred liquidation amount, less any and all mandatory dividends, the holders of preferred stock will not be entitled to any additional accruing dividends; provided that the holders of the preferred stock will share in all dividends and distributions declared by the Board of Directors and paid by the Company with the holders of common stock on an as if converted to common stock basis.

Voting Rights:

The holders of Preferred Stock are entitled to voting rights equal to the number of shares of common stock into which the shares of Preferred Stock can be converted. In addition, as long as there are shares of Preferred Stock outstanding, each of the holders of over 7.5% of the total Preferred Stock outstanding on a converted basis shall be entitled to designate one director of the Company to be elected by the holders of Preferred Stock. The holders of a majority of the then outstanding shares of common stock, voting together as a single class, shall be entitled to elect one director of the Company. If the holders of the Preferred Stock or common stock fail to elect a sufficient number of directors to fulfill directorships for which they are entitled to elect directors, then any directorship shall remain vacant until the holders of the Preferred Stock or common stock elect such person.

Liquidation Rights:

In the event of any liquidation, dissolution or winding up of the Company, whether voluntary or involuntary, the holders of Preferred Stock have liquidation preferences, before any distribution or payment is made to holders of any common stock, in an amount per share equal to the original issue price for such Preferred Stock plus all accruing dividends (the “Preferred Liquidation Amount”). If the assets and funds to be distributed among the holders of Preferred Stock are insufficient to permit the payment to such holders, then the entire assets and funds of the Company legally available for distribution will be distributed ratably among the holders of Preferred Stock in proportion to the Preferred Liquidation Amount each such holder is otherwise entitled to receive on each share, less any mandatory dividends.

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Upon completion of the payment of the full liquidation preference of Preferred Stock less any and all mandatory dividends previously distributed, the remaining assets of the Company, if any, shall be distributed among the holders of common stock and Preferred Stock, pro rata based on the number of common shares held by each (assuming conversion of all shares of the Preferred Stock into common stock).

Conversion:

Each share of Preferred Stock is convertible into shares of common stock, at the option of the holder, at any time after date of issuance. Each share of Preferred Stock automatically converts to the number of shares of common stock determined in accordance with the conversion rate upon the closing of a public offering, at a price per share of not less than three times the highest, then applicable conversion price, resulting in offering proceeds of at least \$30,000 net of underwriting discounts and commissions ("Mandatory Conversion Time"). The conversion ratio will be adjusted in the case of specified changes to the Company's capitalization as a result of stock splits, combinations, common stock dividends and distributions, reclassifications, exchanges, substitutions, reorganizations, mergers or consolidations.

Redemption:

Prior to the July 29, 2020 amendment to the article of incorporation, Preferred Stockholders had the right to redeem shares of preferred stock on or after March 20, 2021 after receipt of written notice requesting redemption from 60% of the then outstanding shares of the preferred stock voting together as a single class on an as-converted to common stock basis at a price equal to the original issue price plus all accruing dividends. As the Preferred Stock was redeemable due to the passage of time prior to the amendment, the Company recorded changes in the redemption value and accreted the Preferred Stock immediately to its redemption value during each reporting period.

On July 29, 2020, the articles of incorporation were amended resulting in the removal of the redemption right. As the redemption option was removed in connection with the amendment, the only option for redemption is based on the occurrence of a deemed liquidation event. As the events that would trigger a deemed liquidation event are corporate transactions that are not certain to occur, the Company determined that post July 29, 2020, the Preferred Stock is no longer considered probable to become redeemable, and is instead contingently redeemable. As a result, the Company ceased the accretion of the Preferred Stock to redemption value upon execution of the amendment to the articles of incorporation.

Protective Provisions:

At any time when shares of Preferred Stock are outstanding, the Company shall not, either directly, indirectly by amendment, merger, consolidation or otherwise, do any of the following without the written consent or affirmative vote of at least 60% of the then outstanding shares of Preferred Stock, voting together as a single class on an as-converted to Common Stock basis: (i) effect the consummation of a liquidation event or any other merger or consolidation, (ii) amend, alter or repeal any provision of the Company's certificate of incorporation or bylaws in a manner that adversely affects the powers, preferences or rights of the Preferred Stock, (iii) amend, alter, or repeal any provision of the by-laws of the Company, in a manner that affects the powers, preferences, or rights of Preferred Stock, (iv) increase or decrease the authorized number of shares of Preferred Stock or Common Stock, (v) reclassify, alter, or amend any existing security of the Company in respect to the distribution of assets on the liquidation, dissolution, or winding up of the Company or payment of dividends, if such reclassification, alteration, or amendment would render such other security senior to Preferred Stock in respect to any such right, preference, or privilege, (vi) purchase or redeem, or declare any dividend, on any shares of capital stock of the Company other than repurchase of stock pursuant to stock restriction agreements approved by the Board of Directors that grant to the Company the right of repurchase upon termination of the service, (vii) borrow or authorize any amount of indebtedness, other than inventory financing in the ordinary course of business and any indebtedness in an

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amount of up to \$250 in aggregate that is approved by the Board of Directors, (viii) increase or decrease the authorized number of directors of the Board of Directors (ix) effect a change in business from the discovery and development of small molecule therapeutics targeting toxic proteins that cause cognitive decline associated with Alzheimer's disease and other neurodegenerative diseases, (x) enter into any transaction with any person other than in the ordinary course of business on an arm's length basis, (xi) increase the number of shares of common stock reserved for issuance, (xii) make any loan except advances in ordinary course of business or advances up to \$50 in aggregate approved by the Board of Directors, (xiii) hire, terminate, or change compensation in excess of \$100 of any officer, director, or employee, unless approved by the Board of Directors, (xiv) own any stock or securities of any other corporation, unless approved by the Board of Directors, (xv) guarantee any indebtedness except for trade accounts of the Company or any guarantee approved by the Board of Directors, (xvi) make any investment other than investments in prime commercial paper, money market funds, certificates of deposits in any United States bank having a net worth in excess of \$100,000 or obligations issued or guaranteed by the United States of America, unless approved by the Board of Directors.

8. Warrants

In conjunction with both debt and equity investments, the Company issued warrants on each of the following classes of stock: Common and Series A-1.

The following is a summary of the Company's outstanding common stock warrants as of December 31, 2020 and March 31, 2021:

Number of Warrants	Exercise Price	Expiration Date
163,334	\$0.21	May 2021
375,741	\$0.01	March 2023
78,194	\$0.01	May 2023
33,387	\$0.01	August 2023

Series A-1 Preferred Stock Warrants

The Company reviewed the classification of the warrants as liabilities or equity under the guidance of ASC 480-10, Distinguishing Liabilities from Equity, and concluded that the Series A-1 convertible preferred stock warrants should be classified as a liability. The Company re-measures the warrant liability to fair market value at the end of each reporting period. The Series A-1 preferred stock warrants expired in October 2020 and were not exercised.

Common Stock Warrants

The Company's common stock warrants are equity classified as there are no features within the warrant agreements that require liability treatment. Accordingly, the warrants are recorded as a component of equity when they are issued.

9. Common Stock

Common stockholders are entitled to dividends if and when declared by the Company's Board of Directors subject to the rights of the preferred stockholders. As of December 31, 2020 and March 31, 2021, no dividends on common stock had been declared by the Company.

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The Company has reserved the following shares of common stock for conversion of preferred stock, exercise of warrants and exercise of stock options as of:

	December 31, 2020	March 31, 2021
Convertible preferred stock (as converted)	40,524,346	40,524,346
Options issued and outstanding	14,839,637	14,414,342
Warrants for common stock	650,656	650,656
Total	<u>56,014,639</u>	<u>55,589,344</u>

10. Equity-based Compensation

On September 15, 2017, the Company's Board of Directors (the Board) approved the 2017 Amended and Restated Equity Incentive Plan (the "Plan"), which provides for the granting of incentive stock options, non-qualified stock options and stock awards to employees, certain consultants and directors. The Board, or its designated committee, has the sole authority to select the individuals to whom awards are granted and determine the terms of each award, including the number of shares and the schedule upon which the award becomes exercisable.

The aggregate number of shares of common stock of the Company that may be issued under the Plan is 15,288,989 (taking into account shares of common stock that may become issuable pursuant to Section 3(b) of the Plan in respect of shares of common stock reserved under the Company's Amended and Restated 2007 Equity Incentive Plan). The Plan also allows for a provision for shares granted which are cancelled, forfeited, exchanged or surrendered without having been exercised to subsequently be available for reissuance under the Plan.

The Company recorded total equity-based compensation expense in the statement of operations and comprehensive loss related to incentive stock options and nonstatutory stock options as follows:

	<u>Three Months Ended March 31,</u>	
	<u>2020</u>	<u>2021</u>
Research and development	\$ 52	\$21
General and administrative	73	77
Total equity-based compensation	<u>\$125</u>	<u>\$98</u>

As of March 31, 2021, total future compensation expense related to unvested awards yet to be recognized by the Company was \$1,080. Total future compensation expense related to unvested awards yet to be recognized by the Company is expected to be recognized over a weighted- average remaining vesting period of approximately 3.1 years.

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The fair value of options granted was estimated on the date of grant using the Black-Scholes option pricing model with the following assumptions:

	Three Months Ended March 31,	
	2020	2021
Fair value of common stock	\$0.37	\$0.54
Expected volatility	104.60% – 109.34%	101.38% – 101.83%
Risk-free interest rate	0.38% – 1.60%	0.67% – 0.84%
Dividend yield	0.00%	0.00%
Expected term (years)	5.00 – 6.08	6.07 – 6.22

Expected Term — The expected term represents the period that the stock-based awards are expected to be outstanding. As the Company does not have sufficient historical experience for determining the expected term of the stock option awards granted, expected term has been calculated using the simplified method.

Risk-Free Interest Rate — The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the date of grant for zero-coupon U.S. Treasury constant maturity notes with terms approximately equal to the stock-based awards' expected term.

Expected Volatility — Since the Company is privately held and does not have a trading history of common stock, the expected volatility was derived from the average historical stock volatilities of the common stock of several public companies within the industry that the Company considers to be comparable to our business over a period equivalent to the expected term of the stock-based awards.

Dividend Yield — The expected dividend yield is zero as the Company has not paid and does not anticipate paying any dividends in the foreseeable future.

Fair Value of Common Stock — The fair value of the shares of common stock underlying the stock-based awards has historically been determined by the Board of Directors with input from management. Because there has been no public market for the common stock, the Board of Directors has determined the fair value of the common stock at the time of grant of the stock-based award by considering a number of objective and subjective factors, including having contemporaneous valuations of the common stock performed by a third-party valuation specialist.

Activity for options was as follows:

	Options Outstanding			
	Number of Options	Weighted Average Exercise Price	Aggregate Intrinsic Value (in 000's)	Weighted Average Remaining Contractual Life (in Years)
Balance, December 31, 2020	14,839,637	\$0.30		
Options granted	180,000	\$0.54		
Options exercised	(67,242)	\$0.21		
Options forfeited	(390,215)	\$0.33		
Options expired	(147,838)	\$0.24		
Balance, March 31, 2021	14,414,342	\$0.31	\$3,371	7.6
Exercisable as of March 31, 2021	8,939,321	\$0.27	\$2,391	6.2
Vested and expected to vest as of March 31, 2021	13,285,016	\$0.30	\$3,134	7.5

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The weighted-average grant date fair value of stock options granted was \$0.29 and \$0.43 during the three months ended March 31, 2020 and 2021, respectively. There were 123,000 stock options granted at an aggregate fair value of \$36 for the three months ended March 31, 2020 and 180,000 stock options granted at an aggregate fair value of \$77 for the three months ended March 31, 2021. The total grant-date fair value of stock options vested during the three months ended March 31, 2020 and 2021 was \$78 and \$33, respectively. There were no stock options exercised during the three months ended March 31, 2020. During the three months ended March 31, 2021, there were 67,242 stock options exercised with an aggregate grant date fair value of \$11. The intrinsic value of stock options exercised during the three months ended March 31, 2021 was \$22.

The Company granted 1,129,326 option awards containing performance conditions to an executive during the three months ended March 31, 2020 and 2021. As of March 31, 2020, and 2021, the Company determined that the achievement of the performance targets was not probable and therefore, there was no expense recognized for these awards during the three months ended March 31, 2020 and 2021, respectively. As of March 31, 2021, total unrecognized compensation expense related to un-vested performance-based awards was \$254, which would be recognized commencing with the period in which the performance condition is deemed probable of achievement.

11. Net Loss per Share

The following outstanding potentially dilutive common stock equivalents have been excluded from the calculation of diluted net loss per share attributable to common stockholders for the periods presented due to their antidilutive effect:

	December 31, 2020	March 31, 2021
Convertible preferred stock (as converted)	40,524,346	40,524,346
Options issued and outstanding	14,839,637	14,414,342
Warrants for common stock	650,656	650,656
Total	<u>56,014,639</u>	<u>55,589,344</u>

The basic and diluted net loss per share attributable to common stockholders has been prepared as follows:

	Three Months Ended March 31, 2020	2021
Net (loss) income	\$ (2,506)	\$ 223
Cumulative preferred stock dividends	(1,053)	(1,128)
Net loss attributable to common stockholders	\$ (3,559)	\$ (905)
Weighted-average common shares outstanding-basic and diluted	1,519,431	1,779,573
Total	<u>\$ (2.34)</u>	<u>\$ (0.51)</u>

12. Simple Agreements for Future Equity (SAFEs)

On March 25, 2021, the Company entered into simple agreements for future equity ("SAFEs") with existing investors, pursuant to which the Company received gross proceeds in an aggregate amount equal to \$8,942. Pursuant to the arrangement, all of the SAFEs were initially issued with a conversion price equal to 80.0% of either the common stock price upon the occurrence of an initial public offering, or the price paid for shares of preferred stock by other investors upon a subsequent private financing. Upon a change of control, investors will be entitled to receive a portion of proceeds equal to the greater of the purchase amount

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or the amount payable on the number of shares of common stock equal to the purchase amount divided by the liquidity price. In a liquidity or dissolution event, the investors' right to receive cash is junior to payment of outstanding indebtedness and creditor claims, on par for other SAFEs and preferred stock, and senior to common stock. The SAFE agreements have no interest rate or maturity date, and the SAFE investors have no voting right prior to conversion.

The SAFEs included a provision allowing for cash redemption upon either the occurrence of a change of control or dissolution event, the occurrence of which is outside the control of the Company. Therefore, the SAFEs are classified as marked-to-market liabilities pursuant to ASC 480, *Distinguishing Liabilities from Equity*.

13. Subsequent Events

Subsequent events have been evaluated through June 23, 2021, which is the date the financial statements were issued.

On May 1, 2021, the holders of the convertible promissory notes agreed to an acceleration of the automatic conversion of all convertible promissory notes from June 30, 2021 to May 1, 2021 into 10,926,089 shares of our class B-1 preferred stock, at a conversion price equal to \$1.385 per share.

Shares



Common stock

Preliminary prospectus

, 2021

Through and including , 2021 (the 25th day after the commencement of this offering), all dealers that buy, sell or trade shares of our common stock, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other expenses of issuance and distribution.

The following table sets forth the costs and expenses, other than the underwriting discounts and commissions, payable by Cognition Therapeutics, Inc., or the Registrant, in connection with the sale of our common stock being registered. All amounts are estimates except for the SEC registration fee, FINRA filing fee and Nasdaq Stock Market listing fee.

Item	Amount
SEC registration fee	\$ *
FINRA filing fee	*
Nasdaq Stock Market listing fee	*
Printing expenses	*
Legal fees and expenses	*
Accounting fees and expenses	*
Blue Sky, qualification fees and expenses	*
Transfer agent fees and expenses	*
Miscellaneous expenses	*
Total	\$ *

* To be filed by amendment.

Item 14. Indemnification of directors and officers.

As permitted by Section 102 of the Delaware General Corporation Law, our third amended and restated certificate of incorporation and amended and restated bylaws to be in effect immediately prior to the closing of this offering will limit or eliminate the personal liability of our directors for a breach of their fiduciary duty of care as a director. The duty of care generally requires that, when acting on behalf of the corporation, directors exercise an informed business judgment based on all material information reasonably available to them. Consequently, a director will not be personally liable to us or our stockholders for monetary damages for breach of fiduciary duty as a director, except for liability for:

- any breach of the director's duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- any act related to unlawful stock repurchases, redemptions or other distributions or payment of dividends; or
- any transaction from which the director derived an improper personal benefit.

These limitations of liability do not affect the availability of equitable remedies such as injunctive relief or rescission. Our third amended and restated certificate of incorporation will authorize us to indemnify our officers, directors and other agents to the fullest extent permitted under Delaware law.

As permitted by Section 145 of the Delaware General Corporation Law, our amended and restated bylaws will provide that:

- we may indemnify our directors, officers and employees to the fullest extent permitted by the Delaware General Corporation Law, subject to limited exceptions;
- we may advance expenses to our directors, officers and employees in connection with a legal proceeding to the fullest extent permitted by the Delaware General Corporation Law, subject to limited exceptions; and

- the rights provided in our amended and restated bylaws are not exclusive.

Our amended and restated certificate of incorporation and our amended and restated bylaws will provide for the indemnification provisions described above and elsewhere herein. We have entered into, and intend to continue to enter into, separate indemnification agreements with our directors and officers that may be broader than the specific indemnification provisions contained in the Delaware General Corporation Law. These indemnification agreements generally require us, among other things, to indemnify our officers and directors against certain liabilities that may arise by reason of their status or service as directors or officers, other than liabilities arising from willful misconduct. These indemnification agreements also generally require us to advance any expenses incurred by the directors or officers as a result of any proceeding against them as to which they could be indemnified. These indemnification provisions and the indemnification agreements may be sufficiently broad to permit indemnification of our officers and directors for liabilities, including reimbursement of expenses incurred, arising under the Securities Act.

We have purchased and currently intend to maintain insurance on behalf of each and every person who is or was a director or officer of the company against any loss arising from any claim asserted against him or her and incurred by him or her in any such capacity, subject to certain exclusions.

The form of underwriting agreement for this initial public offering provides for indemnification by the underwriters of us and our officers and directors who sign this registration statement for specified liabilities, including matters arising under the Securities Act.

Item 15. Recent sales of unregistered securities.

Set forth below is information regarding all unregistered securities sold by us since January 1, 2018. Also included is the consideration received by us for such securities and information relating to the section of the Securities Act, or rule of the SEC, under which exemption from registration was claimed.

Convertible Notes

From March 2018 to July 2020, we issued convertible promissory notes in the aggregate principal amount of \$13.0 million with an interest rate of 8.0% per annum, pursuant to note purchase agreements entered into with certain holders of our capital stock. On May 1, 2021, the holders of all of our outstanding convertible promissory notes agreed to an acceleration of the date of the automatic conversion from June 30, 2021 to May 1, 2021 for all convertible promissory notes. Accordingly, on May 1, 2021, all of our outstanding convertible promissory notes were converted into 10,926,089 shares of our Series B-1 convertible preferred stock at a conversion price equal to \$1.385 per share. As of the date of this prospectus, no notes are outstanding. Pursuant to the terms of our Series B-1 convertible preferred stock all shares will automatically convert into shares of our common stock upon the closing of this offering on a one-for-one basis.

SAFE Financing

In March 2021, we entered into simple agreements for future equity, or SAFEs, with various investors, pursuant to which we received gross proceeds in an aggregate amount equal to \$8.9 million. The amount invested by the investors in the SAFEs is automatically convertible into shares of our common stock upon the closing of our initial public offering at a conversion price equal to 80% of the initial public offering price.

Equity Awards

Since January 1, 2018, we have granted stock options to employees, officers, directors and consultants, covering an aggregate of 7,270,239 shares of our common stock, having a weighted average exercise price of \$0.36 per share, in connection with services provided to us by such parties.

Since January 1, 2018, we have issued an aggregate of 141,848 shares of our common stock to employees, officers, directors and consultants upon their exercise of stock options, for aggregate cash consideration of approximately \$0.031 million.

Unless otherwise stated, the issuances of the above securities were deemed to be exempt from registration under the Securities Act in reliance upon Section 4(a)(2) of the Securities Act or Regulation D promulgated thereunder, or Rule 701 promulgated under Section 3(b) of the Securities Act as transactions by an issuer not involving any public offering or pursuant to benefit plans and contracts relating to compensation as provided under Rule 701. Individuals who purchased securities as described above represented their intention to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were affixed to the share certificates issued in such transactions.

None of the foregoing transactions involved any underwriters, underwriting discounts or commissions or any public offering.

Item 16. Exhibits and financial statement schedules.

(a) Exhibits.

The exhibits listed below are filed as part of this registration statement.

Exhibit number	Exhibit description
1.1†	Form of Underwriting Agreement.
3.1*	Second Amended and Restated Certificate of Incorporation, as filed with the Delaware Secretary of State on dated November 14, 2016, as currently in effect.
3.2*	Amendment to Second Amended and Restated Certificate of Incorporation, as filed with the Delaware Secretary of State on dated January 10, 2017.
3.3*	Second Amendment to Second Amended and Restated Certificate of Incorporation, as filed with the Delaware Secretary of State on dated February 2, 2017.
3.4*	Third Amendment to Second Amended and Restated Certificate of Incorporation, as filed with the Delaware Secretary of State on dated July 29, 2020.
3.5*	Fourth Amendment to Second Amended and Restated Certificate of Incorporation, as filed with the Delaware Secretary of State on dated April 30, 2021.
3.6†	Form of Third Amended and Restated Certificate of Incorporation, which will become effective immediately prior to the closing of this offering.
3.7*	Bylaws, dated August 21, 2007, as currently in effect.
3.8†	Form of Amended and Restated Bylaws, which will become effective immediately prior to the closing of this offering.
4.1†	Specimen Common Stock Certificate of Registrant.
5.1†	Opinion of Troutman Pepper Hamilton Sanders LLP.
10.1†•	Form of Indemnification Agreement by and between the Registrant and its individual directors and officers.
10.2*	Third Amended and Restated Investor Rights Agreement dated as of March 20, 2014, by and among the Registrant and the investors listed therein.
10.3*	First Amendment dated as of March 23, 2020, to the Third Amended and Restated Investor Rights Agreement dated as March 20, 2014, by and among the Registrant and the investors listed therein.
10.4*	Office Lease dated July 1, 2017, by and between the Registrant and RJ Equities LP.
10.5*	First Amendment to Office Lease dated July 1, 2017, by and between the Registrant and RJ Equities LP.
10.6*	Amended and Restated 2007 Equity Incentive Plan
10.7*	2017 Equity Incentive Plan.
10.8*	Amendment to 2017 Equity Incentive Plan.
10.9*	Second Amendment to 2017 Equity Incentive Plan.

Exhibit number	Exhibit description
10.10†•	2021 Equity Incentive Plan.
10.11†•	2021 Employee Stock Purchase Plan.
10.11†•	Form of Restricted Stock Award Agreement.
10.12†•	Form of Non-Qualified Stock Option Agreement.
10.13†•	Form of Incentive Stock Option Agreement.
10.14*	Employment Agreement dated June 1, 2020 by and between the Registrant and Lisa Ricciardi.
10.15*	Separation and Release Agreement dated April 21, 2020 by and between the Registrant and Kenneth Moch.
10.16*	Advisor Services Agreement dated March 17, 2020 by and between the Registrant and Kenneth Moch.
10.17*	Letter Agreement dated October 7, 2019, by and between the Registrant and James M. O'Brien.
10.18†•	Option Agreements for Directors
10.19†•	Letter Agreement between the Registrant and Brett P. Monia, Ph.D.
10.20†•	Letter Agreement between the Registrant and Jack A. Khattar.
10.21	Grant Agreement dated August 14, 2016 by and between the Registrant and the National Institute of Aging.
10.22	Grant Agreement dated September 12, 2017 by and between the Registrant and the National Institute of Aging.
10.23	Grant Agreement dated April 18, 2018 by and between the Registrant and the National Institute of Aging.
10.24	Grant Agreement dated September 8, 2018 by and between the Registrant and the National Institute of Aging.
10.25	Grant Agreement dated August 28, 2020 by and between the Registrant and the National Institute of Aging.
10.26	Grant Agreement dated September 5, 2020 by and between the Registrant and the National Institute of Aging.
10.27	Grant Agreement dated September 18, 2020 by and between the Registrant and the National Institute of Aging.
10.28	Grant Agreement dated February 3, 2021 by and between the Registrant and the National Institute of Aging.
10.29	Grant Agreement dated April 30, 2021 by and between the Registrant and the National Institute of Aging.
10.30	Grant Agreement dated May 6, 2021 by and between the Registrant and the National Institute of Aging.
10.31	Grant Agreement dated May 10, 2021 by and between the Registrant and the National Institute of Aging.
23.1†	Consent of Ernst & Young LLP, an Independent Registered Public Accounting Firm.
23.2†	Consent of Troutman Pepper Hamilton Sanders LLP (included in Exhibit 5.1).
24.1†	Power of Attorney (included on the signature page to this registration statement).

* Previously filed.

† To be filed by amendment.

• Indicates management contract or compensatory plan.

(b) *Financial statement schedules.*

Schedules not listed above have been omitted because the information required to be set forth therein is not applicable or is shown in the consolidated financial statements or notes thereto.

Item 17. Undertakings.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act, and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question of whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned Registrant hereby undertakes that:

1. For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this Registration Statement in reliance upon Rule 430A and contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this Registration Statement as of the time it was declared effective.
2. For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

Signatures

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant has duly caused this registration statement on Form S-1 to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Pittsburgh, Commonwealth of Pennsylvania on _____, 2021.

COGNITION THERAPEUTICS, INC.

By: /s/ Lisa Ricciardi

Lisa Ricciardi
Chief Executive Officer
(Principal Executive Officer)

Power of attorney

KNOW ALL BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Lisa Ricciardi and James M. O'Brien, and each of them, as his or her true and lawful attorneys-in-fact and agents, each with the full power of substitution, for him or her and in his or her name, place or stead, in any and all capacities, to sign any and all amendments to this registration statement (including post-effective amendments), and to sign any registration statement for the same offering covered by this registration statement that is to be effective upon filing pursuant to Rule 462(b) promulgated under the Securities Act, and all post-effective amendments thereto, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or their, his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this registration statement on Form S-1 has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
<u>Lisa Ricciardi</u>	Chief Executive Officer and Director (Principal Executive Officer)	, 2021
<u>James M. O'Brien</u>	Chief Financial Officer (Principal Financial and Accounting Officer)	, 2021
<u>Jack A. Khattar</u>	Director (Chairman of the Board)	, 2021
<u>Mark H. Breedlove</u>	Director	, 2021
<u>Susan Catalano, Ph.D.</u>	Director	, 2021
<u>Aaron Fletcher, Ph.D.</u>	Director	, 2021
<u>Brett P. Monia, Ph.D.</u>	Director	, 2021
<u>Stephen Sands</u>	Director	, 2021
<u>Peggy Wallace</u>	Director	, 2021

Notice of Award



Multi-Year Funded Research Project Grant
Department of Health and Human Services
National Institutes of Health

Federal Award Date: 08/14/2016



NATIONAL INSTITUTE ON AGING

Grant Number: 1RF1AG054176-01

FAIN: RF1AG054176

Principal Investigator(s):

SUSAN M CATALANO, PHD

Project Title: Phase 1b first-in-patient safety trial for CT1812, a novel Alzheimer's synaptic protection therapeutic

Catalano, Susan
Chief Science Officer
2403 Sidney Street
Suite 261
Pittsburgh, PA 152035118

Award e-mailed to: scatalano@cogrx.com

Period Of Performance:

Budget Period: 08/15/2016 - 07/31/2018

Project Period: 08/15/2016 - 07/31/2018

Dear Business Official:

The National Institutes of Health hereby awards a grant in the amount of \$2,410,669 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to COGNITION THERAPEUTICS, INC. in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award including the "Terms and Conditions" is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute On Aging of the National Institutes of Health under Award Number RF1AG054176. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website <http://grants.nih.gov/grants/policy/coi/> for a link to the regulation and additional important information.

If you have any questions about this award, please contact the individual(s) referenced in Section IV.

Sincerely yours,

TRACI LAFFERTY
Grants Management Officer
NATIONAL INSTITUTE ON AGING

Additional information follows

SECTION I - AWARD DATA - 1RF1AG054176-01

Award Calculation (U.S. Dollars)		
Salaries and Wages	\$	200,532
Personnel Costs (Subtotal)	\$	200,532
Other	\$	1,728,003
Federal Direct Costs		
Federal F&A Costs	\$	1,928,535
Approved Budget	\$	482,134
Total Amount of Federal Funds Obligated (Federal Share)	\$	2,410,669
TOTAL FEDERAL AWARD AMOUNT	\$	2,410,669
AMOUNT OF THIS ACTION (FEDERAL SHARE)		
	\$	2,410,669

SUMMARY TOTALS FOR ALL YEARS				
YR	THIS AWARD		CUMULATIVE TOTALS	
1	\$	2,410,669	\$	2,410,669

Fiscal Information:
CFDA Name: Aging Research
CFDA Number: 93.866
EIN: 1134365359A1
Document Number: RAG054176A
PMS Account Type: P (Subaccount)
Fiscal Year: 2016

IC	CAN	2016		
AG	8013663	\$		2,410,669

NIH Administrative Data:
PCC: 3CCCTLR / **OC:** 414A / **Released:** LAFFERTYT 08/11/2016
Award Processed: 08/14/2016 08:10:03 AM

SECTION II - PAYMENT/HOTLINE INFORMATION - 1RF1AG054176-01

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at <http://grants.nih.gov/grants/policy/awardconditions.htm>

SECTION III - TERMS AND CONDITIONS - 1RF1AG054176-01

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

- a. The grant program legislation and program regulation cited in this Notice of Award.
- b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
- c. 45 CFR Part 75.
- d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
- e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
- f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at <http://grants.nih.gov/grants/policy/awardconditions.htm> for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of “Research and Development” at 45 CFR Part § 75.2. As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is excluded from Streamlined Noncompeting Award Procedures (SNAP). **MULTI-YEAR FUNDED AWARD:** This is a multi-year funded award. A progress report is due annually on or before the anniversary of the budget/project period start date of the award, in accord with the instructions posted at: <http://grants.nih.gov/grants/policy/myf.htm>.

This award is subject to the requirements of 2 CFR Part 25 for institutions to receive a Dun & Bradstreet Universal Numbering System (DUNS) number and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a DUNS requirement must be included. See <http://grants.nih.gov/grants/policy/awardconditions.htm> for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) RF1AG054176. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see <http://grants.nih.gov/grants/policy/awardconditions.htm> for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: <http://publicaccess.nih.gov/>.

This award provides support for one or more clinical trials. By law (Title VIII, Section 801 of [Public Law 110-85](#)), the “responsible party” must register “applicable clinical trials” on the [ClinicalTrials.gov Protocol Registration System Information Website](#). NIH encourages registration of all trials whether required under the law or not. For more information, see <http://grants.nih.gov/ClinicalTrials/fdaaa/>

This award represents the final year of the competitive segment for this grant. See the NIH Grants Policy Statement Section 8.6 Closeout for complete closeout requirements at: <http://grants.nih.gov/grants/policy/policy.htm#gps>.

A final expenditure Federal Financial Report (FFR) (SF 425) must be submitted through the eRA Commons (Commons) within 120 days of the expiration date; see the NIH Grants Policy Statement Section 8.6.1 Financial Reports, <http://grants.nih.gov/grants/policy/policy.htm#gps>, for additional information on this submission requirement. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the Payment Management System’s (PMS) quarterly cash transaction data. A final quarterly federal cash transaction report is not required for awards in PMS B subaccounts (i.e., awards to foreign entities and to Federal agencies). NIH will close the awards using the last recorded cash drawdown level in PMS for awards that do not require a final FFR on expenditures or quarterly federal cash transaction reporting. It is important to note that for financial closeout, if a grantee fails to submit a required final expenditure FFR, NIH will close the grant using the last recorded cash drawdown level. If the grantee submits a final expenditure FFR but does not reconcile any discrepancies between expenditures reported on the final expenditure FFR and the last cash report to PMS, NIH will close the award at the lower amount. This could be considered a debt or result in disallowed costs.

A Final Invention Statement and Certification form (HHS 568), (not applicable to training, construction, conference or cancer education grants) must be submitted within 120 days of the expiration date. The HHS 568 form may be downloaded at: <http://grants.nih.gov/grants/forms.htm>. This paragraph does not apply to Training grants, Fellowships, and certain other programs—i.e., activity codes C06, R13, R25, S10.

Unless an application for competitive renewal is submitted, a final progress report must also be submitted within 120 days of the expiration date. Instructions for preparing a Final Progress Report are at: <http://grants.nih.gov/grants/funding/finalprogressreport.pdf>. Any other specific requirements set forth in the terms and conditions of the award must also be addressed in the final progress report. Institute/Centers may accept the progress report contained in competitive renewal (type 2) in lieu of a separate final progress report. Contact the awarding IC for IC- specific policy regarding acceptance of a progress report contained in a competitive renewal application in lieu of a separate final progress report.

NIH strongly encourages electronic submission of the final progress report and the final invention statement through the Closeout feature in the Commons, but will accept an email or hard copy submission as indicated below.

Email: The final progress report and final invention statement may be e-mailed as PDF attachments to: NIHCloseoutCenter@mail.nih.gov.

Hard copy: Paper submissions of the final progress report and the final invention statement may be faxed to the NIH Division of Central Grants Processing, Grants Closeout Center, at 301-4802304, or mailed to:

National Institutes of Health
Office of Extramural Research
Division of Central Grants Processing
Grants Closeout Center
6705 Rockledge Drive
Suite 5016, MSC 7986
Bethesda, MD 20892-7986 (for regular or U.S. Postal Service Express mail)
Bethesda, MD 20817 (for other courier/express deliveries only)

NOTE: If this is the final year of a competitive segment due to the transfer of the grant to another institution, then a Final Progress Report is not required. However, a final expenditure FFR is required and should be submitted electronically as noted above. If not already submitted, the Final Invention Statement is required and should be sent directly to the assigned Grants Management Specialist.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than \$10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:
Additional Costs

SECTION IV - AG Special Terms and Conditions - 1RF1AG054176-01

Restriction: This award restricts all funds requested for F&A that are in excess of 10% of salaries and wages, \$462,081 is restricted pending the negotiation of an F&A rate(s). These restricted funds may not be used for any purpose without the prior approval of the grants management official. If the rate(s) negotiated is(are) lower than originally estimated/funded, this award amount may be revised downward.

Restriction: Recruitment of participants cannot be initiated until the NIA program staff, the IRB and the DSMB have approved the protocol and data and safety monitoring plan.

Funding for this award has been provided by Alzheimer’s Disease Initiative funds.

The progress report for this multi-year funded (MYF) award is due annually on or before the anniversary of the budget/project period start date of the award and must be submitted via the eRA Commons. Additional information on submission requirements and directions can be found at <http://grants.nih.gov/grants/policy/myf.htm>.

None of the funds in this award shall be used to pay the salary of an individual at a rate in excess of the current salary cap. Therefore, this award and/or future years are adjusted accordingly, if applicable. Current salary cap levels can be found at the following URL: http://grants.nih.gov/grants/policy/salcap_summary.htm.

STAFF CONTACTS

The Grants Management Specialist is responsible for the negotiation, award and administration of this project and for interpretation of Grants Administration policies and provisions. The Program Official is responsible for the scientific, programmatic and technical aspects of this project. These individuals work together in overall project administration. Prior approval requests (signed by an Authorized Organizational Representative) should be submitted in writing to the Grants Management Specialist. Requests may be made via e-mail.

Grants Management Specialist: Robin Laney
Email: laneyr@nia.nih.gov Phone: 301-496-1472 Fax: 301-402-3672

Program Official: Laurie M. Ryan
Email: ryanl@nia.nih.gov Phone: 301.496.9350 Fax: 301-496-1494

SPREADSHEET SUMMARY
GRANT NUMBER: 1RF1AG054176-01

INSTITUTION: COGNITION THERAPEUTICS, INC.

Budget	Year 1	
Salaries and Wages	\$	200,532
Personnel Costs (Subtotal)	\$	200,532
Other	\$	1,728,003
TOTAL FEDERAL DC	\$	1,928,535
TOTAL FEDERAL F&A	\$	482,134
TOTAL COST	\$	2,410,669
Facilities and Administrative Costs	Year 1	
F&A Cost Rate 1		25%
F&A Cost Base 1	\$	1,928,535
F&A Costs 1	\$	482,134

Notice of Award



RESEARCH
Department of Health and Human Services National Institutes of Health

Federal Award Date: 09/12/2017



NATIONAL INSTITUTE ON AGING

Grant Number: 1R01AG057553-01
FAIN: R01AG057553

Principal Investigator(s):
SUSAN M CATALANO, PHD

Project Title: A Pilot Synaptic Vesicle Glycoprotein 2A (SV2A) PET Study to Evaluate the Effect of CT1812 Treatment on Synaptic Density in Subjects with Mild to Moderate Alzheimer's Disease

Dr. Catalano, Susan, Ph.D
Chief Science Officer
2403 Sidney Street
Suite 261
Pittsburgh, PA 152035118

Award e-mailed to: scatalano@cogrx.com

Period Of Performance:
Budget Period: 09/15/2017 - 03/31/2018
Project Period: 09/15/2017 - 03/31/2019

Dear Business Official:

The National Institutes of Health hereby awards a grant in the amount of \$2,371,589 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to COGNITION THERAPEUTICS, INC. in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award including the "Terms and Conditions" is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute On Aging of the National Institutes of Health under Award Number R01AG057553. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website <http://grants.nih.gov/grants/policy/coi/> for a link to the regulation and additional important information.

If you have any questions about this award, please contact the individual(s) referenced in Section IV.

Sincerely yours,

Robin Laney
Grants Management Officer

NATIONAL INSTITUTE ON AGING

Additional information follows

SECTION I - AWARD DATA - 1R01AG057553-01

Award Calculation (U.S. Dollars)

Federal Direct Costs	\$	2,261,064
Federal F&A Costs	\$	110,525
Approved Budget	\$	2,371,589
Total Amount of Federal Funds Obligated (Federal Share)	\$	2,371,589
TOTAL FEDERAL AWARD AMOUNT	\$	2,371,589
AMOUNT OF THIS ACTION (FEDERAL SHARE)	\$	2,371,589

SUMMARY TOTALS FOR ALL YEARS				
YR	THIS AWARD		CUMULATIVE TOTALS	
1	\$	2,371,589	\$	2,371,589
2	\$	1,759,152	\$	1,759,152

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:
CFDA Name: Aging Research
CFDA Number: 93.866
EIN: 1134365359A1
Document Number: RAG057553A
PMS Account Type: P (Subaccount)
Fiscal Year: 2017

IC	CAN	2017	2018
AG	8013663	\$ 2,371,589	\$ 1,759,152

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:
PCC: 3CCCTLR / **OC:** 414A / **Released:** LANEYR 09/11/2017 **Award Processed:** 09/12/2017 12:03:11 AM

SECTION II - PAYMENT/HOTLINE INFORMATION - 1R01AG057553-01

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at <http://grants.nih.gov/grants/policy/awardconditions.htm>

SECTION III - TERMS AND CONDITIONS - 1R01AG057553-01

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

- a. The grant program legislation and program regulation cited in this Notice of Award.
- b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
- c. 45 CFR Part 75.
- d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
- e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
- f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at <http://grants.nih.gov/grants/policy/awardconditions.htm> for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of “Research and Development” at 45 CFR Part § 75.2. As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is excluded from Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to receive a Dun & Bradstreet Universal Numbering System (DUNS) number and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a DUNS requirement must be included. See <http://grants.nih.gov/grants/policy/awardconditions.htm> for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01AG057553. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see <http://grants.nih.gov/grants/policy/awardconditions.htm> for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: <http://publicaccess.nih.gov/>.

This award provides support for one or more clinical trials. By law (Title VIII, Section 801 of [Public Law 110-85](#)), the “responsible party” must register “applicable clinical trials” on the [ClinicalTrials.gov Protocol Registration System Information Website](#). NIH encourages registration of all trials whether required under the law or not. For more information, see <http://grants.nih.gov/ClinicalTrials/fdaaa/>.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than \$10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

SECTION IV - AG Special Terms and Conditions - 1R01AG057553-01

RESTRICTION: The present award is being made without a currently valid certification of IRB approval for this project with the following restriction: Only activities that are clearly severable and independent from activities that involve human subjects may be conducted pending the National Institute on Aging's acceptance of the certification of IRB approval.

No funds may be drawn down from the payment system and no obligations may be made against Federal funds for any research involving human subjects prior to the National Institute on Aging's notification to the grantee that the identified issues have been resolved and this restriction removed.

Failure to respond within the 60-day period and/or to otherwise comply with the above requirements may result in suspension and/or termination of this award, audit/or disallowances, and/or other appropriate action.

See the NIH Grants Policy Statement, Chapter 4.1.15 Human Subjects Protections ([http://grants.nih.gov/grants/policy/nihgps/HTML5/section 4/4 public policy requirements objectives and other appropriation mandates.htm](http://grants.nih.gov/grants/policy/nihgps/HTML5/section%204/4%20public%20policy%20requirements%20objectives%20and%20other%20appropriation%20mandates.htm)), for specific requirements related to the protection of human subjects, which are applicable to and a term and condition of this award.

Recruitment of participants cannot be initiated until the NIA program staff, IRB, and the DSMB have approved the protocol and data and safety monitoring plan.

None of the funds in this award shall be used to pay the salary of an individual at a rate in excess of the current salary cap. Therefore, this award and/or future years are adjusted accordingly, if applicable. Current salary cap levels can be found at the following URL: [http://grants.nih.gov/grants/policy/salcap summary.htm](http://grants.nih.gov/grants/policy/salcap%20summary.htm)

This award includes funds awarded for consortium activity with Yale University in the amount of \$1,180,815 (\$704,964 direct costs + \$475,851 facilities and administrative costs). Consortia are to be established and administered as described in the NIH Grants Policy Statement (NIH GPS). The referenced section of the NIH Grants Policy Statement, 2015 is available at: [http://grants.nih.gov/grants/policy/nihgps/HTML5/section 15/15 consortium agreements.htm](http://grants.nih.gov/grants/policy/nihgps/HTML5/section%2015/15%20consortium%20agreements.htm)

This award includes funds for twelve months of support. The competing budget period is awarded for less than 12 months. Continuation awards will cycle each year on 4/1. The Research Performance Progress Reports (RPPR) are due 45 days prior to this date.

Funding for this award has been provided by Alzheimer's Disease Initiative funds.

ClinicalTrials.gov is a federal registry and results database of publicly and privately supported clinical studies of human participants conducted around the world. In September 2016, NIH issued a final policy to promote broad and responsible dissemination of information from NIH-funded clinical trials through ClinicalTrials.gov. Under this policy, every clinical trial funded in whole or in part by NIH is expected to be registered on ClinicalTrials.gov and have summary results information submitted and posted in a timely manner, whether subject to FDAAA 801 or not.

Public Policy Requirements and Objectives: [https://grants.nih.gov/grants/policy/nihgps/HTML5/section 4/4.1 public policy requirements and objectives.htm?Highlight=clinical](https://grants.nih.gov/grants/policy/nihgps/HTML5/section%204/4.1%20public%20policy%20requirements%20and%20objectives.htm?Highlight=clinical)

STAFF CONTACTS

The Grants Management Specialist is responsible for the negotiation, award and administration of this project and for interpretation of Grants Administration policies and provisions. The Program Official is responsible for the scientific, programmatic and technical aspects of this project. These individuals work together in overall project administration. Prior approval requests (signed by an Authorized Organizational Representative) should be submitted in writing to the Grants Management Specialist. Requests may be made via e-mail.

Grants Management Specialist: Richard Proper
Email: properr@mail.nih.gov **Phone:** 301-402-7735 **Fax:** 301-402-3672

Program Official: Laurie M. Ryan
Email: ryanl@nia.nih.gov **Phone:** 301.496.9350 **Fax:** 301-496-1494

SPREADSHEET SUMMARY

GRANT NUMBER: 1R01AG057553-01

INSTITUTION: COGNITION THERAPEUTICS, INC.

Facilities and Administrative Costs	Year 1		Year 2	
F&A Cost Rate 1		10%		10%
F&A Cost Base 1	\$	1,105,249	\$	515,250
F&A Costs 1	\$	110,525	\$	51,525



Multi-Year Funded Research Project Grant
Department of Health and Human Services
National Institutes of Health

Notice of Award

Federal Award Date: 04/18/2018



NATIONAL INSTITUTE ON AGING

Grant Number: 1RF1AG057780-01 REVISED**FAIN:** RF1AG057780**Principal Investigator(s):**

SUSAN M CATALANO, PHD

Project Title: A Pilot CSF Catheter Study to Evaluate the Effect of CT1812 Treatment on A β Oligomer Clearance into CSF in Subjects with Mild to Moderate Alzheimer's Disease

Hank Safferstein
Chief Science Officer
2403 Sidney Street
Suite 261
Pittsburgh, PA 152035118

Award e-mailed to: scatalano@cogrx.com**Period Of Performance:****Budget Period:** 09/30/2017 - 06/30/2019**Project Period:** 09/30/2017 - 06/30/2019

Dear Business Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to COGNITION THERAPEUTICS, INC. in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award including the "Terms and Conditions" is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute On Aging of the National Institutes of Health under Award Number RF1AG057780. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website <http://grants.nih.gov/grants/policy/coi/> for a link to the regulation and additional important information.

If you have any questions about this award, please contact the individual(s) referenced in Section IV.

Sincerely yours,

Robin Laney
Grants Management Officer
NATIONAL INSTITUTE ON AGING

Additional information follows

SECTION I - AWARD DATA - 1RF1AG057780-01 REVISED

Award Calculation (U.S. Dollars) Salaries and Wages	\$	132,000
Personnel Costs (Subtotal)	\$	132,000
Consultant Services	\$	90,000
Materials & Supplies	\$	15,000
Other	\$	937,000
Subawards/Consortium/Contractual Costs	\$	1,230,871
Federal Direct Costs	\$	2,404,871
Federal F&A Costs	\$	122,400
Approved Budget	\$	2,527,271
Total Amount of Federal Funds Obligated (Federal Share)	\$	2,527,271
TOTAL FEDERAL AWARD AMOUNT	\$	2,527,271
AMOUNT OF THIS ACTION (FEDERAL SHARE)	\$	0

SUMMARY TOTALS FOR ALL YEARS

YR	THIS AWARD		CUMULATIVE TOTALS	
1	\$	2,527,271	\$	2,527,271

Fiscal Information:

CFDA Name: Aging Research
CFDA Number: 93.866 1134365359A1
EIN: RAG057780A
Document Number: P (Subaccount) 2017
PMS Account Type:
Fiscal Year:

IC	CAN	2017	
AG	8013663	\$	2,527,271

NIH Administrative Data:

PCC: 3CCCTLR / OC: 414A / Released: LANEYR 04/17/2018
Award Processed: 04/18/2018 12:00:48 AM

SECTION II - PAYMENT/HOTLINE INFORMATION - 1RF1AG057780-01 REVISED

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at <http://grants.nih.gov/grants/policy/awardconditions.htm>

SECTION III - TERMS AND CONDITIONS - 1RF1AG057780-01 REVISED

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

- a. The grant program legislation and program regulation cited in this Notice of Award.
- b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
- c. 45 CFR Part 75.
- d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
- e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
- f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at <http://grants.nih.gov/grants/policy/awardconditions.htm> for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of “Research and Development” at 45 CFR Part § 75.2. As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is excluded from Streamlined Noncompeting Award Procedures (SNAP).

MULTI-YEAR FUNDED AWARD: This is a multi-year funded award. A progress report is due annually on or before the anniversary of the budget/project period start date of the award, in accord with the instructions posted at: <http://grants.nih.gov/grants/policy/myf.htm>.

This award is subject to the requirements of 2 CFR Part 25 for institutions to receive a Dun & Bradstreet Universal Numbering System (DUNS) number and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a DUNS requirement must be included. See <http://grants.nih.gov/grants/policy/awardconditions.htm> for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) RF1AG057780. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see <http://grants.nih.gov/grants/policy/awardconditions.htm> for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: <http://publicaccess.nih.gov/>.

This award provides support for one or more clinical trials. By law (Title VIII, Section 801 of Public Law 110-85), the “responsible party” must register “applicable clinical trials” on the ClinicalTrials.gov Protocol Registration System Information Website. NIH encourages registration of all trials whether required under the law or not. For more information, see <http://grants.nih.gov/ClinicalTrials/fdaaa/>.

This award represents the final year of the competitive segment for this grant. See the NIH Grants Policy Statement Section 8.6 Closeout for complete closeout requirements at: <http://grants.nih.gov/grants/policy/policy.htm#gps>.

A final expenditure Federal Financial Report (FFR) (SF 425) must be submitted through the eRA Commons (Commons) within 120 days of the period of performance end date; see the NIH Grants Policy Statement Section 8.6.1 Financial Reports, <http://grants.nih.gov/grants/policy/policy.htm#gps>, for additional information on this submission requirement. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the Payment Management System’s (PMS) quarterly cash transaction data.

A final quarterly federal cash transaction report is not required for awards in PMS B subaccounts (i.e., awards to foreign entities and to Federal agencies). NIH will close the awards using the last recorded cash drawdown level in PMS for awards that do not require a final FFR on expenditures or quarterly federal cash transaction reporting. It is important to note that for financial closeout, if a grantee fails to submit a required final expenditure FFR, NIH will close the grant using the last recorded cash drawdown level. If the grantee submits a final expenditure FFR but does not reconcile any discrepancies between expenditures reported on the final expenditure FFR and the last cash report to PMS, NIH will close the award at the lower amount. This could be considered a debt or result in disallowed costs.

A Final Invention Statement and Certification form (HHS 568), (not applicable to training, construction, conference or cancer education grants) must be submitted within 120 days of the expiration date. The HHS 568 form may be downloaded at: <http://grants.nih.gov/grants/forms.htm>. This paragraph does not apply to Training grants, Fellowships, and certain other programs—i.e., activity codes C06, D42, D43, D71, DP7, G07, G08, G11, K12, K16, K30, P09, P40, P41, P51, R13, R25, R28, R30, R90, RL5, RL9, S10, S14, S15, U13, U14, U41, U42, U45, UC6, UC7, UR2, X01, X02.

Unless an application for competitive renewal is submitted, a Final Research Performance Progress Report (Final RPPR) must also be submitted within 120 days of the period of performance end date. If a competitive renewal application is submitted prior to that date, then an Interim RPPR must be submitted by that date as well. Instructions for preparing an Interim or Final RPPR are at: https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf. Any other specific requirements set forth in the terms and conditions of the award must also be addressed in the Interim or Final RPPR. *Note that data reported within Section I of the Interim and Final RPPR forms will be made public and should be written for a lay person audience.*

NIH strongly encourages electronic submission of the final invention statement through the Closeout feature in the Commons, but will accept an email or hard copy submission as indicated below.

Email: The final invention statement may be e-mailed as PDF attachments to: NIHCloseoutCenter@mail.nih.gov.

Hard copy: Paper submissions of the final invention statement may be faxed to the NIH Division of Central Grants Processing, Grants Closeout Center, at 301-480-2304, or mailed to:

National Institutes of Health
Office of Extramural Research
Division of Central Grants Processing
Grants Closeout Center
6705 Rockledge Drive
Suite 5016, MSC 7986
Bethesda, MD 20892-7986 (for regular or U.S. Postal Service Express mail)
Bethesda, MD 20817 (for other courier/express deliveries only)

NOTE: If this is the final year of a competitive segment due to the transfer of the grant to another institution, then a Final RPPR is not required. However, a final expenditure FFR is required and should be submitted electronically as noted above. If not already submitted, the Final Invention Statement is required and should be sent directly to the assigned Grants Management Specialist.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than \$10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:

Additional Costs

SECTION IV - AG Special Terms and Conditions - 1RF1AG057780-01 REVISED

Clinical Trial Indicator: Yes

This award supports one or more NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

REVISION: This revised award reflects the Office for Human Research Protections' (OHRP) approval of Assurance(s) of Compliance with 45 CFR 46 the grantee organization.

This revised award reflects the NIH awarding component's acceptance of the certification of Institutional Review Board (IRB) approval for the grantee organization and releases the restriction on the Notice of Award issued on 9/16/2017. Accordingly, the special condition prohibiting research involving human subjects is removed, effective as of the date of IRB approval.

Supersedes Notice of Award issued 9/16/2017. Previous terms and conditions apply:

The progress report for this multi-year funded (MYF) award is due annually on or before the anniversary of the budget/project period start date of the award and must be submitted via the eRA Commons. Additional information on submission requirements and directions can be found at: <http://grants.nih.gov/grants/policy/myf.htm>.

Funds for this award expire on the last day of the 5th Fiscal Year of the Initial Award (06/30/2022).

Funding for this award has been provided by Alzheimer's Disease Initiative funds.

ClinicalTrials.gov is a federal registry and results database of publicly and privately supported clinical studies of human participants conducted around the world. In September 2016, NIH issued a final policy to promote broad and responsible dissemination of information from NIH- funded clinical trials through ClinicalTrials.gov. Under this policy, every clinical trial funded in whole or in part by NIH is expected to be registered on ClinicalTrials.gov and have summary results information submitted and posted in a timely manner, whether subject to FDAAA 801 or not.

Public Policy Requirements and Objectives: <https://grants.nih.gov/grants/policy/nihgps/HTML5/section 4/4.1 public policy requirements and objectives.htm?Highlight=clinical>

This award includes funds for twelve months of support. The competing budget period is awarded for less than 12 months. Continuation awards will cycle each year on 4/1. The Research Performance Progress Report (RPPR) is due 45 days prior to this date.

This award includes funds awarded for consortium activity with the **University of Pennsylvania** in the amount of \$288,525 (\$179,208 direct costs + \$109,317 facilities and administrative costs) **Washington University** in the amount of \$326,165 (\$217,321 direct costs + \$108,844 facilities and administrative costs). Consortia are to be established and administered as described in the NIH Grants Policy Statement (NIH GPS). The referenced section of the NIH Grants Policy Statement, 2015 is available at: <http://grants.nih.gov/grants/policy/nihgps/HTML5/section 15/15 consortium agreements.htm>.

STAFF CONTACTS

The Grants Management Specialist is responsible for the negotiation, award and administration of this project and for interpretation of Grants Administration policies and provisions. The Program Official is responsible for the scientific, programmatic and technical aspects of this project. These individuals work together in overall project administration. Prior approval requests (signed by an Authorized Organizational Representative) should be submitted in writing to the Grants Management Specialist. Requests may be made via e-mail.

Grants Management Specialist: Jessica Perez
Email: perezj@nia.nih.gov **Phone:** 301 496-1472 **Fax:** 301 402-3672

Program Official: Laurie M. Ryan
Email: ryanl@nia.nih.gov **Phone:** 301.496.9350 **Fax:** 301-496-1494

SPREADSHEET SUMMARY
GRANT NUMBER: 1RF1AG057780-01 REVISED
INSTITUTION: COGNITION THERAPEUTICS, INC.

Budget	Year 1	
Salaries and Wages	\$	132,000
Personnel Costs (Subtotal)	\$	132,000
Consultant Services	\$	90,000
Materials & Supplies	\$	15,000
Other	\$	937,000
Subawards/Consortium/Contractual Costs	\$	1,230,871
TOTAL FEDERAL DC	\$	2,404,871
TOTAL FEDERAL F&A	\$	122,400
TOTAL COST	\$	2,527,271
Facilities and Administrative Costs	Year 1	
F&A Cost Rate 1		10%
F&A Cost Base 1	\$	1,067,550
F&A Costs 1	\$	106,755
F&A Cost Rate 2		10%
F&A Cost Base 2	\$	156,450
F&A Costs 2	\$	15,645

Notice of Award



RESEARCH
Department of Health and Human Services
National Institutes of Health

Federal Award Date: 09/08/2018

NATIONAL INSTITUTE ON AGING

Grant Number: 1R01AG058660-01**FAIN:** R01AG058660**Principal Investigator(s):**

SUSAN M CATALANO, PHD

Project Title: A Randomized, Double-blind, Placebo-Controlled, Parallel-Group, Phase II Study to Evaluate the Safety and Efficacy of CT1812 in Subjects with Mild to Moderate Alzheimer's Disease

Dr. Catalano, Susan, Ph.D
Chief Science Officer
2403 Sidney Street
Suite 261
Pittsburgh, PA 153025118

Award e-mailed to: scatalano@cogrx.com**Period Of Performance:****Budget Period:** 09/15/2018 - 05/31/2019**Project Period:** 09/15/2018 - 05/31/2021

Dear Business Official:

The National Institutes of Health hereby awards a grant in the amount of \$5,059,534 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to COGNITION THERAPEUTICS, INC. in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award including the "Terms and Conditions" is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute On Aging of the National Institutes of Health under Award Number R01AG058660. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website <http://grants.nih.gov/grants/policy/coi/> for a link to the regulation and additional important information.

If you have any questions about this award, please contact the individual(s) referenced in Section IV.

Sincerely yours,

Robin Laney
Grants Management Officer
NATIONAL INSTITUTE ON AGING

Additional information follows

SECTION I - AWARD DATA - 1R01AG058660-01

Award Calculation (U.S. Dollars) Salaries and Wages Personnel Costs		
(Subtotal) Consultant Services	\$	171,250
Other	\$	171,250
	\$	70,000
	\$	3,650,699
Federal Direct Costs		
	\$	3,891,949
Federal F&A Costs	\$	1,167,585
Approved Budget	\$	5,059,534
Total Amount of Federal Funds Obligated (Federal Share)	\$	5,059,534
TOTAL FEDERAL AWARD AMOUNT	\$	5,059,534
AMOUNT OF THIS ACTION (FEDERAL SHARE)	\$	5,059,534

SUMMARY TOTALS FOR ALL YEARS

YR	THIS AWARD		CUMULATIVE TOTALS	
1	\$	5,059,534	\$	5,059,534
2	\$	5,735,586	\$	5,735,586
3	\$	5,774,586	\$	5,774,586

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:

CFDA Name: Aging Research
CFDA Number: 93.866
EIN: 1134365359A1
Document Number: RAG058660A
PMS Account Type: P (Subaccount)
Fiscal Year: 2018

IC	CAN	2018	2019	2020
AG	8033159	\$ 5,059,534	\$ 5,735,586	\$ 5,774,586

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:

PCC: 3CCCTLR / OC: 414A / Released: LANEYR 09/07/2018
Award Processed: 09/08/2018 12:03:31 AM

SECTION II - PAYMENT/HOTLINE INFORMATION - 1R01AG058660-01

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at <http://grants.nih.gov/grants/policy/awardconditions.htm>

SECTION III - TERMS AND CONDITIONS - 1R01AG058660-01

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

- a. The grant program legislation and program regulation cited in this Notice of Award.
- b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
- c. 45 CFR Part 75.
- d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
- e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
- f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at <http://grants.nih.gov/grants/policy/awardconditions.htm> for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of “Research and Development” at 45 CFR Part § 75.2. As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to receive a Dun & Bradstreet Universal Numbering System (DUNS) number and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a DUNS requirement must be included. See <http://grants.nih.gov/grants/policy/awardconditions.htm> for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01AG058660. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see <http://grants.nih.gov/grants/policy/awardconditions.htm> for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: <http://publicaccess.nih.gov/>.

This award provides support for one or more clinical trials. By law (Title VIII, Section 801 of [Public Law 110-85](#)), the “responsible party” must register “applicable clinical trials” on the [ClinicalTrials.gov Protocol Registration System Information Website](#). NIH encourages registration of all trials whether required under the law or not. For more information, see http://grants.nih.gov/ClinicalTrials_fdaaa/

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than \$10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:

Additional Costs

SECTION IV - AG Special Terms and Conditions - 1R01AG058660-01

Clinical Trial Indicator: Yes

This award supports one or more NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

Restriction: Participant recruitment cannot begin until the National Institute on Aging (NIA) program staff, the Data and Safety Monitoring Board (DSMB) and the grantee's Institutional Review Board (IRB) has reviewed and approved the Data and Safety Monitoring Plan protocol and the NIA program staff has documentation of the IRB's approval.

Funding for this award has been provided by Alzheimer's Disease Initiative funds.

ClinicalTrials.gov is a federal registry and results database of publicly and privately supported clinical studies of human participants conducted around the world. In September 2016, NIH issued a final policy to promote broad and responsible dissemination of information from NIH-funded clinical trials through ClinicalTrials.gov. Under this policy, every clinical trial funded in whole or in part by NIH is expected to be registered on ClinicalTrials.gov and have summary results information submitted and posted in a timely manner, whether subject to FDAAA 801 or not.

Public Policy Requirements and Objectives:

[https://grants.nih.gov/grants/policy/nihgps/HTML5/section 4/4.1 public policy requirements and objectives.htm?Highlight=clinical](https://grants.nih.gov/grants/policy/nihgps/HTML5/section%204/4.1_public_policy_requirements_and_objectives.htm?Highlight=clinical)

This award includes funds for twelve months of support. The competing budget period is awarded for less than 12 months. Continuation awards will cycle each year on 06/01. The Research Performance Progress Reports (RPPR) are due 45 days prior to this date.

STAFF CONTACTS

The Grants Management Specialist is responsible for the negotiation, award and administration of this project and for interpretation of Grants Administration policies and provisions. The Program Official is responsible for the scientific, programmatic and technical aspects of this project. These individuals work together in overall project administration. Prior approval requests (signed by an Authorized Organizational Representative) should be submitted in writing to the Grants Management Specialist. Requests may be made via e-mail.

Grants Management Specialist: Jennifer Edwards

Email: edwardsj@mail.nih.gov **Phone:** 301-827-6689

Program Official: Laurie M. Ryan

Email: ryanl@nia.nih.gov **Phone:** 301.496.9350 **Fax:** 301-496-1494

SPREADSHEET SUMMARY
GRANT NUMBER: 1R01AG058660-01

INSTITUTION: COGNITION THERAPEUTICS, INC.

Budget	Year 1	Year 2	Year 3
Salaries and Wages	\$ 171,250	\$ 171,250	\$ 176,250
Personnel Costs (Subtotal)	\$ 171,250	\$ 171,250	\$ 176,250
Consultant Services	\$ 70,000	\$ 70,000	\$ 70,000
Other	\$ 3,650,699	\$ 4,170,739	\$ 4,195,739
TOTAL FEDERAL DC	\$ 3,891,949	\$ 4,411,989	\$ 4,441,989
TOTAL FEDERAL F&A	\$ 1,167,585	\$ 1,323,597	\$ 1,332,597
TOTAL COST	\$ 5,059,534	\$ 5,735,586	\$ 5,774,586

Facilities and Administrative Costs	Year 1	Year 2	Year 3
F&A Cost Rate 1	30%	30%	30%
F&A Cost Base 1	\$ 3,891,949	\$ 4,411,989	\$ 4,441,989
F&A Costs 1	\$ 1,167,585	\$ 1,323,597	\$ 1,332,597

Notice of Award



RESEARCH
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE ON AGING

Federal Award Date: 08/28/2020



Grant Number: 3R01AG058660-03S2

FAIN: R01AG058660

Principal Investigator(s):

SUSAN M CATALANO, PHD

Project Title: A Randomized, Double-blind, Placebo-Controlled, Parallel-Group, Phase II Study to Evaluate the Safety and Efficacy of CT1812 in Subjects with Mild to Moderate Alzheimer's Disease

Dr. Susan Catalano
Cognition Therapeutics, Inc.
2403 Sidney Street
Suite 261
Pittsburgh, PA 15302

Award e-mailed to: scatalano@cogrx.com

Period Of Performance:

Budget Period: 09/01/2020 - 05/31/2021

Project Period: 09/15/2018 - 05/31/2021

Dear Business Official:

The National Institutes of Health hereby awards a grant in the amount of \$278,623 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to COGNITION THERAPEUTICS, INC. in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award including the "Terms and Conditions" is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute On Aging of the National Institutes of Health under Award Number R01AG058660. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website <http://grants.nih.gov/grants/policy/coi/> for a link to the regulation and additional important information.

If you have any questions about this award, please contact the individual(s) referenced in Section IV.

Sincerely yours,

Jessica Perez
Grants Management Officer
NATIONAL INSTITUTE ON AGING

Additional information follows

SECTION I - AWARD DATA - 3R01AG058660-03S2

Award Calculation (U.S. Dollars)

Federal Direct Costs	\$	214,325
Federal F&A Costs	\$	64,298
Approved Budget	\$	278,623
Total Amount of Federal Funds Obligated (Federal Share)	\$	278,623
TOTAL FEDERAL AWARD AMOUNT	\$	278,623
AMOUNT OF THIS ACTION (FEDERAL SHARE)	\$	278,623

SUMMARY TOTAL FEDERAL AWARD AMOUNT YEAR (3)

GRANT NUMBER	TOTAL FEDERAL AWARD AMOUNT	
3R01AG058660-03S2	\$	278,623
5R01AG058660-03	\$	5,774,586
TOTAL	\$	6,053,209

SUMMARY TOTALS FOR ALL YEARS

YR	THIS AWARD		CUMULATIVE TOTALS	
3	\$	278,623	\$	6,053,209

Fiscal Information:

CFDA Name:	Aging Research
CFDA Number:	93.866
EIN:	1134365359A1
Document Number:	RAG058660A
PMS Account Type:	P (Subaccount)
Fiscal Year:	2020

IC	CAN	2020
AG	8033159	\$ 278,623

NIH Administrative Data:

PCC: 3CCCTLR / OC: 41023 / Released: PEREZJ 08/25/2020
Award Processed: 08/28/2020 12:18:20 AM

SECTION II - PAYMENT/HOTLINE INFORMATION - 3R01AG058660-03S2

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at <http://grants.nih.gov/grants/policy/awardconditions.htm>

SECTION III - TERMS AND CONDITIONS - 3R01AG058660-03S2

- This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:
- a. The grant program legislation and program regulation cited in this Notice of Award.
 - b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
 - c. 45 CFR Part 75.
 - d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
 - e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
 - f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at <http://grants.nih.gov/grants/policy/awardconditions.htm> for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of “Research and Development” at 45 CFR Part § 75.2. As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This award is subject to the requirements of 2 CFR Part 25 for institutions to receive a Dun & Bradstreet Universal Numbering System (DUNS) number and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a DUNS requirement must be included. See <http://grants.nih.gov/grants/policy/awardconditions.htm> for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01AG058660. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see <http://grants.nih.gov/grants/policy/awardconditions.htm> for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: <http://publicaccess.nih.gov/>.

This award represents the final year of the competitive segment for this grant. See the NIH Grants Policy Statement Section 8.6 Closeout for complete closeout requirements at: <http://grants.nih.gov/grants/policy/policy.htm#gps>.

A final expenditure Federal Financial Report (FFR) (SF 425) must be submitted through the eRA Commons (Commons) within 120 days of the period of performance end date; see the NIH Grants Policy Statement Section 8.6.1 Financial Reports, <http://grants.nih.gov/grants/policy/policy.htm#gps>, for additional information on this submission requirement. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the Payment Management System's (PMS) quarterly cash transaction data. A final quarterly federal cash transaction report is not required for awards in PMS B subaccounts (i.e., awards to foreign entities and to Federal agencies). NIH will close the awards using the last recorded cash drawdown level in PMS for awards that do not require a final FFR on expenditures or quarterly federal cash transaction reporting. It is important to note that for financial closeout, if a grantee fails to submit a required final expenditure FFR, NIH will close the grant using the last recorded cash drawdown level. If the grantee submits a final expenditure FFR but does not reconcile any discrepancies between expenditures reported on the final expenditure FFR and the last cash report to PMS, NIH will close the award at the lower amount. This could be considered a debt or result in disallowed costs.

A Final Invention Statement and Certification form (HHS 568), (not applicable to training, construction, conference or cancer education grants) must be submitted within 120 days of the expiration date. The HHS 568 form may be downloaded at: <http://grants.nih.gov/grants/forms.htm>. This paragraph does not apply to Training grants, Fellowships, and certain other programs—i.e., activity codes C06, D42, D43, D71, DP7, G07, G08, G11, K12, K16, K30, P09, P40, P41, P51, R13, R25, R28, R30, R90, RL5, RL9, S10, S14, S15, U13, U14, U41, U42, U45, UC6, UC7, UR2, X01, X02.

Unless an application for competitive renewal is submitted, a Final Research Performance Progress Report (Final RPPR) must also be submitted within 120 days of the period of performance end date. If a competitive renewal application is submitted prior to that date, then an Interim RPPR must be submitted by that date as well. Instructions for preparing an Interim or Final RPPR are at: https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf. Any other specific requirements set forth in the terms and conditions of the award must also be addressed in the Interim or Final RPPR. *Note that data reported within Section I of the Interim and Final RPPR forms will be made public and should be written for a lay person audience.*

NIH strongly encourages electronic submission of the final invention statement through the Closeout feature in the Commons, but will accept an email or hard copy submission as indicated below.

Email: The final invention statement may be e-mailed as PDF attachments to: NIHCloseoutCenter@mail.nih.gov.

Hard copy: Paper submissions of the final invention statement may be faxed to the NIH Division of Central Grants Processing, Grants Closeout Center, at 301-480-2304, or mailed to:

National Institutes of Health
Office of Extramural Research Division of Central Grants Processing
Grants Closeout Center 6705 Rockledge Drive Suite 5016, MSC 7986
Bethesda, MD 20892-7986 (for regular or U.S. Postal Service Express mail)
Bethesda, MD 20817 (for other courier/express deliveries only)

NOTE: If this is the final year of a competitive segment due to the transfer of the grant to another institution, then a Final RPPR is not required. However, a final expenditure FFR is required and should be submitted electronically as noted above. If not already submitted, the Final Invention Statement is required and should be sent directly to the assigned Grants Management Specialist.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than \$10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:
Additional Costs

SECTION IV - AG Special Terms and Conditions - 3R01AG058660-03S2

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

Funding for this award has been provided by Alzheimer's Disease Initiative funds.

Includes an administrative increase of \$278,623 in accordance with the e-Application submitted on 05/22/2020.

STAFF CONTACTS

The Grants Management Specialist is responsible for the negotiation, award and administration of this project and for interpretation of Grants Administration policies and provisions. The Program Official is responsible for the scientific, programmatic and technical aspects of this project. These individuals work together in overall project administration. Prior approval requests (signed by an Authorized Organizational Representative) should be submitted in writing to the Grants Management Specialist. Requests may be made via e-mail.

Grants Management Specialist: Jennifer Edwards
Email: edwardsj@mail.nih.gov **Phone:** 301-827-6689

Program Official: Laurie M. Ryan
Email: ryanl@nia.nih.gov **Phone:** 301.496.9350 **Fax:** 301-496-1494

SPREADSHEET SUMMARY
GRANT NUMBER: 3R01AG058660-03S2

INSTITUTION: COGNITION THERAPEUTICS, INC.

Facilities and Administrative Costs	Year 3	
F&A Cost Rate 1		30%
F&A Cost Base 1	\$	214,325
F&A Costs 1	\$	64,298

Notice of Award



Multi-Year Funded Research Project Grant
Department of Health and Human Services
National Institutes of Health

Federal Award Date: 09/05/2020



NATIONAL INSTITUTE ON AGING

Grant Number: 1RF1AG051593-01
FAIN: RF1AG051593

Principal Investigator(s):
SUSAN M CATALANO, PHD

Project Title: Phase 1 safety trial for CT1812, a novel small molecule therapeutic targeting a synaptic receptor for Abeta oligomers

Dr. Catalano, Susan
2403 Sidney Street
Suite 261
Pittsburgh, PA 152035118

Award e-mailed to: scatalano@cogrx.com

Period Of Performance:

Budget Period: 09/15/2016 - 06/30/2018

Project Period: 09/15/2016 - 06/30/2018

Dear Business Official:

The National Institutes of Health hereby awards a grant in the amount of \$2,410,669 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to COGNITION THERAPEUTICS, INC. in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award including the "Terms and Conditions" is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute On Aging of the National Institutes of Health under Award Number RF1AG051593. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website <http://grants.nih.gov/grants/policy/coi/> for a link to the regulation and additional important information.

If you have any questions about this award, please contact the individual(s) referenced in Section IV.

Sincerely yours,

TRACI LAFFERTY
Grants Management Officer
NATIONAL INSTITUTE ON AGING

Additional information follows

SECTION I - AWARD DATA - 1RF1AG051593-01		
Award Calculation (U.S. Dollars)		
Salaries and Wages	\$	200,532
Personnel Costs (Subtotal)	\$	200,532
Other	\$	1,728,003
Federal Direct Costs	\$	1,928,535
Federal F&A Costs	\$	482,134
Approved Budget	\$	2,410,669
Total Amount of Federal Funds Obligated (Federal Share)	\$	2,410,669
TOTAL FEDERAL AWARD AMOUNT	\$	2,410,669
AMOUNT OF THIS ACTION (FEDERAL SHARE)	\$	2,410,669

SUMMARY TOTALS FOR ALL YEARS				
YR	THIS AWARD		CUMULATIVE TOTALS	
1	\$	2,410,669	\$	2,410,669

Fiscal Information:
CFDA Name: Aging Research
CFDA Number: 93.866
EIN: 1134365359A1
Document Number: RAG051593A
PMS Account Type: P (Subaccount)
Fiscal Year: 2016

IC	CAN	2016		
AG	8013663	\$		2,410,669

NIH Administrative Data:
PCC: 3CCCTLR / OC: 414A / **Released:** LAFFERTYT 09/02/2016
Award Processed: 09/05/2016 12:01:24 AM

SECTION II - PAYMENT/HOTLINE INFORMATION - 1RF1AG051593-01

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at <http://grants.nih.gov/grants/policy/awardconditions.htm>

SECTION III - TERMS AND CONDITIONS - 1RF1AG051593-01

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

- a. The grant program legislation and program regulation cited in this Notice of Award.
- b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.

- c. 45 CFR Part 75.
- d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
- e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
- f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at <http://grants.nih.gov/grants/policy/awardconditions.htm> for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of “Research and Development” at 45 CFR Part § 75.2. As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

MULTI-YEAR FUNDED AWARD: This is a multi-year funded award. A progress report is due annually on or before the anniversary of the budget/project period start date of the award, in accord with the instructions posted at: <http://grants.nih.gov/grants/policy/myf.htm>.

This award is subject to the requirements of 2 CFR Part 25 for institutions to receive a Dun & Bradstreet Universal Numbering System (DUNS) number and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a DUNS requirement must be included. See <http://grants.nih.gov/grants/policy/awardconditions.htm> for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) RF1AG051593. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see <http://grants.nih.gov/grants/policy/awardconditions.htm> for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: <http://publicaccess.nih.gov/>.

This award provides support for one or more clinical trials. By law (Title VIII, Section 801 of [Public Law 110-85](#)), the “responsible party” must register “applicable clinical trials” on the [ClinicalTrials.gov Protocol Registration System Information Website](#). NIH encourages registration of all trials whether required under the law or not. For more information, see <http://grants.nih.gov/ClinicalTrials fdaaa/>.

This award represents the final year of the competitive segment for this grant. See the NIH Grants Policy Statement Section 8.6 Closeout for complete closeout requirements at: <http://grants.nih.gov/grants/policy/policy.htm#gps>.

A final expenditure Federal Financial Report (FFR) (SF 425) must be submitted through the eRA Commons (Commons) within 120 days of the expiration date; see the NIH Grants Policy Statement Section 8.6.1 Financial Reports, <http://grants.nih.gov/grants/policy/policy.htm#gps>, for additional information on this submission requirement. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the Payment Management System's (PMS) quarterly cash transaction data. A final quarterly federal cash transaction report is not required for awards in PMS B subaccounts (i.e., awards to foreign entities and to Federal agencies). NIH will close the awards using the last recorded cash drawdown level in PMS for awards that do not require a final FFR on expenditures or quarterly federal cash transaction reporting. It is important to note that for financial closeout, if a grantee fails to submit a required final expenditure FFR, NIH will close the grant using the last recorded cash drawdown level. If the grantee submits a final expenditure FFR but does not reconcile any discrepancies between expenditures reported on the final expenditure FFR and the last cash report to PMS, NIH will close the award at the lower amount. This could be considered a debt or result in disallowed costs.

A Final Invention Statement and Certification form (HHS 568), (not applicable to training, construction, conference or cancer education grants) must be submitted within 120 days of the expiration date. The HHS 568 form may be downloaded at: <http://grants.nih.gov/grants/forms.htm>. This paragraph does not apply to Training grants, Fellowships, and certain other programs—i.e., activity codes C06, R13, R25, S10.

Unless an application for competitive renewal is submitted, a final progress report must also be submitted within 120 days of the expiration date. Instructions for preparing a Final Progress Report are at: <http://grants.nih.gov/grants/funding/finalprogressreport.pdf>. Any other specific requirements set forth in the terms and conditions of the award must also be addressed in the final progress report. Institute/Centers may accept the progress report contained in competitive renewal (type 2) in lieu of a separate final progress report. Contact the awarding IC for IC- specific policy regarding acceptance of a progress report contained in a competitive renewal application in lieu of a separate final progress report.

NIH strongly encourages electronic submission of the final progress report and the final invention statement through the Closeout feature in the Commons, but will accept an email or hard copy submission as indicated below.

Email: The final progress report and final invention statement may be e-mailed as PDF attachments to: NIHCloseoutCenter@mail.nih.gov.

Hard copy: Paper submissions of the final progress report and the final invention statement may be faxed to the NIH Division of Central Grants Processing, Grants Closeout Center, at 301-4802304, or mailed to:

National Institutes of Health
Office of Extramural Research
Division of Central Grants Processing
Grants Closeout Center
6705 Rockledge Drive
Suite 5016, MSC 7986
Bethesda, MD 20892-7986 (for regular or U.S. Postal Service Express mail)
Bethesda, MD 20817 (for other courier/express deliveries only)

NOTE: If this is the final year of a competitive segment due to the transfer of the grant to another institution, then a Final Progress Report is not required. However, a final expenditure FFR is required and should be submitted electronically as noted above. If not already submitted, the Final Invention Statement is required and should be sent directly to the assigned Grants Management Specialist.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than \$10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:
Additional Costs

SECTION IV - AG Special Terms and Conditions - 1RF1AG051593-01 Funding for this award has been provided by Alzheimer’s Disease Initiative funds.

RESTRICTION: This award includes \$482,134 for Facilities and Administration (F&A) costs. Of this amount, \$482,134 is restricted pending the negotiation of an F&A rate(s). These restricted funds may not be used for any purpose without the prior approval of the grants management official. If the rate(s) negotiated is(are) lower than originally estimated/funded, this award amount may be revised downward.

The progress report for this multi-year funded (MYF) award is due annually on or before the anniversary of the budget/project period start date of the award and must be submitted via the eRA Commons. Additional information on submission requirements and directions can be found at <http://grants.nih.gov/grants/policy/myf.htm>.

None of the funds in this award shall be used to pay the salary of an individual at a rate in excess of the current salary cap. Therefore, this award and/or future years are adjusted accordingly, if applicable. Current salary cap levels can be found at the following URL: http://grants.nih.gov/grants/policy/salcap_summary.htm.

STAFF CONTACTS

The Grants Management Specialist is responsible for the negotiation, award and administration of this project and for interpretation of Grants Administration policies and provisions. The Program Official is responsible for the scientific, programmatic and technical aspects of this project. These individuals work together in overall project administration. Prior approval requests (signed by an Authorized Organizational Representative) should be submitted in writing to the Grants Management Specialist. Requests may be made via e-mail.

Grants Management Specialist: Robin Laney
Email: laneyr@nia.nih.gov **Phone:** 301-496-1472 **Fax:** 301-402-3672

Program Official: Laurie M. Ryan
Email: ryanl@nia.nih.gov **Phone:** 301.496.9350 **Fax:** 301-496-1494

SPREADSHEET SUMMARY
GRANT NUMBER: 1RF1AG051593-01

INSTITUTION: COGNITION THERAPEUTICS, INC.

Budget	Year 1	
Salaries and Wages	\$	200,532
Personnel Costs (Subtotal)	\$	200,532
Other	\$	1,728,003
TOTAL FEDERAL DC	\$	1,928,535
TOTAL FEDERAL F&A	\$	482,134
TOTAL COST	\$	2,410,669
Facilities and Administrative Costs	Year 1	
F&A Cost Rate 1		25%
F&A Cost Base 1	\$	1,928,535
F&A Costs 1	\$	482,134

Notice of Award



Multi-Year Funded Research Project Grant
Department of Health and Human Services
National Institutes of Health

Federal Award Date: 09/18/2020



NATIONAL INSTITUTE ON AGING

Grant Number: 3RF1AG057553-01S2 REVISED
FAIN: RF1AG057553

Principal Investigator(s):
SUSAN M CATALANO, PHD

Project Title: A Pilot Synaptic Vesicle Glycoprotein 2A (SV2A) PET Study to Evaluate the Effect of CT1812 Treatment on Synaptic Density in Subjects with Mild to Moderate Alzheimer's Disease

Dr. Catalano, Susan, Ph.D
Chief Science Officer
2403 Sidney Street Suite 261
Pittsburgh, PA 152035118

Award e-mailed to: scatalano@cogrx.com

Period Of Performance:

Budget Period: 09/11/2020 - 06/30/2021

Project Period: 09/01/2020 - 06/30/2021

Dear Business Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to COGNITION THERAPEUTICS, INC. in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award including the "Terms and Conditions" is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute On Aging of the National Institutes of Health under Award Number RF1AG057553. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website <http://grants.nih.gov/grants/policy/coi/> for a link to the regulation and additional important information.

If you have any questions about this award, please contact the individual(s) referenced in Section IV.

Sincerely yours,

Robin Laney
Grants Management Officer
NATIONAL INSTITUTE ON AGING

Additional information follows

SECTION I - AWARD DATA - 3RF1AG057553-01S2 REVISED

Award Calculation (U.S. Dollars)

Salaries and Wages	\$	130,601
Personnel Costs (Subtotal)	\$	130,601
Consultant Services	\$	119,000
Federal Direct Costs	\$	249,601
Federal F&A Costs	\$	74,880
Approved Budget	\$	324,481
Total Amount of Federal Funds Obligated (Federal Share) TOTAL	\$	324,481
FEDERAL AWARD AMOUNT	\$	324,481
AMOUNT OF THIS ACTION (FEDERAL SHARE)	\$	0

SUMMARY TOTAL FEDERAL AWARD AMOUNT YEAR (1)

GRANT NUMBER	TOTAL FEDERAL AWARD AMOUNT	
3RF1AG057553-01S2	\$	324,481
1RF1AG057553-01	\$	4,130,741
3RF1AG057553-01S1	\$	340,552
TOTAL	\$	4,795,774

SUMMARY TOTALS FOR ALL YEARS

YR	THIS AWARD		CUMULATIVE TOTALS	
1	\$	324,481	\$	4,795,774

Fiscal Information:

CFDA Name:	Aging Research
CFDA Number:	93.866
EIN:	1134365359A1
Document Number:	RAG057553A
PMS Account Type:	P (Subaccount)
Fiscal Year:	2020

IC	CAN	2020
AG	8034655	\$ 324,481

NIH Administrative Data:

PCC: 3CCCTLR / OC: 41023 / Released: LANEYR 09/17/2020
Award Processed: 09/18/2020 12:02:17 AM

SECTION II - PAYMENT/HOTLINE INFORMATION - 3RF1AG057553-01S2 REVISED

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at <http://grants.nih.gov/grants/policy/awardconditions.htm>

SECTION III - TERMS AND CONDITIONS - 3RF1AG057553-01S2 REVISED

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

- a. The grant program legislation and program regulation cited in this Notice of Award.

- b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
- c. 45 CFR Part 75.
- d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
- e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
- f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at <http://grants.nih.gov/grants/policy/awardconditions.htm> for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of “Research and Development” at 45 CFR Part § 75.2. As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is excluded from Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to receive a Dun & Bradstreet Universal Numbering System (DUNS) number and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a DUNS requirement must be included. See <http://grants.nih.gov/grants/policy/awardconditions.htm> for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) RF1AG057553. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see <http://grants.nih.gov/grants/policy/awardconditions.htm> for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: <http://publicaccess.nih.gov/>.

This award provides support for one or more clinical trials. By law (Title VIII, Section 801 of [Public Law 110-85](#)), the “responsible party” must register “applicable clinical trials” on the [ClinicalTrials.gov Protocol Registration System Information Website](#). NIH encourages registration of all trials whether required under the law or not. For more information, see <http://grants.nih.gov/ClinicalTrials fdaaa/>.

This award represents the final year of the competitive segment for this grant. See the NIH Grants Policy Statement Section 8.6 Closeout for complete closeout requirements at: <http://grants.nih.gov/grants/policy/policy.htm#gps>.

A final expenditure Federal Financial Report (FFR) (SF 425) must be submitted through the eRA Commons (Commons) within 120 days of the period of performance end date; see the NIH Grants Policy Statement Section 8.6.1 Financial Reports, <http://grants.nih.gov/grants/policy/policy.htm#gps>, for additional information on this submission requirement. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the Payment Management System’s (PMS) quarterly cash transaction data. A final quarterly federal cash transaction report is not required for awards in PMS B subaccounts (i.e., awards to foreign entities and to Federal agencies). NIH will close the awards using the last recorded cash drawdown level in PMS for awards that do not require a final FFR on expenditures or quarterly federal cash transaction reporting. It is important to note that for financial closeout, if a grantee fails to submit a required final expenditure FFR, NIH will close the grant using the last recorded cash drawdown level. If the grantee submits a final expenditure FFR but does not reconcile any discrepancies between expenditures reported on the final expenditure FFR and the last cash report to PMS, NIH will close the award at the lower amount. This could be considered a debt or result in disallowed costs.

A Final Invention Statement and Certification form (HHS 568), (not applicable to training, construction, conference or cancer education grants) must be submitted within 120 days of the expiration date. The HHS 568 form may be downloaded at: <http://grants.nih.gov/grants/forms.htm>.

This paragraph does not apply to Training grants, Fellowships, and certain other programs—i.e., activity codes C06, D42, D43, D71, DP7, G07, G08, G11, K12, K16, K30, P09, P40, P41, P51, R13, R25, R28, R30, R90, RL5, RL9, S10, S14, S15, U13, U14, U41, U42, U45, UC6, UC7, UR2, X01, X02.

Unless an application for competitive renewal is submitted, a Final Research Performance Progress Report (Final RPPR) must also be submitted within 120 days of the period of performance end date. If a competitive renewal application is submitted prior to that date, then an Interim RPPR must be submitted by that date as well. Instructions for preparing an Interim or Final RPPR are at: https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf. Any other specific requirements set forth in the terms and conditions of the award must also be addressed in the Interim or Final RPPR. *Note that data reported within Section I of the Interim and Final RPPR forms will be made public and should be written for a lay person audience.*

NIH strongly encourages electronic submission of the final invention statement through the Closeout feature in the Commons, but will accept an email or hard copy submission as indicated below.

Email: The final invention statement may be e-mailed as PDF attachments to: NIHCloseoutCenter@mail.nih.gov.

Hard copy: Paper submissions of the final invention statement may be faxed to the NIH Division of Central Grants Processing, Grants Closeout Center, at 301-480-2304, or mailed to:

National Institutes of Health
Office of Extramural Research
Division of Central Grants Processing
Grants Closeout Center
6705 Rockledge Drive
Suite 5016, MSC 7986
Bethesda, MD 20892-7986 (for regular or U.S. Postal Service Express mail)
Bethesda, MD 20817 (for other courier/express deliveries only)

NOTE: If this is the final year of a competitive segment due to the transfer of the grant to another institution, then a Final RPPR is not required. However, a final expenditure FFR is required and should be submitted electronically as noted above. If not already submitted, the Final Invention Statement is required and should be sent directly to the assigned Grants Management Specialist.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than \$10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:
Additional Costs

SECTION IV - AG Special Terms and Conditions - 3RF1AG057553-01S2 REVISED

Clinical Trial Indicator: Yes
This award supports one or more NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

REVISION: The sole purpose of this revision is to remove the Yale consortia term from the NGA dated 9/8/2020.

Supersedes Notice of Award issued 9/8/2020. Previous terms and conditions apply:

Funding for this award has been provided by Alzheimer’s Disease Initiative funds.

Includes an administrative increase of \$324,481 for AD funds ‘to address increased trial costs related to treatment phase extension and delay in enrollment as a result of contract issues’ in accordance with the letter of 1/7/2020 from Dr. Laurie Ryan.

STAFF CONTACTS

The Grants Management Specialist is responsible for the negotiation, award and administration of this project and for interpretation of Grants Administration policies and provisions. The Program Official is responsible for the scientific, programmatic and technical aspects of this project. These individuals work together in overall project administration. Prior approval requests (signed by an Authorized Organizational Representative) should be submitted in writing to the Grants Management Specialist. Requests may be made via e-mail.

Grants Management Specialist: Jennifer Edwards
Email: edwardsj@mail.nih.gov Phone: 301-827-6689

Program Official: Laurie M. Ryan
Email: ryanl@nia.nih.gov Phone: 301.496.9350 Fax: 301-496-1494

SPREADSHEET SUMMARY
GRANT NUMBER: 3RF1AG057553-01S2 REVISED

INSTITUTION: COGNITION THERAPEUTICS, INC.

Budget	Year 1	
Salaries and Wages	\$	130,601
Personnel Costs (Subtotal)	\$	130,601
Consultant Services	\$	119,000
TOTAL FEDERAL DC	\$	249,601
TOTAL FEDERAL F&A	\$	74,880
TOTAL COST	\$	324,481
Facilities and Administrative Costs	Year 1	
F&A Cost Rate 1		30%
F&A Cost Base 1	\$	249,601
F&A Costs 1	\$	74,880



Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE ON AGING

Notice of Award
FAIN# R01AG065248
Federal Award Date
02/03/2021

Recipient Information**1. Recipient Name**

COGNITION THERAPEUTICS, INC.
2403 SIDNEY ST STE 261

PITTSBURGH, PA 15203

2. Congressional District of Recipient

14

3. Payment System Identifier (ID)

1134365359A1

4. Employer Identification Number (EIN)

134365359

5. Data Universal Numbering System (DUNS)

808434612

6. Recipient's Unique Entity Identifier**7. Project Director or Principal Investigator**

SUSAN M CATALANO, PHD (Contact)
President/founder
scatalano@cogrx.com
(412) 481-2210

8. Authorized Official

Dr. Susan Catalano Ph.D

Federal Agency Information**9. Awarding Agency Contact Information**

Jennifer Edwards

NATIONAL INSTITUTE ON AGING
edwardsj@mail.nih.gov
301-827-6689

10. Program Official Contact Information

Laurie M. Ryan
Health Scientist Administrator
NATIONAL INSTITUTE ON AGING
ryanl@nia.nih.gov
301.496.9350

Federal Award Information**11. Award Number**

1R01AG065248-01

12. Unique Federal Award Identification Number (FAIN)

R01AG065248

13. Statutory Authority

42 USC 241 42 CFR 52

14. Federal Award Project Title

Randomized Double Blind, Placebo Controlled, Parallel Group Trial to Evaluate the
Safety and Efficacy of CT1812 in Early Alzheimer's Disease over 18 Months

15. Assistance Listing Number

93.866

16. Assistance Listing Program Title

Aging Research

17. Award Action Type

New Competing (REVISED)

18. Is the Award R&D?

Yes

Summary Federal Award Financial Information**19. Budget Period Start Date 06/01/2020 - End Date 05/31/2021**

20. Total Amount of Federal Funds Obligated by this Action	\$ 147,190
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20 a. Direct Cost Amount	\$ 0
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20 b. Indirect Cost Amount	\$ 147,190
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21. Authorized Carryover	\$ 0
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22. Offset	\$ 0
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23. Total Amount of Federal Funds Obligated this budget period	\$24,533,829
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24. Total Approved Cost Sharing or Matching, where applicable	\$ 0
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25. Total Federal and Non-Federal Approved this Budget Period	\$24,533,829
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26. Project Period Start Date 06/01/2020 - End Date 05/31/2025

27. Total Amount of the Federal Award including Approved Cost	\$24,533,829
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Sharing or Matching this Project Period

28. Authorized Treatment of Program Income

Additional Costs

29. Grants Management Officer - Signature

Robin Laney

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.



RESEARCH
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE ON AGING



SECTION I - AWARD DATA - 1R01AG065248-01 REVISED

Principal Investigator(s):

Paul S. Aisen, MD
SUSAN M CATALANO (contact),
PHD CHRISTOPHER H VAN DYCK, MD

Award e-mailed to: scatalano@cogrx.com

Dear Authorized Official:

The National Institutes of Health hereby revises this award to reflect an increase in the amount of \$147,190 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to COGNITION THERAPEUTICS, INC. in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute On Aging of the National Institutes of Health under Award Number R01AG065248. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website <http://grants.nih.gov/grants/policy/coi/> for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Robin Laney
Grants Management Officer
NATIONAL INSTITUTE ON AGING

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)		
Salaries and Wages	\$	236,680
Personnel Costs (Subtotal)	\$	236,680
Consultant Services	\$	87,500
Travel	\$	20,000
Other	\$	9,898,865
Subawards/Consortium/Contractual Costs	\$	11,055,680
Federal Direct Costs	\$	21,298,725
Federal F&A Costs	\$	3,235,104
Approved Budget	\$	24,533,829
Total Amount of Federal Funds Authorized (Federal Share)	\$	24,533,829
TOTAL FEDERAL AWARD AMOUNT	\$	24,533,829
AMOUNT OF THIS ACTION (FEDERAL SHARE)	\$	147,190

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)				
YR	THIS AWARD		CUMULATIVE TOTALS	
1	\$	24,533,829	\$	24,533,829
2	\$	14,619,478	\$	14,619,478
3	\$	13,127,747	\$	13,127,747
4	\$	12,199,042	\$	12,199,042
5	\$	16,494,670	\$	16,494,670

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:
Payment System Identifier: 1134365359A1
Document Number: RAG65248A
PMS Account Type: P (Subaccount)
Fiscal Year: 2020

IC	CAN	2020	2021	2022	2023	2024
AG	8033159	\$ 24,533,829	\$ 14,619,478	\$ 13,127,747	\$ 12,199,042	\$ 16,494,670

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:
PCC: 3CCCTLR / **OC:** 41021 / **Released:** Laney, Robin 02/01/2021
Award Processed: 02/03/2021 12:01:18 AM

SECTION II - PAYMENT/HOTLINE INFORMATION - 1R01AG065248-01 REVISED

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at <http://grants.nih.gov/grants/policy/awardconditions.htm>

SECTION III - STANDARD TERMS AND CONDITIONS - 1R01AG065248-01 REVISED

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

- a. The grant program legislation and program regulation cited in this Notice of Award.

- b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
- c. 45 CFR Part 75.
- d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
- e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
- f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at <http://grants.nih.gov/grants/policy/awardconditions.htm> for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of “Research and Development” at 45 CFR Part § 75.2. As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

Carry over of an unobligated balance into the next budget period requires Grants Management Officer prior approval.

This grant is excluded from Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to receive a Dun & Bradstreet Universal Numbering System (DUNS) number and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a DUNS requirement must be included. See <http://grants.nih.gov/grants/policy/awardconditions.htm> for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01AG065248. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see <http://grants.nih.gov/grants/policy/awardconditions.htm> for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: <http://publicaccess.nih.gov/>.

This award provides support for one or more clinical trials. By law (Title VIII, Section 801 of [Public Law 110-85](#)), the “responsible party” must register “applicable clinical trials” on the [ClinicalTrials.gov Protocol Registration System Information Website](#). NIH encourages registration of all trials whether required under the law or not. For more information, see <http://grants.nih.gov/ClinicalTrials fdaaa/>.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than \$10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:

Additional Costs

SECTION IV - AG SPECIFIC AWARD CONDITIONS - 1R01AG065248-01 REVISED

Clinical Trial Indicator: Yes

This award supports one or more NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

This revised award includes an increase of \$147,190 in facilities and administrative costs due to Cognition Therapeutics, Inc's negotiated rate agreement dated 11/06/2020.

This revised award removes the restriction regarding facilities and administrative costs (\$2,058,609).

Supersedes Notice of Award issued 01/12/2021. Previous terms and conditions apply:

This award is revised to change the title in accordance with the grantee's request dated 12/03/2020.

Supersedes Notice of Award issued 08/14/2020. Previous terms and conditions apply:

This revised award corrects the carryover designation: Carryover of an unobligated balance into the next budget period requires Grants Management Officer prior approval.

Supersedes Notice of Award issued 05/29/2020. Previous terms and conditions apply:

RESTRICTION: The present award is being made without a currently valid certification of Institutional Review Board (IRB) approval for this project with the following restriction: Only activities that are clearly severable and independent from activities that involve human subjects may be conducted under this award until the project has received IRB approval consistent with 45 CFR Part 46 and certification of IRB approval has been submitted to and accepted by the NIH awarding component.

No funds may be drawn down from the payment system and no obligations may be made against Federal funds for research involving human subjects by the grantee or any other site engaged in such research for any period not covered by an OHRP-approved Assurance and IRB approval consistent with 45 CFR Part 46.

Failure to comply with the above requirements may result in suspension and/or termination of this award, withholding of support, audit disallowances, and/or other appropriate action.

See the NIH Grants Policy Statement, Chapter 4.1.15 Human Subjects Protections ([http://grants.nih.gov/grants/policy/nihgps/HTML5/section 4/4 public policy requirements objectives and other appropriation mandates.htm](http://grants.nih.gov/grants/policy/nihgps/HTML5/section%204/4%20public%20policy%20requirements%20objectives%20and%20other%20appropriation%20mandates.htm)), for specific requirements related to the protection of human subjects, which are applicable to and a term and condition of this award.

Funding for this award has been provided by Alzheimer's Disease Initiative funds. Funding for this award has been provided by Alzheimer's Disease Initiative funds.

In keeping with NOT-OD-06-054 (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-06-054.html>), as this grant has multiple Principal Investigators (PIs), although the signatures of the PIs are not required on prior approval requests submitted to the agency, the grantee institution must secure and retain the signatures of all of the PIs within their own internal processes.

None of the funds in this award shall be used to pay the salary of an individual at a rate in excess of the current salary cap. Therefore, this award and/or future years are adjusted accordingly, if applicable. Current salary cap levels can be found at the following URL: http://grants.nih.gov/grants/policy/salcap_summary.htm

This award includes funds awarded for consortium activity with the **University of Southern California** in the amount of \$10,993,514 (\$9,379,176 direct costs + \$1,614,338 facilities and administrative costs) and **Yale University** in the amount of \$62,166 (\$37,114 direct costs + \$25,052 facilities and administrative costs). Consortiums are to be established and administered as described in the NIH Grants Policy Statement (NIH GPS). The referenced section of the NIH Grants Policy Statement, 2017 is available at: http://grants.nih.gov/grants/policy/nihgps/HTML5/section_15/15_consortium_agreements.htm.

Recruitment of participants cannot be initiated until the NIA program staff, IRB, and the DSMB have approved the protocol and data and safety monitoring plan.

Per the FOA, sharing of clinical trial data and biosamples will be done through the Alzheimer’s Clinical Trials Consortium (ACTC) and is expected to adhere to the following timelines: a) pivotal trials: follow Collaboration for Alzheimer’s Prevention (CAP) data and biosamples sharing principles to make screening/pre-randomization baseline data available within 12 months of enrollment completion; post-randomization data and biosamples should be made available as soon as possible without compromising trial integrity, i.e., after regulatory approval or trial completion/termination or 18 months whichever comes first; b) other trials and studies: sharing of data and biosamples is expected to at the time of publication of the primary results or within 9 months of database lock, whichever comes first.

ClinicalTrials.gov is a federal registry and results database of publicly and privately supported clinical studies of human participants conducted around the world. In September 2016, NIH issued a final policy to promote broad and responsible dissemination of information from NIH-funded clinical trials through ClinicalTrials.gov. Under this policy, every clinical trial funded in whole or in part by NIH is expected to be registered on ClinicalTrials.gov and have summary results information submitted and posted in a timely manner, whether subject to FDAAA 801 or not.

Public Policy Requirements and Objectives:
https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4.1_public_policy_requirements_and_objectives.htm?Highlight=clinical

SPREADSHEET SUMMARY
AWARD NUMBER: 1R01AG065248-01 REVISED

INSTITUTION: COGNITION THERAPEUTICS, INC.

Budget	Year 1	Year 2	Year 3	Year 4	Year 5
Salaries and Wages	\$ 236,680	\$ 286,680	\$ 306,680	\$ 306,680	\$ 306,680
Personnel Costs (Subtotal)	\$ 236,680	\$ 286,680	\$ 306,680	\$ 306,680	\$ 306,680
Consultant Services	\$ 87,500	\$ 67,500	\$ 67,500	\$ 67,500	\$ 87,500
Travel	\$ 20,000	\$ 25,000	\$ 25,000	\$ 25,000	\$ 25,000
Other	\$ 9,898,865	\$ 3,413,603	\$ 2,258,603	\$ 1,498,603	\$ 4,801,353
Subawards/Consortium/Contractual Costs	\$ 11,055,680	\$ 9,618,908	\$ 9,618,908	\$ 9,689,071	\$ 9,617,608
TOTAL FEDERAL DC	\$ 21,298,725	\$ 13,411,691	\$ 12,276,691	\$ 11,586,854	\$ 14,838,141
TOTAL FEDERAL F&A	\$ 3,235,104	\$ 1,207,787	\$ 851,056	\$ 612,188	\$ 1,656,529
TOTAL COST	\$ 24,533,829	\$ 14,619,478	\$ 13,127,747	\$ 12,199,042	\$ 16,494,670

Facilities and						
Administrative Costs		Year 1	Year 2	Year 3	Year 4	Year 5
F&A Cost Rate 1		31.43%	31.43%	31.43%	31.43%	31.43%
F&A Cost Base 1	\$	10,293,045	\$ 3,842,783	\$ 2,707,783	\$ 1,947,783	\$ 5,270,533
F&A Costs 1	\$	3,235,104	\$ 1,207,787	\$ 851,056	\$ 612,188	\$ 1,656,529



Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE ON AGING

Notice of Award
FAIN# SB1AG073028
Federal Award Date
04/30/2021

Recipient Information 1. Recipient Name COGNITION THERAPEUTICS, INC. 2403 SIDNEY ST STE 261 PITTSBURGH, PA 15203 2. Congressional District of Recipient 14 3. Payment System Identifier (ID) 1134365359A1 4. Employer Identification Number (EIN) 134365359 5. Data Universal Numbering System (DUNS) 808434612 6. Recipient's Unique Entity Identifier 7. Project Director or Principal Investigator ANTHONY O CAGGIANO, MD Senior Vice President Of Research And Development acaggiano@cogrx.com 914 497-6658 8. Authorized Official Dr. Susan Catalano scatalano@cogrx.com 412-481-2210	Federal Award Information 11. Award Number 1SB1AG073028-01A1 12. Unique Federal Award Identification Number (FAIN) SB1AG073028 13. Statutory Authority P.L. 112-81 Section 5123 42 CFR PART 52 14. Federal Award Project Title Human AME study of CT1812, a small molecule in phase 2 clinical trials for the treatment of Alzheimer's disease 15. Assistance Listing Number 93.866 16. Assistance Listing Program Title Aging Research 17. Award Action Type New Competing 18. Is the Award R&D? Yes
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Summary Federal Award Financial Information	
19. Budget Period Start Date 05/01/2021 – End Date 04/30/2022	
20. Total Amount of Federal Funds Obligated by this Action	\$1,642,783
20 a. Direct Cost Amount	\$1,168,159
20 b. Indirect Cost Amount	\$367,152
21. Authorized Carryover	\$0
22. Offset	\$0
23. Total Amount of Federal Funds Obligated this budget period	\$1,642,783
24. Total Approved Cost Sharing or Matching, where applicable	\$0
25. Total Federal and Non-Federal Approved this Budget Period	\$1,642,783
<hr/>	
26. Project Period Start Date 05/01/2021 – End Date 04/30/2022	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	\$2,002,902

Federal Agency Information 9. Awarding Agency Contact Information Jennifer Edwards NATIONAL INSTITUTE ON AGING edwardsj@mail.nih.gov 301-827-6689 10. Program Official Contact Information Laurie M. Ryan Health Scientist Administrator NATIONAL INSTITUTE ON AGING ryanl@nia.nih.gov 301.496.9350	28. Authorized Treatment of Program Income Additional Costs 29. Grants Management Officer - Signature Robin Laney
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30. Remarks
 Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.



Commercialization Readiness Program
Department of Health and Human Services
National Institutes of Health

Notice of Award



NATIONAL INSTITUTE ON AGING

SECTION I – AWARD DATA – 1SB1AG073028-01A1

Principal Investigator(s):
ANTHONY O CAGGIANO, MD

Award e-mailed to: scatalano@cogrx.com

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of \$1,642,783 (see “Award Calculation” in Section I and “Terms and Conditions” in Section III) to COGNITION THERAPEUTICS, INC. in support of the above referenced project. This award is pursuant to the authority of P.L. 112-81 Section 5123 42 CFR PART 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the “Terms and Conditions,” is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as “Research reported in this publication was supported by the National Institute On Aging of the National Institutes of Health under Award Number SB1AG073028. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.” Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator’s Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website <http://grants.nih.gov/grants/policy/coi/> for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Robin Laney
Grants Management Officer
NATIONAL INSTITUTE ON AGING

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Salaries and Wages	\$	78,920
Personnel Costs (Subtotal)	\$	78,920
Consultant Services	\$	28,000
Travel	\$	4,500
Other	\$	1,056,739
Federal Direct Costs	\$	1,168,159
Federal F&A Costs	\$	367,152
Approved Budget	\$	1,535,311
Fee	\$	107,472
Total Amount of Federal Funds Authorized (Federal Share)	\$	1,642,783
TOTAL FEDERAL AWARD AMOUNT	\$	1,642,783
AMOUNT OF THIS ACTION (FEDERAL SHARE)	\$	1,642,783

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)			
YR	THIS AWARD		CUMULATIVE TOTALS
1	\$1,642,783		\$1,642,783

Fiscal Information:
Payment System Identifier: 1134365359 A1
Document Number: SAG073028A
PMS Account Type: P (Subaccount)
Fiscal Year: 2021

IC	CAN	2021
AG	8033287	\$1,642,783

NIH Administrative Data:
PCC: 3CCCTLR / OC: 41030 / Released: Laney, Robin 04/21/2021
Award Processed: 04/30/2021 12:14:14 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1SB1AG073028-01A1

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at <http://grants.nih.gov/grants/policy/awardconditions.htm>

SECTION III – STANDARD TERMS AND CONDITIONS – 1SB1AG073028-01A1

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

- a. The grant program legislation and program regulation cited in this Notice of Award.
- b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
- c. 45 CFR Part 75.
- d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
- e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
- f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at <http://grants.nih.gov/grants/policy/awardconditions.htm> for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of “Research and Development” at 45 CFR Part § 75.2. As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

This award is subject to the life cycle certification requirements set forth in Section 18.5.5.4 of the NIH Grants Policy Statement and NOT-OD-19-025. Effective January 1, 2019, Awardees are required to submit this certification within the I-RPPR and the F-RPPR under Section G.1: Special Notice of Award and Funding Opportunity Announcement Reporting Requirements and maintain it on file in accordance with the records and retention policy in Section 8.4.2 of the NIH Grants Policy Statement.

A certification is required at the following times:

- For SBIR/STTR Phase I Awardees: At the time of receiving final payment or disbursement from the Payment Management System.
- For SBIR/STTR Phase II Awardees: Prior to receiving more than 50% of the total award amount and prior to final payment or disbursement from the Payment Management System.

If the grantee cannot complete this certification or cannot ensure compliance with the certification process, it should notify the GMO immediately. If resolution cannot be reached, the GMO will void or terminate the grant, as appropriate.

The certification form is available in fillable format at: <http://grants.nih.gov/grants/forms.htm#sbir>. Carry over of an unobligated balance into the next budget period requires Grants Management Officer prior approval.

This award is subject to the requirements of 2 CFR Part 25 for institutions to receive a Dun & Bradstreet Universal Numbering System (DUNS) number and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a DUNS requirement must be included. See <http://grants.nih.gov/grants/policy/awardconditions.htm> for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) SB1AG073028. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see <http://grants.nih.gov/grants/policy/awardconditions.htm> for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: <http://publicaccess.nih.gov/>.

This award provides support for one or more clinical trials. By law (Title VIII, Section 801 of [Public Law 110-85](#)), the “responsible party” must register “applicable clinical trials” on the [ClinicalTrials.gov Protocol Registration System Information Website](#). NIH encourages registration of all trials whether required under the law or not. For more information, see <http://grants.nih.gov/ClinicalTrials/fdaaa/>

This award represents the final year of the competitive segment for this grant. See the NIH Grants Policy Statement Section 8.6 Closeout for complete closeout requirements at: <http://grants.nih.gov/grants/policy/policy.htm#gps>.

A final expenditure Federal Financial Report (FFR) (SF 425) must be submitted through the eRA Commons (Commons) within 120 days of the period of performance end date; see the NIH Grants Policy Statement Section 8.6.1 Financial Reports, <http://grants.nih.gov/grants/policy/policy.htm#gps>, for additional information on this submission requirement. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the Payment Management System's (PMS) quarterly cash transaction data. A final quarterly federal cash transaction report is not required for awards in PMS B subaccounts (i.e., awards to foreign entities and to Federal agencies). NIH will close the awards using the last recorded cash drawdown level in PMS for awards that do not require a final FFR on expenditures or quarterly federal cash transaction reporting. It is important to note that for financial closeout, if a grantee fails to submit a required final expenditure FFR, NIH will close the grant using the last recorded cash drawdown level. If the grantee submits a final expenditure FFR but does not reconcile any discrepancies between expenditures reported on the final expenditure FFR and the last cash report to PMS, NIH will close the award at the lower amount. This could be considered a debt or result in disallowed costs.

A Final Invention Statement and Certification form (HHS 568), (not applicable to training, construction, conference or cancer education grants) must be submitted within 120 days of the expiration date. The HHS 568 form may be downloaded at: <http://grants.nih.gov/grants/forms.htm>. This paragraph does not apply to Training grants, Fellowships, and certain other programs—i.e., activity codes C06, D42, D43, D71, DP7, G07, G08, G11, K12, K16, K30, P09, P40, P41, P51, R13, R25, R28, R30, R90, RL5, RL9, S10, S14, S15, U13, U14, U41, U42, U45, UC6, UC7, UR2, X01, X02.

Unless an application for competitive renewal is submitted, a Final Research Performance Progress Report (Final RPPR) must also be submitted within 120 days of the period of performance end date. If a competitive renewal application is submitted prior to that date, then an Interim RPPR must be submitted by that date as well. Instructions for preparing an Interim or Final RPPR are at: https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf. Any other specific requirements set forth in the terms and conditions of the award must also be addressed in the Interim or Final RPPR. *Note that data reported within Section I of the Interim and Final RPPR forms will be made public and should be written for a lay person audience.*

NIH strongly encourages electronic submission of the final invention statement through the Closeout feature in the Commons, but will accept an email or hard copy submission as indicated below.

Email: The final invention statement may be e-mailed as PDF attachments to: NIHCloseoutCenter@mail.nih.gov.

Hard copy: Paper submissions of the final invention statement may be faxed to the NIH Division of Central Grants Processing, Grants Closeout Center, at 301-480-2304, or mailed to:

National Institutes of Health
Office of Extramural Research
Division of Central Grants Processing
Grants Closeout Center
6705 Rockledge Drive
Suite 5016, MSC 7986
Bethesda, MD 20892-7986 (for regular or U.S. Postal Service Express mail)
Bethesda, MD 20817 (for other courier/express deliveries only)

NOTE: If this is the final year of a competitive segment due to the transfer of the grant to another institution, then a Final RPPR is not required. However, a final expenditure FFR is required and should be submitted electronically as noted above. If not already submitted, the Final Invention Statement is required and should be sent directly to the assigned Grants Management Specialist.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than \$10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:

Additional Costs

SECTION IV – AG SPECIFIC AWARD CONDITIONS – 1SB1AG073028-01A1

Clinical Trial Indicator: Yes

This award supports one or more NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

RESTRICTION: The present award is being made without a currently valid certification of IRB approval for this project with the following restriction: Only activities that are clearly severable and independent from activities that involve human subjects may be conducted pending the National Institute on Aging's acceptance of the certification of IRB approval.

No funds may be drawn down from the payment system and no obligations may be made against Federal funds for any research involving human subjects prior to the National Institute on Aging's notification to the grantee that the identified issues have been resolved and this restriction removed.

Failure to respond within the 60-day period and/or to otherwise comply with the above requirements may result in suspension and/or termination of this award, audit/or disallowances, and/or other appropriate action.

See the NIH Grants Policy Statement, Chapter 4.1.15 Human Subjects Protections ([http://grants.nih.gov/grants/policy/nihgps/HTML5/section 4/4 public policy requirements objectives and other appropriation mandates.htm](http://grants.nih.gov/grants/policy/nihgps/HTML5/section%204/4%20public%20policy%20requirements%20objectives%20and%20other%20appropriation%20mandates.htm)), for specific requirements related to the protection of human subjects, which are applicable to and a term and condition of this award.

Recruitment of participants cannot be initiated until the NIA program staff, IRB, and the Safety Monitor have approved the protocol and data and safety monitoring plan.

Funding for this award has been provided by Alzheimer's Disease Initiative funds.

ClinicalTrials.gov is a federal registry and results database of publicly and privately supported clinical studies of human participants conducted around the world. In September 2016, NIH issued a final policy to promote broad and responsible dissemination of information from NIH-funded clinical trials through ClinicalTrials.gov. Under this policy, every clinical trial funded in whole or in part by NIH is expected to be registered on ClinicalTrials.gov and have summary results information submitted and posted in a timely manner, whether subject to FDAAA 801 or not.

Public Policy Requirements and Objectives: [https://grants.nih.gov/grants/policy/nihgps/HTML5/section 4/4.1 public policy requirements and objectives.htm?Highlight=clinical](https://grants.nih.gov/grants/policy/nihgps/HTML5/section%204/4.1%20public%20policy%20requirements%20and%20objectives.htm?Highlight=clinical)

Intellectual property rights: Normally, the awardee(s) organization retains the principal worldwide patent rights to any invention developed with United States Government support. Under Title 37 Code of Federal Regulations Part 401, the Government receives a royalty-free license for its use, reserves the right to require the patent holder to license others in certain circumstances, and requires that anyone exclusively licensed to sell the invention in the United States must normally manufacture it substantially in the United States.

Rights and obligations related to inventions created or reduced to practice as a result of this award are detailed in 35 U.S.C. 205 and 37 CFR Part 401. These inventions must be reported to the Extramural Invention Reporting and Technology Resources Branch, OPERA, NIH, 6701 Rockledge Drive, MSC 7750, Bethesda, MD 20892-7750, (301) 435-1986. For additional information, access the NIH link on the Interagency Edison web site (www.iedison.gov) which includes an electronic invention reporting system, reference information and the text to 37 CFR 401.

To the extent authorized by 35 U.S.C., Section 205, the Government will not make public any information disclosing an NIH-supported invention for a 4-year period to allow the awardee organization a reasonable time to file a patent application, nor will the Government release any information that is part of that patent application.

The fee provided as part of this Notice of Grant Award is in addition to direct and facilities and administrative costs. The fee is to be drawn down from the DHHS Payment Management System in increments proportionate to the drawdown of costs.

Allowable costs conducted by for-profit organizations will be determined by applying the cost principles of Contracts with Commercial Organizations set forth in 48 CFR, Subpart 31.2.

The format for the Final Report is as follows:

1. State the beginning and ending dates for the period covered by the SBIR/STTR Phase I/Phase II grant.
2. List all key personnel who have worked on the project during that period, their titles, dates of service, and number of hours devoted to the project.
3. Summarize the specific aims of the Phase I grant.
4. Provide a succinct account of published and unpublished results, indicating progress toward their achievement. Summarize the importance of the findings. Discuss any changes in the specific aims since the project was initiated. Include the Inclusion Enrollment Report with the final enrollment data for clinical research ([MS Word](#) or [PDF](#)).
5. List titles and complete references to publications, and manuscripts accepted for publication, if any, that resulted from the project's effort. Submit *five copies* of such items, except patent and invention reports, as an *Appendix*.
6. List patents, copyrights, trademarks, invention reports and other printed materials, if any, that resulted from the project or describe patent status, trade secrets or other demonstration of IP protection.
7. Describe the technology developed from this SBIR/STTR, its intended use and who will use it.
8. Describe the current status of the product (e.g., under development, commercialized, in use, discontinued).
9. If applicable, describe the status of FDA approval for your product, process, or service (e.g., continuing pre-IND studies, filed an IND, in Phase I (or II or III) clinical trials, applied for approval, review ongoing, approved, not approved).
10. Describe how your company has benefited from the program and/or the technology developed (e.g., firm's growth, follow-on funding, increased technical expertise, licensing agreements, spin-off companies, public offering [include stock exchange and symbol]).
11. List of the generic and/or commercial name of product, process, or service, if any, that resulted from SBIR/STTR funding. If applicable, indicate the number of products sold.
12. Provide the current number of employees (total full time equivalents [FTEs]).

SPREADSHEET SUMMARY
AWARD NUMBER: 1SB1AG073028-01A1

INSTITUTION: COGNITION THERAPEUTICS, INC.

Budget	Year 1
Salaries and Wages	\$ 78,920
Personnel Costs (Subtotal)	\$ 78,920
Consultant Services	\$ 28,000
Travel	\$ 4,500
Other	\$ 1,056,739
FEE	\$ 107,472
TOTAL FEDERAL DC	\$ 1,168,159
TOTAL FEDERAL F&A	\$ 367,152
TOTAL COST	\$ 1,642,783
Facilities and Administrative Costs	Year 1
F&A Cost Rate 1	31.43%
F&A Cost Base 1	\$ 1,168,159
F&A Costs 1	\$ 367,152



Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE ON AGING

Notice of Award
FAIN# R01AG071643
Federal Award Date
05/06/2021

Recipient Information

1. **Recipient Name**
COGNITION THERAPEUTICS, INC. 2403 SIDNEY ST STE 261
PITTSBURGH, PA 15203
2. **Congressional District of Recipient 14**
3. **Payment System Identifier (ID)**
1134365359A1
4. **Employer Identification Number (EIN)**
134365359
5. **Data Universal Numbering System (DUNS)**
808434612
6. **Recipient's Unique Entity Identifier**
7. **Project Director or Principal Investigator**
ANTHONY O CAGGIANO, MD (Contact)
Senior Vice President Of Research And Development
acaggiano@cogrx.com
914 497-6658
8. **Authorized Official**
Dr. Susan Catalano.
scatalano@cogrx.com
412-481-2210

Federal Agency Information

9. **Awarding Agency Contact Information**
Jennifer Edwards
NATIONAL INSTITUTE ON AGING
edwardsj@mail.nih.gov
301-827-6689
10. **Program Official Contact Information**
Laurie M. Ryan
Health Scientist Administrator
NATIONAL INSTITUTE ON AGING
ryanl@nia.nih.gov
301.496.9350

Federal Award Information

11. **Award Number**
1R01AG071643-01
12. **Unique Federal Award Identification Number (FAIN)**
R01AG071643
13. **Statutory Authority**
42 USC 241 42 CFR 52
14. **Federal Award Project Title**
A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Phase 2 Study to Evaluate the Safety and Efficacy of CT1812 in Subjects with Dementia with Lewy Bodies
15. **Assistance Listing Number**
93.866
16. **Assistance Listing Program Title**
Aging Research
17. **Award Action Type**
New Competing
18. **Is the Award R&D?**
Yes

Summary Federal Award Financial Information

19. Budget Period Start Date 05/15/2021 - End Date 04/30/2022		
20. Total Amount of Federal Funds Obligated by this Action	\$	10,764,669
20 a. Direct Cost Amount	\$	8,294,565
20 b. Indirect Cost Amount	\$	2,470,104
21. Authorized Carryover	\$	0
22. Offset	\$	0
23. Total Amount of Federal Funds Obligated this budget period	\$	10,764,669
24. Total Approved Cost Sharing or Matching, where applicable	\$	0

25. Total Federal and Non-Federal Approved this Budget Period	\$	10,764,669
26. Project Period Start Date 05/15/2021 - End Date 04/30/2024		
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	\$	10,764,669

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Robin Laney

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.



SECTION I - AWARD DATA - 1R01AG071643-01

Principal Investigator(s):

ANTHONY O CAGGIANO (contact), MD
James E Galvin, MD

Award e-mailed to: scatalano@cogrx.com

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of \$10,764,669 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to COGNITION THERAPEUTICS, INC. in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute On Aging of the National Institutes of Health under Award Number R01AG071643. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website <http://grants.nih.gov/grants/policy/coi/> for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Robin Laney
Grants Management Officer
NATIONAL INSTITUTE ON AGING

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)		
Salaries and Wages	\$	195,565
Personnel Costs (Subtotal)	\$	195,565
Consultant Services	\$	1,220,350
Travel	\$	308,600
Other	\$	6,109,550
Subawards/Consortium/Contractual Costs	\$	460,500
Federal Direct Costs	\$	8,294,565
Federal F&A Costs	\$	2,470,104
Approved Budget	\$	10,764,669
Total Amount of Federal Funds Authorized (Federal Share)	\$	10,764,669
TOTAL FEDERAL AWARD AMOUNT	\$	10,764,669
AMOUNT OF THIS ACTION (FEDERAL SHARE)	\$	10,764,669

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)				
YR	THIS AWARD		CUMULATIVE TOTALS	
1	\$	10,764,669	\$	10,764,669
2	\$	10,254,288	\$	10,254,288
3	\$	8,479,107	\$	8,479,107

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:
Payment System Identifier: 1134365359A1
Document Number: RAG071643A
PMS Account Type: P (Subaccount)
Fiscal Year: 2021

IC	CAN	2021	2022	2023
AG	8033159	\$ 10,764,669	\$ 10,254,288	\$ 8,479,107

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:
PCC: 3CCCTLR / **OC:** 41021 / **Released:** Laney, Robin 04/27/2021
Award Processed: 05/06/2021 12:12:57 AM

SECTION II - PAYMENT/HOTLINE INFORMATION - 1R01AG071643-01

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at <http://grants.nih.gov/grants/policy/awardconditions.htm>

SECTION III - STANDARD TERMS AND CONDITIONS - 1R01AG071643-01

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

- a. The grant program legislation and program regulation cited in this Notice of Award.
- b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
- c. 45 CFR Part 75.
- d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
- e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
- f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at <http://grants.nih.gov/grants/policy/awardconditions.htm> for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of “Research and Development” at 45 CFR Part § 75.2. As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

Carry over of an unobligated balance into the next budget period requires Grants Management Officer prior approval.

This grant is excluded from Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to receive a Dun & Bradstreet Universal Numbering System (DUNS) number and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a DUNS requirement must be included. See <http://grants.nih.gov/grants/policy/awardconditions.htm> for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01AG071643. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see <http://grants.nih.gov/grants/policy/awardconditions.htm> for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: <http://publicaccess.nih.gov/>.

This award provides support for one or more clinical trials. By law (Title VIII, Section 801 of [Public Law 110-85](#)), the "responsible party" must register "applicable clinical trials" on the [ClinicalTrials.gov Protocol Registration System Information Website](#). NIH encourages registration of all trials whether required under the law or not. For more information, see http://grants.nih.gov/ClinicalTrials_fdaaa/.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than \$10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:
Additional Costs

SECTION IV - AG SPECIFIC AWARD CONDITIONS - 1R01AG071643-01

Clinical Trial Indicator: Yes
This award supports one or more NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

RESTRICTION: The present award is being made without a currently valid certification of IRB approval for this project with the following restriction: Only activities that are clearly severable and independent from activities that involve human subjects may be conducted pending the National Institute on Aging's acceptance of the certification of IRB approval. No funds may be drawn down from the payment system and no obligations may be made against Federal funds for any research involving human subjects prior to the National Institute on Aging's notification to the grantee that the identified issues have been resolved and this restriction removed.

Failure to respond within the 60-day period and/or to otherwise comply with the above requirements may result in suspension and/or termination of this award, audit/or disallowances, and/or other appropriate action.

See the NIH Grants Policy Statement, Chapter 4.1.15 Human Subjects Protections ([http://grants.nih.gov/grants/policy/nihgps/HTML5/section 4/4 public policy requirements obje ctives and other appropriation mandates.htm](http://grants.nih.gov/grants/policy/nihgps/HTML5/section%204/4%20public%20policy%20requirements%20objectives%20and%20other%20appropriation%20mandates.htm)), for specific requirements related to the protection of human subjects, which are applicable to and a term and condition of this award.

Recruitment of participants cannot be initiated until the NIA program staff, IRB, and the DSMB have approved the protocol and data and safety monitoring plan.

This provisional award is issued subject to the following condition:
Under governing policy, Federal funds administered by the NIH may not be expended for research in a foreign entity (Sweden) pending further administrative review. No funds may be drawn from the payment system for a foreign project pending acceptance of the clearance.

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Sharing of clinical trial data and bio-samples is expected at the time of publication of the primary results or within 9 months of database lock, whichever comes first.

Funding for this award has been provided by Alzheimer's Disease Initiative funds.

In keeping with NOT-OD-06-054 (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-06-054.html>), as this grant has multiple Principal Investigators (PIs), although the signatures of the PIs are not required on prior approval requests submitted to the agency, the grantee institution must secure and retain the signatures of all of the PIs within their own internal processes.

This award includes funds awarded for consortium activity with University of Miami, Miller School of Medicine in the amount of \$460,500 (\$300,000 direct costs + \$160,500 facilities and administrative costs). Consortiums are to be established and administered as described in the NIH Grants Policy Statement (NIH GPS). The referenced section of the NIH Grants Policy Statement is available at: <http://grants.nih.gov/grants/policy/nihgps/HTML5/section15/15consortiumagreements.htm>.

No research involving human subjects may be conducted at any performance site until OHRP has approved a Federalwide Assurance (FWA) for that site and the grantee has ensured that the research has received appropriate Institutional Review Board (IRB) approval.

ClinicalTrials.gov is a federal registry and results database of publicly and privately supported clinical studies of human participants conducted around the world. In September 2016, NIH issued a final policy to promote broad and responsible dissemination of information from NIH- funded clinical trials through ClinicalTrials.gov. Under this policy, every clinical trial funded in whole or in part by NIH is expected to be registered on ClinicalTrials.gov and have summary results information submitted and posted in a timely manner, whether subject to FDAAA 801 or not.

Public Policy Requirements and Objectives: <https://grants.nih.gov/grants/policy/nihgps/HTML5/section4/4.1publicpolicyrequirementsandobjectives.htm?Highlight=clinical>

SPREADSHEET SUMMARY
AWARD NUMBER: 1R01AG071643-01

INSTITUTION: COGNITION THERAPEUTICS, INC.

Budget	Year 1	Year 2	Year 3
Salaries and Wages	\$ 195,565	\$ 195,565	\$ 195,565
Personnel Costs (Subtotal)	\$ 195,565	\$ 195,565	\$ 195,565
Consultant Services	\$ 1,220,350	\$ 665,000	\$ 180,000
Travel	\$ 308,600	\$ 17,500	\$ 10,000
Other	\$ 6,109,550	\$ 6,570,500	\$ 5,715,250
Subawards/Consortium/Contractual Costs	\$ 460,500	\$ 456,782	\$ 452,948
TOTAL FEDERAL DC	\$ 8,294,565	\$ 7,905,347	\$ 6,553,763
TOTAL FEDERAL F&A	\$ 2,470,104	\$ 2,348,941	\$ 1,925,344
TOTAL COST	\$ 10,764,669	\$ 10,254,288	\$ 8,479,107

Facilities and Administrative Costs	Year 1	Year 2	Year 3
F&A Cost Rate 1	31.43%	31.43%	31.43%
F&A Cost Base 1	\$ 7,859,065	\$ 7,473,565	\$ 6,125,815
F&A Costs 1	\$ 2,470,104	\$ 2,348,941	\$ 1,925,344



Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE ON AGING

Notice of Award
FAIN# R01AG058660
Federal Award Date
05/10/2021

Recipient Information

1. Recipient Name

COGNITION THERAPEUTICS, INC.
2403 SIDNEY ST STE 261

PITTSBURGH, PA 15203

2. Congressional District of Recipient

14

3. Payment System Identifier (ID)

1134365359A1

4. Employer Identification Number (EIN)

134365359

5. Data Universal Numbering System (DUNS)

808434612

6. Recipient's Unique Entity Identifier

7. Project Director or Principal Investigator

SUSAN M CATALANO, PHD (Contact)

President/founder

scatalano@cogrx.com

(412) 481-2210

8. Authorized Official

Dr. Susan Catalano Ph.D

scatalano@cogrx.com

412-481-2210

Federal Agency Information

9. Awarding Agency Contact Information

Jennifer Edwards

NATIONAL INSTITUTE ON AGING

edwardsj@mail.nih.gov

301-827-6689

10. Program Official Contact Information

Laurie M. Ryan

Health Scientist Administrator

NATIONAL INSTITUTE ON AGING

ryanl@nia.nih.gov

301.496.9350

Federal Award Information

11. Award Number

3R01AG058660-03S1A1

12. Unique Federal Award Identification Number (FAIN)

R01AG058660

13. Statutory Authority

42 USC 241 42 CFR 52

14. Federal Award Project Title

Randomized Double Blind, Placebo Controlled, Parallel Group, Phase II Study to
Evaluate the Safety and Efficacy of CT1812 in Subjects with Mild to Moderate
Alzheimer's Disease

15. Assistance Listing Number

93.866

16. Assistance Listing Program Title

Aging Research

17. Award Action Type

Supplement (REVISED)

18. Is the Award R&D?

Yes

Summary Federal Award Financial Information

19. Budget Period Start Date 05/01/2020 - End Date 05/31/2022

20. Total Amount of Federal Funds Obligated by this Action

\$ 0

20 a. Direct Cost Amount

\$ 0

20 b. Indirect Cost Amount	\$	0
21. Authorized Carryover	\$	0
22. Offset	\$	0
23. Total Amount of Federal Funds Obligated this budget period	\$	13,634,548
24. Total Approved Cost Sharing or Matching, where applicable	\$	0
25. Total Federal and Non-Federal Approved this Budget Period	\$	13,634,548
26. Project Period Start Date 09/15/2018 - End Date 05/31/2022		
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	\$	30,482,877

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Robin Laney

30. Remarks
Acceptance of this award, including the “Terms and Conditions,” is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.



RESEARCH
Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE ON AGING

Notice of Award



SECTION I - AWARD DATA - 3R01AG058660-03S1A1 REVISED

Principal Investigator(s):
SUSAN M CATALANO, PHD

Award e-mailed to: scatalano@cogrx.com

Dear Authorized Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to COGNITION THERAPEUTICS, INC. in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute On Aging of the National Institutes of Health under Award Number R01AG058660. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website <http://grants.nih.gov/grants/policy/coi/> for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Robin Laney
Grants Management Officer
NATIONAL INSTITUTE ON AGING

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)		
Salaries and Wages	\$	153,350
Personnel Costs (Subtotal)	\$	153,350
Consultant Services	\$	132,000
Materials & Supplies	\$	78,991
Other	\$	10,009,659
Federal Direct Costs	\$	10,374,000
Federal F&A Costs	\$	3,260,548
Approved Budget	\$	13,634,548
Total Amount of Federal Funds Authorized (Federal Share)	\$	13,634,548
TOTAL FEDERAL AWARD AMOUNT	\$	13,634,548
AMOUNT OF THIS ACTION (FEDERAL SHARE)	\$	0

SUMMARY TOTAL FEDERAL AWARD AMOUNT YEAR (3) (for this Document Number)		
AWARD NUMBER	TOTAL FEDERAL AWARD AMOUNT	
3R01AG058660-03S1A1	\$	13,634,548
5R01AG058660-03	\$	5,774,586
3R01AG058660-03S2	\$	278,623
TOTAL	\$	19,687,757

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)				
YR	THIS AWARD		CUMULATIVE TOTALS	
3	\$	13,634,548	\$	19,687,757

Fiscal Information:
Payment System Identifier: 1134365359A1
Document Number: RAG058660A
PMS Account Type: P (Subaccount)
Fiscal Year: 2021

IC	CAN	2021
AG	8033159	\$ 13,634,548

NIH Administrative Data:
PCC: 3CCCTLR / **OC:** 41023 / **Released:** Laney, Robin 05/07/2021
Award Processed: 05/10/2021 12:04:55 AM

SECTION II - PAYMENT/HOTLINE INFORMATION - 3R01AG058660-03S1A1 REVISED

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at <http://grants.nih.gov/grants/policy/awardconditions.htm>

SECTION III - STANDARD TERMS AND CONDITIONS - 3R01AG058660-03S1A1 REVISED

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

- a. The grant program legislation and program regulation cited in this Notice of Award.
- b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
- c. 45 CFR Part 75.
- d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
- e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
- f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at <http://grants.nih.gov/grants/policy/awardconditions.htm> for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of “Research and Development” at 45 CFR Part § 75.2. As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

Carry over of an unobligated balance into the next budget period requires Grants Management Officer prior approval.

This grant is excluded from Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to receive a Dun & Bradstreet Universal Numbering System (DUNS) number and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a DUNS requirement must be included. See <http://grants.nih.gov/grants/policy/awardconditions.htm> for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01AG058660. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see <http://grants.nih.gov/grants/policy/awardconditions.htm> for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: <http://publicaccess.nih.gov/>.

This award provides support for one or more clinical trials. By law (Title VIII, Section 801 of [Public Law 110-85](#)), the “responsible party” must register “applicable clinical trials” on the [ClinicalTrials.gov Protocol Registration System Information Website](#). NIH encourages registration of all trials whether required under the law or not. For more information, see <http://grants.nih.gov/ClinicalTrials fdaaa/>.

This award represents the final year of the competitive segment for this grant. See the NIH Grants Policy Statement Section 8.6 Closeout for complete closeout requirements at: <http://grants.nih.gov/grants/policy/policy.htm#gps>.

A final expenditure Federal Financial Report (FFR) (SF 425) must be submitted through the eRA Commons (Commons) within 120 days of the period of performance end date; see the NIH Grants Policy Statement Section 8.6.1 Financial Reports, <http://grants.nih.gov/grants/policy/policy.htm#gps>, for additional information on this submission requirement. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the Payment Management System's (PMS) quarterly cash transaction data. A final quarterly federal cash transaction report is not required for awards in PMS B subaccounts (i.e., awards to foreign entities and to Federal agencies). NIH will close the awards using the last recorded cash drawdown level in PMS for awards that do not require a final FFR on expenditures or quarterly federal cash transaction reporting. It is important to note that for financial closeout, if a grantee fails to submit a Page 4 of 7 required final expenditure FFR, NIH will close the grant using the last recorded cash drawdown level. If the grantee submits a final expenditure FFR but does not reconcile any discrepancies between expenditures reported on the final expenditure FFR and the last cash report to PMS, NIH will close the award at the lower amount. This could be considered a debt or result in disallowed costs.

A Final Invention Statement and Certification form (HHS 568), (not applicable to training, construction, conference or cancer education grants) must be submitted within 120 days of the expiration date. The HHS 568 form may be downloaded at: <http://grants.nih.gov/grants/forms.htm>. This paragraph does not apply to Training grants, Fellowships, and certain other programs—i.e., activity codes C06, D42, D43, D71, DP7, G07, G08, G11, K12, K16, K30, P09, P40, P41, P51, R13, R25, R28, R30, R90, RL5, RL9, S10, S14, S15, U13, U14, U41, U42, U45, UC6, UC7, UR2, X01, X02.

Unless an application for competitive renewal is submitted, a Final Research Performance Progress Report (Final RPPR) must also be submitted within 120 days of the period of performance end date. If a competitive renewal application is submitted prior to that date, then an Interim RPPR must be submitted by that date as well. Instructions for preparing an Interim or Final RPPR are at: https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf. Any other specific requirements set forth in the terms and conditions of the award must also be addressed in the Interim or Final RPPR. *Note that data reported within Section I of the Interim and Final RPPR forms will be made public and should be written for a lay person audience.*

NIH strongly encourages electronic submission of the final invention statement through the Closeout feature in the Commons, but will accept an email or hard copy submission as indicated below.

Email: The final invention statement may be e-mailed as PDF attachments to: NIHCloseoutCenter@mail.nih.gov.

Hard copy: Paper submissions of the final invention statement may be faxed to the NIH Division of Central Grants Processing, Grants Closeout Center, at 301-480-2304, or mailed to:

National Institutes of Health
Office of Extramural Research
Division of Central Grants Processing
Grants Closeout Center
6705 Rockledge Drive
Suite 5016, MSC 7986
Bethesda, MD 20892-7986 (for regular or U.S. Postal Service Express mail)
Bethesda, MD 20817 (for other courier/express deliveries only)

NOTE: If this is the final year of a competitive segment due to the transfer of the grant to another institution, then a Final RPPR is not required. However, a final expenditure FFR is required and should be submitted electronically as noted above. If not already submitted, the Final Invention Statement is required and should be sent directly to the assigned Grants Management Specialist.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than \$10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:

Additional Costs

SECTION IV - AG SPECIFIC AWARD CONDITIONS - 3R01AG058660-03S1A1 REVISED

Clinical Trial Indicator: Yes

This award supports one or more NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

This revised award changes the budget and project period end dates to coincide with the parent grant.

Supersedes Notice of Award issued 04/29/2021. Previous terms and conditions apply:

Funding for this award has been provided by Alzheimer's Disease Initiative funds.

No research involving human subjects may be conducted at any performance site until OHRP has approved a Federalwide Assurance (FWA) for that site and the grantee has ensured that the research has received appropriate Institutional Review Board (IRB) approval.

This award reflects the acceptance of the single Institutional Review Board (sIRB) plan submitted with the application dated 07/01/2020. Any changes to this plan require the written prior approval of the National Institute on Aging.

None of the funds in this award shall be used to pay the salary of an individual at a rate in excess of the current salary cap. Therefore, this award and/or future years are adjusted accordingly, if applicable. Current salary cap levels can be found at the following URL:
http://grants.nih.gov/grants/policy/salcap_summary.htm.

ClinicalTrials.gov is a federal registry and results database of publicly and privately supported clinical studies of human participants conducted around the world. In September 2016, NIH issued a final policy to promote broad and responsible dissemination of information from NIH- funded clinical trials through ClinicalTrials.gov. Under this policy, every clinical trial funded in whole or in part by NIH is expected to be registered on ClinicalTrials.gov and have summary results information submitted and posted in a timely manner, whether subject to FDAAA 801 or not.

Public Policy Requirements and Objectives:

[https://grants.nih.gov/grants/policy/nihgps/HTML5/section 4/4.1 public policy requirements and objectives.htm?Highlight=clinical](https://grants.nih.gov/grants/policy/nihgps/HTML5/section%204/4.1_public_policy_requirements_and_objectives.htm?Highlight=clinical)

SPREADSHEET SUMMARY
AWARD NUMBER: 3R01AG058660-03S1A1 REVISED

INSTITUTION: COGNITION THERAPEUTICS, INC.

Budget	Year 3	
Salaries and Wages	\$	153,350
Personnel Costs (Subtotal)	\$	153,350
Consultant Services	\$	132,000
Materials & Supplies	\$	78,991
Other	\$	10,009,659
TOTAL FEDERAL DC	\$	10,374,000
TOTAL FEDERAL F&A	\$	3,260,548
TOTAL COST	\$	13,634,548
Facilities and Administrative Costs	Year 3	
F&A Cost Rate 1		31.43%
F&A Cost Base 1	\$	10,374,000
F&A Costs 1	\$	3,260,548