

Confidential Treatment Requested by Cognition Therapeutics, Inc.
Pursuant to 17 C.F.R. Section 200.83

As confidentially submitted to the Securities and Exchange Commission on October 20, 2022. This draft registration statement has not been publicly filed with the 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)

**2500 Westchester Ave.
Purchase, NY 10577
(914) 221-6741**

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

Lisa Ricciardi
President and Chief Executive Officer
Cognition Therapeutics, Inc.
2500 Westchester Ave.
Purchase, NY 10577
(914) 221-6741

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Rachael M. Bushey
Joseph Walsh
Troutman Pepper Hamilton Sanders LLP
3000 Two Logan Square
Philadelphia, Pennsylvania 19103
(215) 981-4331

Stephen Older
David Wolpa
McGuireWoods LLP
1251 Avenue of the Americas, 20th Floor
New York, New York 10020
(212) 548-2100

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 ☐
Non-accelerated filer ☒

Accelerated filer ☐
Smaller reporting company ☒
Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act. ☐

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 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

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SUBJECT TO COMPLETION, DATED OCTOBER 20, 2022

PRELIMINARY PROSPECTUS



**Shares of Common Stock
Pre-Funded Warrants to Purchase Shares of Common Stock**

We are offering _____ shares of our common stock at an assumed public offering price of \$ _____ per share, which was the last reported sale price per share of our common stock on the Nasdaq Global Market on _____, 2022. We are also offering to any purchaser whose purchase of common stock in this offering would otherwise result in such purchaser, together with its affiliates, beneficially owning more than 4.99% (or, at the election of such purchaser, 9.99%) of our outstanding common stock immediately following this offering, the opportunity to purchase pre-funded warrants in lieu of shares of our common stock.

The purchase price of each pre-funded warrant equals the public offering price per share of common stock, minus \$0.0001, and the exercise price of each pre-funded warrant equals \$0.0001 per share. The pre-funded warrants may be exercised at any time until all of the pre-funded warrants are exercised in full, provided that each pre-funded warrant holder will be prohibited from exercising such pre-funded warrants into shares of our common stock if, as a result of such exercise, the holder, together with its affiliates, would own more than 4.99% (or, at the election of such holder, 9.99%) of the total number of shares of our common stock then issued and outstanding, which percentage may change at such holder's election to any other number less than or equal to 9.99% upon notice to us provided that any increase in the percentage shall not be effective until 61 days following notice to us. For each pre-funded warrant we sell, the number of shares of common stock we are offering will be decreased on a one-for-one basis. This prospectus also relates to the offering of the shares of common stock issuable upon exercise of such pre-funded warrants.

Our common stock is listed on the Nasdaq Global Market under the symbol "CGTX." There is no established public market for the pre-funded warrants, and we do not intend to list the pre-funded warrants on the Nasdaq Global Market, any other national securities exchange or any nationally recognized trading system.

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 the documents incorporated by reference herein and may elect to comply with reduced public company reporting requirements in future filings. See "Prospectus Summary-Implications of Being an Emerging Growth Company and a Smaller Reporting Company."

Investing in our common stock involves risks. Before deciding whether to invest in our securities, you should consider carefully the risks that we have described on page 11 of this prospectus under the caption "Risk Factors" and under similar headings in other documents incorporated by reference into this prospectus.

	Per share	Per Pre-Funded Warrant	Total
Public offering price	\$	\$	\$
Underwriting discounts and commissions ⁽¹⁾	\$	\$	\$
Proceeds to us, before expenses	\$	\$	\$

- (1) We have agreed to reimburse the underwriter for certain expenses. See "Underwriting" on page 136 for additional information regarding underwriting compensation.

Neither the Securities and Exchange Commission nor any other regulatory body 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.

We have granted the underwriter an option for a period of 30 days to purchase up to _____ additional shares of common stock on the same terms and conditions as set forth above.

Certain of our affiliated stockholders, including certain of our directors and officers and entities affiliated with certain of our directors, have indicated an interest in purchasing an aggregate of up to approximately \$ _____ in shares of our common stock in this offering at the public offering price. However, because indications of interest are not binding agreements or commitments to purchase, the underwriter may determine to sell more, fewer or no shares in this offering to any or all of these stockholders, or any or all of these stockholders may determine to purchase more, fewer or no shares in this offering. The underwriter will receive the same underwriting discount on any shares purchased by these stockholders as they will on any other shares sold to the public in this offering.

The underwriter expects to deliver the shares of our common stock and pre-funded warrants against payment in New York, NY on or about _____, 2022.

Cantor

, 2022

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.

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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 underwriter 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 and the underwriter 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, results of operations and prospects may have changed since that date.

Neither we nor the underwriter 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.

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PROSPECTUS SUMMARY

This summary highlights information contained 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. You should carefully read the entire prospectus, including the risks of investing in our securities discussed under the heading “Risk Factors” and under similar headings in the other documents that are incorporated by reference into this prospectus. You should also carefully read the information incorporated by reference into this prospectus, including our financial statements, and the exhibits to the registration statement of which this prospectus is a part. Unless the context otherwise requires, the terms “Cognition” “the Company,” “we,” “us,” “our” and similar references in this prospectus refer to Cognition Therapeutics, Inc.

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 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 modulator 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. We believe our evidence demonstrates that by binding to the S2R complex, CT1812 displaces A β oligomers from their neuronal receptors. Based on this mechanism, we believe CT1812 has the potential to slow the loss of synapses and cognitive decline observed in AD. CT1812 is the first S2R selective ligand modulator 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 U.S. 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 three ongoing Phase 2 clinical trials with CT1812: SHINE and SEQUEL in mild-to-moderate AD and SHIMMER in dementia with Lewy bodies, or DLB. 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 monomers 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 completing enrollment in 2023 with top-line data in early 2024. Our ongoing SEQUEL Phase 2 clinical trial is also evaluating changes in brain function, as measured by quantitative electroencephalography, or qEEG, in mild-to-moderate AD, and we anticipate completing enrollment in 2022 and reporting topline data thereafter. We have treated 221 subjects with CT1812 in our clinical trials to date including 90 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 \$171.0 million in cumulative grants awarded primarily by the National Institute of Aging, or NIA, a division of the National Institutes of Health, or NIH, which includes a grant award of approximately \$81.0 million from the NIA to fund our Phase 2 START (COG0203) study of CT1812 in patients with early stage AD. We intend to enroll 540 patients in our START trial with mild cognitive impairment, or MCI, due to AD or mild AD who have elevated levels of A β oligomers as determined by a clinical diagnosis of AD confirmed with amyloid biomarkers positron emission tomography, or PET, imaging and/or cerebrospinal fluid, or CSF, biomarkers. 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 SB, and ADAS-Cog, we intend to

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use a variety of biomarkers to measure target and/or pathway engagement and assess changes in neurodegeneration and disease progression. We are conducting 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 open sites by the end of 2022.

We intend to expand our CT1812 pipeline to include additional indications such as dry age-related macular degeneration, or dry AMD, an eye 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 modulator, such as CT1812, may help to regulate the damage-response processes related to these cells that are impaired in dry AMD. We have completed a pre-IND meeting with the FDA, and, after the completion of our ongoing preclinical studies, we intend to submit an Investigational New Drug, or IND, application to the FDA by the end of 2022, after which we plan to advance into a Phase 2 clinical trial, leveraging our knowledge of CT1812's preclinical and clinical profile to date.

In addition, we are developing 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 DLB.

Our Pipeline

The following chart shows the developmental status of our clinical and preclinical product candidates, all of which are wholly owned:

Product Candidate	Target Indication	Preclinical	Phase 1	Phase 2	Phase 3	Funding
CT1812	SEQUEL Mild-moderate AD					\$5.4M 
CT1812	SHINE Mild-moderate AD					\$30M 
CT1812	SHIMMER DLB					\$30M 
CT1812	START Early-stage AD					\$81M 
CT1812	Dry AMD					
CT2168	Synucleinopathies					
CT2074	Dry AMD					

Intellectual Property

As of October 1, 2022, our intellectual property portfolio contained nine issued U.S. patents, 65 issued foreign patents as well as one pending U.S. provisional application, four pending U.S. patent applications, two pending Patent Cooperation Treaty applications and 26 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.

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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 October 1, 2022, 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, India, Israel, Japan, New Zealand, Mexico, South Korea, 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 and Hong Kong. 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 approval of the New Drug Application, or NDA, in the United States or extension of patent term via a Supplementary Protection Certificate, or SPC, following European Medicines Agency, or EMA, 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," or the Orange Book. These patents complement the regulatory exclusivity by providing the basis for an additional waiting period 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 four families of pending patent applications directed to methods for selecting subsets of patients with AD for treatment with CT1812, methods of modulating amyloid beta monomer and oligomer levels using CT1812, methods of treating dry AMD with CT1812 and methods of treating various neurologic diseases including PD and synucleinopathies with CT1812, as well as a pending provisional application directed to treating certain subsets of AD patients with CT1812. Any of these applications, if issued, will have a natural expiration between 2038 and 2043, 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.

Recent Events

AAIC

In August 2022, at the Alzheimer's Association International Conference, or AAIC, we presented a proteomic analysis of clinical biomarker data from all participants enrolled in our SPARC study for whom end-of-study (at six months) and baseline CSF samples were available (n=18). The SPARC study (COG0105)

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enrolled 23 individuals with mild-to-moderate AD who were randomized to receive oral once-daily treatment with CT1812 or placebo for six months. The analyses demonstrated the effect of CT1812 on multiple priority AD biomarkers, including YKL-40, a biomarker of inflammation, which is upregulated in AD. Participants treated with CT1812 exhibited a downward shift in YKL-40 towards levels observed in healthy, non-demented individuals, supporting a potential positive impact of CT1812 on disease biology. In addition, CT1812 had a significant impact on CSF levels of clusterin which has been identified as a genetic risk factor for AD by several independent, large-scale genome-wide association studies. We believe the analytic results support the proposed synaptoprotective mechanism of action of CT1812 and role in normalizing cellular processes known to be adversely disrupted in AD.

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 are evaluating CT1812 in other AD populations as well and developing CT1812 for patients with earlier symptomatic stages of AD and MCI, which is a slight and noticeable measurable decline in cognitive abilities due to AD. Our START (COG0203) clinical trial in patients with mild dementia associated with early stage AD 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, an 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 modulator, such as CT1812, may help to regulate the damage-response processes related to these cells that are impaired in dry AMD. We have completed a pre-IND meeting with the FDA, and, after the completion of our ongoing preclinical studies, we intend to submit an IND application to the FDA by the end of 2022, after which we plan to advance into a Phase 2 clinical trial, leveraging our knowledge of CT1812's preclinical and clinical profile to date.
- ***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. We are initiating a study of CT1812 in patients with DLB and are currently recruiting for patients at approximately 17 sites, with more expected to follow. 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 in a well-controlled Phase 2 clinical trial.
- ***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 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 research and clinical efforts have been funded by approximately \$171.0 million in cumulative grants awarded primarily by

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the NIA. This includes awards totaling \$10.9 million in support of preclinical studies and \$160.1 million for clinical development, the largest of which was the 2020 award of \$81.0 million supporting our upcoming Phase 2 START (COG0203) study of CT1812 in 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.

Risk Factor Summary

Our business and this offering are subject to numerous risks and uncertainties, including those in the section entitled “Risk Factors,” in our Annual Report on Form 10-K for the year ended December 31, 2021, or our 2021 Annual Report, and in our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2022 and June 30, 2022, or our 2022 Quarterly Reports, and in the other documents we file with the Securities and Exchange Commission, or the SEC, which are incorporated by reference in this prospectus. These risks include, but are not limited to, the following:

Risks Related to Our Financial Position and Capital Needs; Discovery, Development and Regulatory Approval of Our Product Candidates; and Business and Industry

- We will need substantial additional capital to meet our financial obligations in the future 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.
- 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.
- 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 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 have initially concentrated our research and development efforts on the treatment of AD, a disease that has seen limited success in drug development.
- 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.

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.

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

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

Risks Relating to Government Regulation

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

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- 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.
- 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.
- 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.

Risks Relating to Our Common Stock

- 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.
- Concentration of ownership of our common stock among our exiting officers, directors and principal stockholders may prevent new investors from influencing significant corporate decisions.
- Provisions in our charter documents and Delaware law could discourage a takeover that stockholders may consider favorable and may lead to entrenchment of management.

Risks Relating to this Offering

- Purchasers of common stock in this offering will experience immediate and substantial dilution in the net tangible book value of their investment.
- There is no public market for the pre-funded warrants being offered in this offering.
- Holders of pre-funded warrants purchased in this offering will have no rights as common stockholders until such holders exercise their warrants and acquire our common stock, except as provided in the pre-funded warrants.
- A substantial number of shares of common stock may be sold in the market following this offering, which may depress the market price for 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.

Corporate Information

We were incorporated under the laws of the State of Delaware on August 21, 2007. Our principal executive offices are located at 2500 Westchester Ave., Purchase, NY 10577, and our telephone number is (914) 221-6741. 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 and a Smaller Reporting Company

We are an “emerging growth company” as defined in the Jumpstart Our Business Startups Act, or the JOBS Act, enacted in April 2012, and we will remain an emerging growth company until the earliest to occur of: the last day of the fiscal year in which we have more than \$1.07 billion in annual revenue; the date we qualify as a “large accelerated filer,” with at least \$700.0 million of equity securities held by non-affiliates; the issuance, in any three-year period, by us of more than \$1.0 billion in non-convertible debt securities; and December 31, 2026. For so long as we remain an emerging growth company, we are permitted and intend to rely on certain exemptions from various public company reporting requirements, including not being required to have our internal control over financial reporting audited by our independent registered public accounting firm pursuant to Section 404(b) of the Sarbanes-Oxley Act of 2002, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and any golden parachute payments not previously approved.

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We have elected to take advantage of certain of the reduced disclosure obligations in the registration statement of which this prospectus is a part and in the filings we make with the SEC. As a result, the information that we provide to our stockholders may be different than the information you might receive from other public reporting companies that are not emerging growth companies.

In addition, 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 have elected to take advantage of the extended transition period to comply with new or revised accounting standards and to adopt certain of the reduced disclosure requirements available to emerging growth companies. As a result, we will not be subject to the same implementation timing for new or revised accounting standards as other public companies that are not emerging growth companies which may make comparison of our financial statements to those of other public companies more difficult. As a result of this election, the information that we provide in this prospectus may be different than the information you may receive from other public companies in which you hold equity interests.

We are also a smaller reporting company as defined in the Securities Exchange Act of 1934, as amended, or the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as (i) the market value of our voting and non-voting common stock held by non-affiliates is less than \$250 million measured on the last business day of our second fiscal quarter or (ii) our annual revenue is less than \$100 million during the most recently completed fiscal year and the market value of our voting and non-voting common stock held by non-affiliates is less than \$700 million measured on the last business day of our second fiscal quarter. 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 reports on Form 10-K and have reduced disclosure obligations regarding executive compensation, and, similar to emerging growth companies, if we are a smaller reporting company with less than \$100 million in annual revenue, we would not be required to obtain an attestation report on internal control over financial reporting issued by our independent registered public accounting firm.

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The Offering	
Common stock to be offered	shares
Pre-funded warrants offered by us	In lieu of shares of common stock, we are offering to certain purchasers pre-funded warrants to purchase shares of common stock. The purchase price of each pre-funded warrant will equal the public offering price per share of common stock, minus \$0.0001, and the exercise price of each pre-funded warrant will be \$0.0001 per share. Each pre-funded warrant may be exercised at any time until all of the pre-funded warrants are exercised in full. For each pre-funded warrant we sell, the number of shares of common stock we are offering will be decreased on a one-for-one basis. This prospectus also relates to the offering of the shares of common stock issuable upon exercise of such pre-funded warrants. See “Description of Securities We Are Offering” on page 124 of this prospectus.
Common stock to be outstanding after this offering	shares, or shares if the underwriter exercises its option to purchase additional shares in full (in each case, assuming we sell only shares of common stock and no pre-funded warrants).
Option to purchase additional shares	We have granted the underwriter an option for a period of 30 days to purchase up to additional shares of our common stock from us at the public offering price, less the underwriting discounts and commissions. The number of shares subject to the underwriter’s option will equal 15% of the total number of shares of common stock we are offering plus the shares of common stock underlying the pre-funded warrants.
Use of proceeds	We estimate the net proceeds from this offering will be approximately \$ million (or approximately \$ million if the underwriter exercises in full its option to purchase up to additional shares of common stock), after deducting underwriting discounts and commissions, estimated offering expenses payable by us and assuming no sale of any pre-funded warrants offered hereunder. We intend to use the net proceeds from this offering for clinical development of our product candidates and for working capital and general corporate purposes. See “Use of Proceeds” on page 64 of this prospectus.
Lock-up restrictions	We, each of our directors and officers, and certain of our affiliated stockholders are subject to certain lock-up restrictions as identified in the section titled “Underwriting — No Sale of Similar Securities.”
Risk factors	You should read the section entitled “Risk Factors” beginning on page 11 and the documents incorporated by reference in this prospectus for a discussion of factors to consider carefully before deciding to invest in our common stock.
Nasdaq Global Market symbol	“CGTX”

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The number of shares of our common stock to be outstanding after this offering is based on 22,597,907 shares of common stock outstanding as of June 30, 2022, and excludes:

- 3,350,614 shares of our common stock issuable upon the exercise of outstanding stock options as of June 30, 2022, with a weighted-average exercise price of \$3.02 per share;
- 2,350,068 shares of our common stock reserved for future issuance under our 2021 Equity Incentive Plan, or 2021 Plan, plus any future increases in the number of shares of common stock reserved for issuance; and
- 209,532 shares of our common stock reserved for future issuance under our Employee Stock Purchase Plan, or ESPP, plus any future increases, including annual automatic evergreen increases, in the number of shares of common stock reserved for issuance under our ESPP.

Except otherwise indicated, the information in this prospectus assumes no exercise of the outstanding options, no exercise of the pre-funded warrants being offered hereby, and no exercise by the underwriter of its option to purchase additional shares of our common stock.

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RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, and those discussed under the section entitled “Risk Factors” contained in our 2021 Annual Report and our 2022 Quarterly Reports, together with other information in this prospectus, the information and documents incorporated by reference herein, and in any free writing prospectus that we have authorized for use in connection with this offering. 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.

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 \$11.7 million and \$7.8 million for the years ended December 31, 2021 and 2020, respectively. As of December 31, 2021, we had an accumulated deficit of \$94.0 million. Our net losses were \$9.6 million and \$1.3 million for the six months ended June 30, 2022 and 2021, respectively. As of June 30, 2022, we had an accumulated deficit of \$103.6 million. Our clinical trials have been funded by approximately \$171.0 million in cumulative non-dilutive grants, awarded primarily by the National Institute of Aging, or NIA, a division of the National Institutes of Health. On October 13, 2021, we closed our initial public offering, or IPO, whereby we received net proceeds of \$37.9 million, excluding net proceeds from the overallotment exercise. On November 12, 2021, we received \$6.3 million of net proceeds resulting from the exercise of the overallotment option. 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.

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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. 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.

We will need substantial additional capital to meet our financial obligations in the future 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 June 30, 2022, we had \$45.8 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 into . 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:

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- 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 supply chain disruptions 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 non-dilutive grants from the NIA, or 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.

We believe the 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 CT1812 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. 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 NIA Grants. Although we have applied for and currently anticipate 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. Such dilutive financings could have an adverse effect on the price of our common stock.

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 certain government agencies. As part of an audit, these agencies may review our performance, cost structures and

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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.

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 may also reprioritize development of certain product candidates and/or certain disease indications due to limited resources.

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 from time to time and the amount of time and 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;

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- 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.

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;

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- 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;
- supply chain disruptions, which may result in clinical site closures, delays to patient enrollment 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

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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.

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

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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:

- supply chain disruptions, which may result in clinical site closures, delays to patient enrollment 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;

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- 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;

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- 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 health conditions;
- 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:

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- 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.

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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, the European Medicines Agency, or 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

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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.

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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. We are also opening additional clinical trial sites in the Netherlands, the Czech Republic and Spain for our SHINE study. 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 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;

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- 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

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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 October 14, 2022, we had 19 full-time and 3 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

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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

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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 schemes intended to cause an unauthorized transfer of funds 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.

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In November 2021 we were the subject of a phishing scheme involving a fraudulent email and wire instructions, resulting in the loss of approximately \$0.5 million in corporate funds. We took immediate action to contain and eradicate the security breach, including the implementation of control enhancements in an effort to prevent a similar situation from occurring again. We also subsequently submitted a claim for the loss under our cyber-security insurance policy whereby we received net proceeds of \$0.5 million. We believe this was an isolated event and do not believe our technology systems have been compromised. While we have not experienced any other losses relating to cyber-attacks or other information security breaches such as the one that occurred in November 2021, there can be no assurance (i) that we will ever recover the funds lost, (ii) that our insurance carriers will honor our claim and make a payment to us under our cyber-security policy, or (iii) that we will not suffer additional losses in the future.

Additionally, 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 that 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.

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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 European Union or the United Kingdom. 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 European Union or United Kingdom 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 European Union or United Kingdom 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.

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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.

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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 U.S. Patent and Trademark Office, or 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

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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 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.

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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, or 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 Food, Drug and Cosmetic Act, or 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 an 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 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.

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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.

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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.

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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,

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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.

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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 stockholders. 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

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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 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

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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.

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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

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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;

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- 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 that 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.

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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 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

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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 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

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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.

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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.

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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

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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, untitled letters, or Form 483s;
- 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.

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system. 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 products. In recent years, Congress has considered reductions in Medicare reimbursement levels for products administered by physicians. The Centers for Medicare & Medicaid Services, or CMS, the agency that administers the Medicare and Medicaid programs, also has authority to revise reimbursement rates and to implement coverage restrictions for some products. Cost reduction initiatives and changes in coverage implemented through legislation or regulation could decrease utilization of and reimbursement for any approved products. While Medicare regulations apply only to drug benefits for Medicare beneficiaries, private payers often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from federal legislation or regulation may result in a similar reduction in payments from private payers.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively the Affordable Care Act substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacts the pharmaceutical industry. The Affordable Care Act is intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against healthcare fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on pharmaceutical and medical device manufacturers, and impose additional health policy reforms. Among other things, the Affordable Care Act expanded manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum Medicaid rebate for both branded and generic products, expanded the 340B program, and revised the definition of average manufacturer price, or AMP, which could increase the amount of Medicaid rebates manufacturers are required to pay to states. The legislation also extended

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Medicaid rebates, previously due only on fee-for-service Medicaid utilization, to include the utilization of Medicaid managed care organizations as well and created an alternative rebate formula for certain new formulations of certain existing products that is intended to increase the amount of rebates due on those products. On February 1, 2016, CMS issued final regulations to implement the changes to the Medicaid Drug Rebate program under the Affordable Care Act. These regulations became effective on April 1, 2016. Since that time, there have been significant ongoing efforts to modify or eliminate the Affordable Care Act. 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 of 1986, as amended, or the Code or the individual mandate.

Other legislative changes have been proposed and adopted since the passage of the Affordable Care Act. The Budget Control Act of 2011, among other things, created the Joint Select Committee on Deficit Reduction, or the Joint Select Committee, to recommend proposals in spending reductions to Congress. The Joint Select Committee did not achieve its targeted deficit reduction of an amount greater than \$1.2 trillion for the fiscal years 2012 through 2021, triggering the legislation's automatic reductions to several government programs. These reductions included aggregate reductions to Medicare payments to healthcare providers of up to 2.0% per fiscal year, which went into effect in April 2013. Subsequent legislation extended the 2% reduction, on average, to 2030 unless additional Congressional action is taken. However, pursuant to the Coronavirus Aid, Relief and Economic Security Act, or CARES Act, the 2% Medicare sequester reductions were suspended from May 1, 2020 through December 31, 2021 due to the COVID-19 pandemic. The sequester will remain in place through 2030. On January 2, 2013, the American Taxpayer Relief Act was signed into law, which, among other things, reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. The Inflation Reduction Act of 2022 contains substantial drug pricing reforms, including the establishment of a drug price negotiation program within the U.S. Department of Health and Human Services that would require manufacturers to charge a negotiated "maximum fair price" for certain selected drugs or pay an excise tax for noncompliance, the establishment of rebate payment requirements on manufacturers of certain drugs payable under Medicare Parts B and D to penalize price increases that outpace inflation, and requires manufacturers to provide discounts on Part D drugs. Substantial penalties can be assessed for noncompliance with the drug pricing provisions in the Inflation Reduction Act of 2022. The Inflation Reduction Act of 2022 could have the effect of reducing the prices we can charge and reimbursement we receive for our products, if approved, thereby reducing our profitability, and could have a material adverse effect on our financial condition, results of operations and growth prospects. The effect of Inflation Reduction Act of 2022 on our business and the pharmaceutical industry in general is not yet known.

The Affordable Care Act, or ACA, 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. 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 but it is unknown what form any such changes or any law proposed to replace or revise 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 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.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

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We expect that additional federal, state and foreign healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in limited coverage and reimbursement and reduced demand for our products, once approved, or additional pricing pressures.

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 Hatch-Waxman Act, a pharmaceutical manufacturer may file an 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 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 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 activities are subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, the federal civil False Claims Act, and laws and regulations pertaining to limitations on and reporting of healthcare provider payments (physician sunshine laws). These laws and regulations are interpreted and enforced by various federal, state and local authorities including CMS, the Office of Inspector General for the U.S. Department of Health and Human Services, the U.S. Department of Justice, individual U.S. Attorney offices within the Department of Justice, and state and local governments. These laws include:

- the U.S. Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order, or arranging for or recommending the purchase, lease or order of, any good or service, for which payment may be made, in whole or in part, under federal healthcare

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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. False Claims Act (which can be enforced through “qui tam,” or whistleblower actions, by private citizens on behalf of the federal government), prohibits any person from, among other things, knowingly presenting, or causing to be presented false or fraudulent claims for payment of government funds or knowingly making, using or causing to be made or used, a false record or statement material to an obligation to pay money to the government or knowingly and improperly avoiding, decreasing or concealing an obligation to pay money to the U.S. federal government;
- HIPAA, which imposes criminal liability and amends provisions on the reporting, investigation, enforcement, and penalizing of 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 by a healthcare benefit program, which includes both government and privately funded benefits programs; 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;
- state laws and regulations, including state anti-kickback and false claims laws, that 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 payer, 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; and 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;
- the Physician Payments Sunshine Act, implemented as the Open Payments program, and its implementing regulations, requires 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 CMS information related to certain payments made in the preceding calendar year and other transfers of value to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; beginning in 2022, applicable manufacturers are required to report such information regarding payments and transfers of value provided, as well as ownership and investment interests held, during the previous year to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives;
- 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).

Violations of any of these laws or any other governmental regulations that may apply to us, may subject us to significant civil, criminal and administrative sanctions including penalties, damages, fines, imprisonment, and exclusion from government funded healthcare programs, such as Medicare and Medicaid, and/or adverse publicity. Moreover, government entities and private litigants have asserted claims under state consumer protection statutes against pharmaceutical companies for alleged false or misleading statements

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in connection with the marketing, promotion and/or sale of pharmaceutical products. 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. 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 unable to predict whether such changes will occur and, if so, the ultimate impact on our business.

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

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 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 supply chain disruptions and the COVID-19 pandemic. These factors include those discussed in this "Risk Factors" section 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;

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- 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.

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 IPO, (b) in which we have total annual gross revenue of at least \$1.07 billion, or (c) in which

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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.

If we sell shares of our common stock in future financings, stockholders may experience 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 cash, cash equivalents and non-dilutive grant funding, will be sufficient for us to fund our operating and capital expenditures into . As a result, we may from time to time issue additional shares of common stock or other securities to raise capital. These issuances may be at a discount from the current trading price of our common stock. Our stockholders would experience 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.

Based upon shares of our common stock outstanding as of June 30, 2022, upon the completion of this offering and giving effect to any purchases in this offering, and assuming no sale of any pre-funded warrants offered hereunder, our executive officers, directors and stockholders who owned more than 5% of our outstanding common stock before this offering will, in the aggregate, beneficially own shares representing % of our outstanding common stock (or % if the underwriter exercises in full its option to purchase additional shares). 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. The concentration of voting power and transfer restrictions could delay or prevent an acquisition of our company on terms that other stockholders may desire or result in the management of our company in ways with which other stockholders disagree.

Additionally, 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.

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that sales may have on the prevailing market price of our common stock. Sales of significant number of shares of our common stock may make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem reasonable or appropriate, and make it more difficult for you to sell shares of our common stock.

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

As of December 31, 2021, we had federal net operating loss, or NOL, carryforwards of approximately \$44.6 million and state NOL carryforwards of approximately \$44.6 million available to offset future taxable income. Of the federal NOL carryforwards, \$26.2 million begin to expire in 2027, and \$18.4 million can be carried forward indefinitely. State NOL carryforwards will begin to expire in 2027. As of December 31, 2021, we had a foreign NOL carryforward of \$1.2 million in Australia that can be carried forward indefinitely. As of December 31, 2021, we also had \$5.0 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. 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 Code. 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 may be outside of 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 Cuts and Jobs Act, or the TCJA, 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, 2021 are limited to 80% of taxable income. Under the TCJA, 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 and temporarily suspends the 80% limitation mentioned above for this period. 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, 2021, 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 third amended and restated certificate of incorporation and amended and restated bylaws each 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 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 66⅔% 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;

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- 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, or the DGCL. 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.

Our third amended and restated certificate of incorporation and amended and restated bylaws 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 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 United States 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 DGCL, 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.

Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. Our third amended and restated certificate of incorporation and amended and restated bylaws, however, 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. The Supreme Court of Delaware has held that this type of exclusive federal forum provision is enforceable. There may be uncertainty, however, as to whether courts of other jurisdictions would enforce this provision, if applicable.

These choice of forum provisions 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 contained in our third 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.

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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.

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. Further, the impacts of political unrest, including as a result geopolitical tension, such as a deterioration in the relationship between the U.S. and China or escalation in conflict between Russia and Ukraine, including any additional sanctions, export controls or other restrictive actions that may be imposed by the U.S. and/or other countries against governmental or other entities in, for example, Russia, also could lead to disruption, instability and volatility in the global markets, which may have an adverse impact on our business or ability to access the capital markets. A severe or prolonged economic downturn, including rises in interest rates, inflation, recession or depression, 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. In particular, in relation to uncertainty around inflation and the U.S. Federal Reserve's measures to slow inflation, the stock market has been exceptionally volatile. 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 may 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 could 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 have incurred, and will continue to 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 have incurred, and will continue to incur, significant legal, accounting and other expenses as a public company, including costs resulting from public company reporting obligations under the Exchange

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Act and regulations regarding corporate governance practices. The listing requirements of the Nasdaq Global Market and the rules of the 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.

We are 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 are 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 have incurred, and will continue to 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 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

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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.

Risks Related to this Offering

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

The public offering price per share of common stock in this offering is higher than the net tangible book value per share of our common stock before giving effect to this offering. Based on an assumed public offering price of \$ _____ per share, which represents the last reported sale price of our common stock on the Nasdaq Global Market on _____, 2022, if you purchase common stock in this offering, you will incur immediate substantial dilution of approximately \$ _____ per share, representing the difference between the assumed public offering price per share of common stock and our as adjusted net tangible book value as of June 30, 2022. For a further description of the dilution that you will experience immediately after this offering, see the section in this prospectus entitled “Dilution.”

There is no public market for the pre-funded warrants being offered in this offering.

There is no established public trading market for the pre-funded warrants being offered in this offering, and we do not expect a market to develop. In addition, we do not intend to apply to list these pre-funded warrants on the Nasdaq Global Market or any other national securities exchange or nationally recognized trading system. Without an active market, the liquidity of these pre-funded warrants will be limited.

Holders of pre-funded warrants purchased in this offering will have no rights as common stockholders until such holders exercise their warrants and acquire our common stock, except as otherwise provided in the pre-funded warrants.

Until holders of pre-funded warrants acquire shares of our common stock upon exercise of such warrants, the holders will have no rights with respect to the shares of our common stock underlying such warrants, except to the extent that holders of such warrants will have certain rights to participate in distributions or dividends paid on our common stock as set forth in such warrants. Upon exercise of the pre-funded warrants, the holders will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs after the exercise date.

A substantial number of shares of common stock may be sold in the market following this offering, which may depress the market price for our common stock.

Sales of a substantial number of shares of our common stock in the public market following this offering could cause the market price of our common stock to decline. A substantial majority of the outstanding shares of our common stock are, and the shares of common stock offered hereby will be, freely tradable without restriction or further registration under the Securities Act.

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 net proceeds from this offering, and we could spend the net 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 ongoing Phase 2 trials of CT1812 for the treatment of mild-to-moderate AD and DLB, our planned Phase 2 clinical 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, including costs and expenses associated with being a public company. However, our use of these net proceeds may differ substantially from our current plans. If we do not invest or apply the net 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.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, including the information incorporated by reference into this prospectus, contains forward-looking statements about us and our industry that involve substantial risks and uncertainties. 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;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- the clinical nature of our business and our ability to successfully advance our current and future product candidates through our ongoing 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 and our existing cash and cash equivalents and the sufficiency of such resources to fund our planned operations;
- our expectations regarding geopolitical tensions, such as Russia’s war with Ukraine, on our business, our industry and the economy;
- 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 investigational new drug, or 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;

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- 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;
- economic uncertainty resulting from actual or perceived inflation; and
- developments relating to our competitors and our industry.

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 entitled “Risk Factors” in this prospectus and the risk factors set forth in the documents incorporated by reference 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 incorporated by reference in this prospectus 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.

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USE OF PROCEEDS

We estimate that the net proceeds to us from this offering will be approximately \$ million (or approximately \$ million if the underwriter exercises in full its option to purchase up to additional shares of common stock), based on an assumed public offering price of \$ per share, which was the last reported sale price per share of our common stock on the Nasdaq Global Market on , 2022, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us and assuming no sale of any pre-funded warrants offered hereunder.

We intend to use the net proceeds of this offering for clinical development of our product candidates and for working capital and other general corporate purposes. We may also use a portion of the net proceeds from this offering to in-license, acquire or invest in complementary businesses, technologies, products or assets. Although we currently have no agreements, commitments or obligations to do so, we evaluate such opportunities and engage in related discussions with third parties from time to time.

Each \$1.00 increase or decrease in the assumed public offering price of \$ per share, the last reported sale price per share of our common stock on the Nasdaq Global Market on , 2022, would increase or decrease the net proceeds to us from this offering by \$ million, assuming that the number of shares of common stock and pre-funded warrants offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase or decrease of 1.0 million shares of common stock (or common stock underlying pre-funded warrants) offered by us, would increase or decrease the net proceeds to us by \$ million, assuming the assumed public offering price per share remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Our expected use of the net proceeds from this offering represents our intentions based upon our current plans and business conditions. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering or the amounts that we will actually spend on the uses set forth above. The amounts and timing of our actual expenditures and the extent of our preclinical, clinical and future development activities may vary significantly depending on numerous factors, including the progress of our development efforts, the status of and results from our ongoing and planned clinical trials, our ability to take advantage of expedited programs or to obtain regulatory approval for product candidates, the timing and costs associated with the manufacture and supply of product candidates for clinical development or commercialization and any unforeseen cash needs. As a result, our management will retain broad discretion over the allocation of the net proceeds from this offering.

Pending the use of the net proceeds from this offering as described above, we intend to invest the net proceeds in a variety of capital preservation instruments, including short-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government.

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DIVIDEND POLICY

We have never declared or paid cash dividends on our capital stock, and we do not currently intend to pay any cash dividends on our capital stock in the foreseeable future. We currently intend to retain all available funds and any future earnings, if any, to fund the development and expansion of our business.

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CAPITALIZATION

The following table sets forth our cash and our capitalization as of June 30, 2022 on:

- an actual basis; and
- a pro forma basis, giving further effect to the sale of _____ shares of our common stock in this offering (assuming no sale of pre-funded warrants offered hereunder) at an assumed public offering price of \$ _____ per share, which was the last reported sale price of our common stock on the Nasdaq Global Market on _____, 2022, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Our capitalization following the closing of this offering will be adjusted based on the actual public offering price and other terms of this offering determined at pricing. You should read this information together with our financial statements and the related notes included in our 2021 Annual Report and our 2022 Quarterly Reports and incorporated by reference in this prospectus, and the section of this prospectus entitled “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

(in thousands, except share and per share amounts)	As of June 30, 2022	
	Actual	Pro Forma
Cash and cash equivalents	\$ 45,771	\$ _____
Stockholders’ equity		
Common stock, par value \$0.001 per share; 250,000,000 shares authorized at June 30, 2022; 22,597,907 shares issued and outstanding, actual; _____ shares issued and outstanding, pro forma	22	
Additional paid-in capital	147,671	
Accumulated deficit	(103,594)	
Accumulated other comprehensive loss	(200)	\$ _____
Total stockholders’ equity	\$ 43,899	\$ _____
Total capitalization	\$ 43,899	\$ _____

Each \$1.00 increase or decrease in the assumed public offering price of \$ _____ per share, which was the last reported sale price of our common stock on the Nasdaq Global Market on _____, 2022, would increase or decrease each of pro forma cash, additional paid-in capital, total stockholders’ equity and total capitalization by \$ _____ million, 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 estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase or decrease of 1.0 million shares of common stock offered by us would increase or decrease each of pro forma cash, additional paid-in capital, total stockholders’ equity and total capitalization by \$ _____ million, assuming that the assumed public offering price remains the same, and after deducting estimated underwriting discounts and commissions.

The foregoing discussion and tables above are based on 22,597,907 shares of common stock outstanding as of June 30, 2022, and excludes:

- 3,350,614 shares of our common stock issuable upon the exercise of outstanding stock options as of June 30, 2022, with a weighted-average exercise price of \$3.02 per share;
- 2,350,068 shares of our common stock reserved for future issuance under the 2021 Plan, as well as any future increases in the number of shares of common stock reserved for issuance under the 2021 Plan; and
- 209,532 shares of our common stock reserved for future issuance under our ESPP, as well as any future increases in the number of shares of common stock reserved for issuance under our ESPP.

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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 public offering price per share of our common stock and the as adjusted net tangible book value per share of our common stock after this offering.

Our historical net tangible book value as of June 30, 2022 was \$43.9 million, or \$1.94 per share of our common stock. Our historical net tangible book value represents our total tangible assets less total liabilities. Historical net tangible book value per share is our historical net tangible book value divided by the number of shares of our common stock outstanding as of June 30, 2022.

After giving effect to the sale of _____ shares of our common stock to purchase shares of our common stock in this offering at an assumed public offering price of \$ _____ per share, which was the last reporting sale price of our common stock on the Nasdaq Global Market on _____, 2022, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us, and assuming no sale of any pre-funded warrants, our as adjusted net tangible book value as of June 30, 2022 would have been \$ _____ million, or \$ _____ per share. This represents an immediate increase in 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 public offering price per share	\$ _____
Historical net tangible book value per share as of June 30, 2022	\$ 1.94
Increase in net tangible book value per share as of June 30, 2022 attributable to investors purchasing in this offering	_____
As adjusted net tangible book value per share as of June 30, 2022 after giving effect to this offering	_____
Dilution per share to new investors participating in this offering	\$ _____

Each \$1.00 increase or decrease in the assumed public offering price of \$ _____ per share, the last reported sale price of our common stock on the Nasdaq Global Market on _____, 2022, would increase or decrease our 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 estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, an increase of 1.0 million shares of common stock offered by us would increase the 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 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 public offering price remains the same, and after deducting estimated underwriting discounts and commissions.

If the underwriter exercises in full its option to purchase up to _____ additional shares of common stock from us, the as adjusted net tangible book value per share after giving effect to this offering would be \$ _____ per share and dilution to new investors participating in this offering of \$ _____ per share.

The foregoing discussion and tables above are based on 22,597,907 shares of common stock outstanding as of June 30, 2022, and excludes:

- 3,350,614 shares of our common stock issuable upon the exercise of outstanding stock options as of June 30, 2022, with a weighted-average exercise price of \$3.02 per share;
- 2,350,068 shares of our common stock reserved for future issuance under the 2021 Plan, as well as any future increases in the number of shares of common stock reserved for issuance under the 2021 Plan; and

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- 209,532 shares of our common stock reserved for future issuance under our ESPP, as well as any future increases in the number of shares of common stock reserved for issuance under our ESPP.

To the extent that any outstanding options are exercised, new options or other equity awards are issued under our equity incentive plans, or we issue additional shares in the future, there will be further dilution to new investors participating in this offering.

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

The following discussion should be read in conjunction with our financial statements and related notes thereto incorporated by reference into this prospectus. In addition to historical information, this discussion contains forward-looking statements that involve risks, uncertainties and assumptions that could cause actual results to differ materially from management’s expectations. Factors that could cause such differences are discussed in the sections titled “Special note regarding forward-looking statements” and “Risk factors.” We are not undertaking any obligation to update any forward-looking statements or other statements we may make in the following discussion or elsewhere in this prospectus even though these statements may be affected by events or circumstances occurring after the forward-looking statements or other statements were made. Therefore, no reader of this document should rely on these statements being current as of any time other than the time at which this document is declared effective by the SEC.

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 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 June 30, 2022, we had an accumulated deficit of \$103.6 million. We incurred a net loss of \$9.6 million and \$1.3 million for the six months ended June 30, 2022 and 2021, 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, or NIH, and proceeds from our initial public offering, or IPO, the sales of convertible promissory notes, convertible preferred stock, simple agreements for future equity, or SAFEs, and stock option exercises. Since our inception, we have received approximately \$171.0 million in cumulative grant awards to fund our clinical trials, primarily from the NIA. As of June 30, 2022, we have raised approximately \$102.0 million in net proceeds from sales of our equity securities, convertible notes, SAFEs, stock option exercises, and our IPO. As of June 30, 2022, we had cash and cash equivalents of \$45.8 million.

On October 13, 2021, we completed our IPO, pursuant to which we issued and sold 3,768,116 shares of our common stock at a public offering price of \$12.00 per share. Additionally, on November 12, 2021, the underwriters exercise of their over-allotment option in full to purchase 565,217 shares of our common stock closed. In connection with the IPO, we received net proceeds of approximately \$44.2 million, after deducting underwriting discounts and commissions and other offering related expenses payable by us, which includes net proceeds of approximately \$6.3 million from the exercise of the over-allotment option.

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.

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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 or arrangements 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 ongoing COVID-19 pandemic, including, but not limited to, our clinical trials. 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, including the spread of new strains and variants of COVID-19, and actions taken to reduce such 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

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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.

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 our IPO on October 13, 2021, we have incurred, and will continue to 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 SEC, 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

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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, 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. As of June 30, 2022, the Company has been awarded grants with project periods that extend through May 31, 2025, subject to extension. Our clinical trials have been funded by approximately \$168.9 million in cumulative grants awarded primarily by the NIA, which includes an approximately \$81.0 million grant from the NIA to fund our Phase 2 (COG0203) study of CT1812 in patients with early-stage AD, an approximately \$30.5 million grant from the NIA to fund our Phase 2 (COG0201) study of CT1812 in patients with mild to moderate AD, and an approximately \$29.5 million grant from the NIA to fund our Phase 2 (COG1201) study of CT1812 in patients with dementia with lewy bodies.

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. The derivative liability expired unexercised upon the conversion of the convertible notes into Series B-1 convertible preferred stock in May 2021.

Change in Fair Value of SAFEs

Change in fair value of our SAFEs consist of fair value adjustments to these instruments based primarily on the changes in the probability of occurrence and estimated timing of future event inputs in the valuation model. Upon the closing of our IPO on October 13, 2021, the SAFEs were converted into 931,485 shares of our common stock.

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 (Expense) Income, Net

Other (expense) 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 Six Months Ended June 30, 2022 and 2021

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

	Six Months Ended June 30,		
(in thousands)	2022	2021	Change
Consolidated Statements of Operations Data:			
Operating Expenses:			
Research and development	\$ 15,616	\$ 9,324	\$ 6,292
General and administrative	6,010	2,243	3,767
Total operating expenses	21,626	11,567	10,059
Loss from operations	(21,626)	(11,567)	(10,059)

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(in thousands)	Six Months Ended June 30,		Change
	2022	2021	
Other income (expense):			
Grant income	12,289	9,338	2,951
Change in the fair value of the derivative liability	—	2,209	(2,209)
Change in the fair value of SAFEs	—	(1,044)	1,044
Other (expense) income, net	(237)	248	(485)
Gain on debt extinguishment	—	443	(443)
Interest expense, net	(16)	(894)	878
Total other income, net	12,036	10,300	1,736
Loss before income taxes	(9,590)	(1,267)	(8,323)
Net loss	<u>\$ (9,590)</u>	<u>\$ (1,267)</u>	<u>\$ (8,323)</u>

Research and Development Expenses

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

	Six Months Ended June 30,		Change
	2022	2021	
Clinical programs	\$ 9,050	\$1,684	\$ 7,366
Personnel	3,362	1,936	1,426
Manufacturing	2,061	4,719	(2,658)
Preclinical programs	1,036	926	110
Facilities and other costs	107	59	48
	<u>\$15,616</u>	<u>\$9,324</u>	<u>\$ 6,292</u>

Research and development expenses were \$15.6 million for the six months ended June 30, 2022, compared to \$9.3 million for the six months ended June 30, 2021. The increase of \$6.3 million was primarily due to the following:

- an increase of \$7.4 million in clinical programs related to increased Phase 2 trial activity primarily due to increased contract research organization spend;
- an increase of \$1.4 million in personnel costs associated with expanded research and development activities, and equity-based compensation expense;
- a decrease of \$2.6 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 due to the timing of the manufacturing of the pre-clinical and clinical trial materials; and
- an increase of \$0.1 million in preclinical programs due to increased sponsored research spend under grants.

General and Administrative Expenses

General and administrative expenses were \$6.0 million for the six months ended June 30, 2022, compared to \$2.2 million for the six months ended June 30, 2021. The increase of \$3.8 million was primarily due to:

- an increase of \$0.9 million in Director & Officer liability insurance and other expenses;
- an increase of \$0.4 million in compensation driven by increased headcount;

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- an increase of \$0.8 million in professional fees driven by increased audit, tax, and legal services; and
- an increase of \$1.4 million in equity-based compensation from stock option grants.

Other Income (Expense)

Grant Income

Grant income was \$12.3 million for the six months ended June 30, 2022, compared to \$9.3 million for the six months ended June 30, 2021. The change in grant income is correlated with the increase in eligible reimbursable costs incurred during 2022 as compared to 2021.

Change in Fair Value of the Derivative Liability

Changes in the fair value derivative liability resulted in a gain of \$2.2 million for the six months ended June 30, 2021. There was no gain or loss for the six months ended June 30, 2022 as the derecognition of the derivative liability occurred in May 2021 upon the conversion of convertible notes into shares of Series B-1 convertible preferred stock.

Change in Fair Value of the SAFEs

Changes in the fair value of the SAFEs resulted in a loss of \$1.0 million for the six months ended June 30, 2021. There was no change in the fair value for the six months ended June 30, 2022 as the derecognition of the SAFE liability occurred when the SAFEs converted into shares of our common stock upon the closing of our IPO.

Other Income (Expense), Net

Other expense, net was \$0.2 million for the six months ended June 30, 2022, compared to other income, net of \$0.2 million for the six months ended June 30, 2021. Overall, management believes that the change in other expense was not significant in either period.

Gain on Debt Extinguishment

There was no gain or loss on debt extinguishment for the six months ended June 30, 2022. Gain on debt extinguishment was \$0.4 million for the six months ended June 30, 2021 as a result of the forgiveness of the Paycheck Protection Program loan on January 21, 2021.

Interest Expense, Net

Interest expense, net was less than \$0.1 million for the six months ended June 30, 2022, compared to interest expense, net of \$0.9 million for the six months ended June 30, 2021. The change of \$0.9 million in interest expense, net was the result of the convertible notes outstanding balance during the six months ended June 30, 2021, which were subsequently converted into shares of our Series B-1 convertible preferred stock in May 2021.

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Comparison of the Years Ended December 31, 2021 and 2020

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

	Year Ended December 31,		
(in thousands)	2021	2020	Change
Consolidated Statements of Operations Data:			
Operating Expenses:			
Research and development	\$ 18,572	\$ 12,887	\$ 5,685
General and administrative	10,026	4,520	5,506
Total operating expenses	28,598	17,407	11,191
Loss from operations	(28,598)	(17,407)	(11,191)
Other income (expense):			
Grant income	17,447	10,855	6,592
Change in the fair value of the derivative liability	2,209	18	2,191
Change in the fair value of the warrant liability	—	181	(181)
Change in the fair value of the Simple Agreements for Future Equity	(2,236)	—	(2,236)
Other (expense) income, net	(88)	394	(482)
Gain (loss) on debt extinguishment	443	(129)	572
Interest expense, net	(893)	(1,751)	858
Total other income, net	16,882	9,568	7,314
Net loss	\$ (11,716)	\$ (7,839)	\$ (3,877)

Research and Development Expenses

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

	Year Ended December 31,		Change
	2021	2020	
Clinical programs	\$ 4,679	\$ 5,263	\$ (584)
Personnel	4,882	4,026	856
Manufacturing	7,465	1,798	5,667
Preclinical programs	1,426	1,693	(267)
Facilities and other costs	120	107	13
	<u>\$18,572</u>	<u>\$12,887</u>	<u>\$5,685</u>

Research and development expenses were \$18.6 million for the year ended December 31, 2021, compared to \$12.9 million for the year ended December 31, 2020. The increase of \$5.7 million was primarily due to the following:

- a decrease of \$0.6 million in clinical programs related to delays due to COVID 19, resulting in timing and scope changes to clinical studies; and
- an increase of \$0.9 million in personnel costs due to increased salaries and bonus expense, increased headcount associated with expanded research and development activities, and equity-based compensation expense; and
- an increase of \$5.7 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

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- a decrease of \$0.3 million in preclinical programs due to decreased sponsored research spend under grants.

General and Administrative Expenses

General and administrative expenses were \$10.0 million for the year ended December 31, 2021, compared to \$4.5 million for the year ended December 31, 2020. The increase of \$5.5 million was primarily due to the following:

- an increase of \$0.5 million in insurance and employee benefits primarily due to the addition of director and officer liability insurance; and
- an increase of \$1.0 million in professional fees driven by increased audit, tax, valuation and legal services; and
- an increase of \$4.0 million in equity-based compensation primarily driven by option grants made subsequent to the IPO.

Other Income (Expense)

Grant Income

Grant income was \$17.4 million for the year ended December 31, 2021, compared to \$10.9 million for the year ended December 31, 2020. The change in grant income is correlated with the increase in eligible reimbursable costs incurred during 2021 as compared to 2020.

Change in Fair Value of the Derivative Liability

Changes in the fair value derivative liability resulted in a gain of \$2.2 million for the year ended December 31, 2021, compared to a gain of less than \$0.1 million for the year ended December 31, 2020. The increase in the gain recorded for the year ended December 31, 2021 relates to the derecognition of the derivative liability in May 2021 upon the conversion of the convertible notes into Series B-1 convertible preferred stock at that time.

Change in Fair Value of the Warrant Liability

Changes in the fair value of warrant liabilities resulted in no gain or loss for the year ended December 31, 2021, compared to a gain of \$0.2 million for the year ended December 31, 2020. The decrease of \$0.2 million was due to the expiration of warrants to purchase Series A-1 preferred stock in October 2020.

Change in Fair Value of the SAFEs

Changes in the fair value of the SAFEs resulted in a loss of \$2.2 million for the year ended December 31, 2021. There was no change in fair value for the year ended December 31, 2020 as the SAFEs were entered into in March 2021. The change in fair value was primarily driven by the conversion of the SAFE into common shares and the associated discount applied upon the occurrence of the IPO on October 7, 2021.

Other (Expense) Income, Net

Other expense, net was less than \$0.1 million for the year ended December 31, 2021, compared to other income, net of \$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 \$0.4 million.

Gain (Loss) on Debt Extinguishment

Gain on debt extinguishment was \$0.4 million for the year ended December 31, 2021, compared to a loss on debt extinguishment of \$0.1 million for the year ended December 31, 2020. The 2020 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 2021 gain was the result of the forgiveness of the Paycheck Protection Program loan on January 21, 2021.

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Interest Expense, Net

Interest expense, net was \$0.9 million for the year ended December 31, 2021 compared to interest expense, net of \$1.8 million for the year ended December 31, 2020. The change of \$0.9 million in interest expense, net was the result of a higher overall convertible note balance during 2020.

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, SAFEs, stock option exercises, and our IPO. Since our inception, we have received grant awards primarily from the NIA in the aggregate amount of approximately \$171.0 million. As of June 30, 2022, we have raised approximately \$102.0 million in net proceeds from sales of our equity securities, convertible notes and SAFEs, stock option exercises, and our IPO. 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. On October 13, 2021, we closed our IPO, selling 3,768,116 shares of our common stock at a public offering price of \$12.00 per share. Additionally, on November 12, 2021, the underwriters exercise of their over-allotment option to purchase 565,217 shares of our common stock closed. The net proceeds were approximately \$44.2 million, after deducting underwriting discounts and commissions and other offering related expenses payable by the Company, which includes net proceeds of approximately \$6.3 million from the exercise of the over-allotment option. As of June 30, 2022, we had \$45.8 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 into . 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.

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 diseases, global or political instability, such as the ongoing conflict between Ukraine and Russia, inflation, 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;

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- 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 or other diseases, the ongoing conflict between Ukraine and Russia, inflation, 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.

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Cash Flows

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

	Six Months Ended June 30,	
	2022	2021
Cash flows used in operating activities	\$(8,345)	\$(1,682)
Cash flows used in investing activities	(138)	—
Cash flows (used in) provided by financing activities	(465)	7,801
Effect of exchange rate changes on cash and cash equivalents	(2)	(8)
Net (decrease) increase in cash and cash equivalents	<u>\$(8,950)</u>	<u>\$ 6,111</u>

Operating Activities

Net cash used in operating activities for the six months ended June 30, 2022 was \$8.3 million, which consisted primarily of our net loss of \$9.6 million, offset by the impact of equity-based compensation of \$1.9 million and a net change of \$0.8 million in our operating assets and liabilities. The net change in our operating assets and liabilities was primarily due to an increase in grant receivables of \$1.5 million, an increase in other assets of \$1.3 million, offset by an increase in other noncurrent liabilities of \$1.7 million, and an increase in deferred grant income of \$0.5 million.

Net cash used in operating activities for the six months ended June 30, 2021 was \$1.7 million, which consisted primarily of our net loss of \$1.3 million as well as net non-cash gains of \$1.0 million and a net change of \$0.6 million in our operating assets and liabilities. The net non-cash gains primarily consisted of amortization of debt discounts of \$0.4 million, change in derivative liabilities of \$2.2 million, change in fair value of the SAFEs of \$1.0 million, a gain on debt extinguishment of \$0.4 million, and equity-based compensation of \$0.2 million. The net change in our operating assets and liabilities was primarily due to an increase in grant receivables of \$1.7 million, an increase in prepaid expenses and other current assets of \$0.3 million, a decrease in other receivables of \$0.3 million, an increase in accounts payable of \$0.4 million, an increase in accrued expenses of \$1.3 million, and an increase in other current liabilities of \$0.5 million.

Net cash used in operating activities for the year ended December 31, 2021 was \$3.6 million, which consisted primarily of our net loss of \$11.7 million partially offset by net non-cash charges of \$5.2 million and a net change of \$2.8 million in our operating assets and liabilities. The non-cash charges primarily consisted of depreciation and amortization of \$0.1 million, amortization of debt discount of \$0.4 million, change in fair value of SAFE of \$2.2 million, and equity-based compensation of \$5.1 million, partially offset by a change in the fair value of the derivative liability of \$2.2 million. The net change in our operating assets and liabilities was primarily due to an increase in accounts payable of \$2.2 million, an increase in accrued expenses of \$1.3 million, and an increase in other current liabilities of \$0.5 million, partially offset by an increase in grant receivables of \$1.2 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 and liabilities. 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.

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Investing Activities

Net cash used in investing activities for the six months ended June 30, 2022 was \$0.1 million related to purchases of fixed assets. We did not use any cash for investing activities for the six months ended June 30, 2021.

During the years ended December 31, 2021 and 2020, we used less than \$0.1 million of cash, respectively, for investing activities related to purchases of property and equipment.

Financing Activities

Net cash used in financing activities was \$0.5 million for the six months ended June 30, 2022, and net cash provided by financing activities was \$7.8 million for the six months ended June 30, 2021. The decrease in cash relates primarily to the \$8.9 million of SAFEs issued during the six months ended June 30, 2021.

Net cash provided by financing activities was \$53.2 million and \$5.8 million for the years ended December 31, 2021 and 2020, respectively. The increase in cash provided by financing activities in 2021 relates primarily to proceeds received in connection with the IPO in the amount of \$44.2 million.

Contractual Obligations

The following table summarizes our contractual obligations as of June 30, 2022 (in thousands):

	Less than 1 Year	1 to 3 Years	3 to 5 Years	More than 5 years	Total
Operating lease obligations:	\$ 149	\$ 193	\$ 170	\$ 191	\$ 703
Total:	\$ 149	\$ 193	\$ 170	\$ 191	\$ 703

We have entered into operating leases for office and laboratory facilities under agreements that run through May 31, 2029. The amounts reflected in the table above consist of the future minimum lease payments under the non-cancelable lease arrangements.

On July 1, 2021, we entered into an agreement to lease 2,864 square feet of office space in Purchase, New York. The lease has a term of 89 months and commenced on December 9, 2021. The annual base rent under the lease is less than \$0.1 million for the first lease year and is subject to annual increases of between 1.82% and 2.04%. We provided a security deposit in the form of a Letter of Credit in the amount of less than \$0.1 million pursuant to the terms of the lease.

In addition, in October 2021, we entered into an insurance premium financing arrangement with a lender. Under the agreement, we financed \$1.5 million of certain premiums at a 3.25% annual interest rate. Payments of \$0.1 million are due monthly from October 2021 through September 2022. As of June 30, 2022, the outstanding principal of the loan was \$0.4 million.

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,

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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.* Up until October 13, 2021, the Company was privately held and did not have a trading history of common stock. As such, 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. The Company will continue to derive expected volatility from average historical stock volatilities of industry peers until the Company has compiled a trading history of its own for a sufficient period of time.
- *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.* Prior to the IPO, the fair value of the shares of common stock underlying the stock-based awards had historically been determined by the board of directors with input from management. Because there was 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. Subsequent to the IPO, the board of directors will determine the fair value of the shares of common stock underlying the stock-based awards based off of the closing price as reported on the Nasdaq Stock Market LLC on the grant date.

See Note 7 to our consolidated financial statements included in our Quarterly Report on Form 10-Q for the six months ended June 30, 2022 incorporated by reference into this prospectus and elsewhere 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.

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As of June 30, 2022, the total unrecognized compensation expense related to unvested time-based vesting awards was \$9.0 million, which is expected to be recognized over weighted-average remaining vesting period of approximately 2.5 years.

Recent Accounting Pronouncements

See Note 2 to our consolidated financial statements included in our Quarterly Report on Form 10-Q for the six months ended June 30, 2022 incorporated by reference into this prospectus and elsewhere for more information about recent accounting pronouncements, the timing of their adoption, and our assessment, to the extent we have made one yet, of their potential impact on our financial condition of results of operations.

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 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 our IPO.

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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 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 modulator 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. We believe our evidence demonstrates that by binding to the S2R complex, CT1812 displaces A β oligomers from their neuronal receptors. Based on this mechanism, we believe CT1812 has the potential to slow the loss of synapses and cognitive decline observed in AD. CT1812 is the first S2R selective ligand modulator 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 U.S. 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 three ongoing Phase 2 clinical trials with CT1812: SHINE and SEQUEL in mild-to-moderate AD and SHIMMER in dementia with Lewy bodies, or DLB. 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 monomers 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 completing enrollment in 2023 with top-line data in early 2024. Our ongoing SEQUEL Phase 2 clinical trial is also evaluating changes in brain function, as measured by quantitative electroencephalography, or qEEG, in mild-to-moderate AD, and we anticipate completing enrollment in 2022 and reporting topline data thereafter. We have treated 221 subjects with CT1812 in our clinical trials to date including 90 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 \$171.0 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 Phase 2 START (COG0203) study of CT1812 in patients with early stage AD. We intend to enroll 540 patients in our START trial with mild cognitive impairment, or MCI, due to AD or mild AD who have elevated levels of A β oligomers as determined by a clinical diagnosis of AD confirmed with amyloid biomarkers' positron emission tomography, or PET, imaging and/or cerebrospinal fluid, or CSF, biomarkers. 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 SB, 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 are conducting 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 open sites by the end of 2022.

We intend to expand our CT1812 pipeline to include additional indications such as dry age-related macular degeneration, or dry AMD, an eye 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













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epithelial cells, or RPE, photoreceptors and retinal ganglion cells. We believe that an S2R modulator, such as CT1812, may help to regulate the damage-response processes related to these cells that are impaired in dry AMD. We have completed a pre-IND meeting with the FDA, and, after the completion of our ongoing preclinical studies, we intend to submit an Investigational New Drug, or IND, application to the FDA by the end of 2022, after which we plan to advance into a Phase 2 clinical trial, leveraging our knowledge of CT1812's preclinical and clinical profile to date.

In addition, we are developing 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 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	Funding
CT1812	SEQUEL Mild-moderate AD					\$5.4M 
CT1812	SHINE Mild-moderate AD					\$30M 
CT1812	SHIMMER DLB					\$30M 
CT1812	START Early-stage AD					\$81M 
CT1812	Dry AMD					
CT2168	Synucleinopathies					
CT2074	Dry AMD					

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 oligomer, 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 144 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-SB, ADAS-Cog and volume magnetic resonance imaging, or MRI, we intend to use a variety of biomarkers to measure target and/or pathway engagement and assess changes in neurodegeneration and disease progression. We expect to open sites by the end of 2022. This trial has been funded by a grant of approximately \$81.0 million from the NIA.

DLB

We are evaluating 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 are assessing cognitive and functional measures such as Montreal Cognitive Assessment (MoCA), Cognitive Drug Research Battery (CDR), Clinician

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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 are currently evaluating sites to commence our trial. 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 modulator, such as CT1812, may help to regulate the damage-response processes related to these cells that are impaired in dry AMD. We have completed a pre-IND meeting with the FDA, and, after the completion of our ongoing preclinical studies, we intend to submit an IND application to the FDA by the end of 2022, after which we plan to advance into a Phase 2 clinical trial, leveraging our knowledge of CT1812's preclinical and clinical profile to date. We are evaluating candidates for synucleinopathies and dry AMD as potential IND candidates.

Discovery Initiatives

We are pursuing 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. A few of these next-generation S2R modulators have been identified for synucleinopathies and dry AMD and are being assessed as potential IND candidates.

For example, one of our next-generation S2R modulators, CT2074, 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 are evaluating CT1812 in other AD populations as well and developing CT1812 for patients with earlier symptomatic stages of AD and MCI, which is a slight and noticeable measurable decline in cognitive abilities due to AD. Our START (COG0203) clinical trial in patients with mild dementia associated with early stage AD 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, an 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 modulator, such as CT1812, may help to regulate the damage-response processes related to these cells that are impaired in dry AMD. We have completed a pre-IND meeting with the FDA, and, after the completion of our ongoing preclinical studies, we intend to submit an IND application to the FDA by the end of 2022, after which we plan to advance into a Phase 2 clinical trial, leveraging our knowledge of CT1812's preclinical and clinical profile to date.

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- ***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. We are initiating a study of CT1812 in patients with DLB and are currently recruiting for patients at approximately 17 sites, with more expected to follow. 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 in a well-controlled Phase 2 clinical trial.
- ***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 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 research and clinical efforts have been funded by approximately \$171.0 million in cumulative grants awarded primarily by the NIA. This includes awards totaling \$10.9 million in support of preclinical studies and \$160.1 million for clinical development, the largest of which was the 2020 award of \$81.0 million supporting our upcoming Phase 2 START (COG0203) study of CT1812 in 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. 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 \$171.0 million in cumulative grants awarded 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 modulators, such

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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.

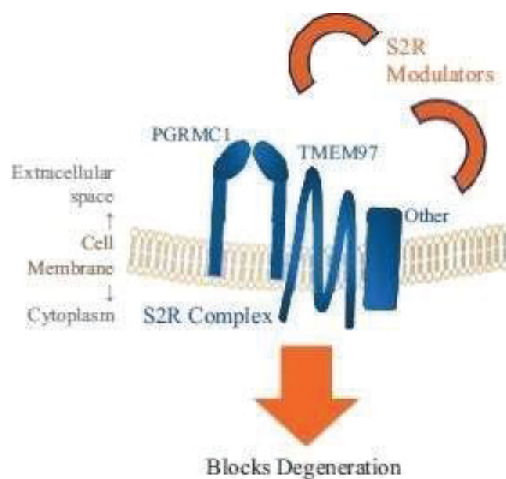
Based on this expertise, we are able to discover and optimize small molecule receptor modulators like CT1812 that we believe represent a functionally distinct and promising approach to synaptorestorative AD therapeutics where neurons remain viable and functional. These molecules were designed to displace 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 modulator, such as CT1812, may help to regulate the damage-response processes related to these cells that are impaired in dry AMD. We have completed a pre-IND meeting with the FDA and, after the completion of our ongoing preclinical studies, we intend to submit an IND application to the FDA by the end of 2022, after which we plan to advance into a Phase 2 clinical trial, leveraging our knowledge of CT1812's preclinical and clinical profile to date. 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.

The sigma-2 receptor (S2R) complex



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

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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 modulators 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 a 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 predicative 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.

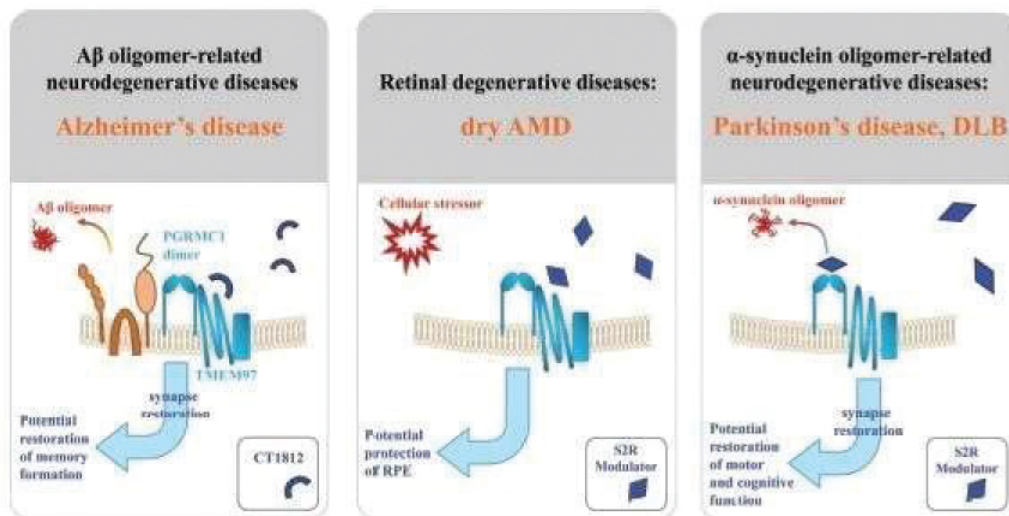
The candidate library produced by the NICE screening platform is predisposed to compounds with attractive drug-like properties such as low molecular weight, low number of reactive hydrogen bonds, lipophilicity and relatively neutral chemistry properties. These characteristics reduce the reactivity of 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,

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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 modulator 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.

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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 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.

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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

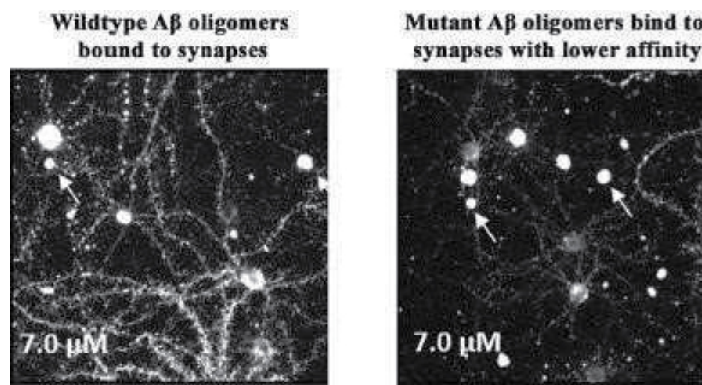
We believe the benefit of the mechanism by which CT1812 stops the toxic impact of A β oligomers on cellular function is further supported by an analysis of the A β sequence variant, A673T, which is commonly referred to as the “Icelandic” mutation. The A673T mutation is the first variant associated with 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.

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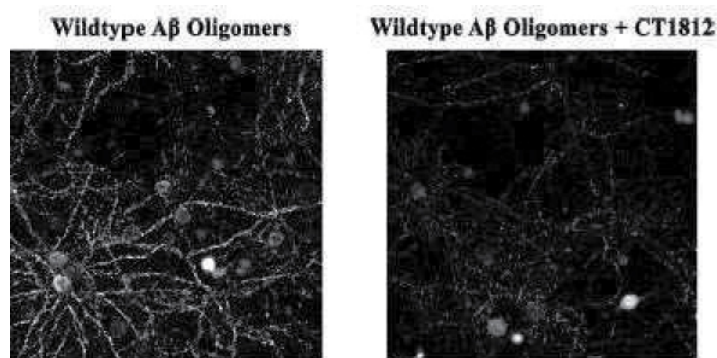
**Binding affinities of wildtype versus mutant A β oligomers to synapses
(intensity in arbitrary fluorescent units)**

	Kd (nM)	B maxa
wt A β (1 – 42) oligomers	Site 1:442 \pm 70	$7.98 \times 105 \pm 0.29 \times 105$
A673T mutant A β (1 – 42) oligomers	Site 1:1,955 \pm 502	$5.98 \times 105 \pm 0.50 \times 105$

Kd is a constant used to evaluate and rank the strengths of interactions for ligands and their receptors. The smaller the Kd value, the greater the binding affinity. Bmax 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 Trials in AD and DLB

We have completed six clinical trial evaluations of CT1812, in both healthy volunteers and patients with mild-to-moderate AD, with three clinical trials ongoing and one additional trial with topline results currently available and final results expected by the end of 2022. The clinical trials we have conducted to date have enabled us to evaluate the safety profile of CT1812, as well as validate its mechanism through proof-of-concept trials and conduct initial assessments of its therapeutic potential. The following is the status of our completed and ongoing clinical trials.

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Overview of our completed, ongoing and planned clinical studies

	Proof of Concept / Mechanism				Impact on Disease Pathology		
Study	COG0102 (n=19)	SNAP COG0104 (n=3)	SPARC COG0105 (n=23)	SEQUEL COG0202 (n=16)	SHINE COG0201 (n=144)	START COG0203 (n=540)	SHIMMER COG1201 (n=120)
Population	Mild-to-Moderate Alzheimer's				Mild-to-Moderate Alzheimer's	Early Alzheimer's	Mild-to-Moderate DLB
Status	Completed 2018	Completed 1H2021	Topline results 1H2021	Ongoing Enrollment expected to conclude 4Q2022	Ongoing	Site selection underway	Ongoing
Results	Well tolerated	Evidence of target engagement	Evidence of reduced brain atrophy		<i>Interim:</i> trend in cognitive improvement		

COG0201 - Phase 2 (SHINE) Clinical Trial

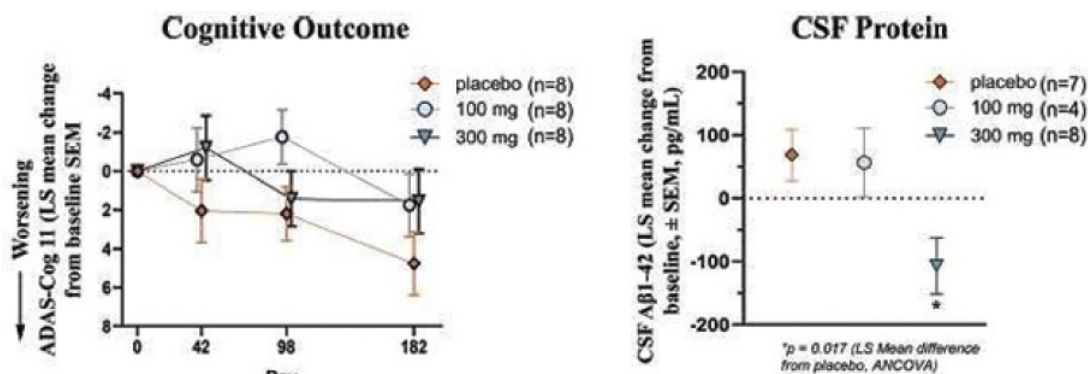
Our COG0201 SHINE study is a randomized, double-blind, placebo-controlled Phase 2 clinical trial designed to enroll up to a total of 144 patients with mild-to-moderate AD to evaluate the safety and potential efficacy of CT1812. Participants are divided in two CT1812 dose groups (100 mg or 300 mg) and 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 monomers 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 are identifying sites and screening patients for this study.

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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 completing enrollment in 2022 and reporting topline data thereafter.

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.

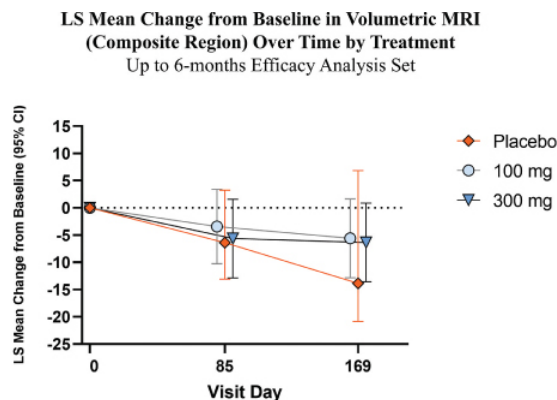
Participants were randomized to receive treatment with 100 mg or 300 mg of CT1812 or placebo once daily for 24 weeks. A preliminary analysis has been made of safety, clinical laboratory measurements, PET

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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.



MRI Brain Volume 60mo change from baseline			
	CT1812 Pooled	Placebo	P-value vs placebo
Hippocampus	-0.09 (0.08)	-0.40 (0.11)	0.0412
Prefrontal Cortex	-0.41 (0.95)	-4.80 (1.37)	0.0125
Pericentral Cortex	0.07 (0.53)	-2.90 (0.77)	0.0032

COG0104 - Phase 1 (SNAP) Trial

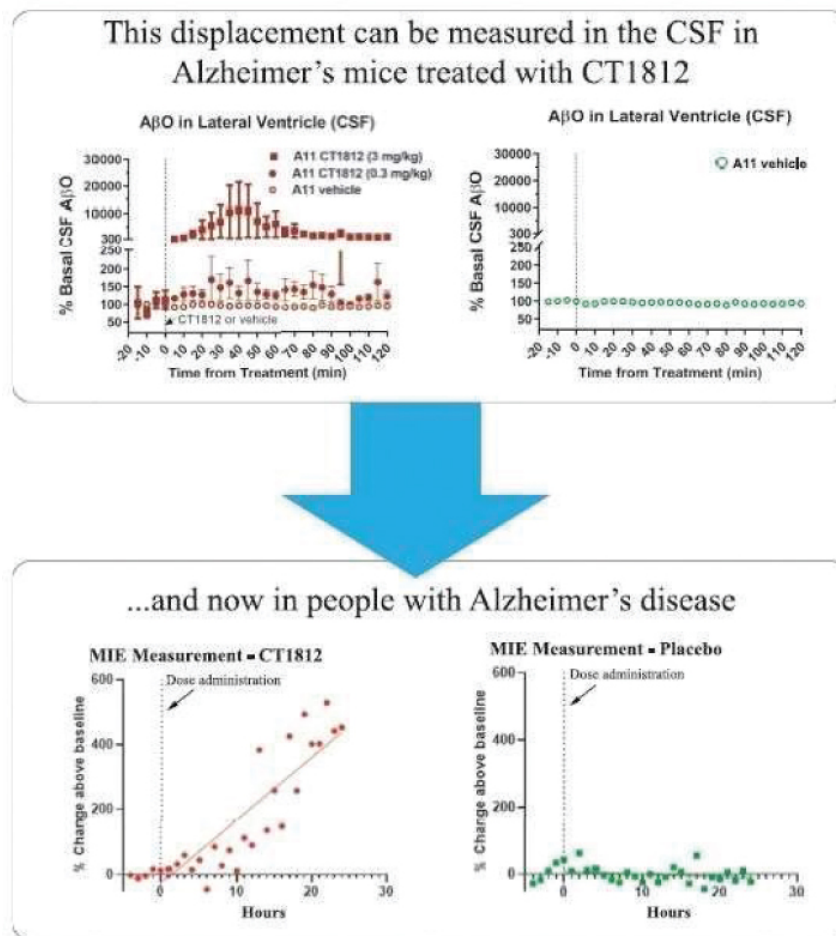
Our COG0104 SNAP study was a randomized, double-blind, placebo-controlled Phase 1 clinical trial that enrolled three patients with mild-to-moderate AD to measure the effects of CT1812 on displacement of A β oligomers. Patients were randomized 2:1 to receive a single dose of CT1812 or placebo. Patients 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.

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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.

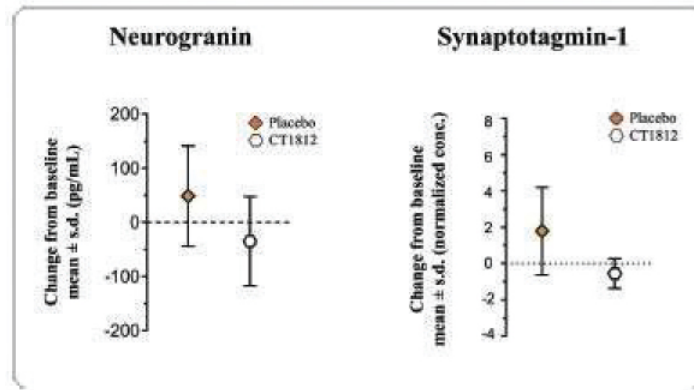
In order to gauge the impact of CT1812 on synaptic damage due to AD, we measured concentrations of synaptic proteins, neurogranin and synaptotagmin-1, in CSF samples from these patients using clinically validated standardized assays. Our evaluation of AD protein biomarkers in the CSF revealed that neurogranin 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,

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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 evaluate 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

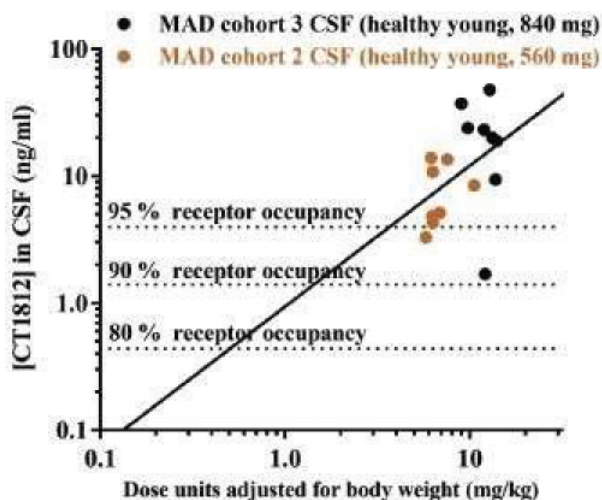
Our COG0101 study was a randomized, double-blind, placebo-controlled ascending dose Phase 1 multi-cohort clinical trial of 93 healthy volunteers to assess the safety and potential drug-food interactions of CT1812. The trial was conducted in two segments.

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.

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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 Funded by NIA Grant of approximately \$81.0 million

Our COG0203 study is 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 is being conducted in collaboration with the ACTC and will utilize approximately 50-60 academic sites associated with the consortium, as well as other qualified sites that are not part of 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

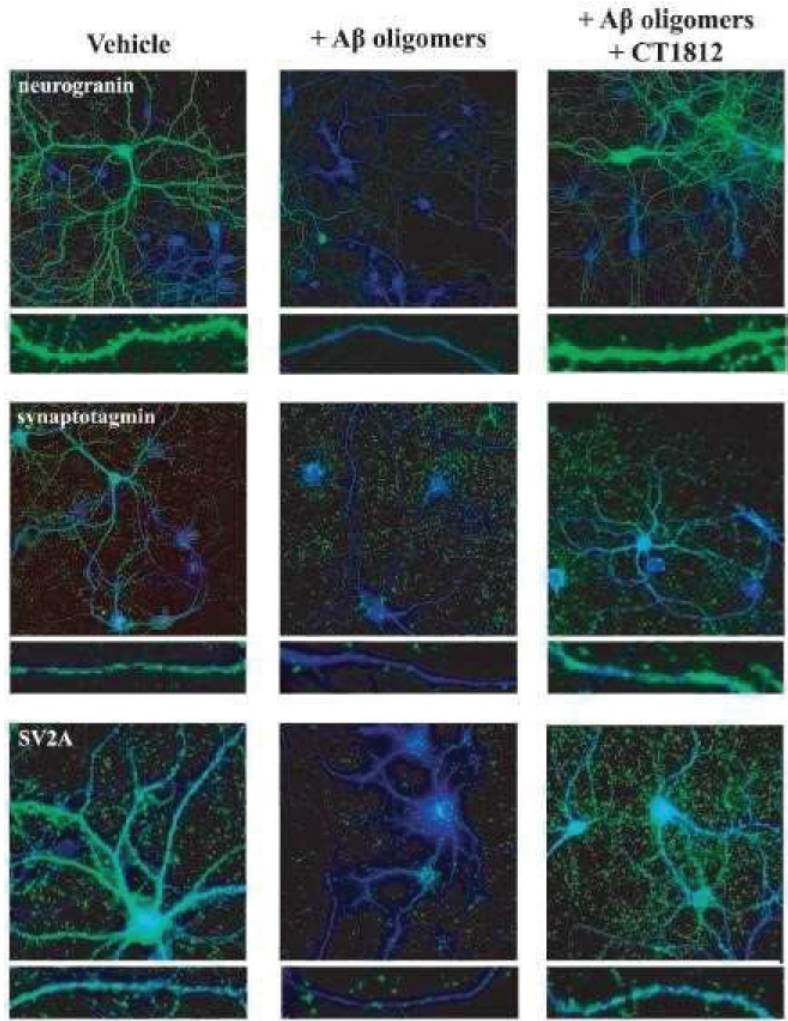
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biomarkers to measure target engagement and assess changes in neurodegeneration and disease progression. We have received a grant of approximately \$81.0 million from the NIA to fund this trial.

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 Aβ oligomers to neuronal cell cultures resulted in synaptotoxicity as illustrated by the reduced expression of synaptic markers neurogranin, synaptotagmin and SV2A. 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 Aβ oligomer-induced loss of synapses, as reflected by the presence of synaptic protein expression displayed in the right-hand column below.

CT1812 prevents Aβ oligomer-mediated synaptic damage



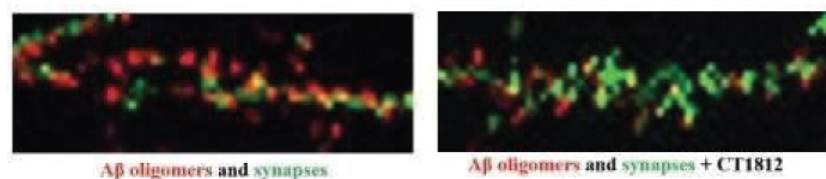
Immunofluorescent images of cultured brain cells:
green = synaptic markers; blue = neuronal MAP2

Results showed that CT1812 also slowed the loss of synapses that is triggered by Aβ oligomers. A higher resolution image of the cell culture exposed to Aβ oligomer is shown below, before the addition of

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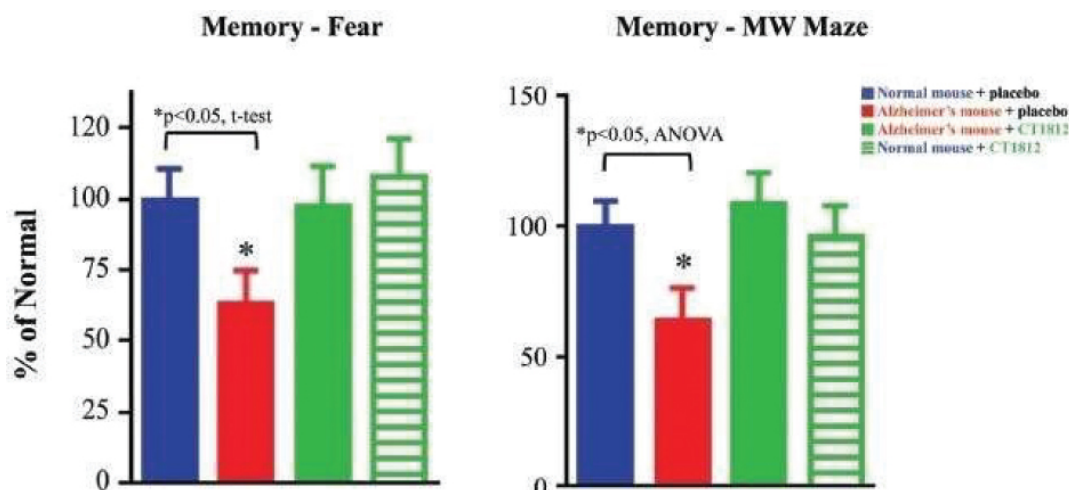
CT1812, which is presented on the left, and after the addition of CT1812, which is presented on the right. A β oligomers shown in red bind to synaptic receptors and reduce numbers of synapses shown in green. The addition of CT1812 displaces A β oligomer binding and appears to block the effects induced 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

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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.

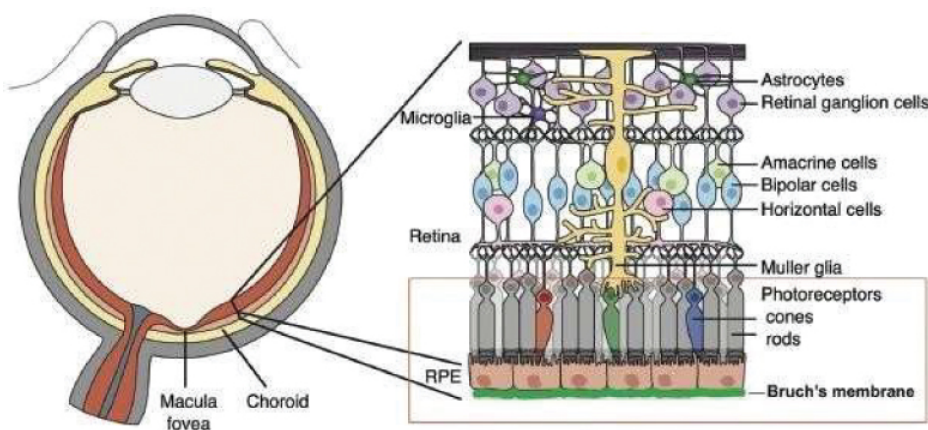
We have completed a pre-IND meeting with the FDA, and, after the completion of our ongoing preclinical studies, we intend to submit an IND application to the FDA by the end of 2022, after which we plan to advance into a Phase 2 clinical trial, leveraging our knowledge of CT1812's preclinical and clinical profile to date. 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 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.

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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 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 modulators, 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

We believe that proof-of-concept studies indicate a clear role of S2R modulators in rescuing key aspects of dry AMD. Pathway analysis of transcriptomic data suggest a key role of S2R modulators in regulating pathways involved in cell survival and inflammation.

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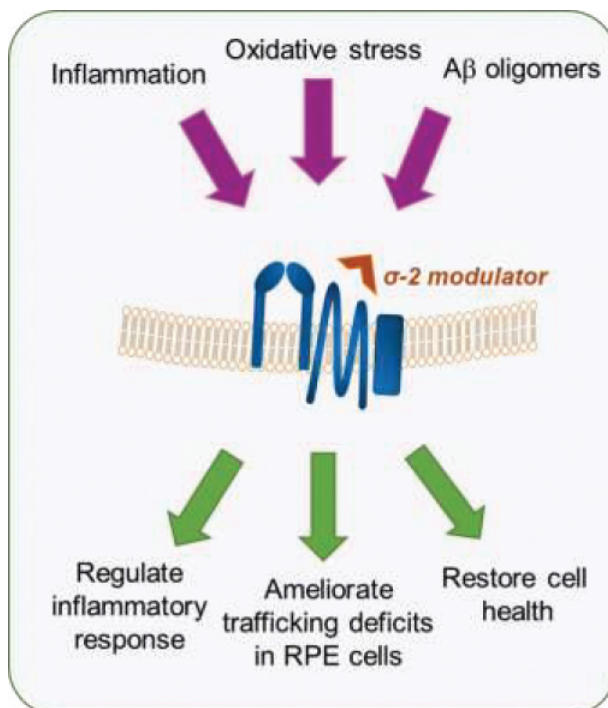
*Mechanistic Studies Indicate CT1812 Plays a Role in Cell Survival
and Inflammatory Pathways in RPE Cells*

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

Additional functional studies indicate 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.

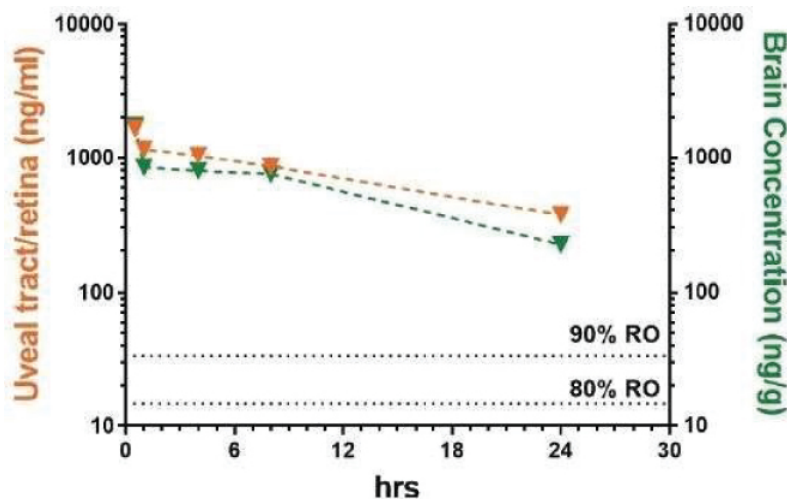
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Working Hypothesis of Mechanism of Action in Dry AMD



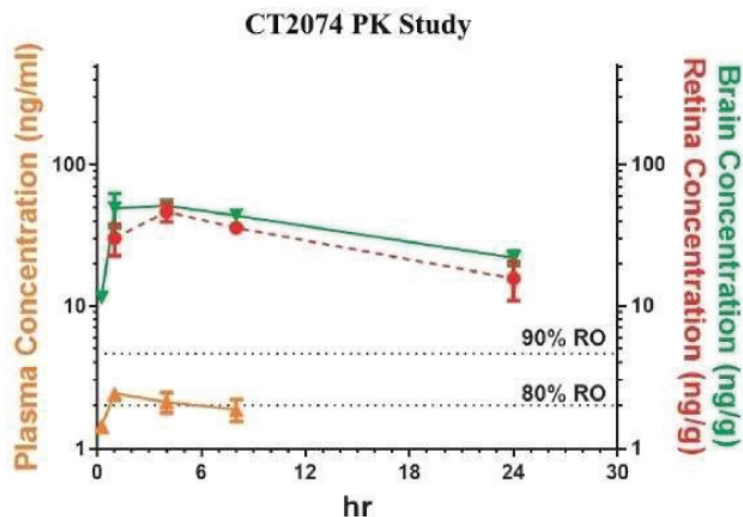
We believe preclinical studies provide further evidence supporting a clinical trial for CT1812 as a potential treatment for dry AMD. PK assessment indicates that we can achieve therapeutic levels (>80% receptor occupancy) of CT1812 in retinal tissue through oral administration. Moreover, as is illustrated 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



Our next-generation S2R modulator, CT2074, 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.

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Additional studies have been conducted to elucidate the key mechanisms by which CT1812 and the S2R complex alter the biological processes that contribute to dry AMD. *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.

Proposed Phase 2 Clinical Trial Design

We believe that an S2R modulator, such as CT1812, may help to regulate the damage-response processes related to these cells that are impaired in dry AMD. We have completed a pre-IND meeting with the FDA, and, after the completion of our ongoing preclinical studies, we intend to submit an IND application to the FDA by the end of 2022, after which we plan to advance into a Phase 2 clinical trial, leveraging our knowledge of CT1812's preclinical and clinical profile to date.

We anticipate 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-to-six-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 modulators 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

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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 brain 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.

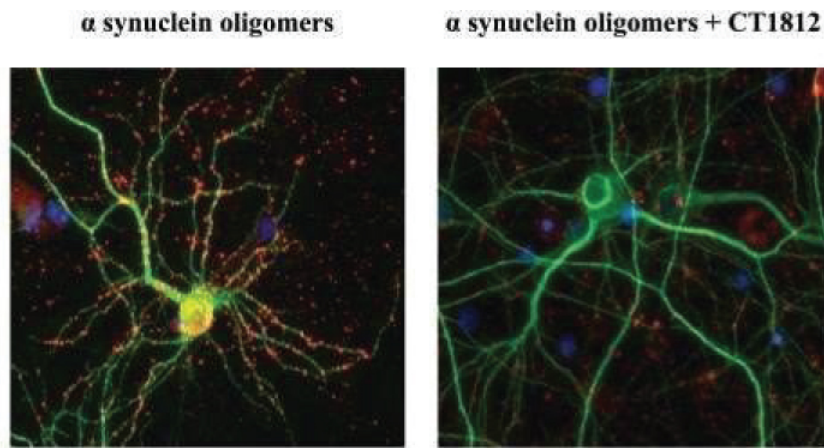
Compounds that bind to S2R and block α -synuclein binding and/or internalization are therefore expected to be disease-modifying.

Preclinical Study Support for Clinical Trials

The results of *in vitro* studies suggest that S2R modulator, 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 grants 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 modulator 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

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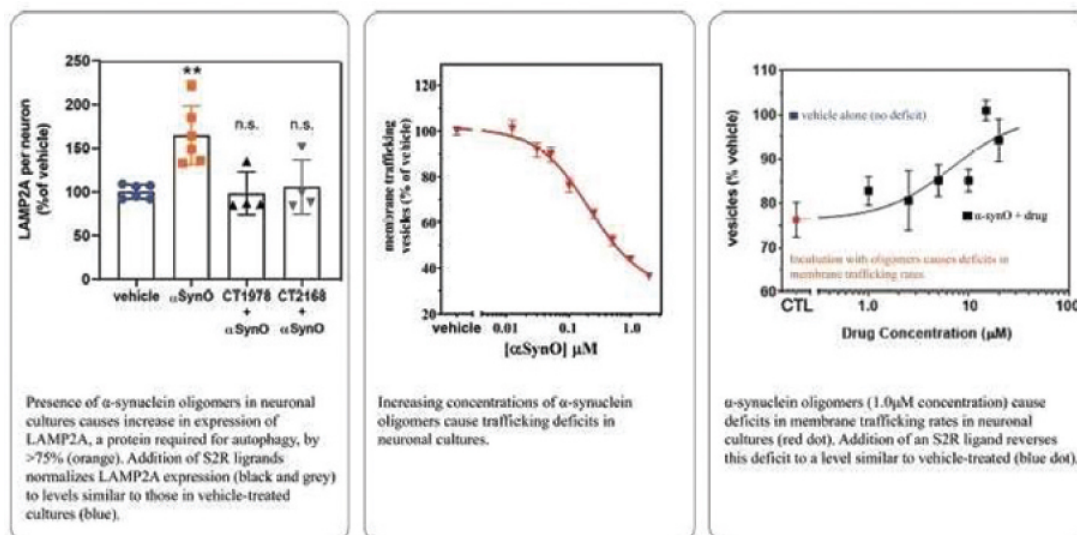


The potential for S2R modulators to reverse the deleterious cellular effects of α -synuclein oligomers is also reflected in the *in vitro* analysis of LAMP2A expression presented below. LAMP2A is a critical component of chaperone-mediated autophagy, one of several processes that eliminate damaged cellular 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 modulators, 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.

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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 are actively enrolling in approximately 17 sites for our Phase 2 clinical trial studying the use of CT1812 to treat patients diagnosed with DLB. The design of this trial is a double-blind, randomized trial involving three dose groups, two active treatment cohorts and a placebo group. We are enrolling 120 patients in a six-month study, with equal participant numbers in each of the three dose groups, with daily (QD) dosing. Eligibility requirements 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. 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.

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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 and other groups to pursue our commonly aligned interests of developing therapeutics for neurodegenerative disorders. Taken together, the company has been awarded approximately \$171.0 million in cumulative grants for the advancement of our pipeline programs. Of this, approximately \$130.6 million in cumulative non-dilutive grants have been awarded by the NIA to fund development of CT1812 for the treatment of AD.

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	\$ 5,445,051
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 – 2021	Ten Preclinical Programs	\$ 10,859,971
			<u>\$171,047,879</u>

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 Grants 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.

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Company Owned Intellectual Property

As of October 1, 2022, our intellectual property portfolio contained nine issued U.S. patents, 65 issued foreign patents as well as one pending U.S. provisional application, four pending U.S. patent applications, two pending Patent Cooperation Treaty applications and 26 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 October 1, 2022, 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, India, Israel, Japan, New Zealand, Mexico, South Korea, 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 and Hong Kong. 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 approval of the New Drug Application, or NDA, 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," or the Orange Book. These patents complement the regulatory exclusivity by providing the basis for an additional waiting period 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.

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We also own four families of pending patent applications directed to methods for selecting subsets of patients with AD for treatment with CT1812, methods of modulating amyloid beta monomer and oligomer levels using CT812, methods of treating dry AMD with CT1812 and methods of treating various neurologic diseases including PD and synucleinopathies with CT1812, as well as a pending provisional application directed to treating certain subsets of AD patients with CT1812. Any of these applications, if issued, will have a natural expiration between 2038 and 2043, 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, including CT2168 and CT2074, among others. 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 to support the commercial launch of the product, if approved. 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.

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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 October 14, 2022, we had 22 employees, 19 of whom were full-time and 15 of whom were engaged in research and development activities. Seven 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 6,686 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,

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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

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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

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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.

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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

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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

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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 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,

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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 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 ½ 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

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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

Our activities are subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, the federal civil False Claims Act, and laws and regulations pertaining to limitations on and reporting of healthcare provider payments (physician sunshine laws). These laws and regulations are interpreted and enforced by various federal, state and local authorities including CMS, the Office of Inspector General for the U.S. Department of Health and Human Services, the U.S. Department of Justice, individual U.S. Attorney offices within the Department of Justice, and state and local governments. These laws include:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order, or arranging for or recommending the purchase, lease or order of, any good or service, for which payment may be made, in whole or in part, under federal 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. civil False Claims Act (which can be enforced through “qui tam,” or whistleblower actions, by private citizens on behalf of the federal government), prohibits any person from, among other things, knowingly presenting, or causing to be presented false or fraudulent claims for payment of government funds or knowingly making, using or causing to be made or used, a false record or statement material to an obligation to pay money to the government or knowingly and improperly avoiding, decreasing or concealing an obligation to pay money to the U.S. federal government;
- U.S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal liability and amends provisions on the reporting, investigation, enforcement, and penalizing of 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 by a healthcare benefit program, which includes both government and privately funded benefits programs; 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;
- state laws and regulations, including state anti-kickback and false claims laws, that 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 payer, 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; and 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
- the Physician Payments Sunshine Act, implemented as the Open Payments program, and its implementing regulations, requires 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 CMS information related to certain payments made in the preceding calendar year and other transfers of value to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; beginning in 2022, applicable manufacturers are required to report such information regarding payments and transfers of value provided, as well as ownership and investment interests held, during the previous year to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives.

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Violations of any of these laws or any other governmental regulations that may apply to us, may subject us to significant civil, criminal and administrative sanctions including penalties, damages, fines, imprisonment, and exclusion from government funded healthcare programs, such as Medicare and Medicaid, and/or adverse publicity. Moreover, government entities and private litigants have asserted claims under state consumer protection statutes against pharmaceutical companies for alleged false or misleading statements in connection with the marketing, promotion and/or sale of pharmaceutical products.

Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act, or the FCPA, generally prohibits offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action, or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our industry is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, the health care providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers are subject to regulation under the FCPA. Recently, the SEC and Department of Justice have increased their FCPA enforcement activities with respect to pharmaceutical companies. Violations could result in fines, criminal sanctions against us, our officers, or our employees, the closing down of our facilities, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs, and prohibitions on the conduct of our business. Enforcement actions may be brought by the Department of Justice or the SEC, and recent enacted legislation has expanded the SEC's power to seek disgorgement in all FCPA cases filed in federal court and extended the statute of limitations in SEC enforcement actions in intent-based claims such as those under the FCPA from five years to ten years.

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. 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.

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. On August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 into law. This legislation contains substantial drug pricing reforms, including the establishment of a drug price negotiation program within the U.S. Department of Health and Human Services that would require manufacturers to charge a negotiated "maximum fair price" for certain selected drugs or pay an excise tax for noncompliance, the establishment of rebate payment requirements on manufacturers of certain drugs payable under Medicare Parts B and D to penalize price increases that outpace inflation, and requires

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manufacturers to provide discounts on Part D drugs. The Inflation Reduction Act of 2022 also caps Medicare beneficiaries' annual out-of-pocket drug expenses. Substantial penalties can be assessed for noncompliance with the drug pricing provisions in the Inflation Reduction Act of 2022. Additional drug pricing proposals could appear in future federal legislation.

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

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system. 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 products. In recent years, Congress has considered reductions in Medicare reimbursement levels for products administered by physicians. CMS, the agency that administers the Medicare and Medicaid programs, also has authority to revise reimbursement rates and to implement coverage restrictions for some products. Cost reduction initiatives and changes in coverage implemented through legislation or regulation could decrease utilization of and reimbursement for any approved products. While Medicare regulations apply only to drug benefits for Medicare beneficiaries, private payers often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from federal legislation or regulation may result in a similar reduction in payments from private payers.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively the Affordable Care Act substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacts the pharmaceutical industry. The Affordable Care Act is intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against healthcare fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on pharmaceutical and medical device manufacturers, and impose additional health policy reforms. Among other things, the Affordable Care Act expanded manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum Medicaid rebate for both branded and generic products, expanded the 340B program, and revised the definition of average manufacturer price, or AMP, which could increase the amount of Medicaid rebates manufacturers are required to pay to states. The legislation also extended Medicaid rebates, previously due only on fee-for-service Medicaid utilization, to include the utilization of Medicaid managed care organizations as well and created an alternative rebate formula for certain new formulations of certain existing products that is intended to increase the amount of rebates due on those products. On February 1, 2016, CMS issued final regulations to implement the changes to the Medicaid

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Drug Rebate program under the Affordable Care Act. These regulations became effective on April 1, 2016. Since that time, there have been significant ongoing efforts to modify or eliminate the Affordable Care Act. 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 of 1986, as amended, or the Code, commonly referred to as the individual mandate.

Other legislative changes have been proposed and adopted since the passage of the Affordable Care Act. The Budget Control Act of 2011, among other things, created the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. The Joint Select Committee did not achieve its targeted deficit reduction of an amount greater than \$1.2 trillion for the fiscal years 2012 through 2021, triggering the legislation's automatic reductions to several government programs. These reductions included aggregate reductions to Medicare payments to healthcare providers of up to 2.0% per fiscal year, which went into effect in April 2013. Subsequent legislation extended the 2% reduction, on average, to 2030 unless additional Congressional action is taken. However, pursuant to the Coronavirus Aid, Relief and Economic Security Act, or CARES Act, the 2% Medicare sequester reductions were suspended from May 1, 2020 through December 31, 2021 due to the COVID-19 pandemic. The sequester will remain in place through 2030. On January 2, 2013, the American Taxpayer Relief Act was signed into law, which, among other things, reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

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. 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 but it is unknown what form any such changes or any law proposed to replace or revise 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 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.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that additional federal, state and foreign healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in limited coverage and reimbursement and reduced demand for our products, once approved, or additional pricing pressures.

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.

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DESCRIPTION OF SECURITIES WE ARE OFFERING

Common Stock

The description of our common stock under the section “Description of Capital Stock” in this prospectus is incorporated herein by reference.

Pre-Funded Warrants

General

The term “pre-funded” refers to the fact that the purchase price of the pre-funded warrants in this offering includes almost the entire exercise price that will be paid under the pre-funded warrants, except for a nominal remaining exercise price of \$0.0001. The purpose of the pre-funded warrants is to enable any purchaser that may have restrictions on its ability to beneficially own more than 4.99% (or, at the election of such purchaser, 9.99%) of our outstanding common stock following the consummation of this offering the opportunity to invest capital into the Company without triggering its ownership restrictions, by receiving pre-funded warrants in lieu of shares of our common stock which would result in such ownership of more than 4.99% or 9.99%, as applicable, and receiving the ability to exercise their option to purchase the shares underlying the pre-funded warrants at a nominal price at a later date.

The following is a brief summary of certain terms and conditions of the pre-funded warrants being offered by us. The following description is subject in all respects to the provisions contained in the form of pre-funded warrant, the form of which will be filed as an exhibit to the registration statement of which this prospectus forms a part.

Exercise Price

Pre-funded warrants will have an exercise price of \$0.0001 per share. The exercise price is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our common stock and also upon any distributions of assets, including cash, stock or other property to our stockholders.

Exercisability

The pre-funded warrants are exercisable at any time after their original issuance until all of the pre-funded warrants are exercised in full. The pre-funded warrants will be exercisable, at the option of each holder, in whole or in part by delivering to us a duly executed exercise notice and by payment in full of the exercise price in immediately available funds for the number of shares of common stock purchased upon such exercise. As an alternative to payment in immediately available funds, the holder may elect to exercise the pre-funded warrant through a cashless exercise, in which the holder would receive upon such exercise the net number of shares of common stock determined according to the formula set forth in the pre-funded warrant. No fractional shares of common stock will be issued in connection with the exercise of a pre-funded warrant.

Exercise Limitations

The pre-funded warrants may not be exercised by any holder to the extent that such holder, together with its affiliates, would beneficially own after such exercise, more than 4.99% (or, at the option of the purchaser, 9.99%) of the shares of our common stock then outstanding (including for such purpose the shares of our common stock issuable upon such exercise). However, any holder may increase or decrease such beneficial ownership limitation upon notice to us, provided that such limitation cannot exceed 9.99%, and provided that any increase in the beneficial ownership limitation shall not be effective until 61 days after such notice is delivered.

Term

The pre-funded warrants may be exercised at any time until all of the pre-funded warrants are exercised in full.

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Transferability

Subject to applicable laws, the pre-funded warrants may be offered for sale, sold, transferred or assigned without our consent.

Exchange Listing

There is no established trading market for the pre-funded warrants and we do not expect a market to develop. In addition, we do not intend to apply for the listing of the pre-funded warrants on the Nasdaq Global Market, any other national securities exchange or any trading market. Without an active trading market, the liquidity of the pre-funded warrants will be limited.

Fundamental Transactions

In the event of a fundamental transaction, as described in the pre-funded warrants and generally including any reorganization, recapitalization or reclassification of our common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of our outstanding common stock, or any person or group becoming the beneficial owner of 50% of the voting power represented by our outstanding common stock, upon consummation of such a fundamental transaction, the holders of the pre-funded warrants will be entitled to receive upon exercise of the pre-funded warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the pre-funded warrants immediately prior to such fundamental transaction without regard to any limitations on exercise contained in the pre-funded warrants.

No Rights as a Stockholder

Except as otherwise provided in the pre-funded warrant or by virtue of such holder's ownership of shares of our common stock, the holder of a pre-funded warrant does not have the rights or privileges of a holder of our common stock, including any voting rights, until the holder exercises the pre-funded warrant. The pre-funded warrants will provide that holders have the right to participate in distributions or dividends paid on our common stock.

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DESCRIPTION OF CAPITAL STOCK

The following description of our capital stock is not complete and may not contain all the information you should consider before investing in our capital stock. This description is summarized from, and qualified in its entirety by reference to, our third amended and restated certificate of incorporation, which has been publicly filed with the SEC. See “Where You Can Find Additional Information and Incorporation of Certain Information by Reference.”

Common Stock

Voting Rights

Each holder of 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. The affirmative vote of holders of at least 66⅔% of the voting power of all of the then-outstanding shares of capital stock, voting as a single class, will be required to amend certain provisions of our third amended and restated certificate of incorporation, including 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, subject to 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 or subscription 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 and issue in the future.

Preferred Stock

Under our third amended and restated certificate of incorporation, our board of directors has the authority, without further action by the stockholders, to issue up to 10,000,000 shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the rights, preferences and privileges of the shares of each wholly unissued series and any qualifications, limitations or restrictions thereon and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding. Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of the common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in our control that may otherwise benefit holders of our common stock and may adversely affect the market price of the common stock and the voting and other rights of the holders of common stock. We have no current plans to issue any shares of preferred stock.

Registration Rights

Certain holders of shares of our common stock are entitled to certain rights with respect to registration of such shares under the Securities Act. These shares are referred to as registrable securities. The holders of

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these registrable securities possess registration rights pursuant to the terms of our investors' rights agreement and are described in additional detail below. The registration of shares of our common stock pursuant to the exercise of the registration rights described below would enable the holders to trade these shares without restriction under the Securities Act when the applicable registration statement is declared effective. We will pay the registration expenses, other than underwriting discounts, selling commissions and stock transfer taxes, of the shares registered pursuant to the demand, piggyback and Form S-3 registrations described below.

Generally, in an underwritten offering, the managing underwriter, if any, has the right, subject to specified conditions and limitations, to limit the number of shares the holders may include. The demand, piggyback and Form S-3 registration rights described below will expire no later than four years after the completion of our initial public offering in October 2021, or with respect to any particular holder, at such time that such holder can sell its shares under Rule 144, or other similar exemption, of the Securities Act during any three-month period.

Demand Registration Rights

Certain holders of our common stock are entitled to certain demand registration rights. The holders of a majority of the registrable securities may request that we register all or a portion of their shares, subject to certain specified exceptions.

Piggyback Registration Rights

Certain holders of our common stock are entitled to rights to notice of this offering and to include their shares of registrable securities in this offering, which we expect the requisite percentage of holders to waive. In the event that we propose to register any of our securities under the Securities Act in another offering, either for our own account or for the account of other security holders, the holders of registrable securities will be entitled to certain "piggyback" registration rights allowing them to include their shares in such registration, subject to specified conditions and limitations.

S-3 Registration Rights

Certain holders of our common stock are entitled to certain Form S-3 registration rights. The holders of at least 10% of registrable securities may request that we register all or a portion of their shares on Form S-3 if we are qualified to file a registration statement on Form S-3, subject to specified exceptions. Such request for registration on Form S-3 must cover securities with an aggregate offering price which equals or exceeds \$1.0 million, net of selling expenses. The right to have such shares registered on Form S-3 is further subject to other specified conditions and 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

Certificate of Incorporation and Bylaws

Among other things, our third amended and restated certificate of incorporation and amended and restated bylaws:

- permit our board of directors to issue up to 10,000,000 shares of preferred stock, with any rights, preferences and privileges as they may designate;
- provide that the authorized number of directors may be changed only by resolution of our board of directors;

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- provide that our board of directors will be classified into three classes of directors;
- provide that, subject to the rights of any series of preferred stock to elect directors, directors may only be removed for cause, which removal may be effected, subject to any limitation imposed by law, by the holders of at least 66⅔% of the voting power of all of our then-outstanding shares of the capital stock entitled to vote generally at an election of directors;
- provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent or electronic transmission;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide advance notice in writing, and also specify requirements as to the form and content of a stockholder's notice;
- provide that special meetings of our stockholders may be called only by the chairman of our board of directors, our chief executive officer or by our board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors; and
- not provide for cumulative voting rights, therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose.

The amendment of any of these provisions would require approval by the holders of at least 66⅔% of the voting power of all of our then-outstanding common stock entitled to vote generally in the election of directors, voting together as a single class.

The combination of these provisions will make it more difficult for our existing stockholders to replace our board of directors as well as for another party to obtain control of us by replacing our board of directors. Because our board of directors has the power to retain and discharge our officers, these provisions could also make it more difficult for existing stockholders or another party to effect a change in management. In addition, the authorization of 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 our control.

These provisions are intended to enhance the likelihood of continued stability in the composition of our board of directors and its policies and to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to reduce our vulnerability to hostile takeovers and to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and may have the effect of delaying changes in our control or management. As a consequence, these provisions may also inhibit fluctuations in the market price of our stock that could result from actual or rumored takeover attempts. We believe that the benefits of these provisions, including increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure our company, outweigh the disadvantages of discouraging takeover proposals, because negotiation of takeover 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 a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, with the following exceptions:

- before such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;

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- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction began, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned (i) by persons who are directors and also officers and (ii) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or after such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least 66⅔% of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 defines a “business combination” to include the following:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;
- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder; and
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits by or through the corporation.

In general, Section 203 defines an “interested stockholder” as an entity or person who, together with the person’s affiliates and associates, beneficially owns, or within three years prior to the time of determination of interested stockholder status did own, 15% or more of the outstanding voting stock of the corporation.

The statute could prohibit or delay mergers or other takeover or change in control attempts and, accordingly, may discourage attempts to acquire us even though such a transaction may offer our stockholders the opportunity to sell their stock at a price above the prevailing market price.

A Delaware corporation may “opt out” of these provisions with an express provision in its certificate of incorporation. We have not opted out of these provisions, which may as a result, discourage or prevent mergers or other takeover or change of control attempts of us.

Choice of Forum

Our third amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware (or, if and only if, the Court of Chancery of the State of Delaware lacks subject matter jurisdiction, any state court located within the State of Delaware or, if and only if, all such state courts lack subject matter jurisdiction, the United States District Court for the District of Delaware) and any appellate court therefrom shall be the sole and exclusive forum for the following claims or causes of action brought under Delaware statutory or common law: (1) any derivative claim or action brought on our behalf; (2) any claim or cause of action asserting a breach of fiduciary duty by any of our current or former directors, officers or other employees; (3) any claim or cause of action asserting a claim against us arising out of, or pursuant to, the DGCL, our third amended and restated certificate of incorporation or our amended and restated bylaws; (4) any claim or cause of action seeking to interpret, apply, enforce or determine the validity of our third amended and restated certificate of incorporation or our amended and restated bylaws (including any right, obligation, or remedy thereunder); (5) any claim or cause of action as to which the DGCL confers jurisdiction to the Court of Chancery of the State of Delaware; or (6) any claim or cause of action asserting a claim against us or any of our current or former directors, officers or other employees, that is governed by the internal affairs doctrine, in all cases to the fullest extent permitted by law and subject to the court having personal jurisdiction over the indispensable parties named as defendants. The aforementioned provision will not apply to claims or causes of action brought to enforce a duty or liability created by the Securities Act, the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction.

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In addition, our third amended and restated certificate of incorporation further provides that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America will be the exclusive forum, to the fullest extent permitted by law, for resolving any complaint asserting a cause or causes of action arising under the Securities Act, including all causes of action asserted against any defendant to such complaint. 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, in connection with one or more actions or proceedings described above, a court could find the choice of forum provisions contained in our third amended and restated certificate of incorporation to be inapplicable or unenforceable.

Limitations of Liability and Indemnification

Our third amended and restated certificate of incorporation and our amended and restated bylaws limit our directors' liability and may indemnify our directors and officers to the fullest extent permitted under the 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 into indemnification agreements with 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 third amended and restated certificate of incorporation, our 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 material 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 material 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.

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Listing

Our common stock is listed on the Nasdaq Global Market under the trading symbol “CGTX.”

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company, LLC.

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MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS

The following is a discussion of the material U.S. federal income tax consequences applicable to non-U.S. holders (as defined below) with respect to their ownership and disposition of shares of our common stock or pre-funded warrants to purchase our common stock issued pursuant to this offering, but does not purport to be a complete analysis of all potential tax effects. All prospective non-U.S. holders of our common stock or pre-funded warrants should consult their tax advisors with respect to the U.S. federal income tax consequences of the ownership and disposition of our common stock or pre-funded warrants, as well as any consequences arising under the laws of any other taxing jurisdiction, including any state, local and non-U.S. tax consequences and any U.S. federal non-income tax consequences. In general, a non-U.S. holder means a beneficial owner of our common stock or pre-funded warrant (other than a partnership or an entity or arrangement treated as a partnership for U.S. federal income tax purposes) that is not a U.S. holder. A U.S. holder is, for U.S. federal income tax purposes:

- an individual who is a citizen or resident of the United States;
- a corporation, or an entity treated as a corporation for U.S. federal income tax purposes, created or organized in the United States or under the laws of the United States or of 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 if (1) a U.S. court can exercise primary supervision over the trust's administration and one or more U.S. persons have the authority to control all of the trust's substantial decisions or (2) the trust has a valid election in effect under applicable U.S. Treasury Regulations to be treated as a U.S. person.

This discussion is based on current provisions of the U.S. Internal Revenue Code of 1986, as amended, or the Code, existing U.S. Treasury Regulations promulgated thereunder, published administrative rulings and judicial decisions, all as in effect as of the date of this prospectus supplement. These laws are subject to change and to differing interpretation, possibly with retroactive effect. Any change or differing interpretation could alter the tax consequences to non-U.S. holders described in this prospectus supplement.

This discussion is limited to non-U.S. holders that hold shares of our common stock or pre-funded warrants as a capital asset within the meaning of Section 1221 of the Code (generally, for investment). This discussion does not address all aspects of U.S. federal income taxation that may be relevant to a particular non-U.S. holder in light of that non-U.S. holder's individual circumstances, nor does it address the effect of the alternative minimum tax or Medicare contribution tax on net investment income, the impact of special tax accounting rules under Section 451(b) of the Code, any aspects of U.S. estate or gift tax, or any state, local or non-U.S. taxes. This discussion also does not address all special tax rules applicable to particular non-U.S. holders, such as holders that own, or are deemed to own, more than 5% of our capital stock (except to the extent specifically set forth below), corporations that accumulate earnings to avoid U.S. federal income tax, tax-exempt organizations, banks, financial institutions, insurance companies, brokers, dealers or traders in securities, commodities or currencies, tax-qualified retirement plans, holders who hold or receive our common stock pursuant to the exercise of employee stock options or otherwise as compensation, holders holding our common stock or pre-funded warrants as part of a hedge, straddle or other risk reduction strategy, conversion transaction or other integrated investment, holders deemed to sell our common stock or pre-funded warrants under the constructive sale provisions of the Code, "qualified foreign pension funds" as defined in Section 897(l)(2) of the Code and entities all of the interests of which are held by qualified foreign pension funds, controlled foreign corporations, passive foreign investment companies and certain former citizens or long-term residents of the United States.

In addition, this discussion does not address the tax treatment of partnerships (or entities or arrangements that are treated as partnerships for U.S. federal income tax purposes) or persons that hold our common stock or pre-funded warrants through such partnerships or such entities or arrangements. If a partnership, including any entity or arrangement treated as a partnership for U.S. federal income tax purposes, holds shares of our common stock or pre-funded warrants, the U.S. federal income tax treatment of a partner in such partnership will generally depend upon the status of the partner, the activities of the partnership and certain determinations made at the partner level. Such partners and partnerships should

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consult their tax advisors regarding the tax consequences of the purchase, ownership and disposition of our common stock or pre-funded warrants.

There can be no assurance that the U.S. Internal Revenue Service, or the IRS, will not challenge one or more of the tax consequences described herein, and we have not obtained, nor do we intend to obtain, a ruling with respect to the U.S. federal income tax consequences with respect to the matters discussed below.

Treatment of Pre-Funded Warrants

Although it is not entirely free from doubt, we believe a pre-funded warrant should be treated as a share of our common stock for U.S. federal income tax purposes and a holder of pre-funded warrants should generally be taxed in the same manner as a holder of such shares, as described below. Accordingly, no gain or loss should be recognized upon the exercise of a pre-funded warrant and, upon exercise, the holding period of a pre-funded warrant should carry over to the share received. Similarly, the tax basis of the pre-funded warrant should carry over to the share received upon exercise, increased by the exercise price of \$0.0001 per share. If a pre-funded warrant expires without being exercised, the holder should recognize a capital loss in an amount equal to such holder's tax basis in the pre-funded warrant. This loss will be long-term capital loss if, at the time of the expiration, the holder's holding period in the pre-funded warrant is more than one year. The deductibility of capital losses is subject to limitations.

Our characterization is not binding on the IRS, and the IRS may treat our pre-funded warrants as warrants to acquire our common stock. In that case, the amount and character of your gain with respect to an investment in our pre-funded warrants could be materially different than the discussion set forth below. Accordingly, each holder should consult his, her or its own tax advisor regarding the risks associated with the acquisition of pre-funded warrants pursuant to this offering (including potential alternative characterizations). The balance of this discussion generally assumes that a pre-funded warrant is treated as a share of our common stock for U.S. federal income tax purposes.

Distributions on Our Common Stock

As described in the section entitled "Dividend Policy," we do not anticipate declaring or paying dividends to holders of our common stock in the foreseeable future. However, distributions, if any, on our common stock generally 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. If a distribution exceeds our current and accumulated earnings and profits, the excess will be treated as a tax-free return of the non-U.S. holder's investment, up to such holder's adjusted tax basis in the common stock. Any remaining excess will be treated as capital gain from the sale or exchange of such common stock, subject to the tax treatment described below in "Gain on Sale, Exchange or Other Disposition of Our Common Stock or Pre-Funded Warrants."

Subject to the discussions below regarding effectively connected income, dividends paid to a non-U.S. holder will generally be subject to withholding of U.S. federal income tax at a 30% rate, or such lower rate as may be specified by an applicable income tax treaty. A non-U.S. holder that is eligible for a reduced rate of U.S. withholding tax under an income tax treaty may obtain a refund or credit of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. A non-U.S. holder of our common stock who claims the benefit of an applicable income tax treaty generally will be required to provide a properly executed IRS Form W-8BEN or W-8BEN-E (or successor form) and satisfy relevant certification and other requirements. Non-U.S. holders are urged to consult their tax advisors regarding their entitlement to benefits under a relevant income tax treaty.

Dividends that are treated as effectively connected with a trade or business conducted by a non-U.S. holder within the United States (and, if an applicable income tax treaty so provides, that are attributable to a permanent establishment or a fixed base maintained by the non-U.S. holder within the United States) are generally exempt from the 30% withholding tax if the non-U.S. holder satisfies applicable certification requirements. To claim the exemption, the non-U.S. holder must furnish to us or the applicable withholding agent a valid IRS Form W-8ECI (or applicable successor form), certifying that the dividends are effectively connected with the non-U.S. holder's conduct of a trade or business within the United States. However, such U.S. effectively connected income, net of specified deductions and credits, is taxed at the U.S. federal

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income tax rates applicable to a “United States person” (as defined in the Code), which we refer to as a United States person, unless a specific treaty exemption applies. Any U.S. effectively connected income received by a non-U.S. holder that is a corporation, under certain circumstances, also may be subject to an additional “branch profits tax” at a 30% rate or such lower rate as may be specified by an applicable income tax treaty.

Gain on Sale, Exchange or Other Disposition of Our Common Stock

Subject to the discussions below regarding backup withholding and foreign accounts, in general, a non-U.S. holder will not be subject to any U.S. federal income tax on any gain realized upon such holder’s sale, exchange or other disposition of shares of our common stock unless:

- the gain is effectively connected with a U.S. trade or business of the non-U.S. holder (and, if an applicable income tax treaty so provides, is attributable to a permanent establishment or a fixed base maintained in the United States by such non-U.S. holder), in which case the non-U.S. holder generally will be taxed at the U.S. federal income tax rates applicable to United States persons and, if the non-U.S. holder is a foreign corporation, the branch profits tax described above in “Distributions on Our Common Stock” may also apply;
- the non-U.S. holder is a nonresident alien individual who is present in the United States for 183 days or more in the taxable year of the disposition and certain other conditions are met, in which case the non-U.S. holder will be subject to a 30% tax (or such lower rate as may be specified by an applicable income tax treaty) on the net gain derived from the disposition, which may be offset by certain U.S. source capital losses of the non-U.S. holder, if any (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; or
- our common stock constitutes a U.S. real property interest because we are, or have been, at any time during the five-year period preceding such disposition (or the non-U.S. holder’s holding period, if shorter) a “U.S. real property holding corporation.” Even if we are or become a U.S. real property holding corporation, provided that our common stock is “regularly traded” (as defined by U.S. Treasury Regulations) on an established securities market, our common stock will be treated as a U.S. real property interest only with respect to a non-U.S. holder that holds more than 5% of our outstanding common stock, directly or indirectly, actually or constructively, during the shorter of the five-year period ending on the date of the disposition or the period that the non-U.S. holder held our common stock. In such case, such non-U.S. holder generally will be taxed on its net gain derived from the disposition at the U.S. federal income tax rates applicable to United States persons. Generally, a corporation is a U.S. real property holding corporation only if the fair market value of its U.S. real property interests equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business. Although there can be no assurance, we do not believe that we are, or have been, a U.S. real property holding corporation, or that we are likely to become one in the future. No assurance can be provided that our common stock will be regularly traded on an established securities market for purposes of the rules described above.

Backup Withholding and Information Reporting

We must report annually to the IRS and to each non-U.S. holder the gross amount of distributions on our common stock or pre-funded warrants paid to such holder, regardless of whether such distributions constitute dividends or whether any tax was actually withheld. Non-U.S. holders will have to comply with specific certification procedures to establish that the holder is not a United States person in order to avoid backup withholding at the applicable rate with respect to dividends on our common stock or pre-funded warrants. U.S. backup withholding generally will not apply to a non-U.S. holder who provides a properly executed IRS Form W-8BEN or W-8BEN-E (or successor form) or otherwise establishes an exemption.

Information reporting and backup withholding will generally apply to the proceeds of a disposition of our common stock or pre-funded warrants by a non-U.S. holder effected by or through the U.S. office of any broker, U.S. or foreign, unless the holder certifies its status as a non-U.S. holder and satisfies certain

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other requirements, or otherwise establishes an exemption. Generally, information reporting and backup withholding will not apply to a payment of disposition proceeds to a non-U.S. holder where the transaction is effected outside the United States through a non-U.S. office of a broker. However, for information reporting purposes, dispositions effected through a non-U.S. office of a broker with substantial U.S. ownership or operations generally will be treated in a manner similar to dispositions effected through a U.S. office of a broker.

Non-U.S. holders should consult their tax advisors regarding the application of the information reporting and backup withholding rules to them.

Copies of information returns may be made available to the tax authorities of the country in which the non-U.S. holder resides or is incorporated under the provisions of a specific treaty or agreement.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules from a payment to a non-U.S. holder may be allowed as a credit against the non-U.S. holder's U.S. federal income tax liability, if any, and may entitle such holder to a refund, provided that the required information is timely furnished to the IRS.

Foreign Accounts

Sections 1471 through 1474 of the Code (commonly referred to as FATCA) generally impose a U.S. federal withholding tax of 30% on certain payments made to a "foreign financial institution" (as specifically defined for this purpose), unless such institution enters into an agreement with the U.S. government to, among other things, withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding U.S. account holders of such institution (which may include certain equity and debt holders of such institution, as well as certain account holders that are foreign entities with U.S. owners). Foreign financial institutions located in jurisdictions that have an intergovernmental agreement with the United States governing these withholding and reporting requirements may be subject to different rules. FATCA also generally imposes a 30% withholding tax on certain payments made to a non-financial foreign entity, unless such entity provides the withholding agent with either a certification that it does not have any substantial direct or indirect U.S. owners or information regarding substantial direct and indirect U.S. owners of the entity. The withholding tax under FATCA described above will not apply if the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from the rules. The FATCA withholding provisions described above currently apply to dividends on our common stock or pre-funded warrants. The FATCA withholding provisions also would apply to the gross proceeds of a disposition of our common stock or pre-funded warrants, except that the U.S. Treasury Department has released proposed regulations which, if finalized in their present form, would eliminate such withholding. In its preamble to such proposed regulations, the U.S. Treasury Department stated that taxpayers generally may rely on the proposed regulations until final regulations are issued.

Under certain circumstances, a non-U.S. holder might be eligible for refunds or credits of such taxes. Non-U.S. holders are encouraged to consult with their tax advisors regarding the possible implications of FATCA on their investment in our common stock.

EACH PROSPECTIVE INVESTOR SHOULD CONSULT ITS TAX ADVISORS REGARDING THE TAX CONSEQUENCES OF PURCHASING, HOLDING AND DISPOSING OF OUR COMMON STOCK OR PRE-FUNDED WARRANTS, AS WELL AS TAX CONSEQUENCES ARISING UNDER ANY STATE, LOCAL, NON-U.S. OR U.S. FEDERAL NON-INCOME TAX LAWS.

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UNDERWRITING

Subject to the terms and conditions set forth in the underwriting agreement, dated _____, 2022, between us and Cantor Fitzgerald & Co., or Cantor, 499 Park Avenue, New York, New York 10022, as the sole book-running manager of this offering, we have agreed to sell to Cantor, and Cantor has agreed to purchase from us, the shares of common stock (or pre-funded warrants, as applicable) offered hereby.

The underwriting agreement provides that the obligations of Cantor are subject to certain conditions precedent such as the receipt by Cantor of officers' certificates and legal opinions and approval of certain legal matters by their counsel. The underwriting agreement provides that Cantor will purchase all of the shares of common stock (or pre-funded warrants, as applicable) if any of them are purchased. We have agreed to indemnify Cantor and certain of its controlling persons against certain liabilities, including liabilities under the Securities Act, and to contribute to payments that Cantor may be required to make in respect of those liabilities.

Cantor is offering the shares of common stock and pre-funded warrants subject to its acceptance of the shares of common stock and pre-funded warrants from us and subject to prior sale. Cantor reserves the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part. In addition, Cantor has advised us that it does not intend to confirm sales to any account over which it exercises discretionary authority.

Option to Purchase Additional Shares

We have granted to Cantor an option, exercisable 30 days from the date of this prospectus supplement, to purchase, from time to time, in whole or in part, up to an aggregate of _____ shares from us at the public offering price set forth on the cover page of this prospectus supplement, less underwriting discounts and commissions.

Commission and Expenses

Cantor has advised us that it proposes to offer the shares of common stock and pre-funded warrants to the public at the public offering price set forth on the cover page of this prospectus supplement and to certain dealers, which may include the underwriters, at that price less a concession not in excess of \$ _____ per share of common stock or pre-funded warrant. Cantor may allow, and certain dealers may reallocate, a discount from the concession not in excess of \$ _____ per share of common stock (or pre-funded warrant, as applicable) to certain brokers and dealers. After the initial offering, Cantor may change the offering price and other selling terms.

The following table shows the public offering price, the underwriting discounts and commissions that we are to pay Cantor and the proceeds, before expenses, to us in connection with this offering. Such amounts are shown assuming both no exercise and full exercise of Cantor's option to purchase additional shares.

	Per Share		Total	
	Without Option to Purchase Additional Shares	With Option to Purchase Additional Shares	Without Option to Purchase Additional Shares	With Option to Purchase Additional Shares
Public offering price	\$ _____	\$ _____	\$ _____	\$ _____
Underwriting discounts and commissions	\$ _____	\$ _____	\$ _____	\$ _____
Proceeds to us, before expenses	\$ _____	\$ _____	\$ _____	\$ _____

We estimate expenses payable by us in connection with this offering, other than the underwriting discounts and commissions referred to above, will be approximately \$ _____. We have also agreed to reimburse Cantor for up to \$ _____ of certain of its counsels' fees and expenses, which reimbursed fee is deemed underwriting compensation for this offering by FINRA.

Listing

Our common stock is listed on the Nasdaq Global Market under the trading symbol "CGTX."

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No Sales of Similar Securities

We, our officers and our directors and certain of our affiliated stockholders have agreed, subject to certain specified exceptions, not to directly or indirectly, for a period of 90 days after the date of the underwriting agreement:

1. sell, offer, contract or grant any option to sell (including any short sale), pledge, transfer, establish an open “put equivalent position” within the meaning of Rule 16a-1(h) under the Exchange Act or otherwise dispose of, any shares of common stock, options or warrants to acquire shares of common stock, or securities exchangeable or exercisable for or convertible into shares of common stock currently or hereafter owned either of record or beneficially,
2. enter into any swap, hedge or other agreement or transaction that transfers, in whole or in part, the economic consequence of ownership of common stock, or securities exchangeable or exercisable for or convertible into shares of common stock, or
3. publicly announce an intention to do any of the foregoing for a period of 90 days after the date of this prospectus supplement without the prior written consent of Cantor.

In addition, we and each such person agrees that, without the prior written consent of Cantor, we or such other person will not, during the restricted period, make any demand for, or exercise any right with respect to, the registration of any shares of common stock or any security convertible into or exercisable or exchangeable for common stock.

Cantor may, in its sole discretion and at any time or from time to time before the termination of the 90-day period release all or any portion of the securities subject to lock-up agreements.

Market Making, Stabilization and Other Transactions

Cantor may make a market in the common stock as permitted by applicable laws and regulations. However, Cantor is not obligated to do so, and Cantor may discontinue any market-making activities at any time without notice in its sole discretion. Accordingly, no assurance can be given as to the liquidity of the trading market for the common stock, that you will be able to sell any of the common stock held by you at a particular time or that the prices that you receive when you sell will be favorable.

The underwriter has advised us that it, pursuant to Regulation M under the Exchange Act, certain persons participating in the offering may engage in short sale transactions, stabilizing transactions, syndicate covering transactions or the imposition of penalty bids in connection with this offering. These activities may have the effect of stabilizing or maintaining the market price of the common stock at a level above that which might otherwise prevail in the open market. Establishing short sales positions may involve either “covered” short sales or “naked” short sales.

“Covered” short sales are sales made in an amount not greater than the underwriter’s option to purchase additional shares of our common stock in this offering. The underwriter may close out any covered short position by either exercising its option to purchase additional shares of our common stock or purchasing shares of our common stock in the open market. In determining the source of shares to close out the covered short position, the underwriter 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 option to purchase additional shares.

“Naked” short sales are sales in excess of the option to purchase additional shares of our common stock. The underwriter must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriter is concerned that there may be downward pressure on the price of the shares of our common stock in the open market after pricing that could adversely affect investors who purchase in this offering.

A stabilizing bid is a bid for the purchase of shares of common stock on behalf of the underwriter for the purpose of fixing or maintaining the price of the common stock. A syndicate covering transaction is the bid for or the purchase of shares of common stock on behalf of the underwriter to reduce a short position incurred by the underwriter in connection with the offering. Similar to other purchase transactions, the

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underwriter's purchases to cover the syndicate short sales 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 our common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. A penalty bid is an arrangement permitting the underwriter to reclaim the selling concession otherwise accruing to a syndicate member in connection with the offering if the common stock originally sold by such syndicate member are purchased in a syndicate covering transaction and therefore have not been effectively placed by such syndicate member.

Neither we, nor the underwriter 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 our common stock. The underwriter is not obligated to engage in these activities and, if commenced, may end any of these activities at any time. These transactions may be effected on the Nasdaq Global Market, in the over-the-counter market or otherwise.

Passive Market Making

The underwriter may also engage in passive market making transactions in our common stock on the NASDAQ in accordance with Rule 103 of Regulation M during a period before the commencement of offers or sales of shares of our common stock in this offering and extending through the completion of distribution. A passive market maker must display its bid at a price not in excess of the highest independent bid of that security. However, if all independent bids are lowered below the passive market maker's bid, that bid must then be lowered when specified purchase limits are exceeded. Passive market making may cause the price of our common stock to be higher than the price that otherwise would exist in the open market in the absence of those transactions. The underwriter is not required to engage in passive market making and, if commenced, may end passive market making activities at any time.

Electronic Distribution

A prospectus in electronic format may be made available by e-mail or on the web sites or through online services maintained by one or more of the underwriters, selling group members (if any) or their affiliates. Other than the prospectus in electronic format, the information on the underwriter's web site and any information contained in any other web site maintained by the underwriter is not part of this prospectus supplement, has not been approved and/or endorsed by us or the underwriter and should not be relied upon by investors.

Other Activities and Relationships

Cantor and certain of its affiliates are full service financial institutions engaged in a wide range of activities for their own accounts and the accounts of customers, which may include, among other things, corporate finance, mergers and acquisitions, merchant banking, equity and fixed income sales, trading and research, derivatives, foreign exchange, futures, asset management, custody, clearance and securities lending. Cantor and certain of its affiliates have, from time to time, performed, and may in the future perform, various investment banking and financial advisory services for us and our affiliates, for which it received or will receive customary fees and expenses.

In addition, in the ordinary course of its business, Cantor and its affiliates may, directly or indirectly, hold long or short positions, trade and otherwise conduct such activities in or with respect to debt or equity securities and/or bank debt of, and/or derivative products. Such investment and securities activities may involve our securities and instruments. Cantor and its affiliates may also make investment recommendations or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long or short positions in such securities and instruments.

Stamp Taxes

If you purchase shares of common stock offered in this prospectus supplement, you may be required to pay stamp taxes and other charges under the laws and practices of the country of purchase, in addition to the offering price listed on the cover page of this prospectus supplement.

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Selling Restrictions

Canada

This prospectus supplement constitutes an “exempt offering document” as defined in and for the purposes of applicable Canadian securities laws. No prospectus has been filed with any securities commission or similar regulatory authority in Canada in connection with the offer and sale of the securities. No securities commission or similar regulatory authority in Canada has reviewed or in any way passed upon this prospectus supplement or on the merits of the securities and any representation to the contrary is an offence.

Canadian investors are advised that this prospectus supplement has been prepared in reliance on section 3A.3 of National Instrument 33-105 *Underwriting Conflicts*, or NI 33-105. Pursuant to section 3A.3 of NI 33-105, this prospectus supplement is exempt from the requirement that the issuer and the underwriter(s) provide investors with certain conflicts of interest disclosure pertaining to “connected issuer” and/or “related issuer” relationships that may exist between the issuer and the underwriter(s) as would otherwise be required pursuant to subsection 2.1(1) of NI 33-105.

Resale Restrictions

The offer and sale of the securities in Canada is being made on a private placement basis only and is exempt from the requirement that the issuer prepares and files a prospectus under applicable Canadian securities laws. Any resale of the securities acquired by a Canadian investor in this offering must be made in accordance with applicable Canadian securities laws, which may vary depending on the relevant jurisdiction, and which may require resales to be made in accordance with Canadian prospectus requirements, pursuant to a statutory exemption from the prospectus requirements, in a transaction exempt from the prospectus requirements or otherwise under a discretionary exemption from the prospectus requirements granted by the applicable local Canadian securities regulatory authority. These resale restrictions may under certain circumstances apply to resales of the securities outside of Canada.

Representations of Purchasers

Each Canadian investor who purchases the securities will be deemed to have represented to the issuer and the underwriter(s) that the investor (i) is purchasing the securities as principal, or is deemed to be purchasing as principal in accordance with applicable Canadian securities laws, for investment only and not with a view to resale or redistribution; (ii) is an “accredited investor” as such term is defined in section 1.1 of National Instrument 45-106 *Prospectus Exemptions*, or NI 33-105, or, in Ontario, as such term is defined in section 73.3(1) of the *Securities Act* (Ontario); and (iii) is a “permitted client” as such term is defined in section 1.1 of National Instrument 31-103 *Registration Requirements, Exemptions and Ongoing Registrant Obligations*.

Taxation and Eligibility for Investment

Any discussion of taxation and related matters contained in this prospectus supplement does not purport to be a comprehensive description of all of the tax considerations that may be relevant to a Canadian investor when deciding to purchase the securities and, in particular, does not address any Canadian tax considerations. No representation or warranty is hereby made as to the tax consequences to a resident, or deemed resident, of Canada of an investment in the securities or with respect to the eligibility of the securities for investment by such investor under relevant Canadian federal and provincial legislation and regulations.

Rights of Action for Damages or Rescission

Securities legislation in certain of the Canadian jurisdictions provides certain purchasers of securities pursuant to an offering memorandum (such as this prospectus supplement), including where the distribution involves an “eligible foreign security” as such term is defined in Ontario Securities Commission Rule 45-501 *Ontario Prospectus and Registration Exemptions* and in Multilateral Instrument 45-107 *Listing Representation and Statutory Rights of Action Disclosure Exemptions*, as applicable, with a remedy for damages or rescission,

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or both, in addition to any other rights they may have at law, where the offering memorandum, or other offering document that constitutes an offering memorandum, and any amendment thereto, contains a “misrepresentation” as defined under applicable Canadian securities laws. These remedies, or notice with respect to these remedies, must be exercised or delivered, as the case may be, by the purchaser within the time limits prescribed under, and are subject to limitations and defences under, applicable Canadian securities legislation. In addition, these remedies are in addition to and without derogation from any other right or remedy available at law to the investor.

Language of Documents

Upon receipt of this document, each Canadian investor hereby confirms that it has expressly requested that all documents evidencing or relating in any way to the sale of the securities described herein (including for greater certainty any purchase confirmation or any notice) be drawn up in the English language only. *Par la réception de ce document, chaque investisseur Canadien confirme par les présentes qu’il a expressément exigé que tous les documents faisant foi ou se rapportant de quelque manière que ce soit à la vente des valeurs mobilières décrites aux présentes (incluant, pour plus de certitude, toute confirmation d’achat ou tout avis) soient rédigés en anglais seulement.*

Australia

This document does not constitute a prospectus, product disclosure statement or other disclosure document under the Australia’s Corporations Act 2001 (Cth), or the Corporations Act, of Australia. This document has not been lodged with the Australian Securities & Investments Commission and is only directed to the categories of exempt persons set out below. Accordingly, if you receive this document in Australia:

You confirm and warrant that you are either:

- a “sophisticated investor” under section 708(8)(a) or (b) of the Corporations Act;
- a “sophisticated investor” under section 708(8)(c) or (d) of the Corporations Act and that you have provided an accountant’s certificate to the company which complies with the requirements of section 708(8)(c)(i) or (ii) of the Corporations Act and related regulations before the offer has been made; or
- a “professional investor” within the meaning of section 708(11)(a) or (b) of the Corporations Act.

To the extent that you are unable to confirm or warrant that you are an exempt sophisticated investor or professional investor under the Corporations Act any offer made to you under this document is void and incapable of acceptance.

You warrant and agree that you will not offer any of the shares issued to you pursuant to this document for resale in Australia within 12 months of those securities being issued unless any such resale offer is exempt from the requirement to issue a disclosure document under section 708 of the Corporations Act.

European Economic Area

In relation to each member state of the European Economic Area, or a Member State, no securities have been offered or will be offered pursuant to the offer described herein in that Member State prior to the publication of a prospectus in relation to the securities which has been approved by the competent authority in that Member State or, where appropriate, approved in another Member State and notified to the competent authority in that Member State, all in accordance with the Prospectus Regulation, except that the securities may be offered to the public in that Member State at any time:

- (i) to any legal entity which is a qualified investor as defined under Article 2 of the Prospectus Regulation;
- (ii) to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the Prospectus Regulation), subject to obtaining the prior consent of the underwriters for any such offer; or
- (iii) in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

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provided that no such offer of securities shall require the issuer or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation.

Each person in a Member State who acquires any securities in the offer or to whom any offer is made will be deemed to have represented, acknowledged and agreed to and with the issuer and the underwriter that it is a qualified investor within the meaning of the Prospectus Regulation.

In the case of any securities being offered to a financial intermediary as that term is used in Article 5(1) of the Prospectus Regulation, each such financial intermediary will be deemed to have represented, acknowledged and agreed to and with the issuer and the underwriter that the securities acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer to the public other than their offer or resale in a Member State to qualified investors, in circumstances in which the prior consent of the underwriter has been obtained to each such proposed offer or resale. Neither the issuer nor the underwriter have authorised, nor do they authorise, the making of any offer of securities through any financial intermediary, other than offers made by the underwriter which constitute the final placement of securities contemplated in this document.

The issuer and the underwriter and their affiliates will rely upon the truth and accuracy of the foregoing representations, acknowledgements and agreements.

For the purposes of this provision, the expression an “offer to the public” in relation to any securities in any Member State means the communication in any form and by any means of sufficient information on the terms of the offer and any securities to be offered so as to enable an investor to decide to purchase, or subscribe for, any securities and the expression “Prospectus Regulation” means Regulation (EU) 2017/1129.

In Member States, this document is being distributed only to, and is directed only at, persons who are “qualified investors” within the meaning of Article 2(e) of the Prospectus Regulation, or Qualified Investors. This document must not be acted on or relied on in any Member State by persons who are not Qualified Investors. Any investment or investment activity to which this document relates is available in any Member State only to Qualified Investors and will be engaged in only with such persons.

Hong Kong

No securities have been, may be or will be offered or sold in Hong Kong, by means of any document, other than to persons whose ordinary business is to buy or sell shares or debentures, whether as principal or agent; or to “professional investors” as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong, or the SFO and any rules made thereunder; or in other circumstances which do not result in the document being a “prospectus” as defined in the Companies (Winding UP and Miscellaneous Provisions) Ordinance (Cap. 32) of Hong Kong, or the C(WUMP)O, or which do not constitute an offer to the public within the meaning of the C(WUMP)O. No document, invitation or advertisement relating to the securities has been issued or may be issued or will be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted under the securities laws of Hong Kong) other than with respect to securities which are or are intended to be disposed of only to persons outside Hong Kong or only to “professional investors” as defined in the SFO and any rules made thereunder.

This document has not been and will not be registered with the Registrar of Companies in Hong Kong. Accordingly, this document may not be issued, circulated or distributed in Hong Kong, and the securities may not be offered for subscription to members of the public in Hong Kong. Each person acquiring the securities will be required, and is deemed by the acquisition of the securities, to confirm that he is aware of the restriction on offers of the securities described in this document and the relevant offering documents and that he is not acquiring, and has not been offered any securities in circumstances that contravene any such restrictions.

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Japan

The offering has not been and will not be registered under the Financial Instruments and Exchange Act of Japan (Act No. 25 of 1948 of Japan, as amended), or the FIEA, and the Initial Purchaser will not offer or sell any securities, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan (which term as used herein means, unless otherwise provided herein, any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan or to a resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the FIEA and any other applicable laws, regulations and ministerial guidelines of Japan.

Singapore

This document has not been and will not be lodged or registered with the Monetary Authority of Singapore. Accordingly, this document and any other document or material in connection with the offer or sale, or the invitation for subscription or purchase of the securities may not be issued, circulated or distributed, nor may the securities be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to any person in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore, or the SFA, (ii) to a relevant person as defined under Section 275(2) of the SFA, or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions, specified in Section 275 of the SFA and where (where applicable) Regulation 3 of the Securities and Futures (Classes of Investors) Regulations 2018, or (iii) otherwise pursuant to, and in accordance with the conditions of any other applicable provision of the SFA. **In the event that you are not an investor falling within any of the categories set out above, please return this document immediately. You may not forward or circulate this document to any other person in Singapore.**

No offer is made to you with a view to the securities being subsequently offered for sale to any other party. There are on-sale restrictions that may be applicable to investors who acquire securities. As such, investors are advised to acquaint themselves with the provisions of the SFA relating to resale restrictions and comply accordingly.

Where the securities are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

- a corporation (which is not an accredited investor as defined under Section 4A of the SFA) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or
- a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary is an accredited investor,

securities or securities-based derivatives contracts (each term as defined in Section 2(1) of the SFA) of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferable within six months after that corporation or that trust has acquired the securities under Section 275 of the SFA except:

- to an institutional investor under Section 274 of the SFA or to a relevant person defined in Section 275(2) of the SFA, or to any person pursuant to an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;
- where no consideration is given for the transfer;
- where the transfer is by operation of law;
- as specified in Section 276(7) of the SFA; or
- as specified in Regulation 37A of the Securities and Futures (Offers of Investments) (Securities and Securities-based Derivatives Contracts) Regulations 2018 of Singapore.

Switzerland

The securities may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange, or SIX, or on any other stock exchange or regulated trading facility in Switzerland. This

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document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the securities or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, the issuer or the securities have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of securities will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA, or FINMA, and the offer of securities has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes, or CISA. The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of securities.

Israel

This document does not constitute a prospectus under the Israeli Securities Law, 5728-1968, or the Securities Law, and has not been filed with or approved by the Israel Securities Authority. In the State of Israel, this document is being distributed only to, and is directed only at, and any offer of the shares is directed only at, investors listed in the first addendum, or the Addendum, to the Israeli Securities Law, consisting primarily of joint investment in trust funds, provident funds, insurance companies, banks, portfolio managers, investment advisors, members of the Tel Aviv Stock Exchange, underwriters, venture capital funds, entities with equity in excess of NIS 50 million and “qualified individuals”, each as defined in the Addendum (as it may be amended from time to time), collectively referred to as qualified investors (in each case purchasing for their own account or, where permitted under the Addendum, for the accounts of their clients who are investors listed in the Addendum). Qualified investors will be required to submit written confirmation that they fall within the scope of the Addendum, are aware of the meaning of same and agree to it.

United Kingdom

In relation to the United Kingdom, no securities have been offered or will be offered pursuant to the offer described herein to the public in the United Kingdom prior to the publication of a prospectus in relation to the securities which has been approved by the United Kingdom Financial Conduct Authority, except that the securities may be offered to the public in the United Kingdom at any time:

- (i) to any legal entity which is a qualified investor as defined under Article 2 of the United Kingdom Prospectus Regulation;
- (ii) to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the UK Prospectus Regulation), subject to obtaining the prior consent of the underwriter for any such offer; or
- (iii) in any other circumstances falling within Section 86 of the Financial Services and Markets Act 2000 (as amended), or the FSMA.

provided that no such offer of the securities shall require the issuer or any underwriter to publish a prospectus pursuant to Section 85 of the FSMA or supplement a prospectus pursuant to Article 23 of the United Kingdom Prospectus Regulation.

Each person in the United Kingdom who acquires any securities in the offer or to whom any offer is made will be deemed to have represented, acknowledged and agreed to and with the issuer and the underwriter that it is a qualified investor within the meaning of the United Kingdom Prospectus Regulation.

In the case of any securities being offered to a financial intermediary as that term is used in Article 5(1) of the UK Prospectus Regulation, each such financial intermediary will be deemed to have represented, acknowledged and agreed to and with the issuer and the underwriter that the securities acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer to the public other than their offer or resale in the United Kingdom to qualified investors, in circumstances in which the prior

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consent of the underwriter has been obtained to each such proposed offer or resale. Neither the issuer nor the underwriter have authorised, nor do they authorise, the making of any offer of securities through any financial intermediary, other than offers made by the underwriter which constitute the final placement of securities contemplated in this document.

The issuer and the underwriter and their affiliates will rely upon the truth and accuracy of the foregoing representations, acknowledgements and agreements.

For the purposes of this provision, the expression an “offer to the public” in relation to the securities in the United Kingdom means the communication in any form and by any means of sufficient information on the terms of the offer and any securities to be offered so as to enable an investor to decide to purchase or subscribe for any securities and the expression “UK Prospectus Regulation” means Regulation (EU) 2017/1129 as it forms part of United Kingdom law by virtue of the European Union (Withdrawal) Act 2018.

In the United Kingdom, this document is being distributed only to, and is directed only at, persons who are “qualified investors” within the meaning of Article 2(e) of the United Kingdom Prospectus Regulation who are also: (i) persons who fall within the definition of “investment professionals” in Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended, or the Order; (ii) persons falling within Article 49(2) of the Order; or (iii) persons to whom it may otherwise lawfully be communicated (all such persons together being referred to as “relevant persons”). This document must not be acted on or relied on in the United Kingdom by persons who are not relevant persons. Any investment or investment activity to which this document relates is available in the United Kingdom only to relevant persons and will be engaged in only with such persons.

Any invitation or inducement to engage in investment activity (within the meaning of Section 21 of the FSMA) may only be communicated or caused to be communicated in connection with the issue or sale of the securities in circumstances in which Section 21(1) of the FSMA does not apply. All applicable provisions of the FSMA and the Order must be complied with in respect of anything done by any person in relation to the securities in, from or otherwise involving the United Kingdom.

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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 underwriter by McGuireWoods LLP, New York, New York.

EXPERTS

The consolidated financial statements of Cognition Therapeutics, Inc. at December 31, 2021 and 2020, and for each of the two years in the period ended December 31, 2021, 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 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 and to the documents incorporated by reference herein. 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 or a document incorporated by reference herein. 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 completion 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 on the web site of the SEC referred to above. We also maintain a website at www.cogrx.com, at which 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, and the inclusion of our website address in this prospectus is an inactive textual reference only.

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INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

The SEC allows us to “incorporate by reference” information from other documents that we file with it, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus. Information in this prospectus supersedes information incorporated by reference that we filed with the SEC prior to the date of this prospectus. We incorporate by reference into this prospectus and the registration statement of which this prospectus is a part the information or documents listed below that we filed with the SEC (File No. 001-40886):

- our Annual Report on Form 10-K for the year ended December 31, 2021, filed with the SEC on March 30, 2022, and the information specifically incorporated by reference into our Annual Report on Form 10-K for the year ended December 31, 2021 from our Definitive Proxy Statement on Schedule 14A, filed with the SEC on April 25, 2022;
- our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2022 and June 30, 2022, filed with the SEC on May 11, 2022 and August 9, 2022, respectively;
- our Current Reports on Form 8-K filed with the SEC on June 13, 2022 and July 27, 2022; and
- the description of our common stock contained in our registration statement on Form 8-A filed with the SEC on October 6, 2021, including any amendments or reports filed for the purposes of updating this description.

Notwithstanding the statements in the preceding paragraphs, no document, report or exhibit (or portion of any of the foregoing) or any other information that we have “furnished” to the SEC pursuant to the Exchange Act shall be incorporated by reference into this prospectus.

We also incorporate by reference into this prospectus all documents (other than current reports furnished under Item 2.02 or Item 7.01 of Form 8-K and exhibits filed on such form that are related to such items) that are filed by us with the SEC pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act (i) after the date of the initial filing of the registration statement of which this prospectus forms a part and prior to effectiveness of the registration statement, or (ii) after the date of this prospectus but prior to the termination of the offering. These documents include periodic reports, such as Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, as well as proxy statements on Schedule 14A.

We will provide to each person, including any beneficial owner, to whom a prospectus is delivered, without charge upon written or oral request, a copy of any or all of the documents that are incorporated by reference into this prospectus but not delivered with the prospectus, including exhibits that are specifically incorporated by reference into such documents. You should direct any requests for documents to Cognition Therapeutics, Inc., 2500 Westchester Ave., Purchase, New York 10577, Attn: Chief Executive Officer.

You also may access these filings on our website at www.cogrx.com. We do not incorporate the information on our website into this prospectus or any supplement to this prospectus and you should not consider any information on, or that can be accessed through, our website as part of this prospectus or any supplement to this prospectus (other than those filings with the SEC that we specifically incorporate by reference into this prospectus or any supplement to this prospectus). You may also access these filings at the SEC’s website at www.sec.gov.

Any statement contained in a document incorporated or deemed to be incorporated by reference in this prospectus will be deemed modified, superseded or replaced for purposes of this prospectus to the extent that a statement contained in this prospectus modifies, supersedes or replaces such statement.

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Shares of Common Stock

Pre-Funded Warrants to Purchase

Shares of Common Stock

Preliminary Prospectus
, 2022

Cantor

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**PART II
INFORMATION NOT REQUIRED IN PROSPECTUS**

Item 13. Other Expenses of Issuance and Distribution.

The following table sets forth the fees and expenses in connection with the issuance and distribution of the securities being registered (excluding the underwriting discount and management fee). Except for the SEC registration fee and the FINRA filing fee, all amounts are estimates.

Item	Amount
SEC registration fee	\$
FINRA filing fee	
Legal fees and expenses	
Accounting fees and expenses	
Printing expenses	
Transfer agent fees	
Miscellaneous expenses	
Total	

Item 14. Indemnification of Directors and Officers.

As permitted by Section 102 of the DGCL, we have adopted provisions in our amended and restated certificate of incorporation and bylaws that 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 amended and restated certificate of incorporation also authorizes us to indemnify our officers, directors and other agents to the fullest extent permitted under Delaware law.

As permitted by Section 145 of the DGCL, our amended and restated bylaws provide that:

- we may indemnify our directors, officers and employees to the fullest extent permitted by the DGCL, 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 DGCL, subject to limited exceptions; and
- the rights provided in our bylaws are not exclusive.

Our third amended and restated certificate of incorporation and our amended and restated bylaws provide for the indemnification provisions described above and elsewhere herein. We have entered or will enter 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 DGCL. These indemnification agreements generally require us, among other things, to indemnify our officers and directors against liabilities that may arise by reason of their status or service as directors or officers, other than

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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 intends 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.

Item 15. Recent Sales of Unregistered Securities.

The following list sets forth information as to all unregistered securities we have sold since January 1, 2019 through the date of the prospectus that is a part of this registration statement:

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 automatically converted into shares of our common stock upon the closing of our initial public offering in October 2021 on a one-for-one basis, after taking into effect a reverse split effected on October 1, 2021.

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 automatically converted into shares of our common stock upon the closing of our initial public offering in October 2021 at a conversion price equal to 80% of the initial public offering price of our common stock.

Equity Awards

Since January 1, 2019, we have granted stock options to employees, officers, directors and consultants, covering an aggregate of 3,602,416 shares of our common stock, having a weighted average exercise price of \$5.55 per share, in connection with services provided to us by such parties.

Since January 1, 2019, we have issued an aggregate of 98,753 shares of our common stock to employees, officers, directors and consultants upon their exercise of stock options, for aggregate cash consideration of approximately \$0.1 million.

Exercises of Warrants

Since January 1, 2019, we have issued an aggregate of 248,755 shares of our common stock upon the exercise of common stock warrants, for aggregate cash consideration of approximately \$0.1 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.

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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	Third Amended and Restated Certificate of Incorporation (incorporated by reference to exhibit 3.1 of the Company's Current Report on Form 8-K filed on October 14, 2021).
3.2	Amended and Restated Bylaws (incorporated by reference to exhibit 3.2 of the Company's Current Report on Form 8-K filed on October 14, 2021).
4.1	Specimen Common Stock Certificate of Registrant (incorporated by reference to exhibit 4.1 to the Company's Registration Statement on Form S-1 (File No. 333-257999) dated July 29, 2021).
4.2	Description of the Registrant's Securities (incorporated herein by reference to Exhibit 4.1 to the Registrant's Annual Report on Form 10-K, filed with the SEC on March 30, 2022).
4.3*	Form of Pre-Funded Warrant.
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 (incorporated by reference to exhibit 10.1 to the Company's Registration Statement on Form S-1 (File No. 333-257999) dated July 29, 2021).
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 (incorporated by reference to exhibit 10.2 to the Company's Registration Statement on Form S-1 (File No. 333-257999) dated July 29, 2021).
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 (incorporated by reference to exhibit 10.3 to the Company's Registration Statement on Form S-1 (File No. 333-257999) dated July 29, 2021).
10.4	Office Lease dated July 1, 2017, by and between the Registrant and RJ Equities LP (incorporated by reference to exhibit 10.4 to the Company's Registration Statement on Form S-1 (File No. 333-257999) dated July 29, 2021).
10.5	First Amendment to Office Lease dated July 1, 2017, by and between the Registrant and RJ Equities LP (incorporated by reference to exhibit 10.5 to the Company's Registration Statement on Form S-1 (File No. 333-257999) dated July 29, 2021).
10.6	Office Lease dated July 1, 2021, by and between the Registrant and 2500/2700 Westchester Avenue Owner SPE LLC (incorporated by reference to exhibit 10.6 to the Company's Registration Statement on Form S-1 (File No. 333-257999) dated July 29, 2021).
10.7•	Amended and Restated 2007 Equity Incentive Plan (incorporated by reference to exhibit 10.7 to the Company's Registration Statement on Form S-1 (File No. 333-257999) dated July 29, 2021).
10.8•	2017 Equity Incentive Plan (incorporated by reference to exhibit 10.8 to the Company's Registration Statement on Form S-1 (File No. 333-257999) dated July 29, 2021).
10.9•	Amendment to 2017 Equity Incentive Plan (incorporated by reference to exhibit 10.9 to the Company's Registration Statement on Form S-1 (File No. 333-257999) dated July 29, 2021).
10.10•	Second Amendment to 2017 Equity Incentive Plan (incorporated by reference to exhibit 10.10 to the Company's Registration Statement on Form S-1 (File No. 333-257999) dated July 29, 2021).
10.11•	2021 Equity Incentive Plan (incorporated by reference to exhibit 10.11 to the Company's Registration Statement on Form S-1 (File No. 333-257999) dated July 29, 2021).

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Exhibit number	Exhibit description
10.12•	2021 Employee Stock Purchase Plan (incorporated by reference to exhibit 10.12 to the Company's Registration Statement on Form S-1 (File No. 333-257999) dated July 29, 2021).
10.13•	Form of Restricted Stock Award Agreement (incorporated by reference to exhibit 10.13 to the Company's Registration Statement on Form S-1 (File No. 333-257999) dated July 29, 2021).
10.14•	Form of Stock Option Grant Notice and Award Agreement (incorporated by reference to exhibit 10.14 to the Company's Registration Statement on Form S-1 (File No. 333-257999) dated July 29, 2021).
10.15•	Amended and Restated Employment Agreement by and between the Registrant and Lisa Ricciardi, (incorporated by reference to exhibit 10.16 to the Company's Registration Statement on Form S-1 (File No. 333-257999) dated July 29, 2021).
10.16•	Form of Restrictive Covenant Agreement (incorporated by reference to exhibit 10.21 to the Company's Registration Statement on Form S-1 (File No. 333-257999) dated July 29, 2021).
10.17•	Option Agreements for Directors (incorporated by reference to exhibit 10.22 to the Company's Registration Statement on Form S-1 (File No. 333-257999) dated July 29, 2021).
10.18	Grant Agreement dated August 14, 2016 by and between the Registrant and the National Institute of Aging (incorporated by reference to exhibit 10.25 to the Company's Registration Statement on Form S-1 (File No. 333-257999) dated July 29, 2021).
10.19	Grant Agreement dated September 12, 2017 by and between the Registrant and the National Institute of Aging (incorporated by reference to exhibit 10.26 to the Company's Registration Statement on Form S-1 (File No. 333-257999) dated July 29, 2021).
10.20	Grant Agreement dated April 18, 2018 by and between the Registrant and the National Institute of Aging (incorporated by reference to exhibit 10.27 to the Company's Registration Statement on Form S-1 (File No. 333-257999) dated July 29, 2021).
10.21	Grant Agreement dated September 8, 2018 by and between the Registrant and the National Institute of Aging (incorporated by reference to exhibit 10.28 to the Company's Registration Statement on Form S-1 (File No. 333-257999) dated July 29, 2021).
10.22	Grant Agreement dated August 28, 2020 by and between the Registrant and the National Institute of Aging (incorporated by reference to exhibit 10.29 to the Company's Registration Statement on Form S-1 (File No. 333-257999) dated July 29, 2021).
10.23	Grant Agreement dated September 5, 2020 by and between the Registrant and the National Institute of Aging (incorporated by reference to exhibit 10.30 to the Company's Registration Statement on Form S-1 (File No. 333-257999) dated July 29, 2021).
10.24	Grant Agreement dated September 18, 2020 by and between the Registrant and the National Institute of Aging (incorporated by reference to exhibit 10.31 to the Company's Registration Statement on Form S-1 (File No. 333-257999) dated July 29, 2021).
10.25	Grant Agreement dated February 3, 2021 by and between the Registrant and the National Institute of Aging (incorporated by reference to exhibit 10.32 to the Company's Registration Statement on Form S-1 (File No. 333-257999) dated July 29, 2021).
10.26	Grant Agreement dated April 30, 2021 by and between the Registrant and the National Institute of Aging (incorporated by reference to exhibit 10.33 to the Company's Registration Statement on Form S-1 (File No. 333-257999) dated July 29, 2021).
10.27	Grant Agreement dated May 6, 2021 by and between the Registrant and the National Institute of Aging (incorporated by reference to exhibit 10.34 to the Company's Registration Statement on Form S-1 (File No. 333-257999) dated July 29, 2021).
10.28	Grant Agreement dated May 10, 2021 by and between the Registrant and the National Institute of Aging (incorporated by reference to exhibit 10.35 to the Company's Registration Statement on Form S-1 (File No. 333-257999) dated July 29, 2021).

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Exhibit number	Exhibit description
21.1	Subsidiaries of Cognition Therapeutics, Inc. (incorporated by reference to exhibit 21.1 of the Company's Annual Report on Form 10-K filed on March 30, 2022).
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).
107*	Filing Fee Table.

* 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 financial statements or notes thereto.

Item 17. Undertakings.

The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the U.S. Securities and Exchange Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

provided, however, that paragraphs (1)(i), (1)(ii) and (1)(iii) above do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Securities and Exchange Commission by the registrant pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment 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.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering,

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other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. *Provided, however*, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

(5) That for the purpose of determining liability of the registrant under the Securities Act of 1933 to any purchaser in the initial distribution of securities, the undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

- (i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;
- (ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;
- (iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and
- (iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

(6) That, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement 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.

(7) For purposes of determining any liability under the Securities Act of 1933, 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.

(8) For the purpose of determining any liability under the Securities Act of 1933, 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.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to any charter provision, by law or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act of 1933 and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than 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 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.

**Confidential Treatment Requested by Cognition Therapeutics, Inc.
Pursuant to 17 C.F.R. Section 200.83**

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Purchase, State of New York, on this day of , 2022.

COGNITION THERAPEUTICS, INC.

By: _____

Lisa Ricciardi
Chief Executive Officer and President
(Principal Executive Officer)

POWER OF ATTORNEY

KNOW ALL BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Lisa Ricciardi and Andrew Einhorn, 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 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, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
_____ Lisa Ricciardi	Chief Executive Officer, President and Director (Principal Executive Officer)	, 2022
_____ Andrew Einhorn	Interim Chief Financial Officer (Principal Financial and Accounting Officer)	, 2022
_____ Jack A. Khattar	Director (Chairman of the Board)	, 2022
_____ Aaron G. L. Fletcher, Ph.D.	Director	, 2022
_____ Brett P. Monia, Ph.D.	Director	, 2022
_____ Ellen B. Richstone	Director	, 2022
_____ Peggy Wallace	Director	, 2022