Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2021

or

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

For the transition period from _____ to _____

Commission File Number: 001-40886

Cognition Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**13-4365359**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**

2500 Westchester Ave.
Purchase, NY 10577
(Address of Principal Executive Offices)

(412) 481-2210
(Registrant's telephone number)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☐ No ☒

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

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

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

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

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

Title of Each Class	**Trading symbol**	**Name of Exchange on which registered**
Common Stock, par value $0.001 per share	**CGTX**	**The Nasdaq Stock Market LLC**

As of November 17, 2021, there were 22,036,382 shares of the registrant's common stock issued and outstanding.

TABLE OF CONTENTS

Cautionary Note on Forward-Looking Statements

This Quarterly Report on Form 10-Q, or Quarterly Report, contains forward-looking statements concerning our business, operations and financial performance, as well as our plans, objectives and expectations for our business operations and financial performance and condition. All statements other than statements of historical or current facts included in this Quarterly Report 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 candidtates;
- 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 our initial public offering, or IPO;
- the extent to which the continuing 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;

- our ability to successfully commercialize our product candidates and develop sales and marketing capabilities, if our product candidates are approved;
- the size and growth of the potential markets for our product candidates and our ability to serve those markets;
- regulatory developments and approval pathways in the United States and foreign countries for our product candidates;
- the potential scope and value of our intellectual property and proprietary rights;
- our ability, and the ability of any future licensors, to obtain, maintain, defend, and enforce intellectual property and proprietary rights protecting our product candidates, and our ability to develop and commercialize our product candidates without infringing, misappropriating, or otherwise violating the intellectual property or proprietary rights of third parties;
- our ability to recruit and retain key members of management and other clinical and scientific personnel;
- developments relating to our competitors and our industry; and
- other risk and uncertainties, including those described in Part II, Item 1A “Risk Factors” in this Quarterly Report.

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 Quarterly Report, we cannot guarantee that the future results, levels of activity, performance, or events and circumstances reflected in the forward-looking statements will be achieved or occur at all. You should refer to the section titled “Risk Factors” set forth in Part II, Item 1A of this Quarterly Report for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. 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 Quarterly Report completely and with the understanding that our actual future results may be materially different from what we expect. We intend the forward-looking statements contained in this Quarterly Report to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act.

Summary Risk Factors

Below is a summary of material factors that make an investment in our common stock speculative or risky. Importantly, this summary does not address all the risks and uncertainties that we face. Additional discussion of the risks and uncertainties summarized in this risk factor summary, as well as other risks and uncertainties that we face, can be found under "Cautionary Note Regarding Forward-Looking Statements" and Part II, Item 1A, "Risk Factors" in this Quarterly Report. The below summary is qualified in its entirety by those more complete discussions of such risks and uncertainties. You should consider carefully the risks and uncertainties described under Part II, Item 1A, "Risk Factors" in this Quarterly Report as part of your evaluation of an investment in our common stock.

- 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;
- We have never generated revenue from product sales 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;
- We are highly dependent on the success of our lead product candidate, CT1812 and our other product candidates;
- We will need substantial additional financing to meet our financial obligations and to pursue our business objectives;
- The COVID-19 pandemic may materially and adversely affect our business and our financial results and could cause a disruption to our supply chain and the development of our product candidates;
- 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;
- 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 U.S. Food and Drug Adminisitration, or 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;
- 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;

- Unfavorable global economic or political conditions could adversely affect our business, financial condition or results of operations;
- We may be subject to securities litigation, which is expensive and could divert our management's attention;
- We have incurred, and will continue to incur, increased costs and demands upon management as a result of being a public company;
- 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; and
- Our stock price may be volatile and stockholders may not be able to resell shares of our common stock at or above the price orignally paid for such shares.

PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

COGNITION THERAPEUTICS, INC. AND SUBSIDIARY

CONSOLIDATED BALANCE SHEETS

(in thousands, except share and per share amounts)

	As of	
	September 30, 2021 (unaudited)	December 31, 2020
Assets		
Current assets		
Cash and cash equivalents	$ 8,310	$ 5,189
Grant receivables	847	564
Prepaid expenses	571	544
Other receivables	300	588
Other current assets	10	23
Total current assets	10,038	6,908
Deferred offering costs	3,210	—
Property and equipment, net	141	211
Total assets	$ 13,389	$ 7,119
Liabilities, Convertible Preferred Stock, and Stockholders' Deficit		
Current liabilities		
Accounts payable	2,775	2,003
Accrued expenses	740	994
Other current liabilities	913	253
Total current liabilities	4,428	3,250
Simple Agreements for Future Equity	10,918	—
Paycheck protection program loan	—	443
Derivative liability	—	2,209
Convertible notes, net	—	12,409
Accrued interest	—	1,622
Total liabilities	15,346	19,933
Commitments and contingencies		
Convertible preferred stock:		
Series A convertible preferred stock, par value $0.001 per share, 3,067,519 shares authorized at September 30, 2021 and December 31, 2020, 2,819,027 shares issued and outstanding as of September 30, 2021 and December 31, 2020; liquidation preference of $5,051 as of September 30, 2021	4,616	4,616
Series A-1 convertible preferred stock, par value $0.001 per share, 3,970,776 shares authorized at September 30, 2021 and December 31, 2020, 3,730,366 shares issued and outstanding as of September 30, 2021 and December 31, 2020; liquidation preference of $5,906 as of September 30, 2021	5,398	5,398
Series A-2 convertible preferred stock, par value $0.001 per share, 3,565,063 shares authorized at September 30, 2021 and December 31, 2020, 3,565,063 shares issued and outstanding as of September 30, 2021 and December 31, 2020; liquidation preference of $6,355 as of September 30, 2021	5,809	5,809
Series B convertible preferred stock, par value $0.001 per share, 30,450,000 shares authorized at September 30, 2021 and December 31, 2020, 30,409,890 shares issued and outstanding as of September 30, 2021 and December 31, 2020; liquidation preference of $43,269 as of September 30, 2021	39,547	39,547
Series B-1 convertible preferred stock, par value $0.001 per share, 10,928,155 and 0 shares authorized at September 30, 2021 and December 31, 2020, respectively, 10,926,089 and 0 shares issued and outstanding as of September 30, 2021 and December 31, 2020; liquidation preference of $16,038 as of September 30, 2021	29,391	—
Total convertible preferred stock	84,761	55,370
Stockholders' deficit:		
Common stock, $0.001 par value, 70,000,000 and 58,000,000 shares authorized at September 30, 2021 and December 31, 2020, respectively; 615,907 and 538,793 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	1	1
Additional paid-in capital	142	222
Accumulated deficit	(86,665)	(68,220)
Accumulated other comprehensive loss	(196)	(187)
Total stockholders' deficit	(86,718)	(68,184)
Total liabilities, convertible preferred stock, and stockholders' deficit	$ 13,389	$ 7,119

The accompanying notes are an integral part of these consolidated financial statements.

COGNITION THERAPEUTICS, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Operating Expenses:				
Research and development	$ 3,675	$ 3,399	$ 12,999	$ 9,600
General and administrative	1,548	1,062	3,791	3,687
Total operating expenses	5,223	4,461	16,790	13,287
Loss from operations	(5,223)	(4,461)	(16,790)	(13,287)
Other income (expense):				
Grant income	3,037	3,192	12,375	8,146
Change in the fair value of the derivative liability	—	(112)	2,209	135
Change in the fair value of the warrant liability	—	1	—	33
Change in the fair value of the Simple Agreements for Future Equity	(932)	—	(1,976)	—
Other income, net	8	95	256	353
Gain (loss) on debt extinguishment	—	—	443	(129)
Interest expense, net	—	(506)	(894)	(1,222)
Total other income, net	2,113	2,670	12,413	7,316
Net loss	(3,110)	(1,791)	(4,377)	(5,971)
Cumulative preferred stock dividends	(1,859)	(1,064)	(4,326)	(3,170)
Net loss attributable to common stockholders	$ (4,969)	$ (2,855)	$ (8,703)	$ (9,141)
Unrealized (loss) gain on foreign currency translation	(3)	18	(9)	(40)
Total comprehensive loss	$ (3,113)	$ (1,773)	$ (4,386)	$ (6,011)
Net loss per share attributable to common stockholders, basic and diluted	$ (8.12)	$ (5.31)	$ (14.87)	$ (18.34)
Weighted-average common shares outstanding, basic and diluted	611,680	537,315	585,320	498,415

The accompanying notes are an integral part of these consolidated financial statements.

COGNITION THERAPEUTICS, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT
(unaudited)
(in thousands, except share amounts)

	Series A Convertible Preferred Stock		Series A-1 Convertible Preferred Stock		Series A-2 Convertible Preferred Stock		Series B Convertible Preferred Stock		Series B-1 Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Balances as of December 31, 2020	2,819,027	$ 4,616	3,730,366	$ 5,398	3,565,063	$ 5,809	30,409,890	$39,547	—	$ —	538,793	$ 1	$ 222	$ (68,220)	$ (187)	$ (68,184)
Exercise of stock options	—	—	—	—	—	—	—	—	—	—	20,787	—	14	—	—	14
Equity-based compensation	—	—	—	—	—	—	—	—	—	—	—	—	98	—	—	98
Other comprehensive loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(5)	(5)
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	223	—	223
Balances as of March 31, 2021	2,819,027	4,616	3,730,366	5,398	3,565,063	5,809	30,409,890	39,547	—	—	559,580	1	334	(67,997)	(192)	(67,854)
Exercise of common stock warrants	—	—	—	—	—	—	—	—	—	—	50,497	—	34	—	—	34
Equity-based compensation	—	—	—	—	—	—	—	—	—	—	—	—	94	—	—	94
Issuance of Series B-1 Convertible Preferred Stock upon conversion of debt	—	—	—	—	—	—	—	—	10,926,089	29,391	—	—	(397)	(14,068)	—	(14,465)
Other comprehensive loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(1)	(1)
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	(1,490)	—	(1,490)
Balances as of June 30, 2021	2,819,027	4,616	3,730,366	5,398	3,565,063	5,809	30,409,890	39,547	10,926,089	29,391	610,077	1	65	(83,555)	(193)	(83,682)
Exercise of stock options	—	—	—	—	—	—	—	—	—	—	4,996	—	5	—	—	5
Exercise of common stock warrants	—	—	—	—	—	—	—	—	—	—	834	—	—	—	—	—
Equity-based compensation	—	—	—	—	—	—	—	—	—	—	—	—	72	—	—	72
Other comprehensive loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(3)	(3)
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	(3,110)	-	(3,110)
Balances as of September 30, 2021	2,819,027	$ 4,616	3,730,366	$ 5,398	3,565,063	$ 5,809	30,409,890	$39,547	10,926,089	$29,391	615,907	$ 1	$ 142	$ (86,665)	$ (196)	$ (86,718)

	Series A Convertible Preferred Stock		Series A-1 Convertible Preferred Stock		Series A-2 Convertible Preferred Stock		Series B Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive (Loss) Gain	Total Stockholders Deficit
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Balances as of December 31, 2019	2,819,027	$ 4,413	3,730,366	$ 5,160	3,565,063	$ 5,552	30,409,890	$37,802	469,751	$ 1	$ 1	$ (58,239)	$ (185)	$ (58,422
Equity-based compensation	—	—	—	—	—	—	—	—	—	—	125	—	—	125
Accretion of convertible preferred stock to redemption value	—	88	—	102	—	111	—	752	—	—	(125)	(928)	—	(1,053
Other comprehensive loss	—	—	—	—	—	—	—	—	—	—	—	—	(114)	(114
Net loss	—	—	—	—	—	—	—	—	—	—	—	(2,506)	—	(2,506
Balances as of March 31, 2020	2,819,027	4,501	3,730,366	5,262	3,565,063	5,663	30,409,890	38,554	469,751	1	1	(61,673)	(299)	(61,970
Exercise of stock options	—	—	—	—	—	—	—	—	16,694	—	11	—	—	11
Exercise of common stock warrants	—	—	—	—	—	—	—	—	50,497	—	34	—	—	34
Equity-based compensation	—	—	—	—	—	—	—	—	—	—	88	—	—	88
Accretion of convertible preferred stock to redemption value	—	88	—	102	—	111	—	752	—	—	(133)	(920)	—	(1,053
Other comprehensive gain	—	—	—	—	—	—	—	—	—	—	—	—	56	56
Net loss	—	—	—	—	—	—	—	—	—	—	—	(1,674)	—	(1,674
Balances as of June 30, 2020	2,819,027	4,589	3,730,366	5,364	3,565,063	5,774	30,409,890	39,306	536,942	1	1	(64,267)	(243)	(64,508
Exercise of stock options	—	—	—	—	—	—	—	—	429	—	—	—	—	—
Equity-based compensation	—	—	—	—	—	—	—	—	—	—	129	—	—	129
Accretion of convertible preferred stock to redemption value	—	27	—	34	—	35	—	241	—	—	(44)	(293)	—	(337
Other comprehensive gain	—	—	—	—	—	—	—	—	—	—	—	—	18	18
Net loss	—	—	—	—	—	—	—	—	—	—	—	(1,791)	—	(1,791
Balances as of September 30, 2020	2,819,027	$ 4,616	3,730,366	$ 5,398	3,565,063	$ 5,809	30,409,890	$39,547	537,371	$ 1	$ 86	$ (66,351)	$ (225)	$ (66,489

The accompanying notes are an integral part of these consolidated financial statements.

COGNITION THERAPEUTICS, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF CASH FLOWS
(unaudited)
(in thousands)

	Nine Months Ended September 30,	
	2021	2020
Cash flows from operating activities:		
Net loss	$ (4,377)	$ (5,971)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	70	74
Amortization of debt issuance costs	31	34
Amortization of debt discount	352	536
Change in the fair value of the derivative liability	(2,209)	(135)
Change in the fair value of the warrant liability	—	(33)
Change in the fair value of the Simple Agreements for Future Equity	1,976	—
(Gain) loss on debt extinguishment	(443)	129
Equity-based compensation	264	342
Changes in operating assets and liabilities:		
Grant receivables	(283)	11
Prepaid expenses and other current assets	(18)	(214)
Other receivables	264	966
Accounts payable	(278)	286
Accrued expenses and interest	258	275
Other current liabilities	661	747
Net cash used in operating activities	(3,732)	(2,953)
Cash flows from investing activities:		
Payments for property and equipment	—	(10)
Net cash used in investing activities	—	(10)
Cash flows from financing activities:		
Payments on capital lease obligation	—	(4)
Proceeds from issuance of Simple Agreements for Future Equity	8,942	—
Proceeds from the exercise of stock warrants	34	34
Proceeds from the exercise of stock options	19	11
Proceeds from the issuance of convertible notes	—	5,372
Deferred offering costs	(2,155)	—
Debt issuance costs related to convertible notes	—	(93)
Net cash provided by financing activities	6,840	5,320
Effect of exchange rate changes on cash and cash equivalents	13	(4)
Net increase in cash and cash equivalents	3,121	2,353
Cash and cash equivalents		
Cash and cash equivalents – beginning of period	5,189	2,890
Cash and cash equivalents – end of period	$ 8,310	$ 5,243
Supplemental disclosures of non-cash financing activities:		
Non-cash accretion of convertible preferred stock to redemption value	$ —	$ 2,443
Deferred offering costs included in accounts payable	$ 1,055	$ —
Issuance of Series B-1 Convertible Preferred Stock upon conversion of debt	$ 29,391	$ —

The accompanying notes are an integral part of these consolidated financial statements.

Cognition Therapeutics, Inc. and Subsidiary

Notes to Consolidated Financial Statements
(unaudited)
(in thousands, except share and per share amounts)

1. Description of Business and Financial Condition

Cognition Therapeutics, Inc. (the "Company") was incorporated as a Delaware corporation on August 21, 2007. The Company is a biopharmaceutical company developing disease modifying therapies for central nervous system (CNS) disorders. The Company's pipeline candidates were discovered using proprietary biology and chemistry platforms designed to identify novel drug targets and disease-modifying therapies that address dysregulated pathways specifically associated with neurodegenerative diseases. The Company was founded on the unique combination of biological expertise around these targets, including proprietary assays that emphasize functional responses, and proprietary medicinal chemistry intended to produce novel, high-quality small-molecule drug candidates.

On July 14, 2015, the Company formed Cognition Therapeutics PTY LTD, as its wholly owned subsidiary (the "Subsidiary"), primarily for the purpose of conducting research and development efforts at facilities located in Australia. Assets and liabilities of the Company's Australian subsidiary, which uses the Australian dollar as its local functional currency, are translated to United States (U.S.) dollars at year-end exchange rates. Income statement accounts are translated using the average exchange rates prevailing during the month in which income and expenses are generated. Translation adjustments are recorded to accumulated other comprehensive income (loss) ("AOCI") within stockholders' deficit. Gains and losses from foreign currency transactions are included in net loss as a part of other income, net.

On October 13, 2021, the Company closed its initial public offering ("IPO") of 3,768,116 shares of the Company's common stock at a public offering price of $12.00 per share. The gross proceeds from the IPO, including the overallotment exercise, were $45.2 million and the net proceeds were approximately $38.1 million, after deducting underwriting discounts and commissions and other offering related expenses payable by the Company. Upon completion of the IPO, all of the Company's then outstanding preferred stock as of September 30, 2021 was automatically converted into an aggregate of 15,906,537 shares of common stock and an aggregate amount of $8.9 million of simple agreements for future equity ("SAFEs"), as of September 30, 2021, was automatically converted into an aggregate of 931,485 shares of common stock (see Note 13).

On November 10, 2021, the representative of the underwriters for the IPO provided notice to the Company that it had elected to exercise its over-allotment option in full to purchase 565,217 shares of the Company's common stock. The representative's exercise of the over-allotment option closed on November 12, 2021, resulting in gross proceeds of $6.8 million and net proceeds to the Company of approximately $6.3 million, after deducting underwriting discounts and commissions and other offering related expenses.

The Company held cash and cash equivalents of $8.3 million at September 30, 2021. The Company expects that its cash and cash equivalents, including the net proceeds from its IPO, will enable it to fund its operating expenses and capital expenditure requirements for at least twelve months from November 17, 2021, the filing date of this Quarterly Report on Form 10-Q. However, additional funding will be necessary beyond this point to fund future preclinical and clinical activities. The Company expects to finance its future cash needs through a combination of equity or debt financings, collaboration agreements, strategic alliances and licensing arrangements.

2. Summary of Significant Accounting Policies

The Company's significant accounting policies are disclosed in the audited financial statements for the year ended December 31, 2020, which are contained in the Company's final prospectus for its IPO, dated October 7, 2021, and filed with the Securities and Exchange Commission ("SEC") pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended (the "Prospectus"). Since the date of those financial statements, there have been no changes to its significant accounting policies.

Basis of Presentation

The accompanying consolidated financial statements as of September 30, 2021, and for the three and nine months ended September 30, 2021 and 2020, have been prepared in accordance with the rules and regulations of the SEC and generally accepted accounting principles in the United States of America ("U.S. GAAP"). Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete financial statements. In the opinion of the Company's management, the accompanying unaudited interim consolidated financial statements contain all adjustments that are necessary to present fairly the Company's financial position as of September 30, 2021, the statements of operations and comprehensive loss and convertible preferred stock and stockholders' deficit for the three and nine months ended September 30, 2021 and 2020, and the statement of cash flows for the nine months ended September 30, 2021 and 2020. Such adjustments are of a normal and recurring nature. The results for the three and nine months ended September 30, 2021 are not necessarily indicative of the results for the year ending December 31, 2021, or for any future period. These interim financial statements should be read in conjunction with the audited financial statements as of and for the year ended December 31, 2020, and the notes thereto, which are included in the Prospectus.

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosures of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of other income and expenses during the reporting period. Actual results could differ from those estimates.

Cash and Cash Equivalents

Cash and cash equivalents consist primarily of interest-bearing deposits at various financial institutions. The Company considers all highly liquid investments with an original maturity of three months or less when purchased to be cash equivalents.

Receivables

Grant Receivables

Grant receivables relate to outstanding amounts due for reimbursable expenditures of awarded grants issued by the National Institute of Health and are carried at their estimated collectible amounts. The Company expects all receivables to be collectible, and accordingly, there is no allowance for doubtful accounts required on these grant receivables.

Other Receivables

Other receivables consist of research and development tax credits from the Commonwealth of Pennsylvania and the Australian research and development tax credit from the Australian Tax Authority. Historically, the Company has sold the Pennsylvania tax credits to third parties, while the Australian tax refund is paid directly to the Company by the Australian Tax Authority. Research and development tax refunds and credits are carried at their estimated collectible amounts. The Company expects all receivables to be collectible and accordingly, there is no allowance for doubtful accounts required on these other receivables.

Deferred Offering Costs

The Company capitalizes certain legal, accounting and other third-party fees that are directly associated with in-process equity financings, including the IPO, as deferred costs until such financings are consummated. After consummation of the equity financing, these costs are recorded in stockholders' deficit as a reduction of proceeds generated as a result of the offering. Should an in-process equity financing be abandoned, the deferred offering costs will be expensed immediately in the consolidated statement of operations and comprehensive loss. During the three and nine months ended September 30, 2021, the Company incurred $769 and $3,210 of deferred offering costs in connection with

its IPO registration process, respectively. During the three and nine months ended September 30, 2020, the Company incurred $0 of deferred offering costs.

Property and Equipment

Property and equipment is recorded at cost, less accumulated depreciation. Depreciation is computed on the straight-line basis over the estimated useful life of the asset. The Company estimates the useful life to be 5 and 6 years for equipment and furniture and fixtures, respectively. The cost of repairs and maintenance is charged to expense as incurred.

Property and equipment is evaluated for impairment whenever events or changes in circumstances indicate the carrying value of an asset may not be recoverable from the estimated future cash flows expected to result from its use and eventual disposition. If expected cash flows are less than the carrying value, an impairment loss is recognized equal to an amount by which the carrying value exceeds the fair value of the assets. There were no indicators of impairment of long-lived assets during the three and nine months ended September 30, 2021 or 2020.

Convertible Instruments

ASC 815, *Derivatives and Hedging Activities* ("ASC 815") requires companies to bifurcate certain conversion options and redemption features from their host instruments and account for them as freestanding derivative financial instruments should certain criteria be met.

The Company also follows ASC 480-10, *Distinguishing Liabilities from Equity* ("ASC 480-10") when evaluating the accounting for its hybrid instruments. A financial instrument that embodies an unconditional obligation, or a financial instrument other than an outstanding share that embodies a conditional obligation, that the issuer must or may settle by issuing a variable number of its equity shares shall be classified as a liability (or an asset in some circumstances) if, at inception, the monetary value of the obligation is based solely or predominantly on any one of the following: (a) a fixed monetary amount known at inception; (b) variations in something other than the fair value of the issuer's equity shares; or (c) variations inversely related to changes in the fair value of the issuer's equity shares. Hybrid instruments meeting these criteria are not further evaluated for any embedded derivatives and are carried as a liability at fair value at each balance sheet date.

Debt Issuance Costs and Discounts

The Company incurred third-party costs in connection with the convertible notes as described in Note 6. These costs are classified on the balance sheet as a direct deduction from the convertible notes and amortized over the term of the agreement as interest expense using the effective interest rate method.

Discounts related to bifurcated derivatives resulting from the convertible note issuances are recorded as a reduction to the carrying value of the debt and amortized over the life of the debt using the effective interest method.

Warrants Issued in Connection with Financings

The Company generally accounts for warrants issued in connection with debt and equity financings as a component of equity, unless the warrants include specific features, such as if the warrants are exercisable for securities that are considered contingently redeemable. For warrants that are exercisable for securities that are considered contingently redeemable, the Company records the fair value of the warrants as a liability at each balance sheet date and records changes in fair value in other income (expense) in the consolidated statement of operations and comprehensive loss.

Convertible Preferred Stock

The Company has classified convertible preferred stock outside of stockholders' deficit in the accompanying balance sheets due to the convertible preferred stock's redemption features. Originally, the convertible preferred stock was eligible to become redeemable at the holders' option at any time after March 20, 2021. This right was removed in

connection with an amendment to the Company's articles of incorporation on July 29, 2020. Pre-amendment, the convertible preferred stock was redeemable due to the passage of time, and therefore, the Company recorded changes in the redemption value and accreted the convertible preferred stock immediately to the redemption value during each period presented. These increases were affected through charges against retained earnings, if any, and then to additional paid-in capital. In the absence of additional paid-in capital, the accretion is charged to accumulated deficit. Post-amendment, the convertible preferred stock is considered to be contingently redeemable only upon the occurrence of a deemed liquidation event (Note 7). As a result, the Company ceased accreting the convertible preferred stock on July 29, 2020. To evaluate whether the changes to the terms of the preferred stock should be accounted for as a modification or extinguishment, the Company follows the qualitative approach, in which amendments to preferred shares are analyzed based on the expected economics as well as the business purpose of the amendment. The Company concluded that the amendment did not result in a significant change to the fundamental nature of the preferred stock, and accordingly, the amendment was accounted for as a modification, and there was no accounting impact for the modification.

Grant income

For the three and nine months ended September 30, 2021, the Company generated grant income of $3,037 and $12,375, respectively, from reimbursements from the National Institute of Health ("NIH") for aging research. For the three and nine months ended September 30, 2020, the Company generated grant income of $3,192 and $8,146, respectively. The Company records grant income in other income (expense) in the period in which the reimbursable research and development services are incurred and the right to payment is realized. The grants awarded relate to agreed upon direct and indirect costs for specific studies or clinical trials, which may include personnel and consulting costs, costs paid to contract research organizations ("CROs"), research institutions and/or consortiums involved in the grant, as well as facilities and administrative costs. These grants are cost plus fixed fee arrangements in which the Company is reimbursed for its eligible direct and indirect costs over time, up to the maximum amount of each specific grant award. Only costs that are allowable under the grant award, certain government regulations and the NIH's supplemental policy and procedure manual may be claimed for reimbursement, and the reimbursements are subject to routine audits from governmental agencies from time to time.

Research and Development Costs

The Company is involved in research and development aimed at the development of treatments for a variety of diseases related to the central nervous system, with a primary focus on Alzheimer's Disease. Research and development costs are expensed as incurred. Research and development expenses consist principally of personnel costs, including salaries, stock-based compensation, and benefits for employees, third-party license fees and other operational costs related to our research and development activities, including allocated facility-related expenses and external costs of outside vendors, and other direct and indirect costs. Non-refundable research and development costs are deferred and expensed as the related goods are delivered or services are performed. Costs for external development activities are recognized based on an evaluation of the progress to completion of specific tasks. Costs for certain research and development activities are recognized based on the pattern of performance of the individual arrangements, which may differ from the pattern of billings incurred, and are reflected in the consolidated financial statements as prepaid expenses or as accrued research and development expenses.

Equity-based Compensation

Following the provisions of ASC 718, *Compensation — Stock Compensation*, the Company recognizes compensation expense for equity-based grants using the straight-line attribution method, in which the expense is recognized ratably over the requisite service period within operating expenses based on the grant date fair value. The Company also has granted awards subject to performance-based vesting. The Company would recognize compensation expense for these awards commencing in the period in which the vesting condition becomes probable of achievement. Grant date fair value is estimated on the date of grant using the Black-Scholes option pricing model. Forfeitures are recognized in the period in which they occur.

Black-Scholes requires inputs based on certain subjective assumptions, including (i) the expected stock price volatility, (ii) the expected term of the award, (iii) the risk-free interest rate and (iv) expected dividends. Due to the lack

of a public market for the Company's common stock and lack of company specific historical and implied volatility data, the Company has based its computation of expected volatility on the historical volatility of a representative group of public companies with similar characteristics to the Company, including stage of product development and life science industry focus. The historical volatility is calculated based on a period of time commensurate with expected term assumption. The Company uses the simplified method to calculate the expected term for stock options granted to employees whereby the expected term equals the arithmetic average of the vesting term and the original contractual term of the stock options due to its lack of sufficient historical data. The risk-free interest rate is based on U.S. Treasury securities with a maturity date commensurate with the expected term of the associated award. The expected dividend yield is assumed to be zero as the Company has never paid dividends and has no current plans to pay any dividends on its common stock.

Due to the absence of an active market for the Company's common stock, the Company utilized methodologies in accordance with the framework of the American Institute of Certified Public Accountants Technical Practice Aid, *Valuation of Privately-Held Company Equity Securities Issued as Compensation*, to estimate the fair value of its common stock. In determining the exercise prices for stock options granted, the Company has considered the estimated fair value of the common stock as of the measurement date. The estimated fair value of the common stock has been determined at each grant date based upon a variety of factors, including the illiquid nature of the common stock, arm's-length sales of the Company's capital stock (including convertible preferred stock), the effect of the rights and preferences of the preferred stockholders and the prospects of a liquidity event. Among other factors are the Company's financial position and historical financial performance, the status of technological developments within the Company's research, the composition and ability of the current research and management team, an evaluation or benchmark of the Company's competition and the current business climate in the marketplace. Significant changes to the key assumptions underlying the factors used could result in different fair values of common stock at each valuation date.

Concentration of Credit Risk

The Company's financial instruments that are exposed to credit risks consist of cash and cash equivalents. The Company maintains its cash and cash equivalents in bank deposit accounts which, at times, may exceed the federally insured limit. The Company has not experienced any losses in these accounts and does not believe it is exposed to any significant credit risk related to these funds.

Fair Value of Financial Instruments

The Company applies ASC 820, *Fair Value Measurement* ("ASC 820"), which establishes a framework for measuring fair value and clarifies the definition of fair value within that framework. ASC 820 defines fair value as an exit price, which is the price that would be received for an asset or paid to transfer a liability in the Company's principal or most advantageous market in an orderly transaction between market participants on the measurement date. The fair value hierarchy established in ASC 820 generally requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. Observable inputs reflect the assumptions that market participants would use in pricing the asset or liability and are developed based on market data obtained from sources independent of the reporting entity. Unobservable inputs reflect the entity's own assumptions based on market data and the entity's judgments about the assumptions that market participants would use in pricing the asset or liability and are to be developed based on the best information available in the circumstances.

The carrying value of the Company's cash and cash equivalents, grants receivable, prepaid expense, other receivables, other current assets, accounts payable, accrued expenses and other current liabilities approximate fair value because of the short-term maturity of these financial instruments. In addition, the Company records its warrant liability, derivative liability, and SAFEs at fair value.

The valuation hierarchy is composed of three levels. The classification within the valuation hierarchy is based on the lowest level of input that is significant to the fair value measurement. The levels within the valuation hierarchy are described below:

- Level 1 — Assets and liabilities with unadjusted, quoted prices listed on active market exchanges. Inputs to the fair value measurement are observable inputs, such as quoted prices in active markets for identical assets or liabilities.

- Level 2 — Inputs to the fair value measurement are determined using prices for recently traded assets and liabilities with similar underlying terms, as well as direct or indirect observable inputs, such as interest rates and yield curves that are observable at commonly quoted intervals.

- Level 3 — Inputs to the fair value measurement are unobservable inputs, such as estimates, assumptions, and valuation techniques when little or no market data exists for the assets or liabilities.

Comprehensive Loss

The Company recorded $3 and $9 in other comprehensive loss related to foreign currency translation for the three and nine months ended September 30, 2021, respectively. The Company recorded $18 in other comprehensive gain and $40 in other comprehensive loss for the three and nine months ended September 30, 2020, respectively. The Company presents comprehensive loss in a single statement within its consolidated financial statements.

Net Loss Per Share Attributable to Common Stockholders

Basic net loss attributable to common shares is computed by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding during each period. Diluted net loss attributable to common shares includes the effect, if any, from the potential exercise or conversion of securities, such as convertible preferred stock and stock options, which would result in the issuance of incremental shares of common stock. For diluted net loss per share, the weighted-average number of shares of common stock is the same for basic net loss per share due to the fact that when a net loss exists, dilutive securities are not included in the calculation as the impact is anti-dilutive. The Company's convertible preferred stock entitles the holder to participate in dividends and earnings of the Company, and, if the Company were to recognize net income attributable to common stockholders, it would have to use the two-class method to calculate earnings per share. The two-class method is not applicable during periods with a net loss attributable to common stockholders, as the holders of the convertible preferred stock have no obligation to fund losses.

Segments

The Company has determined that it operates and manages one operating segment, which is the business of developing and commercializing therapeutics. The Company's chief operating decision maker, its chief executive officer, reviews financial information on an aggregate basis for the purpose of allocating resources.

Emerging Growth Company Status

The Company is an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 (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. The Company has elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that it is (a) no longer an emerging growth company or (b) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, these financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

Recent Accounting Pronouncements

In February 2016, the FASB issued Accounting Standards Update (ASU) No. 2016-02, *Leases* (Topic 842). ASU No. 2016-02 requires lessees to recognize the assets and liabilities that arise from leases on the balance sheet. A lessee should recognize in the statement of financial position a liability to make lease payments (the lease liability) and a right-of-use asset representing its right to use the underlying asset for the lease term. ASU No. 2016-02 is effective for the Company for annual periods beginning after December 15, 2021. Early adoption is permitted. The Company expects to adopt this guidance when effective and is assessing what effect the adoption of ASU 2016-02 will have on its consolidated financial statements and accompanying notes. The Company expects to record right-of-use assets and liabilities upon adoption.

In June 2018, the FASB issued ASU 2018-07, *Compensation — Stock Compensation* (Topic 718) Improvements to Nonemployee Share-Based Payment Accounting. The new ASU simplifies the accounting for share-based payments to non-employees by aligning it with the accounting for share-based payments to employees, with certain exceptions. The Company adopted the standard on January 1, 2020 and it did not have a material impact on the Company's financial condition, results of operations and cash flows.

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement* (Topic 820). This standard modifies disclosure requirements related to fair value measurement and is effective for all entities for fiscal years beginning after December 15, 2019. Among other things, ASU 2018-13 requires public entities to disclose the range and weighted average used to develop significant unobservable inputs for level 3 fair value measurements, while eliminating the requirement for public entities to disclose the amount of and reasons for transfers between level 1 and level 2 of the fair value hierarchy. Implementation on a prospective or retrospective basis varies by specific disclosure requirement. The standard also allows for early adoption of any removed or modified disclosures upon issuance while delaying adoption of the additional disclosures until their effective date. The Company adopted this guidance on January 1, 2020 and the adoption did not have a material impact on its financial statements.

In August 2020, the FASB issued ASU 2020-06, *Debt — Debt with Conversion and Other Options* (Subtopic 470-20) and *Derivatives and Hedging — Contracts in Entity's Own Equity* (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity. This ASU simplifies the accounting for certain convertible instruments. ASU 2020-06 will be effective for fiscal years beginning after December 15, 2021, with early adoption permitted for interim and annual reporting periods beginning after December 15, 2020. The Company adopted ASU 2020-06 on January 1, 2021, and the adoption did not have a material impact on the Company's consolidated financial statements and related disclosures.

In October 2020, the FASB issued ASU 2020-10, *Codification Improvements*, which updates various codification topics by clarifying or improving disclosure requirements to align with the SEC's regulations. The Company adopted ASU 2020-10 on January 1, 2021. The adoption of ASU 2020-10 did not have a material impact on the Company's consolidated financial statements and related disclosures.

All other new accounting pronouncements issued, but not yet effective or adopted have been deemed to be not relevant to the Company and, accordingly, are not expected to have a material impact once adopted.

Reverse Stock Split

In July 2021, the Company's Board of Directors approved an amendment to the Company's second amended and restated certificate of incorporation to effect a 1-for-3.2345 reverse stock split of the Company's common stock, which was effected on October 1, 2021 with a filing made with the Secretary of State of the State of Delaware. Stockholders entitled to fractional shares as a result of the reverse stock split will receive a cash payment in lieu of receiving fractional shares. The par value of the common stock was not adjusted as a result of the reverse stock split. Shares of common stock underlying outstanding stock options and other equity instruments were proportionately reduced and the respective exercise prices, if applicable, were proportionately increased in accordance with the terms of the appropriate securities agreements. Shares of common stock reserved for issuance upon the conversion of our convertible preferred stock were

proportionately reduced and the respective conversion prices were proportionately increased. All common share and per share data have been retrospectively revised to reflect the reverse stock split.

3. Financial Instruments and Fair Value Measurements

Financial assets and liabilities measured at fair value are summarized below:

	As of September 30, 2021			
	Quoted Priced in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets:				
Money market funds	$ 7,252	$ —	$ —	$ 7,252
Total assets	$ 7,252	$ —	$ —	$ 7,252
Liabilities:				
Simple Agreements for Future Equity	$ —	$ —	$ 10,918	$ 10,918
Total liabilities	$ —	$ —	$ 10,918	$ 10,918

	As of December 31, 2020			
	Quoted Priced in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets:				
Money market funds	$ 2,853	$ —	$ —	$ 2,853
Total assets	$ 2,853	$ —	$ —	$ 2,853
Liabilities:				
Derivative liability	$ —	$ —	$ 2,209	$ 2,209
Total liabilities	$ —	$ —	$ 2,209	$ 2,209

The following table sets forth a summary of the changes in fair value of the Level 3 liabilities for the nine months ended September 30, 2021 and 2020:

	Nine Months Ended September 30, 2021		
	SAFE	Derivative Liability	Total
Balance at December 31, 2020	$ —	$ 2,209	$ 2,209
Change in the fair value of the warrant liability	—	—	—
Fair value recognized upon the issuance of SAFE	8,942	—	8,942
Change in the fair value of the liability	1,976	(2,209)	(233)
Balance at September 30, 2021	$ 10,918	$ —	$ 10,918

	Nine Months Ended September 30, 2020		
	Warrant Liability	Derivative Liability	Total
Balance at December 31, 2019	$ 181	$ 1,493	$ 1,674
Change in the fair value of the warrant liability	—	—	—
Fair value recognized upon the issuance of Convertible Notes	—	718	718
Change in the fair value of the liability	(33)	(135)	(168)
Balance at September 30, 2020	$ 148	$ 2,076	$ 2,224

Derivative Liability — The Company recognizes derivative liabilities as a result of the issuance of the convertible notes that contain conversion and redemption features that are required to be bifurcated. The fair value measurement of the derivative liability is classified as Level 3 under the fair value hierarchy as it has been valued using certain unobservable inputs. These inputs include: (1) probability of occurrence of future events (such as a qualified financing or a sale), and (2) discount rate for implied return required by investor. Significant increases or decreases in any of those inputs in isolation could result in a significantly lower or higher fair value measurement.

The fair value of the derivative liability was determined by calculating the fair value of the notes with the conversion and redemption features as compared to the fair value of the notes without such features, with the difference representing the value of the conversion and redemption features, or the derivative liability. The conversion and redemption features are measured at fair value as of each reporting date and the change in the fair value for the period is recorded in the consolidated statements of operations as a change in the fair value of the derivative liability. The fair value of the derivative liability is based on Level 3 unobservable inputs. Changes in fair value are recognized as a gain or loss within other income (expense) on the consolidated statements of operations and comprehensive loss. The derivative liability expired unexercised upon the conversion of the convertible notes into Series B-1 Convertible Preferred Stock in May of 2021 (Note 7).

Warrant Liability — The Company issued 180,724 Series A-1 preferred stock warrants in December 2010. The Company recorded a change in fair value adjustment of $1 and $33 in the consolidated statement of operations and comprehensive loss for the three and nine months ended September 30, 2020, respectively. The warrants expired unexercised in October 2020.

Simple Agreements for Future Equity — On March 25, 2021, the Company entered into SAFEs with existing investors, pursuant to which the Company received gross proceeds in an aggregate amount equal to $8,942. The fair value of the SAFE liability is estimated using a fair value model that includes inputs such as: (1) probability of occurrence of future events (such as a change of control or public offering), and (2) discount rate for implied return required by investor. The Company recorded a change in fair value adjustment of $932 and $1,976 in the consolidated statement of operations and comprehensive loss for the three and nine months ended September 30, 2021, respectively.

The fair value of the SAFEs was determined using a probability weighted expected return method (PWERM), in which the probability and timing of potential future events is considered in order to estimate the fair value of the SAFEs as of each valuation date. Management determined the fair value of the SAFEs using the following significant unobservable inputs:

	September 30, 2021	March 25, 2021 (Issuance)
Expected term (in years)	0.02	0.35
Discount upon conversion	20.0%	20.0%
Discount upon implied return	18.9%	18.9%
Probability of initial public offering occurrence	90.0%	45.0%
Probability of dissolution event occurrence	2.0%	15.0%
Probability of equity financing occurrence	7.0%	37.0%
Probability of change of control occurrence	1.0%	3.0%

In addition, the Company recorded the Series B-1 convertible preferred stock within mezzanine equity at fair value on the date of issuance, May 1, 2021 (Note 7). This non-recurring fair value measure was based on level 3 unobservable inputs.

4. Accrued Expenses

Accrued expense consists of the following as of:

	Costs as of	
	September 30, 2021	December 31, 2020
Employee compensation, benefits, and related accruals	$ 679	$ 732
Research and development costs	44	143
Professional fees	—	119
Other accrued	17	—
Total	$ 740	$ 994

5. Commitments and Contingencies

The Company has operating leases for its office and laboratory facilities under agreements that run through February 28, 2029.

Minimum lease commitments consisted of the following as of September 30, 2021:

For the Years Ended December 31,	Operating Leases
2021	$ 49
2022	197
2023	140
2024	82
Thereafter	357
Total lease commitments	$ 825

Rent expense was $34 and $116 for the three and nine months ended September 30, 2021, respectively, and $40 and $145 for the three and nine months ended September 30, 2020, respectively.

From time to time, the Company may be involved in disputes or regulatory inquiries that arise in the ordinary course of business. When the Company determines that a loss is both probable and reasonably estimable, a liability is recorded and disclosed if the amount is material to the financial statements taken as a whole. When a material loss contingency is only reasonably possible, the Company does not record a liability, but instead discloses the nature and the amount of the claim, and an estimate of the loss or range of loss, if such an estimate can reasonably be made.

As of September 30, 2021 and December 31, 2020, there was no litigation or contingency with at least a reasonable possibility of a material loss.

6. Debt

On March 8, 2018, the Company entered into a Convertible Note Purchase Agreement (the “Original Agreement”) with existing investors of the Company. Under the terms of the Original Agreement, the Company agreed to issue up to $5,000 in principle Convertible Notes (the “Original Notes”). The Original Notes accrued interest at 4.0% per annum from the date of issuance with a maturity date of February 27, 2020 (subsequently extended — see below). The Company issued $2,965 in Original Notes in March and April 2018. Under the terms of the Original Agreement, the following features were included:

- Automatic conversion into equity securities upon the closing of an equity financing with aggregate gross proceeds of at least $10,000, at the conversion price equal to 90.0% of the lowest price per share of the equity financing securities sold (a “Automatic Conversion Upon a Qualified Financing”);

- Optional conversion into equity securities upon the closing of an equity financing that does not constitute a Qualified Financing at a conversion price equal to 90.0% of the price per share of the equity financing securities sold (a “Optional Conversion Upon a Non-Qualified Financing”);

- Optional conversion of the unpaid principal balance plus accrued and unpaid interest to into B-1 Convertible Preferred Stock at a conversion price of $1.385 per share or redemption of the unpaid principal balance plus accrued and unpaid interest if (i) a transaction results in any person or group with over 50.0% voting power, (ii) any consolidation or merger transaction, or (iii) a sale or transfer of substantially all of the Company’s assets (“Option Conversion or Redemption”) Optional conversion of the unpaid principal balance plus accrued and unpaid interest to into Series B-1 convertible preferred stock at a conversion price of $1.385 per share or redemption of the unpaid principal balance plus accrued and unpaid interest if (i) a transaction results in any person or group with over 50.0% voting power, (ii) any consolidation or merger transaction, or (iii) a sale or transfer of substantially all of the Company’s assets (“Option Conversion or Redemption”); and

- Automatic redemption of unpaid principal and all accrued and unpaid interest upon maturity, liquidation, dissolution, winding up, or event of default (“Automatic Redemption”).

On November 15, 2018, the Company entered into a Convertible Note Purchase Agreement (the “Additional Agreement”) with existing investors of the Company. Under the terms of the Additional Agreement, the Company agreed to issue up to an aggregate of $8,000 in principle Convertible Notes (the “Additional Notes”). In connection with the Additional Agreement, the Company amended the Original Notes (the “Amendment”). The Amendment resulted in the following changes to the Original Notes:

- the interest rate of the Original Notes accrue interest at 4.0% from issuance to November 15, 2018, and accrue interest at 8.0% from November 15, 2018 to maturity or conversion;

- the conversion price was amended to 80.0% of the price per share in connection with conversion of the notes upon a Qualified or Non-Qualified Financing;

- the holder’s option upon a sale event to receive repayment, at two times the principal plus accrued and unpaid interest, (“Optional Redemption Upon a Sales Transaction”); and

- a condition that each holder of $1,000 in aggregate principal must be included in the 66 2/3% of the holders of the principal amount of the Notes to provide consent to make any further amendments or waivers.

On February 27, 2020, the Company entered into a Convertible Note Purchase Agreement (the “Second Amendment”) with existing investors of the Company. Under the terms of the Second Amendment, the Company agreed to issue up to an aggregate of $10,035 in principle Convertible Notes (the “Second Amendment Notes”). In connection with the Second Amendment, the Company amended the Original Notes and Additional Notes. The Second Amendment resulted in the following changes:

- extend the maturity date to June 30, 2021;

- add a cap for a conversion in connection with a Qualified Financing; and

- provide for mandatory conversion of the Combined Notes into Series B-1 Preferred Convertible Stock of the Company if the Company has not completed a Qualified Financing on or before June 30, 2021.

The Company applied extinguishment accounting to the Original Notes upon execution of the Amendment in 2018 on the basis that the present value of the cash flows under the terms of the Amendment of the Original notes were determined to be substantially different. The Company applied extinguishment accounting upon execution of the Second Amendment as the addition of the conversion features are substantive and recorded a loss on debt extinguishment of $0

and $129 in the consolidated statement of operations and comprehensive loss for the three and nine months ended September 30, 2020, respectively.

Each Additional Note and Second Amendment Note (collectively with the Original Notes, the "Convertible Notes" or the "Notes) included the features set forth above. The Company issued $2,965 Original Notes in 2018, $4,661 Additional Notes in 2018 and 2019, and $5,372 Second Amendment Notes in 2020.

The total issuance costs incurred in connection with all closings of the Convertible Notes was $205.

The Convertible Notes were considered to be a hybrid financial instrument consisting of a fixed interest rate host with certain embedded features requiring evaluation for bifurcation and separate accounting. The Company determined that the Automatic Conversion Upon a Qualified Financing, Optional Conversion Upon a Non-Qualified Financing and the Optional Redemption Upon a Sales Transaction were considered freestanding financial instruments which required bifurcation from the host debt instruments.

The resulting debt discount from the derivative liabilities was presented as a direct deduction from the carrying amount of the Convertible Notes and amortized to interest expense using the effective interest rate method.

Interest expense on the convertible notes, including amortization of debt issuance costs, consisted of the following for the three and nine months ended September 30, 2021 and 2020:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Coupon interest	$ —	$ 262	$ 512	$ 660
Issuance costs amortization	—	18	31	34
Discount amortization	—	228	352	536
	$ —	$ 508	$ 895	$ 1,230

In May of 2021, the convertible notes and accrued interest thereon were converted into shares of the Company's Series B-1 convertible preferred stock (Note 7).

In April 2020, the Company received a $443 unsecured loan, bearing interest at 1.0%, pursuant to the Paycheck Protection Program (the "PPP"), a program implemented by the U.S. Small Business Administration (the "SBA") under the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") (the "PPP Loan"). The PPP provides for loans to qualifying businesses for amounts up to 2.5 times of the average monthly payroll expenses of the qualifying business. The loan and accrued interest are forgivable after eight weeks if the borrower uses the loan proceeds for eligible purposes, including payroll, benefits, rent and utilities. The amount of loan forgiveness may be reduced if the borrower terminates employees or reduces salaries during the eight-week period. The unforgiven portion of the PPP loan is payable over two years at an interest rate of 1.0%, with a deferral of payments for the first six months. The Company used the proceeds for purposes consistent with the PPP.

On January 21, 2021, the Company received confirmation from the SBA that the PPP Loan had been forgiven in full, including all interest incurred. Accordingly, the Company recognized $0 and $443 of income for the debt extinguishment pursuant to ASC 470-50-15-4 for the three and nine months ended September 30, 2021, respectively.

7. Preferred Stock

Convertible preferred stock consisted of the following:

As of September 30, 2021:

Class of Preferred	Preferred Stock Authorized	Preferred Stock Issued and Outstanding	Carrying Value	Liquidation Preference	Common Stock Issuable Upon Conversion
Series A Convertible Preferred Stock	3,067,519	2,819,027	$ 4,616	$ 5,051	871,541
Series A-1 Convertible Preferred Stock	3,970,776	3,730,366	5,398	5,906	1,153,290
Series A-2 Convertible Preferred Stock	3,565,063	3,565,063	5,809	6,355	1,102,182
Series B Convertible Preferred Stock	30,450,000	30,409,890	39,547	43,269	9,401,599
Series B-1 Convertible Preferred Stock	10,928,155	10,926,089	29,391	16,038	3,377,925
Total	51,981,513	51,450,435	$ 84,761	$ 76,619	15,906,537

As of December 31, 2020:

Class of Preferred	Preferred Stock Authorized	Preferred Stock Issued and Outstanding	Carrying Value	Liquidation Preference	Common Stock Issuable Upon Conversion
Series A Convertible Preferred Stock	3,067,519	2,819,027	$ 4,616	$ 4,766	871,541
Series A-1 Convertible Preferred Stock	3,970,776	3,730,366	5,398	5,572	1,153,290
Series A-2 Convertible Preferred Stock	3,565,063	3,565,063	5,809	5,997	1,102,182
Series B Convertible Preferred Stock	30,450,000	30,409,890	39,547	40,826	9,401,599
Total	41,053,358	40,524,346	$ 55,370	$ 57,161	12,528,612

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. The Series B-1 convertible preferred stock was recorded within mezzanine equity at fair value on the date of issuance. On October 13, 2021, upon the closing of the IPO, all shares of preferred stock were converted into 15,906,537 shares of common stock (see Note 13).

Rights, preferences, privileges, and restrictions:

The holders of shares of Series A, A-1, A-2, B and B-1 convertible preferred stock (collectively, the “Preferred Stock”) have the rights, preferences, privileges, and restrictions as set forth below:

Dividends:

The holders of the Preferred Stock are entitled to receive cumulative dividends when, as and if declared by the Company’s Board of Directors. Accrued dividends shall accrue only on the unreturned amount of the original issue price taking into account the payment of any mandatory dividend. As used herein, “original issue price” means $0.69 per share with respect to the Series A and A-1 convertible preferred stock, $0.8415 per share with respect to the Series A-2 convertible preferred Stock, $0.923 per share with respect to the Series B convertible preferred stock, and $1.385 per share with respect to the Series B-1 convertible preferred stock. After such time the holders receive their full preferred liquidation amount, less any and all mandatory dividends, the holders of preferred stock will not be entitled to any additional accruing dividends; provided that the holders of the preferred stock will share in all dividends and distributions declared by the board of directors and paid by the Company with the holders of common stock on an as if converted to common stock basis.

Voting Rights:

The holders of Preferred Stock are entitled to voting rights equal to the number of shares of common stock into which the shares of Preferred Stock can be converted. In addition, as long as there are shares of Preferred Stock outstanding, each of the holders of over 7.5% of the total Preferred Stock outstanding on a converted basis are entitled to designate one director of the Company to be elected by the holders of Preferred Stock. The holders of a majority of the then outstanding shares of common stock, voting together as a single class, are entitled to elect one director of the Company. If the holders of the Preferred Stock or common stock fail to elect a sufficient number of directors to fulfill directorships for which they are entitled to elect directors, then any directorship shall remain vacant until the holders of the Preferred Stock or common stock elect such person.

Liquidation Rights:

In the event of any liquidation, dissolution or winding up of the Company, whether voluntary or involuntary, the holders of Preferred Stock have liquidation preferences, before any distribution or payment is made to holders of any common stock, in an amount per share equal to the original issue price for such Preferred Stock plus all accruing dividends (the “Preferred Liquidation Amount”). If the assets and funds to be distributed among the holders of Preferred Stock are insufficient to permit the payment to such holders, then the entire assets and funds of the Company legally available for distribution will be distributed ratably among the holders of Preferred Stock in proportion to the Preferred Liquidation Amount each such holder is otherwise entitled to receive on each share, less any mandatory dividends.

Upon completion of the payment of the full liquidation preference of Preferred Stock less any and all mandatory dividends previously distributed, the remaining assets of the Company, if any, shall be distributed among the holders of common stock and Preferred Stock, pro rata based on the number of common shares held by each (assuming conversion of all shares of the Preferred Stock into common stock).

Conversion:

Each share of Preferred Stock is convertible into shares of common stock, at the option of the holder, at any time after date of issuance. Each share of Preferred Stock automatically converts to the number of shares of common stock determined in accordance with the conversion rate upon the closing of a public offering, at a price per share of not less than three times the highest, then applicable conversion price, resulting in offering proceeds of at least $30,000 net of underwriting discounts and commissions. The conversion ratio will be adjusted in the case of specified changes to the Company’s capitalization as a result of stock splits, combinations, common stock dividends and distributions, reclassifications, exchanges, substitutions, reorganizations, mergers or consolidations.

Redemption:

Prior to the July 29, 2020 amendment to the Company’s second amended and restated certificate of incorporation, holders of Preferred Stock had the right to redeem shares of preferred stock on or after March 20, 2021 after receipt of written notice requesting redemption from 60% of the then outstanding shares of the preferred stock voting together as a single class on an as-converted to common stock basis at a price equal to the original issue price plus all accruing dividends. As the Preferred Stock was redeemable due to the passage of time prior to the amendment, the Company recorded changes in the redemption value and accreted the Preferred Stock immediately to its redemption value during each reporting period.

On July 29, 2020, the Company’s second amended and restated certificate of incorporation was amended resulting in the removal of the redemption right. As the redemption option was removed in connection with the amendment, the only option for redemption is based on the occurrence of a deemed liquidation event. As the events that would trigger a deemed liquidation event are corporate transactions that are not certain to occur, the Company determined that post July 29, 2020, the Preferred Stock is no longer considered probable to become redeemable, and is instead contingently redeemable. As a result, the Company ceased the accretion of the Preferred Stock to redemption value upon execution of the amendment to the articles of incorporation.

Protective Provisions:

At any time when shares of Preferred Stock are outstanding, the Company shall not, either directly, indirectly by amendment, merger, consolidation or otherwise, do any of the following without the written consent or affirmative vote of at least 60% of the then outstanding shares of Preferred Stock, voting together as a single class on an as-converted to Common Stock basis: (i) effect the consummation of a liquidation event or any other merger or consolidation, (ii) amend, alter or repeal any provision of the Company's certificate of incorporation of bylaws in a manner that adversely affects the powers, preferences or rights of the Preferred Stock, (iii) amend, alter, or repeal any provision of the by-laws of the Company, in a manner that affects the powers, preferences, or rights of Preferred Stock, (iv) increase or decrease the authorized number of shares of Preferred Stock or Common Stock, (v) reclassify, alter, or amend any existing security of the Company in respect to the distribution of assets on the liquidation, dissolution, or winding up of the Company or payment of dividends, if such reclassification, alteration, or amendment would render such other security senior to Preferred Stock in respect to any such right, preference, or privilege, (vi) purchase or redeem, or declare any dividend, on any shares of capital stock of the Company other than repurchase of stock pursuant to stock restriction agreements approved by the board of directors that grant to the Company the right of repurchase upon termination of the service, (vii) borrow or authorize any amount of indebtedness, other than inventory financing in the ordinary course of business and any indebtedness in an amount of up to $250 in aggregate that is approved by the board of directors, (viii) increase or decrease the authorized number of directors of the board of directors (ix) effect a change in business from the discovery and development of small molecule therapeutics targeting toxic proteins that cause cognitive decline associated with Alzheimer's disease and other neurodegenerative diseases, (x) enter into any transaction with any person other than in the ordinary course of business on an arm's length basis, (xi) increase the number of shares of common stock reserved for issuance, (xii) make any loan except advances in ordinary course of business or advances up to $50 in aggregate approved by the board of directors, (xiii) hire, terminate, or change compensation in excess of $100 of any officer, director, or employee, unless approved by the board of directors, (xiv) own any stock or securities of any other corporation, unless approved by the board of directors, (xv) guarantee any indebtedness except for trade accounts of the Company or any guarantee approved by the board of directors, (xvi) make any investment other than investments in prime commercial paper, money market funds, certificates of deposits in any United States bank having a net worth in excess of $100,000 or obligations issued or guaranteed by the United States of America, unless approved by the board of directors.

8. Warrants

In conjunction with both debt and equity investments, the Company issued warrants on each of the following classes of stock: common stock and Series A-1 convertible preferred stock.

The following is a summary of the Company's outstanding common stock warrants:

As of September 30, 2021:

Number of Warrants	Exercise Price	Expiration Date
115,310	$ 0.03	March 2023
24,171	$ 0.03	May 2023
10,319	$ 0.03	August 2023

As of December 31, 2020:

Number of Warrants	Exercise Price	Expiration Date
50,497	$ 0.68	May 2021
116,144	$ 0.03	March 2023
24,171	$ 0.03	May 2023
10,319	$ 0.03	August 2023

Series A-1 Convertible Preferred Stock Warrants

The Company reviewed the classification of the warrants as liabilities or equity under the guidance of ASC 480-10, Distinguishing Liabilities from Equity, and concluded that the Series A-1 convertible preferred stock warrants should be classified as a liability. The Company re-measures the warrant liability to fair market value at the end of each reporting period. The Series A-1 convertible preferred stock warrants expired in October 2020 and were not exercised.

Common Stock Warrants

The Company's common stock warrants are equity classified as there are no features within the warrant agreements that require liability treatment. Accordingly, the warrants are recorded as a component of equity when they are issued. Upon the closing of the IPO on October 13, 2021, 147,702 warrants were exercised into shares of common stock (see Note 13). The remaining warrants were not exercised and expired pursuant to their terms.

9. Common Stock

Common stockholders are entitled to dividends if and when declared by the Company's board of directors subject to the rights of the preferred stockholders. As of September 30, 2021 and December 31, 2020, no dividends on common stock had been declared by the Company.

The Company has reserved the following shares of common stock for conversion of preferred stock, exercise of warrants and exercise of stock options as of:

	September 30, 2021	December 31, 2020
Convertible preferred stock (as converted)	15,906,537	12,528,612
Options issued and outstanding	4,318,992	4,587,865
Warrants for common stock	149,800	201,131
Total	20,375,329	17,317,608

10. Equity-based Compensation

On September 15, 2017, the Company's board of directors approved the 2017 Amended and Restated Equity Incentive Plan (the "Plan"), which provides for the granting of incentive stock options, non-qualified stock options and stock awards to employees, certain consultants and directors. The Board, or its designated committee, has the sole authority to select the individuals to whom awards are granted and determine the terms of each award, including the number of shares and the schedule upon which the award becomes exercisable.

The aggregate number of shares of common stock of the Company that may be issued under the Plan is 4,726,847 (taking into account shares of common stock that may become issuable pursuant to Section 3(b) of the Plan in respect of shares of common stock reserved under the Company's Amended and Restated 2007 Equity Incentive Plan). The Plan also allows for a provision for shares granted which are cancelled, forfeited, exchanged or surrendered without having been exercised to subsequently be available for reissuance under the Plan.

The Company recorded total equity-based compensation expense in the statement of operations and comprehensive loss related to incentive stock options and nonstatutory stock options as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Research and development	$ (4)	$ 56	$ 30	$ 161
General and administrative	76	73	234	181
Total equity-based compensation	$ 72	$ 129	$ 264	$ 342

As of September 30, 2021, total future compensation expense related to unvested awards yet to be recognized by the Company was $887. Total future compensation expense related to unvested awards yet to be recognized by the Company is expected to be recognized over a weighted-average remaining vesting period of approximately 2.6 years.

The fair value of options granted was estimated on the date of grant using the Black-Scholes option pricing model with the following assumptions:

	Nine Months Ended September 30,	
	2021	2020
Fair value of common stock	$1.75 - $6.15	$1.20
Expected volatility	100.82% - 101.83%	104.60% - 109.34%
Risk-free interest rate	0.67% - 1.06%	0.38% - 1.60%
Dividend yield	0.00%	0.00%
Expected term (years)	5.00 - 6.22	5.00 - 6.25

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

Risk-Free Interest Rate — The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the date of grant for zero-coupon U.S. Treasury constant maturity notes with terms approximately equal to the stock-based awards' expected term.

Expected Volatility — Since the Company is privately held and does not have a trading history of common stock, the expected volatility was derived from the average historical stock volatilities of the common stock of several public companies within the industry that the Company considers to be comparable to our business over a period equivalent to the expected term of the stock-based awards.

Dividend Yield — The expected dividend yield is zero as the Company has not paid and does not anticipate paying any dividends in the foreseeable future.

Fair Value of Common Stock — The fair value of the shares of common stock underlying the stock-based awards has historically been determined by the board of directors with input from management. Because there has been no public market for the common stock, the board of directors has determined the fair value of the common stock at the time of grant of the stock-based award by considering a number of objective and subjective factors, including having contemporaneous valuations of the common stock performed by a third-party valuation specialist.

Activity for options was as follows:

	Options Outstanding			
	Number of Options	Weighted-Average Exercise Price	Aggregate Intrinsic Value (in 000's)	Weighted Average Remaining Contractual Life (In Years)
Balance, December 31, 2020	4,587,865	$ 0.98		
Options granted	67,232	$ 2.25		
Options exercised	(25,783)	$ 0.73		
Options forfeited	(161,479)	$ 1.12		
Options expired	(148,843)	$ 0.94		
Balance, September 30, 2021	4,318,992	$ 1.00	$ 22,213	6.4
Exercisable as of September 30, 2021	3,023,934	$ 0.92	$ 15,800	5.6
Vested and expected to vest as of September 30, 2021	3,982,080	$ 1.00	$ 20,494	6.3

The weighted-average grant date fair value of stock options granted was $1.79 during the nine months ended September 30, 2021. There were no stock options granted for the three months ended September 30, 2021 and 67,232 stock options granted at an aggregate fair value of $121 for the nine months ended September 30, 2021. The total grant-date fair value of stock options vested during the three and nine months ended September 30, 2021 was $83 and $383, respectively. During the three and nine months ended September 30, 2021, there were 4,996 and 25,783 stock options exercised, respectively, with an aggregate grant date fair value of $3 and $14, respectively. The intrinsic value of stock options exercised during the three and nine months ended September 30, 2021 was $26 and $140, respectively.

The Company granted 349,150 option awards containing performance conditions to an executive during 2019. As of September 30, 2021, the Company determined that the achievement of the performance targets was not probable and therefore, there was no expense recognized for these awards during the three and nine months ended September 30, 2021. As of September 30, 2021, total unrecognized compensation expense related to un-vested performance-based awards was $254, which would be recognized commencing with the period in which the performance condition is deemed probable of achievement.

11. Net Loss per Share

The following outstanding potentially dilutive common stock equivalents have been excluded from the calculation of diluted net loss per share attributable to common stockholders for the periods presented due to their antidilutive effect:

	September 30, 2021	December 31, 2020
Convertible preferred stock (as converted)	15,906,537	12,528,612
Options issued and outstanding	4,318,992	4,587,865
Warrants for common stock	149,800	201,131
Total	20,375,329	17,317,608

The basic and diluted net loss per share attributable to common stockholders has been prepared as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Net loss	$ (3,110)	$ (1,791)	$ (4,377)	$ (5,971)
Cumulative preferred stock dividends	(1,859)	(1,064)	(4,326)	(3,170)
Net loss attributable to common stockholders	$ (4,969)	$ (2,855)	$ (8,703)	$ (9,141)
Weighted-average common shares outstanding - basic and diluted	611,680	537,315	585,320	498,415
Total	$ (8.12)	$ (5.31)	$ (14.87)	$ (18.34)

12. Simple Agreements for Future Equity (SAFEs)

On March 25, 2021, the Company entered into SAFEs with existing investors, pursuant to which the Company received gross proceeds in an aggregate amount equal to $8,942. Pursuant to the arrangement, all of the SAFEs were initially issued with a conversion price equal to 80.0% of either the common stock price upon the occurrence of an IPO, or the price paid for shares of preferred stock by other investors upon a subsequent private financing. Upon a change of control, investors are entitled to receive a portion of proceeds equal to the greater of the purchase amount or the amount payable on the number of shares of common stock equal to the purchase amount divided by the liquidity price. In a liquidity or dissolution event, the investors' right to receive cash is junior to payment of outstanding indebtedness and creditor claims, on par for other SAFEs and preferred stock, and senior to common stock. The SAFE agreements have no interest rate or maturity date, and the SAFE investors have no voting right prior to conversion.

The SAFEs included a provision allowing for cash redemption upon either the occurrence of a change of control or dissolution event, the occurrence of which is outside the control of the Company. Therefore, the SAFEs are classified as marked-to-market liabilities pursuant to ASC 480, *Distinguishing Liabilities from Equity*. The Company recorded a change in fair value adjustment of $932 and $1,976 in the consolidated statement of operations and comprehensive loss for the three and nine months ended September 30, 2021. In connection with the close of the Company's IPO, the SAFEs were automatically converted into 931,485 shares of common stock (see Note 13).

13. Subsequent Events

Initial Public Offering:

On October 13, 2021, the Company closed its initial public offering of 3,768,116 shares of the Company's common stock at a public offering price of $12.00 per share. The gross proceeds from the IPO were $45.2 million and the net proceeds were approximately $38.1 million, after deducting underwriting discounts and commissions and other offering expenses payable by the Company. Upon the completion of the Company's IPO, all of the Company's then outstanding preferred stock was automatically converted into an aggregate of 15,906,537 shares of common stock. In addition, 931,485 shares of common stock were issued in connection with the automatic conversion of the SAFEs in the aggregate amount of $8.9 million and 147,702 shares of common stock were issued in connection with the exercise of common stock warrants.

On November 10, 2021, the representative of the underwriters for the IPO provided notice to the Company that it had elected to exercise its over-allotment option in full to purchase 565,217 shares of the Company's common stock. The representative's exercise of the over-allotment option closed on November 12, 2021, resulting in gross proceeds of $6.8 million and net proceeds to the Company of approximately $6.3 million, after deducting underwriting discounts and commissions and other offering related expenses.

Changes to the Certificate of Incorporation:

In connection with the reverse stock split effected on October 1, 2021, the number of shares of common stock the Company is authorized to issue increased from 70,000,000 to 80,000,000. Subsequently, in connection with the completion of the IPO, a third amended and restated certificate of incorporation was filed with the Secretary of State of the State of Delaware on October 13, 2021 to, among other things, provide for 250,000,000 authorized shares of common stock, par value $0.001 per share, and 10,000,000 authorized shares of "blank check" preferred stock, par value $0.001 per share.

Stock Plans:

The Company's board of directors adopted the Company's 2021 Equity Incentive Plan ("2021 Plan") and an Employee Stock Purchase Plan (the "ESPP") in July 2021, each of which became effective upon the effectiveness of the registration statement filed in connection with the IPO on October 7, 2021. Since October 7, 2021, the Company has granted 1,942,804 options to purchase shares of the Company's common stock to certain executives and directors under the 2021 Plan. As of September 30, 2021, 209,532 shares of common stock have been reserved for future issuance under the ESPP.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial conditions and results of operations should be read together with our condensed consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q, or Quarterly Report, and our final prospectus, or the Prospectus, for our initial public offering, or IPO, dated October 7, 2021 and filed with the United States Securities and Exchange Commission, or SEC, pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended, or the Securities Act. Some of the information with respect to our plans and strategy for our business, including forward-looking statements that involve risks and uncertainties. As a result of many factors, including those set forth in the section entitled "Risk Factors in Part II, Item 1A of this Quarterly Report, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. You should carefully read the section entitled "Risk Factors" in Part II, Item 1A of this Quarterly Report to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements.

Overview

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

Since our inception in 2007, we have incurred significant operating losses and devoted substantially all of our time and resources to developing our lead product candidate, CT1812, building our intellectual property portfolio, raising capital and recruiting management and technical staff to support these operations. As of September 30, 2021 and December 31, 2020, we had an accumulated deficit of $86.7 and $68.2 million, respectively. We incurred net losses of $3.1 million and $4.4 million for the three and nine months ended September 30, 2021, respectively, and $1.8 million and $6.0 million for the three and nine months ended September 30, 2020, respectively.

To date, we have funded our operations primarily with proceeds from grants awarded by the National Institute of Aging, or NIA, a division of the National Institutes of Health, or NIH, and proceeds from the sales of our convertible promissory notes, convertible preferred stock, Simple Agreements for Future Equity, or SAFEs, and stock option exercises. Since our inception, we have received approximately $168.4 million in cumulative grant awards to fund our clinical trials, primarily from the NIA, and we have raised approximately $106.9 million in net proceeds from sales of our equity securities, convertible notes, SAFEs, stock option exercises, and our IPO. On March 25, 2021, we entered into SAFEs, with various investors, pursuant to which we received gross proceeds in an aggregate amount equal to $8.9 million. As of September 30, 2021, we had cash and cash equivalents of $8.3 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. We received net proceeds of approximately $38.1 million, after deducting underwriting discounts and commissions and other offering related expenses payable by us. On November 12, 2021, the underwriters exercise of their over-allotment option in full to purchase 565,217 shares of our common stock closed. We received net proceeds of approximately $6.3 million, after deducting underwriting discounts and commissions and other offering related expenses payable by us. We expect to continue to incur significant and increasing expenses and net losses for the foreseeable future, as we advance our current and future product candidates through preclinical and clinical development, manufacture drug product and drug supply, seek regulatory approval for our current and future product candidates, maintain and expand our intellectual property portfolio, hire additional research and development and business personnel and operate as a public company. We will not generate revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for our product candidates. In addition, if we obtain regulatory approval for our product candidates and do not enter into a third-party commercialization

partnership, we expect to incur significant expenses related to developing our commercialization capability to support product sales, marketing, manufacturing and distribution activities.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of public or private equity offerings, debt financings or other sources, such as potential collaboration agreements and strategic alliances, licensing or similar arrangements with third parties. To the extent available, we expect to continue our pursuit of non-dilutive research contributions, or grants, including additional NIA grant funding. However, we may fail to receive additional NIA grants, or we may be unable to raise additional funds or enter into such other agreements or arrangements when needed on acceptable terms, or at all. Our failure to obtain additional NIA grants or raise capital or enter into such agreements as and when needed could have a material adverse effect on our business, results of operations and financial condition.

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

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

Impact of COVID-19 on Our Business

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

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

The spread of COVID-19, 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 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 expect that we will incur substantially increased expenses as a result of operating as a public company, including expenses related to compliance with the rules and regulations of the 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 payment is realized. The grants awarded relate to agreed upon direct and indirect costs for specific studies or clinical trials, which may include personnel and consulting costs, costs paid to contract research organizations, or CROs, research institutions and /or consortiums involved in the grant , as well as facilities and administrative costs. These grants are cost plus fixed fee arrangements in which we are reimbursed for eligible direct and indirect costs over time, up to the maximum amount of each specific grant award. Only costs that are allowable under the grant award, certain government regulations and the NIH's supplemental policy and procedure manual may be claimed for reimbursement, and the reimbursements are subject to routine audits from governmental agencies from time to time. Our clinical trials have been funded by approximately $168.4 million in cumulative grants awarded primarily by the NIA, which includes an approximately $81.0 million grant from the NIA to fund our upcoming Phase 2 (COG0203) study of CT1812 in patients with early-stage AD.

Change in fair value of derivative liability

Change in fair value of our derivative liability consists of changes in the fair value of certain conversion and redemption features associated with our convertible notes that are required to be bifurcated and accounted for as free-standing derivative financial instruments. The derivative liability expired unexercised upon the conversion of the convertible notes into Series B-1 convertible preferred stock in May of 2021.

Change in fair value of warrant liability

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

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.

Interest expense, net

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

Other income, net

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

Results of Operations

Comparison of the Three Months Ended September 30, 2021 and 2020

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

	Three Months Ended September 30,		
	2021	2020	Change
Operating Expenses:			
Research and development	$ 3,675	$ 3,399	$ 276
General and administrative	1,548	1,062	486
Total operating expenses	5,223	4,461	762
Loss from operations	(5,223)	(4,461)	(762)
Other income (expense):			
Grant income	3,037	3,192	(155)
Change in the fair value of the derivative liability	—	(112)	112
Change in the fair value of the warrant liability	—	1	(1)
Change in the fair value of the Simple Agreements for Future Equity	(932)	—	
Other income, net	8	95	(87)
Interest expense, net	—	(506)	506
Total other income, net	2,113	2,670	(557)
Net loss	$ (3,110)	$ (1,791)	$ (1,319)

Research and Development Expenses

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

	Three Months Ended September 30,		
	2021	2020	Change
Clinical programs	$ 575	$ 1,257	$ (682)
Personnel	967	1,066	(99)
Manufacturing	1,849	601	1,248
Preclinical programs	258	448	(190)
Facilities and other costs	26	27	(1)
	$ 3,675	$ 3,399	$ 276

Research and development expenses were $3.7 million for the three months ended September 30, 2021, compared to $3.4 million for the three months ended September 30, 2020. The increase of $0.3 million was primarily due to the following:

- a decrease of $0.7 million in clinical programs related to delays due to COVID 19, resulting in timing and scope changes to clinical studies; and
- an increase of $1.2 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.

General and Administrative Expenses

General and administrative expenses were $1.6 million for the three months ended September 30, 2021, compared to $1.1 million for the three months ended September 30, 2020. The increase of $0.5 million was primarily due to:

- an increase of $0.5 million in professional fees and consulting services and stock compensation.

Other Income (Expense)

Grant Income

Grant income was $3.0 million for the three months ended September 30, 2021, compared to $3.2 million for the three months ended September 30, 2020. Overall, the change in grant income was not significant in either period.

Change in Fair Value of the Derivative Liability

Changes in the fair value derivative liability resulted in no gain or loss for the three months ended September 30, 2021, compared to a loss of $0.1 million for the three months ended September 30, 2020. There was no gain or loss for the three months ended September 30, 2021 as the derecognition of the derivative liability occurred May of 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 three months ended September 30, 2021, and a gain of less than $0.1 million for the three months ended September 30, 2020. There was no gain or loss for the three months ended September 30, 2021 as the warrants to purchase Series A-1 preferred stock expired in October 2020.

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 three months ended September 30, 2021. There was no change in fair value for the three months ended September 30, 2020 as the SAFEs were entered into in March 2021. The change was primarily driven by the change in the probability of occurrence of future event inputs in the valuation model during the period.

Other Income (Expense), Net

Other income, net was less than $0.1 million for the three months ended September 30, 2021, and less than $0.1 million for the three months ended September 30, 2020. Overall, the change in other expense was not significant in either period.

Interest Expense, Net

There was no interest expense, net for the three months ended September 30, 2021, compared to Interest expense, net of $0.5 million for the three months ended September 30, 2020. The change of $0.5 million in interest expense, net was the result of the conversion of the convertible notes into Series B-1 convertible preferred stock in May 2021.

Comparison of the Nine Months Ended September 30, 2021 and 2020

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

(in thousands)	Nine Months Ended September 30, 2021	2020	Change
Consolidated Statements of Operations Data:			
Operating Expenses:			
Research and development	$ 12,999	$ 9,600	$ 3,399
General and administrative	3,791	3,687	104
Total operating expenses	16,790	13,287	3,503
Loss from operations	(16,790)	(13,287)	(3,503)
Other income (expense):			
Grant income	12,375	8,146	4,229
Change in the fair value of the derivative liability	2,209	135	2,074
Change in the fair value of the warrant liability	—	33	(33)
Change in the fair value of the Simple Agreements for Future Equity	(1,976)	—	(1,976)
Other income, net	256	353	(97)
(Gain) loss on debt extinguishment	443	(129)	572
Interest expense, net	(894)	(1,222)	328
Total other income, net	12,413	7,316	5,097
Net loss	$ (4,377)	$ (5,971)	$ 1,594

Research and Development Expenses

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

	Nine Months Ended September 30, 2021	2020	Change
Clinical programs	$ 2,259	$ 4,217	$ (1,958)
Personnel	2,903	3,042	(139)
Manufacturing	6,568	863	5,705
Preclinical programs	1,184	1,396	(212)
Facilities and other costs	85	82	3
	$ 12,999	$ 9,600	$ 3,399

Research and development expenses were $13.0 million for the nine months ended September 30, 2021, compared to $9.6 million for the nine months ended September 30, 2020. The increase of $3.4 million was primarily due to the following:

- 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
- a decrease of $2.0 million in spending on clinical programs related to delays due to COVID 19, resulting in timing and scope changes to clinical studies.

General and Administrative Expenses

General and administrative expenses were $3.8 million for the nine months ended September 30, 2021, compared to $3.7 million for the nine months ended September 30, 2020. The decrease of $0.1 million was primarily due to the following:

- a decrease of $0.6 million in compensation expenses; and
- an increase of $0.5 million in professional fees and consulting services.

Other Income (Expense)

Grant Income

Grant income was $12.4 million for the nine months ended September 30, 2021, compared to $8.1 million for the nine months ended September 30, 2020. The change in grant income is correlated with the increase in eligible reimbursable costs incurred during the nine months ended September 30, 2021 as compared to the nine months ended September 30, 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 nine months ended September 30, 2021, compared to a gain of $0.1 million for the nine months ended September 30, 2020. The increase in the gain recorded in the nine months ended September 30, 2021 relates to the derecognition of the derivative liability in May of 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 nine months ended September 30, 2021, compared to a gain of less than $0.1 million for the nine months ended September 30, 2020. There was no gain or loss for the nine months ended September 30, 2021 as the warrants to purchase Series A-1 convertible preferred stock expired in October 2020.

Change in Fair Value of the SAFEs

Changes in the fair value of the SAFEs resulted in a loss of $2.0 million for the nine months ended September 30, 2021. There was no change in fair value for the nine months ended September 30, 2020 as the SAFEs were entered into in March 2021. The change was primarily driven by the change in the probability of occurrence of future event inputs in the valuation model during the period.

Other Income (Expense), Net

Other income, net was $0.3 million for the nine months ended September 30, 2021, and income of $0.4 million for the nine months ended September 30, 2020. Overall, the change in other income was not significant in either period.

(Loss) gain on Debt Extinguishment

Gain on debt extinguishment was $0.4 million for the nine months ended September 30, 2021. Loss on debt extinguishment was $0.1 million for the nine months ended September 30, 2020. The loss was the result of the execution of the second amendment to the convertible notes on February 27, 2020, which resulted in an extinguishment of the existing notes for accounting purposes. The gain was the result of the forgiveness of the Paycheck Protection Program loan on January 21, 2021.

Interest Expense, Net

Interest expense, net was $0.9 million for the nine months ended September 30, 2021 compared to interest expense, net of $1.2 million for the nine months ended September 30, 2020. The change of $0.3 million in interest expense, net was the result of the conversion of the convertible notes into Series B-1 convertible preferred stock in May of 2021.

Liquidity and Capital Resources

Sources of Liquidity

To date, we have funded our operations primarily with proceeds from grants awarded by the NIA, and proceeds from the sales of our convertible promissory notes, convertible preferred stock, 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 $168.4 million and have raised approximately $106.9 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. As of September 30, 2021, we had $8.3 million in cash and cash equivalents and have not generated positive cash flows from operations. 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. The gross proceeds from the IPO, including the exercise of the over-allotment, were $45.2 million and the net proceeds were approximately $38.1 million, after deducting underwriting discounts and commissions and other offering related expenses payable by the Company. On November 12, 2021, the underwriters exercise of their over-allotment option to purchase 565,217 shares of our common stock closed. The gross proceeds from the exercise of the over-allotment were $6.8 million and the net proceeds were approximately $6.3 million, after deducting underwriting discounts and commissions and other offering related expenses payable by the Company. Based on our current business plans, we believe that the net proceeds from the IPO, together with our existing cash and cash equivalents and income from non-dilutive grants, will be sufficient for us to fund our operating expenses and capital expenditures requirements through at least the next 24 months. We have based these estimates on assumptions that may prove to be incorrect or require adjustment as a result of business decisions, and we could utilize our available capital resources sooner than we currently expect.

Future Funding Requirements

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

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

- the scope, progress, costs and results of our ongoing and planned clinical trials of CT1812, as well as the associated costs, including any unforeseen costs we may incur as a result of preclinical study or clinical trial delays due to the COVID-19 pandemic or other delays;
- the scope, progress, costs and results of preclinical development, laboratory testing and clinical trials for any future product candidates we may decide to pursue;
- the extent to which we develop, in-license or acquire other product candidates and technologies;

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

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

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

Cash Flows

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

	Nine Months Ended September 30,	
	2021	2020
Cash flows used in operating activities	$ (3,732)	$ (2,953)
Cash flows used in investing activities	—	(10)
Cash flows provided by financing activities	6,840	5,320
Effect of exchange rate changes on cash and cash equivalents	13	(4)
Net (decrease) increase in cash and cash equivalents	$ 3,121	$ 2,353

Operating Activities

Net cash used in operating activities for the nine months ended September 30, 2021 was $3.7 million, which consisted primarily of our net loss of $4.4 million as well as net non-cash gains of less than $0.1 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 Simple Agreements for Future Equity of $2.0 million, a gain on debt extinguishment of $0.4 million, and equity-based compensation of $0.3 million. The net change in our operating assets and liabilities was primarily due to an increase in grant receivables of $0.3 million, an increase in prepaid expenses and other current assets of less than $0.1 million, a decrease in other receivables of $0.3 million, a decrease in accounts payable of $0.3 million, an increase in accrued expenses of $0.3 million, and an increase in other current liabilities of $0.7 million.

Net cash used in operating activities for the nine months ended September 30, 2020 was $3.0 million, which consisted primarily of our net loss of $6.0 million partially offset by net non-cash charges of $1.0 million and a net change of $2.1 million in our operating assets and liabilities. The non-cash charges primarily consisted of amortization of debt discounts of $0.5 million, change in derivative liabilities of $0.1 million, loss on debt extinguishment of $0.1 million, and equity-based compensation of $0.3 million. The net change in our operating assets and liabilities was primarily due to a decrease in grant receivables of less than $0.1 million, net decrease in other receivables of $1.0 million, an increase in accounts payable of $0.3 million, an increase in accrued expenses of $0.3 million, and an increase in other current liabilities of $0.8 million.

Investing Activities

We did not use any cash for investing activities for the nine months ended September 30, 2021. During the nine months ended September 30, 2020 we used less than $0.1 million of cash for investing activities related to purchases of property and equipment.

Financing Activities

Net cash provided by financing activities was $6.8 million and $5.3 million for the nine months ended September 30, 2021 and 2020, respectively. The increase in cash provided by financing activities in 2021 relates primarily to the $8.9 million of SAFEs issued during the nine months ended September 30, 2021 partially offset by $2.2 million in deferred offering costs, as compared to $5.2 million of convertible notes issued in the nine months ended September 30, 2020.

Off-Balance Sheet Arrangements

We have not entered into any off-balance sheet arrangements as defined under the rules and regulations of the SEC.

Contractual Obligations

The following table summarizes our contractual obligations as of September 30, 2021 (in thousands):

	Less than 1 Year	1 to 3 Years	3 to 5 Years	More than 5 years	Total
Operating lease obligations:	$ 197	$ 250	$ 168	$ 210	$ 825
Total:	$ 197	$ 250	$ 168	$ 210	$ 825

We have entered into an operating lease for office and laboratory facilities under agreements that run through February 28, 2029. The amounts reflected in the table above consist of the future minimum lease payments under the non-cancelable lease arrangements.

In March 2021, we entered into SAFEs with various investors, pursuant to which we received gross proceeds in an aggregate amount equal to $8.9 million. In October 2021, the amount invested by the investors in the SAFEs automatically converted into 931,485 shares of our common stock upon the closing of our IPO at a conversion price equal to 80.0% of the IPO per share price of our common stock. The amounts reflected in the table above do not include cash payments that would be payable by us to the holders of the SAFEs if, prior to the closing of the IPO: (i) we underwent a change of control, (ii) we voluntarily terminated our operations, (iii) there was a general assignment for the benefit of our creditors or (iv) we effected any other liquidation, dissolution or winding up of our company, whether voluntary or involuntary.

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.

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 is expected to commence on October 1, 2021. The annual base rent under the lease is $0.07 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 $0.04 million pursuant to the terms of the lease.

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

Critical Accounting Policies and Use of Estimates

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

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

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

individual arrangements, which may differ from the pattern of billings incurred, and are reflected in the consolidated financial statements as prepaid expenses or as accrued research and development expenses.

Equity-Based Compensation

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

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

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

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

- *Risk-Free Interest Rate.* The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the date of grant for zero-coupon U.S. Treasury constant maturity notes with terms approximately equal to the stock-based awards' expected term.

- *Expected Volatility.* Because we have been privately held and do not have a trading history of common stock, the expected volatility was derived from the average historical stock volatilities of the common stock of several public companies within the industry that we consider to be comparable to our business over a period equivalent to the expected term of the stock-based awards.

- *Expected Dividend Yield.* The expected dividend yield is zero as we have not paid and do not anticipate paying any dividends in the foreseeable future.

- *Fair Value of Common Stock.* — The fair value of the shares of common stock underlying the stock-based awards has historically been determined by the board of directors with input from management. Because there has been no public market for the common stock, the board of directors has determined the fair value of the common stock at the time of grant of the stock-based award by considering a number of objective and subjective factors, including having contemporaneous valuations of the common stock performed by a third-party valuation specialist.

See Note 13 to our audited financial statements for the fiscal year ended December 31, 2020 included in our Prospectus for more information concerning certain of the specific assumptions we used in applying the Black-Scholes option pricing model to determine the estimated fair value of our stock options. Certain of such assumptions involve inherent uncertainties and the application of significant judgment.

As of September 30, 2021, the total unrecognized compensation expense related to unvested time-based vesting awards was $0.9 million, which is expected to be recognized over weighted-average remaining vesting period of approximately 2.6 years. As of September 30, 2021, total unrecognized compensation expense related to un-vested performance-based awards was $0.3 million, which would be recognized commencing with the period in which the performance condition is deemed probable of achievement.

Convertible Instruments

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

Recent Accounting Pronouncements

For a description of recent accounting pronouncements, see Note 2 of the notes to our financial statements included in this Quarterly Report.

Emerging Growth Company Status

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

We will remain an emerging growth company until the earliest to occur of: (1) the last day of the fiscal year in which we have at least $1.07 billion in annual revenue; (2) the last day of the fiscal year in which we are deemed to be a “large accelerated filer,” as defined in Rule 12b 2 under the Securities Exchange Act of 1934, as amended, 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.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Interest Rate Risk

We are exposed to market risk related to changes in interest rates. We had cash and cash equivalents of $8.3 million as of September 30, 2021. Our exposure to interest rate risk is not significant and a hypothetical 1% change in interest rates during any of the periods presented would not have had a material impact on our financial statements included in this Quarterly Report.

Foreign Currency

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

Effects of Inflation

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

Item 4. Controls and Procedures

Evaluation of disclosure controls and procedures

Our management, including our President and Chief Executive Officer (principal executive officer) and our Chief Financial Officer (principal financial and accounting officer), do not expect that our disclosure controls or our internal control over financial reporting will prevent all error and all fraud. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Controls can also be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected. In designing and evaluating the disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives and our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Our President and Chief Executive Officer and our Chief Financial Officer have evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) and Rule 15d-15(e) of the Exchange Act) as of the end of the period covered by this Quarterly Report. Based on this evaluation, our President and Chief Executive Officer and our Chief Financial Officer concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our President and Chief Executive Officer and our Chief Financial Officer, to allow for timely decisions regarding required disclosures, and recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms.

Changes in Internal Control

There were no changes in our internal control over financial reporting identified in connection with the evaluation described above that occurred during the quarter ended September 30, 2021 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings

We are not aware of any pending legal actions that would, if determined adversely to us, have a material adverse effect on our business and operations.

We may, from time to time, become involved in disputes and proceedings arising in the ordinary course of business. In addition, as a public company, we are also potentially susceptible to litigation, such as claims asserting violations of securities laws. Any such claims, with or without merit, if not resolved, could be time-consuming and result in costly litigation. There can be no assurance that an adverse result in any future proceeding would not have a potentially material adverse effect on our business, results of operations, and financial condition.

Item 1A. Risk Factors

An investment in our securities involves a high degree of risk. You should carefully consider the following risk factors, as well as all of the other information contained in this Quarterly Report on Form 10-Q, before making an investment decision. The risks described below are not the only ones facing us. The occurrence of any of the following risks, or of additional risks and uncertainties not presently known to us or that we currently believe to be immaterial, could significantly harm our business, financial condition, results of operations and growth prospects. In such case, the trading price of shares of our common stock could decline, and you may lose part or all 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 $4.8 million and $7.8 million for the years ended December 31, 2019 and 2020, respectively, and $4.4 million for the nine months ended September 30, 2021. As of September 30, 2021, we had an accumulated deficit of $86.7 million. Our clinical trials have been funded by approximately $168.4 million in cumulative nondilutive grants, awarded primarily by the National Institute of Aging, or NIA, a division of the National Institutes of Health. We have also raised $57.5 million in gross proceeds through our private placements of convertible preferred stock, convertible promissory notes and Simple Agreements for Future Equity, or SAFEs. We have no products approved for commercialization and have never generated any revenue from product sales.

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

- conduct our ongoing and planned clinical trials of CT1812, as well as initiate and complete additional clinical trials;
- pursue regulatory approval of CT1812 for the treatment of mild-to-moderate Alzheimer’s disease, or AD, dry age-related macular degeneration, or dry AMD, and Parkinson’s disease, or PD, and dementia with Lewy bodies, or DLB, and other age-related degenerative diseases and disorders of the central nervous system, or CNS, and retina;
- seek to discover and develop additional clinical and preclinical product candidates using Novel Improved Conditioned Extraction, or NICE, screening platform;
- adapt our regulatory compliance efforts to incorporate requirements applicable to marketed products;

- maintain, expand and protect our intellectual property portfolio;
- hire additional clinical, manufacturing and scientific personnel;
- add operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts;
- incur additional legal, accounting and other expenses in operating as a public company;
- scale up our clinical and regulatory capabilities; and
- establish a commercialization infrastructure and scale up external manufacturing and distribution capabilities to commercialize any product candidates for which we may obtain regulatory approval, including CT1812.

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

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

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

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

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 September 30, 2021, we had $8.3 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 our IPO that we completed on October 13, 2021, together with our existing cash and cash equivalents and income from our non-dilutive grants, will be sufficient for us to fund our operating expenses and capital expenditures requirements through at least the next 24 months. We have based these estimates on assumptions that may prove to be incorrect or require adjustment as a result of business decisions, and we could utilize our available capital resources sooner than we currently expect. Our future capital requirements will depend on many factors, including, but not limited to:

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

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

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

To date, we have partially relied on the availability of non-dilutive grants from the NIA, or NIA Grants. Although we currently anticipate applying for and potentially receiving additional NIA Grants, we cannot be certain that our grant applications will be successful, that additional NIA Grants will be made available to support our clinical trials or that we will continue to satisfy the award criteria of prior NIA Grants that have already been awarded to us. If we fail to continue to receive NIA Grants, our ability to continue our clinical programs for CT1812 may be impaired and delayed, and we may otherwise need to seek additional financing through dilutive methods, such as through equity or debt financings. 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 compliance with applicable laws, regulations, policies and standards and the terms and conditions of the applicable NIA Grant. If any of our expenditures are found to be unallowable or allocated improperly or if we have otherwise violated terms of such NIA Grant, the expenditures may not be reimbursed and/or we may be required to repay funds already disbursed. Any audit by the NIA could require significant financial and management resources and may result in a material adjustment to our results of operations and financial condition and harm our ability to operate in accordance with our business plan. Additionally, negative results in any of our ongoing and planned clinical trials of CT1812 that are funded with NIA Grants may result in our failure to receive additional NIA Grants to fund future clinical trials.

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

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

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

Our decisions concerning the allocation of research, development, collaboration, management and financial resources toward particular product candidates or therapeutic areas may not lead to the development of any viable commercial product and may divert resources away from better opportunities. Similarly, any decision to delay, terminate or collaborate with third parties with respect to certain programs may subsequently also prove to be suboptimal and could cause us to miss valuable opportunities. If we make incorrect determinations regarding the viability or market potential of any of our programs or product candidates or misread trends in the market of age-

related degenerative diseases and disorders of the CNS and retina or pharmaceutical, biopharmaceutical or biotechnology industry, our business, financial condition and results of operations could be materially adversely affected. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other product candidates or other diseases and disease pathways that may later prove to have greater commercial potential than those we choose to pursue, or relinquish valuable rights to such product candidates through collaboration, licensing or other royalty arrangements in cases in which it would have been advantageous for us to invest additional resources to retain development and commercialization rights.

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

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

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

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

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

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

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

As COVID-19, including any new strains or variants of COVID-19, continue to spread, we may experience ongoing disruptions that could severely impact our business and clinical trials, including:

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

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

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

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

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

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

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

The spread of COVID-19, including any new strains or 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 pharmaceutical companies have been highly volatile as a result of the COVID-19 pandemic. As a result, we may face difficulties raising capital through sales of our common stock or such sales may be on unfavorable terms.

COVID-19, including any new strains or variants of COVID-19, and actions taken to reduce its spread continue to rapidly evolve. The extent to which COVID-19 may impede the development of our product

candidates, reduce the productivity of our employees, disrupt our supply chains, delay our clinical trials, reduce our access to capital or limit our business development activities, will depend on future developments, which are highly uncertain and cannot be predicted with confidence.

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

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

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

We currently have no products approved for sale, and our lead product candidate is in early stages of clinical development. The success of our business, including our ability to finance our company and generate revenue in the future, will primarily depend on the successful development, regulatory approval and commercialization of our product candidates and, in particular, the advancement of CT1812, currently our only clinical-stage product candidate. However, given our stage of development, it may be many years, if we succeed at all, before we have demonstrated the safety and efficacy of a product candidate sufficient to warrant approval for commercialization. We cannot be certain that our product candidates will receive regulatory approval or be successfully commercialized even if we receive regulatory approval.

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

- our ability to raise any additional required capital on acceptable terms, or at all;
- our ability to complete an investigational new drug application, or IND, enabling studies and successfully submit INDs or comparable applications;
- timely completion of our preclinical studies and clinical trials, which may be significantly slower or cost more than we currently anticipate and will depend substantially upon the performance of third-party contractors;
- delays or difficulties in enrolling and retaining patients in our clinical trials;
- whether we are required by the U.S. Food and Drug Administration, or FDA, or similar foreign regulatory agencies to conduct additional clinical trials or other studies beyond those planned to support the approval and commercialization of our product candidates or any future product candidates;
- acceptance of our proposed indications and primary endpoint assessments relating to the proposed indications of our product candidates by the FDA and similar foreign regulatory authorities;
- our ability to demonstrate to the satisfaction of the FDA and similar foreign regulatory authorities the safety, efficacy and acceptable risk to benefit profile of our product candidates or any future product candidates;
- the prevalence, duration and severity of potential side effects or other safety issues experienced with our product candidates or future approved products, if any;
- achieving and maintaining, and, where applicable, ensuring that our third-party contractors achieve and maintain, compliance with our contractual obligations and with all regulatory requirements applicable to our product candidates or any future product candidates or approved products, if any;
- the ability of third parties with whom we contract to manufacture adequate clinical trial and commercial supplies of our product candidates or any future product candidates remain in good standing with regulatory agencies and develop, validate and maintain commercially viable manufacturing processes that are compliant with current good manufacturing practices, or cGMPs;
- the convenience of our treatment or dosing regimen;
- the timely receipt of necessary marketing approvals from the FDA and similar foreign regulatory authorities;

- acceptance by physicians, payors and patients of the benefits, safety and efficacy of our product candidates or any future product candidates, if approved, including relative to alternative and competing treatments;
- the willingness of physicians, operators of clinics and patients to utilize or adopt any of our product candidates or any future product candidates, if approved;
- our ability to achieve sufficient market acceptance, coverage and adequate reimbursement from third-party payors and adequate market share and revenue for any approved products;
- the COVID-19 pandemic, which may result in clinical site closures, delays to patient enrollment, patients discontinuing their treatment or follow up visits or changes to trial protocols;
- our ability to successfully develop a commercial strategy and thereafter commercialize our product candidates or any future product candidates in the United States and internationally, if approved for marketing, reimbursement, sale and distribution in such countries and territories, whether alone or in collaboration with others;
- patient demand for our product candidates, if approved, including patients' willingness to pay out-of-pocket for any approved products in the absence of coverage and/or adequate reimbursement from third-party payors;
- our ability to establish and enforce intellectual property rights in and to our product candidates or any future product candidates; and
- our ability to avoid third-party patent interference, intellectual property challenges or intellectual property infringement claims.

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

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

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

Our recurring losses from operations raise substantial doubt about our ability to continue as a going concern. As a result, our independent registered public accounting firm included an explanatory paragraph in its report on our financial statements for the years ended December 31, 2020 and 2019 with respect to this uncertainty. While we believe that the net proceeds from our IPO, together with the cash and cash equivalents and the income from non-dilutive grants that we had prior to our IPO, will be sufficient for us to fund our operating expenses and capital expenditures requirements through at least the next 24 months, we have based these estimates on assumptions that may prove to be wrong, and we may need to raise additional funds. If we are unable to raise capital when needed or on acceptable terms, we could be forced to delay, reduce or eliminate the development and commercialization of our product candidates.

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

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

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

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

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

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

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

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

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

Clinical trials are expensive and can take many years to complete, and the outcome is inherently uncertain. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical trials can occur at any stage and our future clinical trials may not be successful. Clinical trials can be delayed or terminated for a variety of reasons, including delays or failures related to:

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

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

- we may receive feedback from regulatory authorities that requires us to modify the design of our clinical trials or require that we submit additional data or information before allowing a clinical trial to be initiated or continue;

- clinical studies of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon drug development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements, fail to maintain adequate quality controls or be unable to provide us with sufficient product supply to conduct and complete preclinical studies or clinical trials of our product candidates in a timely manner, or at all;
- we or our investigators might have to suspend or terminate clinical trials of our product candidates for various reasons, including non-compliance with regulatory requirements, a finding that our product candidates have undesirable side effects or other unexpected characteristics or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- the quality of our product candidates or other materials necessary to conduct preclinical studies or clinical trials of our product candidates may be insufficient or inadequate;
- regulators may revise the requirements for approving our product candidates or such requirements may not be as we anticipate; and
- any future collaborators may conduct clinical trials in ways they view as advantageous to them but that are suboptimal for us.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only moderately positive or if there are safety concerns, we may:

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

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

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

- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating; the severity and difficulty of diagnosing the disease under investigation;

- the patient eligibility and exclusion criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to trial sites;
- competition with other companies for clinical trial sites or patients;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- the existing body of safety and efficacy data with respect to the study drug and safety concerns;
- patient referral practices of physicians;
- risk that enrolled subjects will drop out before completion of the trial, including as a result of contracting COVID-19 or other health conditions or being forced to quarantine;
- ability to monitor patients adequately during and after treatment;
- availability and efficacy of approved medications or therapies, or other clinical trials, for the disease or condition under investigation;
- our ability to obtain and maintain patient consents.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We will need to successfully complete pivotal clinical trials in order to obtain the approval of the FDA, EMA or other regulatory agencies to market CT1812 or any future product candidate. Carrying out pivotal clinical trials is a complicated process that requires significant financial resources. As an organization, we have not previously conducted any later stage or pivotal clinical trials. In order to do so, we will need to expand our clinical development and regulatory capabilities, and we may be unable to recruit and train qualified personnel. We also expect to continue to rely on third parties to conduct our pivotal clinical trials. Consequently, we may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to NDA submission

and approval of CT1812 or future product candidates. We may require more time and incur greater costs than our competitors and may not succeed in obtaining regulatory approvals of product candidates that we develop. Failure to commence or complete, or delays in, our planned clinical trials, could prevent us from or delay us in commercializing our product candidates.

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

We may seek a "breakthrough therapy" designation for our product candidates if the clinical data support such a designation for one or more product candidates. A breakthrough therapy is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug, in our case, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For product candidates that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a Breakthrough Therapy designation for a product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under non-expedited FDA review procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

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

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

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

The ability of the FDA to review and/or approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the FDA have fluctuated in recent years as a

result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

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

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

We have conducted clinical trials of our product candidates outside the United States, and plan to continue to do so in the future. For example, we initially conducted our Phase 1b SNAP clinical trial of CT1812 in collaboration with the Karolinska Institute in Sweden. In addition, the Phase 1 single and multiple ascending dose studies of CT1812 in healthy volunteers (COG0101) as well as the first-in-patient study (COG0102) were conducted in Australia. The acceptance of study data from clinical trials conducted outside the United States or another jurisdiction by the FDA, any comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless:

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

Many foreign regulatory authorities have similar requirements. In addition, foreign trials are subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in product candidates that we may develop not receiving approval or clearance for commercialization in the applicable jurisdiction.

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

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

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

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

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

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

Risks Related to Our Business and Industry

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

The success of our business, including our ability to finance our company and generate revenue in the future, will primarily depend on the successful development, regulatory approval and commercialization of CT1812, currently our only clinical-stage product candidate. To date, we have invested a significant portion of our efforts and financial resources in the development of CT1812 for the treatment of AD. Our future success is substantially dependent on our ability to successfully complete clinical development for, obtain regulatory approval for and

successfully commercialize CT1812, which may never occur. We expect that a substantial portion of our efforts and expenditures over the next few years will be devoted to CT1812, which will require additional clinical development, management of clinical and manufacturing activities, regulatory approval in multiple jurisdictions, obtaining manufacturing supply, building of a commercial organization, substantial investment and significant marketing efforts before we can generate any revenues from any commercial sales. We cannot be certain that we will be able to successfully complete any of these activities.

Furthermore, while inhibition of Aβ oligomers has been validated as a therapeutic approach, the use of small molecule receptor antagonists, such as CT1812, to inhibit the synaptic binding and signaling of soluble Aβ 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 September 30, 2021, we had 15 full-time and three part-time employees. We will need to continue to expand our managerial, operational, finance and other resources in order to manage our operations and clinical trials, continue our development activities and commercialize CT1812, our lead product candidate, or any future product candidates. Our management and personnel, systems and facilities currently in place may not be adequate to support this future growth. Our need to effectively execute our growth strategy requires that we:

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

Our future financial performance and our ability to develop, manufacture and commercialize CT1812 and our product candidates, if approved, will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert financial and other resources, and a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time, to managing these growth activities.

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

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

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

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

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

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

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

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

we intend to expand our insurance coverage to include the sale of such product candidate; however, we may be unable to obtain this liability insurance on commercially reasonable terms or at all.

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

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

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

From time to time, we may consider opportunities to acquire other companies, products or technologies that may enhance our manufacturing capabilities, expand the breadth of our markets or customer base, or advance our business strategies. Potential acquisitions involve numerous risks, including: problems assimilating the acquired service offerings, products or technologies; issues maintaining uniform standards, procedures, quality control and policies; unanticipated costs associated with acquisitions; diversion of management's attention from our existing business; risks associated with entering new markets in which we have limited or no experience; increased legal and accounting costs relating to the acquisitions or compliance with regulatory matters; and unanticipated or undisclosed liabilities of any target.

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

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

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

phishing 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.

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 to prevent a similar situation from occurring again. We also subsequently submitted a claim for the loss under our cyber-security insurance policy and our insurance carriers are reviewing the same. 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 which address privacy and data security. In the United States, numerous federal and state laws and regulations, including the U.S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and its implementing regulations, or HITECH, state data breach notification laws, state health information privacy laws and federal and state consumer protection laws, including Section 5 of the Federal Trade Commission Act, which govern the collection, use, disclosure and protection of health-related and other personal information, may apply to our operations and the operations of any future collaborators. In addition, we may obtain health information from third parties, including

research institutions from which we obtain clinical trial data, that are subject to privacy and security requirements under HIPAA, as amended by HITECH, and other privacy and data security laws. Depending on the facts and circumstances, we could be subject to significant administrative, civil and criminal penalties if we obtain, use or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA. Further, various states have implemented similar privacy laws and regulations. For example, California also recently enacted the California Consumer Privacy Act of 2018, or CCPA. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing and receive detailed information about how their personal information is used. The CCPA also provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA went into effect on January 1, 2020 and grants the California Attorney General the power to bring enforcement actions for violations beginning July 1, 2020. The CCPA has been amended from time to time, and it remains unclear what, if any, further modifications will be made to this legislation or how it will be interpreted. As currently written, the CCPA may impact our business activities and as a result may increase our compliance costs and potential liability. Many similar privacy laws have been proposed at the federal level and in other states.

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

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

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

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

We are exposed to the risk that our employees and independent contractors, including principal investigators, consultants, any future commercial collaborators, service providers and other vendors may engage in misconduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or other unauthorized activities that violate the laws and regulations of the FDA and other similar regulatory bodies, including those laws that require the reporting of true, complete and accurate information to such regulatory bodies; manufacturing standards; U.S. federal and state healthcare fraud and abuse, data privacy laws and other similar non-U.S. laws; or laws that require the true, complete and accurate reporting of financial information or

data. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, the creation of fraudulent data in our preclinical studies or clinical trials, or illegal misappropriation of product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. In addition, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and financial results, including, without limitation, the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid and other U.S. healthcare programs, other sanctions, imprisonment, contractual damages, reputational harm, diminished profits and future earnings and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Risks Related to Our Intellectual Property

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

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

It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. We may choose not to seek patent protection for certain innovations or products and may choose not to pursue patent protection in certain jurisdictions, and under the laws of certain jurisdictions, patents or other intellectual property rights may be unavailable or limited in scope and, in any event, any patent protection we obtain may be limited. As a result, some of our product candidates are not, and in the future may not be, protected by patents. We generally apply for patents in those countries where we intend to make, have made, use, offer for sale, or sell products and where we assess the risk of infringement to justify the cost of seeking patent protection. However, we do not seek protection in all countries where we intend to sell products and we may not accurately predict all the countries where patent protection would ultimately be desirable. If we fail to timely file a patent application in any such country, we may be precluded from doing so at a later date. The patent applications that we own may fail to result in issued patents with claims that cover any of our product candidates in the United States or in other foreign countries. We may also inadvertently make statements to regulatory agencies during the regulatory approval process that may be inconsistent with positions that have been taken during prosecution of our patents, which may result in such patents being narrowed, invalidated or held unenforceable, and vice versa that may affect the regulatory approval process.

The patents and patent applications that we own may fail to result in issued patents with claims that protect any of our product candidates in the United States or in other foreign countries. We cannot guarantee any current or future patents will provide us with any meaningful protection or competitive advantage. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which can prevent a patent from issuing from a pending patent application, or be used to invalidate a patent. The examination process may require us to narrow our claims, which may limit the scope of patent protection that we

may obtain. Even if patents do successfully issue based on our patent applications, and even if such patents cover our product candidates, uses of our product candidates, or other aspects related to our product candidates, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, invalidated or held unenforceable, any of which could limit our ability to prevent competitors and other third parties from developing and marketing similar products or limit the length of terms of patent protection we may have for our products and technologies. Other companies may also design around technologies we have patented or developed. Any successful opposition to these patents or any other patents owned by us in the future could deprive us of rights necessary for the successful commercialization of any of our product candidates, if approved. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced. If any of our patents are challenged, invalidated, circumvented by third parties or otherwise limited or expire prior to the commercialization of our products, and if we do not own or have exclusive rights to other enforceable patents protecting our products or other technologies, competitors and other third parties could market products and use processes that are substantially similar to, or superior to, ours and our business would suffer.

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

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has in recent years been the subject of much litigation. The standards that the USPTO and its foreign counterparts use to grant patents are not always applied predictably or uniformly. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States, and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions. For example, European patent law restricts the patentability of methods of treatment of the human body more than U.S. law does. Publications of discoveries in scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or product candidates, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

Patent reform legislation in the United States, including the Leahy-Smith America Invents Act, or the Leahy-Smith Act, could increase those uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. The Leahy-Smith Act was signed into law on September 16, 2011 and includes a number of significant changes to U.S. patent law. These includen provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. After March 15, 2013, under the Leahy-Smith Act, the United States transitioned to a first inventor to file system in which, assuming that the other statutory requirements are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications, our ability to obtain future patents, and the enforcement or defense of our issued patents, all of which could harm our business, financial condition, results of operations and prospects.

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

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Moreover, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Without patent protection for our current or future product candidates, we may be open to competition from generic versions of such products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

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

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

We do not have patent rights in certain foreign countries in which a market may exist. Moreover, in foreign jurisdictions where we do have patent rights, proceedings to enforce such rights could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, and our patent applications at risk of not issuing. Additionally, such proceedings could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Thus, we may not be able to stop a competitor from marketing and selling in foreign countries products and services that are the same as or similar to our products and services, and our competitive position in the international market would be harmed.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent

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

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

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

Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. We expect to seek extensions of patent terms in the United States and, if available, in other countries where we are prosecuting patents.

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

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

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

Our commercial success will largely depend on our ability to obtain market exclusivity in the United States and other countries with respect to our drug candidates and their target indications. Depending upon the timing, duration and specifics of FDA marketing approval of our drug candidates, certain of our product candidates may be eligible for marketing exclusivity. The FDCA provides a five-year period of non-patent marketing exclusivity

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

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

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

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

Moreover, a third party may challenge the current patents, or patents that may issue in the future, within our portfolio which could result in the invalidation of some or all of the patents that might otherwise be eligible for listing in the Orange Book for one of our products. If a third party successfully challenges all of the patents that might otherwise be eligible for listing in the Orange Book for one of our products, we will not be entitled to the

30-month stay of FDA approval upon the filing of an ANDA for a generic drug containing any of our product candidates, and relies in whole or in part on studies conducted by or for us.

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

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

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

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

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

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

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

Our commercial success depends in part on our avoiding infringement and other violations of the patents and proprietary rights of third parties. However, while certain research, development and commercialization activities may be protected by the safe harbor provision of the Hatch Waxman Act, other activities may subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement

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

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

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful infringement or other intellectual property claim against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our affected products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates, and we have done so from time to time. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

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

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim

proceedings or developments, which could adversely impact the price of our common shares. If securities analysts or investors perceive these results to be negative, it could adversely impact the price of our common shares. The occurrence of any of these events may harm our business, results of operation, financial condition or cash flows.

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

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

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

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

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

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

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

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

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

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

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

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

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

The United States has recently enacted and implemented wide-ranging patent reform legislation. In addition, patent reform legislation may pass in the future that could lead to additional uncertainties and increased costs surrounding the prosecution, enforcement and defense of our patents and pending patent applications. The United States Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the United States Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we own or that we might obtain in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we own or that we may obtain in the future. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by United States and foreign legislative bodies.

Those changes may materially affect our patents or patent applications and our ability to obtain additional patent protection in the future. The United States federal government retains certain rights in inventions produced with its financial assistance under the Bayh-Dole Act. The federal government retains a "nonexclusive, nontransferable, irrevocable, paid-up license" for its own benefit. The Bayh-Dole Act also provides federal agencies with "march-in rights." March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a "nonexclusive, partially exclusive, or exclusive license" to a "responsible applicant or applicants." If the patent owner refuses to do so, the government may grant the license itself.

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

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

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

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

Because we expect to rely on third parties to manufacture our product candidates, and we expect to continue to collaborate with third parties on the development of our product candidates, we must, at times, share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Any disclosure, either intentional or unintentional, by our employees, the employees of third parties with whom we share our facilities or third-party consultants and vendors that we engage to perform research, clinical trials or manufacturing activities, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market. Further, adequate remedies may not exist in the event of unauthorized use or disclosure. Given that our proprietary position

is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may harm our business and results of operations.

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

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

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

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

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

In addition, while it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Our and their assignment agreements may not be self-executing or may be breached, and we

may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Commercialization, Manufacturing and Reliance on Third Parties

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Many of our current or potential competitors, either alone or with their strategic partners, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing,

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

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

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

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

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

we may not be able to successfully commercialize our product candidates and may not be able to obtain a satisfactory financial return on our investment in the development of product candidates.

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

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

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

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

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

We currently do not have a marketing or sales organization. In order to commercialize our product candidates in the United States and foreign jurisdictions, we must build our marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. If any of our product candidates receive regulatory approval, we expect to establish a sales organization with technical expertise and supporting distribution capabilities to commercialize each such product candidate, which will be expensive and time consuming. We have no prior experience in the marketing, sale and distribution of biopharmaceutical products, and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. We may

choose to collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize our product candidates. If we are not successful in commercializing our product candidates or any future product candidates, either on our own or through arrangements with one or more third parties, we may not be able to generate any future product revenue and we would incur significant additional losses.

Risks Related to Government Regulation

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

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

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

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

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

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

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

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

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

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

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

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

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

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we or any related third parties are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or any related third parties are not able to maintain regulatory compliance, CT1812 or any future product candidates may lose any marketing approval that may have been obtained and we may not achieve or sustain profitability, which would materially affect our business, financial condition and results of operations.

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

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

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

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

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

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

- the U.S. federal civil and criminal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or providing any remuneration (including any kickback, bribe, or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under U.S. federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the U.S. federal false claims laws, including the False Claims Act, which can be enforced through whistleblower actions, and civil monetary penalties laws, which, among other things, impose criminal and civil penalties against individuals or entities for knowingly presenting, or causing to be presented, to the U.S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services; similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the HITECH and its implementing regulations, which also imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by covered entities, such as health plans, healthcare clearinghouses and healthcare providers, as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- the U.S. Physician Payments Sunshine Act and its implementing regulations, which require certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid or the Children's Health Insurance Program to report annually to the government information related to certain payments and other transfers of value to physicians, as defined by such law, and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members. Effective January 1, 2022, the U.S. federal physician transparency reporting requirements will extend to include transfers of value made during the previous year to certain non-physician providers such as physician assistants and nurse practitioners;
- analogous U.S. state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state and local laws that require the registration of pharmaceutical sales representatives; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; and state laws governing the privacy, security and disposal of personal information and health information in certain circumstances, many of

which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts;

- the U.S. Foreign Corrupt Practices Act of 1977, as amended, which prohibits, among other things, U.S. companies and their employees and agents from authorizing, promising, offering or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public international organizations and foreign government owned or affiliated entities, candidates for foreign political office and foreign political parties or officials thereof; and
- similar data protection and healthcare laws and regulations in the European Union and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers and laws governing the privacy and security of personal data, including the GDPR,which imposes obligations and restrictions on the collection and use of personal data relating to individuals located in the European Union and European Economic Area (including with regard to health data).

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

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

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

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

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, or FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA

PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors and other collaborators from authorizing, promising, offering or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties to sell our products outside the United States, to conduct clinical trials and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors and other collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences.

Risks Related to Our Common Stock

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 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;
- 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 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 immediate dilution and, as a result, our stock price may decline.

Because we expect our expenses to increase significantly in the foreseeable future and because, based on our current business plans, we believe that the net proceeds from our IPO, together with our cash, cash equivalents, and marketable securities prior to the IPO, will be insufficient for us to fund our operating and capital expenditures through at least the next 24 months, we may from time to time issue additional shares of common stock. These issuances may be at a discount from the current trading price of our common stock. As a result, our stockholders would experience immediate dilution upon the purchase of any shares of our common stock sold at such discount. In addition, as opportunities present themselves, we may enter into financing or similar arrangements in the future, including the issuance of debt securities, preferred stock or common stock. If we issue common stock or securities convertible into common stock, our common stockholders will experience additional dilution and, as a result, our stock price may decline.

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

As of the closing of our IPO on October 13, 2021, our executive officers, directors and beneficial owners of 5% or more of our common stock and their respective affiliates beneficially owned approximately 51% of our outstanding common stock. As a result, these persons, acting together, would be able to significantly influence all matters requiring stockholder approval, including the election and removal of directors, any merger, consolidation, sale of all or substantially all of our assets, or other significant corporate transactions.

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

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

If our stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after the lock-up and other legal restrictions on resale in connection with our IPO terminate, the trading price of our common stock could decline.

The lock-up agreements pertaining to our IPO will expire 180 days from the October 7, 2021. Based upon the number of shares outstanding as of September 30, 2021, after the lock-up agreements expire, up to approximately 10,931,039 additional shares of common stock will be eligible for sale in the public market, all of which shares are held by directors, executive officers, affiliates, and certain significant stockholders and will be subject to Rule 144 under the Securities Act. The underwriters may, however, in their sole discretion, permit our officers, directors and other stockholders who are subject to these lock-up agreements to sell shares prior to the expiration of the lock-up agreements.

In addition, following the closing of our IPO, we filed a registration statements on Form S-8 (File No. 333-260686) under the Securities Act, registering the issuance of 7,334,485 shares of our common stock subject to options or other equity awards issued or reserved for future issuance under our equity incentive plans. Shares registered under the registration statement on Form S-8 will be available for sale in the public market subject to vesting arrangements and exercise of options, the lock-up agreements described above and the restrictions of Rule 144 in the case of our affiliates.

Subsequent to the IPO, holders of approximately 3,377,925 shares of our common stock, or approximately 15.8% of our total outstanding shares of common stock, were entitled to rights with respect to the registration of their shares under the Securities Act, subject to the lock-up agreements described above (as applicable). Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares purchased by affiliates. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

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

As of December 31, 2020, we had federal net operating loss, or NOL, carryforwards of approximately $37.9 million and state NOL carryforwards of approximately $37.9 million available to offset future taxable income. If not utilized, the federal and state NOL carryforwards will begin to expire in various years beginning in 2027. As of December 31, 2020, we also had $3.7 million of federal research and development tax credit carryforwards available to reduce future income taxes. The federal research and development tax credits will begin to expire in 2027, if not utilized. The state research and development tax credits have no expiration date. Utilization of NOL carryforwards and credits may be subject to an annual limitation due to the “ownership change” provisions under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or 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 changes are outside our control. Such ownership changes could result in the expiration of our NOL carryforwards and other tax attributes before they can be utilized and, if we are profitable, our future cash flows could be adversely affected due to our increased tax liability.

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

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

Our 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 will include the following:

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

We are also subject to the anti-takeover provisions contained in Section 203 of the Delaware General Corporation Law. Under Section 203, a corporation may not, in general, engage in a business combination with

any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other exceptions, the board of directors has approved the transaction.

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 Delaware General Corporation Law, our third amended and restated certificate of incorporation or our amended and restated bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine; provided that, the exclusive forum provision will not apply to suits brought to enforce any liability or duty created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction; and provided further that, if and only if the Court of Chancery of the State of Delaware dismisses any such action for lack of subject matter jurisdiction, such action may be brought in another state or federal court sitting in the State of Delaware.

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.

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

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

The trading market for our common stock 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 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.

As of the completion of our IPO on October 13, 2021, 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 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.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Recent Sales of Unregistered Securities

During the period covered by this Quarterly Report, we issued the following securities that were not registered under the Securities Act:

1. We issued an aggregate of 4,996 shares of our common stock to employees for cash consideration in the aggregate amount of $4,613 upon the exercise of stock options.

2. We issued an aggregate of 834 shares of our common stock to consultants upon the net exercise of common stock warrants.

The offering and sale of the securities described above were made pursuant to the exemption from the registration requirements of the Securities Act of 1933, as amended, provided by Section 4(a)(2) thereof or in reliance on Rule 701 promulgated thereunder.

Use of Proceeds from our Iniitial Public Offering of Common Stock

On October 13, 2021, we completed our IPO. Our registration statement on Form S-1 (File No. 333- 257999) relating to the IPO was declared effective by the SEC on October 7, 2021. We issued 3,768,116 shares of our common stock at a price of $12.00 per share for aggregate net cash proceeds of $38.1 million, after deducting underwriting discounts and commissions and other offering related costs. None of the expenses associated with the IPO were paid to directors, officers, persons owning 10% or more of any class of equity securities, or to their associates, or to our affiliates. B. Riley Securities, Inc., or the Representative, acted as lead book running manager of the offering and as representative of the underwriters.

On November 10, 2021, the Representative provided notice to us that it had elected to exercise its over-allotment option in full to purchase 565,217 shares of our common stock. The Representative’s exercise of the over-allotment option closed on November 12, 2021, resulting in gross proceeds of approximately $6.8 million and net proceeds of $6.3 million to us, after deducting underwriting discounts and commissions and other offering related expenses.

There has been no material change in the planned use of proceeds from our IPO as described in our Prospectus. As our IPO closed on October 13, 2021, we had not yet received any of the proceeds from our IPO as of September 30, 2021.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
31.1	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
31.2	Certification of Principal Financial and Accounting Officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.					X
101.SCH	Inline XBRL Taxonomy Extension Schema Document					X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document					X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document					X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document					X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document					X
104	Cover Page Interactive Data File (formatted as Inline XBRL with applicable taxonomy extension information contained in Exhibits 101).					X

* This certification is being furnished solely to accompany this Quarterly Report on Form 10-Q pursuant to 18 U.S.C. Section 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing of the registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

SIGNATURES

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

Cognition Therapeutics, Inc.

Date: November 17, 2021

By: /s/ Lisa Ricciardi
Lisa Ricciardi
Chief Executive Officer
(Principal Executive Officer)

Date: November 17, 2021

By: /s/ James O'Brien
James O'Brien
Chief Financial Officer
(Principal Financial Officer)

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302
OF THE SARBANES-OXLEY ACT OF 2002

I, Lisa Ricciardi, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Cognition Therapeutics, Inc. (the "registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal controls over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 17, 2021

By: /s/ Lisa Ricciardi
Lisa Ricciardi
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 302
OF THE SARBANES-OXLEY ACT OF 2002

I, James O'Brien, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Cognition Therapeutics, Inc. (the "registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal controls over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 17, 2021

By: /s/ James O'Brien
James O'Brien
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

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

In connection with the quarterly report of Cognition Therapeutics, Inc. (the "Company") on Form 10-Q for the quarterly period ended September 30, 2021, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Lisa Ricciardi, do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to the best of my knowledge, that:

(1) The Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 17, 2021

By: /s/ Lisa Ricciardi
Lisa Ricciardi
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

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

In connection with the quarterly report of Cognition Therapeutics, Inc. (the "Company") on Form 10-Q for the quarterly period ended September 30, 2021, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, James O'Brien, do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to the best of my knowledge, that:

(1) The Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 17, 2021

By: /s/ James O'Brien
James O'Brien
Chief Financial Officer
(Principal Financial Officer)