UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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, 2020

OR

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

For the transition period from _____ to _____

Commission File Number: 001-39567

C4 Therapeutics, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**47-5617627**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
490 Arsenal Way, Suite 200 Watertown, MA	**02472**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (617) 231-0700

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	CCCC	The Nasdaq Global Select Market

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, 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 ☒

As of November 10, 2020, the registrant had 43,029,500 shares of common stock, $0.0001 par value per share, outstanding.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q ("Form 10-Q"), including the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations," contains express or implied forward-looking statements that are based on our management's belief and assumptions and on information currently available to our management. Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements relate to future events or our future operational or financial performance, and involve known and unknown risks, uncertainties, and other factors that may cause our actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by these forward-looking statements. Forward-looking statements in this Form 10-Q include, but are not limited to, statements about:

- the initiation, timing, progress, results, safety and efficacy, and cost of our research and development programs and our current and future preclinical studies and clinical trials, including statements regarding the timing of initiation and completion of studies or trials, the period during which the results of the trials will become available, and our research and development programs;
- the ultimate impact of the current coronavirus pandemic, or the COVID-19 pandemic, or any other health epidemic, on our business, manufacturing, clinical trials, research programs, supply chain, regulatory review, healthcare systems or the global economy as a whole;
- risks related to the direct or indirect impact of the COVID-19 pandemic or any future large-scale adverse health event, such as the scope and duration of the outbreak, government actions and restrictive measures implemented in response, material delays in diagnoses, initiation or continuation of treatment for diseases that may be addressed by our development candidates and investigational medicines, or in patient enrollment in clinical trials, potential clinical trials, regulatory review or supply chain disruptions, and other potential impacts to our business, the effectiveness or timeliness of steps taken by us to mitigate the impact of the pandemic, and our ability to execute business continuity plans to address disruptions caused by the COVID-19 pandemic or future large-scale adverse health event;
- our ability to obtain funding for our operations necessary to complete further development, manufacturing and commercialization of our product candidates;
- our ability to obtain and maintain regulatory approval for any of our current or future product candidates;
- the period over which we anticipate our existing cash and cash equivalents and short-term investments will be sufficient to fund our operating expenses and capital expenditure requirements;
- our ability to identify and develop product candidates for treatment of additional disease indications;
- the potential attributes and benefits of our product candidates;
- the rate and degree of market acceptance and clinical utility for any product candidates we may develop;
- the pricing and reimbursement of our product candidates, if approved;
- the effects of competition with respect to any of our current or future product candidates, as well as innovations by current and future competitors in our industry;
- the implementation of our strategic plans for our business, any product candidates we may develop and our TORPEDO platform;
- the ability and willingness of our third-party strategic collaborators to continue research, development and manufacturing activities relating to our product candidates, including our ability to advance programs under our existing collaboration agreements with F. Hoffman-La Roche Ltd., or Roche, Biogen MA, Inc., or Biogen, and Calico Life Sciences LLC, or Calico, or other new collaboration agreements;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates;
- estimates of our future expenses, revenues, capital requirements, and our needs for additional financing;
- future agreements with third parties in connection with the manufacturing and commercialization of our product candidates, if approved;
- the size and growth potential of the markets for our product candidates, and our ability to serve those markets;
- our financial performance;
- regulatory developments in the United States and foreign countries;
- our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately;
- the success of competing therapies that are or may become available;
- our ability to attract and retain key scientific or management personnel;
- developments relating to our competitors and our industry; and
- other risks and uncertainties, including those discussed in Part II, Item 1A - Risk Factors in this Form 10-Q.

In some cases, forward-looking statements can be identified by terminology such as “will,” “may,” “should,” “could,” “expects,” “intends,” “plans,” “aims,” “anticipates,” “believes,” “estimates,” “predicts,” “potential,” “continue,” or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. These statements are only predictions. You should not place undue reliance on forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, which are, in some cases, beyond our control and which could materially affect results. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under the section entitled “Risk Factors” and elsewhere in this Form 10-Q. If one or more of these risks or uncertainties occur, or if our underlying assumptions prove to be incorrect, actual events or results may vary significantly from those expressed or implied by the forward-looking statements. No forward-looking statement is a promise or a guarantee of future performance.

The forward-looking statements in this Form 10-Q represent our views as of the date of this Form 10-Q. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should therefore not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Form 10-Q.

This Form 10-Q includes statistical and other industry and market data that we obtained from industry publications and research, surveys, and studies conducted by third parties. Industry publications and third-party research, surveys, and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. We have not independently verified the information contained in such sources.

RISKS ASSOCIATED WITH OUR BUSINESS

Our ability to implement our business strategy is subject to numerous risks that you should be aware of before making an investment decision. These risks are described more fully in the section entitled “Risk Factors” in this Form 10-Q. These risks include, among others:

- We are an early stage biopharmaceutical company with a limited operating history and have incurred significant losses since our inception. To date, we have not generated any revenue from product sales. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years and may never achieve or maintain profitability. Our net loss was $44.5 million for the nine months ended September 30, 2020, $34.1 million for the year ended December 31, 2019 and $15.7 million for the year ended December 31, 2018.
- We will need substantial additional funding to pursue our business objectives and continue our operations. If we are unable to raise capital when needed, we may be required to delay, limit, reduce or terminate our research or product development programs or future commercialization efforts.
- Our approach to the discovery and development of product candidates based on our TORPEDO platform is unproven, which makes it difficult to predict the time, cost of development and likelihood of successfully developing any products.
- All of our product candidates are still in preclinical development. Our business could be harmed if we are unable to advance to clinical development, develop, obtain regulatory approval for and commercialize our product candidates or experience significant delays in doing any of these things.
- We cannot be certain of the timely completion or outcome of our preclinical testing and clinical trials. In addition, the results of preclinical studies may not be predictive of the results of clinical trials and the results of any early-stage clinical trials we commence may not be predictive of the results of later-stage clinical trials.
- Our preclinical studies and clinical trials may fail to demonstrate adequately the safety, potency, purity and efficacy of any of our product candidates, which would prevent or delay development, regulatory approval and commercialization of our current and future product candidates.
- We have entered into collaboration agreements with Roche, Biogen and Calico and may in the future seek to enter into collaborations with third parties for the development and commercialization of certain of our product candidates. If we fail to enter into these types of new collaborations, or if our existing collaborations are not successful, we may be unable to continue development of our product candidates, we would not receive any contemplated milestone payments or royalties, and we could fail to capitalize on the market potential of our product candidates.
- The continuing effects of the novel coronavirus disease, COVID-19, could adversely impact our business, including our preclinical studies and clinical trials.
- We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.
- We rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for preclinical and clinical testing, as well as for commercial manufacture if any of our product candidates receive marketing approval. This reliance on third parties may increase the risk that we will not have sufficient quantities of our product candidates in a timely manner, or at an acceptable cost or quality.

- If we are unable to obtain required marketing approvals for, commercialize, manufacture, obtain and maintain patent protection for or gain market acceptance of our product candidates, or if we experience significant delays in doing so, our business will be materially harmed and our ability to generate revenue from product sales will be materially impaired.
- If we are unable to obtain and maintain patent protection for our technology and products or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and products may be impaired.

NOTE REGARDING COMPANY REFERENCES

Unless the context otherwise requires, the terms “C4 Therapeutics,” “the Company,” “we,” “us,” and “our” in this Form 10-Q refer to C4 Therapeutics, Inc. and its consolidated subsidiary.

NOTE REGARDING TRADEMARKS

We own or have rights to various trademarks, service marks and trade names that are used in connection with the operation of our business, including our company name, C4 Therapeutics, our logo, the name of our TORPEDO™ technology platform and the names of our BIDAC™ and MONODAC™ protein degrader product candidates. This Form 10-Q may also contain trademarks, service marks and trade names of third parties, which are the property of their respective owners. Our use or display of third parties’ trademarks, service marks, trade names or products in this prospectus is not intended to and does not imply a relationship with, or endorsement or sponsorship by, us. Solely for convenience, the trademarks, service marks and trade names referred to in this prospectus may appear without the ®, TM or SM symbols, but the omission of such references is not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the right of the applicable owner of these trademarks, service marks and trade names.

Table of Contents

Item 1. Financial Statements.

C4 THERAPEUTICS, INC.

Condensed Consolidated Balance Sheets
(In thousands, except share and per share data)
(Unaudited)

	SEPTEMBER 30, 2020	DECEMBER 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 63,434	$ 90,549
Short-term investments	135,979	—
Accounts receivable	4,141	4,623
Prepaid expenses and other current assets	5,370	1,595
Total current assets	208,924	96,767
Property and equipment, net	3,580	4,463
Right-of-use asset	13,544	14,453
Restricted cash	2,577	2,577
Other assets	502	—
Total assets	$ 229,127	$ 118,260
Total Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 5,264	$ 5,385
Accrued expenses and other current liabilities	9,830	6,671
Deferred revenue, current	23,915	20,705
Operating lease liability, current	1,000	880
Total current liabilities	40,009	33,641
Deferred revenue, net of current	61,083	72,718
Operating lease liability, net of current	12,097	12,869
Warrant liability	5,465	—
Long-term debt	9,877	—
Total liabilities	128,531	119,228
Commitments and Contingencies (see Note 5 and Note 8)		
Series Seed redeemable convertible preferred stock, par value of $0.0005 per share; 4,000,000 shares authorized as of September 30, 2020 and December 31, 2019; 4,000,000 shares issued and outstanding as of September 30, 2020 and December 31, 2019; liquidation and redemption value of $1,000 as of September 30, 2020 and December 31, 2019	1,000	1,000
Series A redeemable convertible preferred stock, par value of $0.0005 per share; 110,000,000 shares authorized as of September 30, 2020 and December 31, 2019; 109,145,900 shares issued and outstanding as of September 30, 2020 and December 31, 2019, liquidation and redemption value of $109,995 as of September 30, 2020 and December 31, 2019	109,995	109,995
Series B redeemable convertible preferred stock, par value of $0.0005 per share; 150,000,000 and 0 shares authorized as of September 30, 2020 and December 31, 2019; 142,857,142 and 0 shares issued and outstanding as of September 30, 2020 and December 31, 2019; liquidation and redemption value of $145,525 and $0 as of September 30, 2020 and December 31, 2019	145,525	—
Stockholders' deficit:		
Common stock, par value of $0.0001 per share; 370,000,000 and 180,000,000 shares authorized as of September 30, 2020 and December 31, 2019; 1,634,121 and 1,426,641 shares issued and outstanding as of September 30, 2020 and December 31, 2019	1	1
Additional paid-in capital	6,095	5,524
Accumulated other comprehensive loss	8	—
Accumulated deficit	(162,028)	(117,488)
Total stockholders' deficit	(155,924)	(111,963)
Total liabilities, redeemable convertible preferred stock and stockholders' deficit	229,127	118,260

See accompanying notes to condensed consolidated financial statements.

C4 THERAPEUTICS, INC.

Condensed Consolidated Statement of Operations and Comprehensive Loss
(In thousands, except share and per share data)
(Unaudited)

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2020	2019	2020	2019
Revenue from collaboration agreements	$ 8,447	$ 5,364	$ 24,933	$ 13,172
Operating expenses:				
Research and development	23,935	12,948	58,007	32,042
General and administrative	2,861	2,417	8,472	6,083
Total operating expenses	26,796	15,365	66,479	38,125
Operating loss	(18,349)	(10,001)	(41,546)	(24,953)
Other income (expense), net:				
Interest income (expense)	(352)	558	(170)	1,454
Amortization of debt discount	(203)	—	(229)	—
Change in fair value of warrant liability	(3,141)	—	(3,141)	—
Other (expense) income, net	43	(1)	44	323
Total other income (expense), net	(3,653)	557	(3,496)	1,777
Loss before income taxes	(22,002)	(9,444)	(45,042)	(23,176)
Income tax expense (benefit)	(167)	650	(502)	900
Net loss	(21,835)	(10,094)	(44,540)	(24,076)
Other comprehensive loss:				
Unrealized gain (loss) on short-term investments	(10)	5	8	(4)
Comprehensive loss	(21,845)	(10,089)	(44,532)	(24,080)
Accrual of preferred stock dividends	(5,212)	(2,201)	(10,363)	(6,531)
Net loss attributable to common stockholders	(27,047)	(12,295)	(54,903)	(30,607)
Net loss per share attributable to common stockholders—basic and diluted (Note 12)	$ (17.55)	$ (8.93)	$ (36.76)	$ (22.59)
Weighted-average number of shares used in computed net loss per share —basic and diluted	1,540,902	1,376,365	1,493,521	1,354,734

See accompanying notes to condensed consolidated financial statements.

C4 THERAPEUTICS, INC.

Condensed Consolidated Statement of Redeemable Convertible Preferred Stock and Stockholder's Deficit
(In thousands, except share and per share data)
(Unaudited)

	SERIES SEED REDEEMABLE CONVERTIBLE PREFERRED STOCK		SERIES A REDEEMABLE CONVERTIBLE PREFERRED STOCK		SERIES B REDEEMABLE CONVERTIBLE PREFERRED STOCK		COMMON STOCK		ADDITIONAL PAID-IN	ACCUMULATED OTHER COMPREHENSIVE	ACCUMULATED	TOTAL STOCK HOLDERS'
	SHARES	AMOUNT	SHARES	AMOUNT	SHARES	AMOUNT	SHARES	AMOUNT	CAPITAL	INCOME (LOSS)	DEFICIT	DEFICIT
Balance as of June 30, 2019	4,000,000	$ 1,000	109,145,900	$ 109,995	—	—	1,354,373	$ 1	$ 3,957	4	$ (97,371)	$ (93,409)
Exercise of stock options	—	—	—	—	—	—	72,511	—	213	—	—	213
Stock-based compensation	—	—	—	—	—	—	—	—	627	—	—	627
Repurchase of common stock	—	—	—	—	—	—	(6,112)	—	(6)	—	—	(6)
Net unrealized gain on available-for-sale securities	—	—	—	—	—	—	—	—	—	(4)	—	(4)
Net loss	—	—	—	—	—	—	—	—	—	—	(10,094)	(10,094)
Balance as of September 30, 2019	4,000,000	$ 1,000	109,145,900	$ 109,995	—	$ —	1,420,772	$ 1	$ 4,791	$ —	$ (107,465)	$ (102,673)
Balance as of June 30, 2020	4,000,000	$ 1,000	109,145,900	$ 109,995	138,571,428	$ 141,026	1,490,336	$ 1	$ 5,129	(2)	$ (140,193)	$ (135,065)
Issuance of Series B convertible preferred stock	—	—	—	—	4,285,714	4,499	—	—	—	—	—	—
Exercise of stock options	—	—	—	—	—	—	164,057	—	530	—	—	530
Stock-based compensation	—	—	—	—	—	—	—	—	436	—	—	436
Repurchase of common stock	—	—	—	—	—	—	(20,272)	—	—	—	—	—
Unrealized loss on investments	—	—	—	—	—	—	—	—	—	10	—	10
Net loss	—	—	—	—	—	—	—	—	—	—	(21,835)	(21,835)
Balance as of September 30, 2020	4,000,000	$ 1,000	109,145,900	$ 109,995	142,857,142	$ 145,525	1,634,121	$ 1	$ 6,095	$ 8	$ (162,028)	$ (155,924)

	SERIES SEED REDEEMABLE CONVERTIBLE PREFERRED STOCK		SERIES A REDEEMABLE CONVERTIBLE PREFERRED STOCK		SERIES B REDEEMABLE CONVERTIBLE PREFERRED STOCK		COMMON STOCK		ADDITIONAL PAID-IN	ACCUMULATED OTHER COMPREHENSIVE	ACCUMULATED	TOTAL STOCK HOLDERS'
	SHARES	AMOUNT	SHARES	AMOUNT	SHARES	AMOUNT	SHARES	AMOUNT	CAPITAL	INCOME (LOSS)	DEFICIT	DEFICIT
Balance as of December 31, 2018	4,000,000	$ 1,000	109,145,900	$ 109,995	—	—	1,338,956	$ 1	$ 3,638	—	$ (83,389)	$ (79,750)
Exercise of stock options	—	—	—	—	—	—	87,928	—	260	—	—	260
Stock-based compensation	—	—	—	—	—	—		—	913	—	—	913
Repurchase of common stock	—	—	—	—	—	—	(6,112)	—	(20)	—	—	(20)
Net loss	—	—	—	—	—	—	—	—	—	—	(24,076)	(24,076)
Balance as of September 30, 2019	4,000,000	$ 1,000	109,145,900	$ 109,995	—	$ —	1,420,772	$ 1	$ 4,791	$ —	$ (107,465)	$ (102,673)
Balance as of December 31, 2019	4,000,000	$ 1,000	109,145,900	$ 109,995	—	—	1,426,641	$ 1	$ 5,524	—	$ (117,488)	$ (111,963)
Issuance of Series B convertible preferred stock	—	—	—	—	142,857,142	145,525	—	—		—	—	—
Exercise of stock options	—	—	—	—	—	—	251,466	—	795	—	—	795
Stock-based compensation	—	—	—	—	—	—	—	—	713	—	—	713
Repurchase of common stock	—	—	—	—	—	—	(43,986)	—	(210)	—	—	(210)
Vested stock option settlement	—	—	—	—	—	—	—	—	(727)	—	—	(727)
Unrealized loss on investments	—	—	—	—	—	—	—	—	—	8	—	8
Net loss	—	—	—	—	—	—	—	—	—	—	(44,540)	(44,540)
Balance as of September 30, 2020	4,000,000	$ 1,000	109,145,900	$ 109,995	142,857,142	$ 145,525	1,634,121	$ 1	$ 6,095	$ 8	$ (162,028)	$ (155,924)

See accompanying notes to condensed consolidated financial statements.

C4 THERAPEUTICS, INC.

Condensed Consolidated Statement of Cash Flows
(In thousands)
(Unaudited)

	NINE MONTHS ENDED SEPTEMBER 30,	
	2020	**2019**
Cash flows used in operating activities:		
Net loss	$ (44,540)	$ (24,076)
Adjustments to reconcile net loss to cash provided by (used in) operating activities:		
Depreciation and amortization	1,252	1,173
Stock-based compensation expense	713	913
Loss on disposal of fixed assets	—	9
Unrealized loss on short-term investments	(53)	—
Accretion of discount on investments	8	—
Reduction in carrying amount of right-of-use assets	910	850
Amortization of debt discount	229	—
Change in fair value of warrant liability	3,141	—
Changes in operating assets and liabilities:		
Accounts receivable	482	83,846
Prepaid expenses, other current assets and other assets	(1,798)	(655)
Accounts payable	(132)	3,071
Accrued expenses and other liabilities	3,157	1,729
Operating lease liability	(651)	(544)
Deferred revenue	(8,425)	(398)
Net cash provided by (used in) operating activities	(45,710)	65,918
Cash flows used in investing activities:		
Purchases of property and equipment	(359)	(1,422)
Purchase of short-term investments	(135,926)	(14,902)
Proceeds received from maturities of short-term investments	—	14,902
Net cash used in investing activities	(136,284)	(1,422)
Cash flows provided by financing activities:		
Proceeds from the issuance of Series B convertible preferred stock, net of issuance costs of $4,473	145,525	—
Proceeds from the issuance of common stock	764	206
Financing costs paid in connection with initial public offering	(2,446)	—
Vested stock option settlement	(727)	—
Repurchase of common stock	(210)	(40)
Proceeds from long-term debt, net of issuance costs of $527	11,973	—
Net cash provided by financing activities	154,879	166
Net increase (decrease) in cash, cash equivalents and restricted cash	(27,115)	64,662
Cash, cash equivalents and restricted cash at beginning of period	93,126	38,888
Cash, cash equivalents and restricted cash at end of period	$ 66,011	$ 103,550
Reconciliation of cash, cash equivalents and restricted cash:		
Cash, cash equivalents and restricted cash at end of period	$ 66,011	$ 103,550
Less restricted cash	(2,577)	(2,577)
Cash and cash equivalents at end of the period	$ 63,434	$ 100,973
Supplemental disclosures of non-cash investing and financing activities:		
Capital expenditures in accounts payable	$ 10	$ 98
Accrued deferred initial public offering costs	$ 474	$ —
Stock option exercises included in prepaid and other current assets	$ 33	$ 53
Fair value of warrants issued in connection with debt issuance	$ 5,465	$ —

See accompanying notes to condensed consolidated financial statements.

(1) The Company

C4 Therapeutics, Inc. (together with its subsidiary, the “Company”) is a biopharmaceutical company focused on harnessing the body’s natural regulation of protein levels to develop novel therapeutic candidates to target and eliminate disease-causing proteins for the treatment of cancer, neurodegenerative conditions and other diseases. The Company was incorporated in Delaware on October 7, 2015 and has its principal office in Watertown, Massachusetts. The Company is subject to risks common to other life science companies in the early development stage including, but not limited to, uncertainty of product development and commercialization, lack of marketing and sales history, development by its competitors of new technological innovations, dependence on key personnel, market acceptance of products, product liability, protection of proprietary technology, ability to raise additional financing and compliance with the Food and Drug Administration (“FDA”) and other government regulations. If the Company does not successfully advance its programs into and through human clinical trials and/or enter into collaborations for its programs and commercialize any of its product candidates, the Company may be unable to produce product revenue or achieve profitability.

Initial Public Offering

As further described in Note 13, in October 2020, the Company completed an initial public offering (IPO) of its common stock.

Liquidity

The Company has evaluated whether there are certain conditions and events, considered in the aggregate, that raise substantial doubt about the Company’s ability to continue as a going concern within one year after the date that the financial statements are issued.

The Company has incurred recurring losses since its inception, including net losses of $44.5 million and $24.1 million for the nine months ended September 30, 2020 and 2019, respectively. In addition, as September 30, 2020, the Company had an accumulated deficit of $162.0 million. To date, the Company has not generated any revenue from product sales as none of its product candidates has been approved for commercialization. The Company expects to continue to generate operating losses for the foreseeable future.

The Company’s primary activities since inception have been focused around research and development activities, building the Company’s intellectual property, recruiting personnel and raising capital to support these activities. Through September 30, 2020, the Company has funded its operations primarily with proceeds received from the sale of redeemable convertible preferred stock (collectively, the “Preferred Stock”) and through its collaboration agreements. In addition, the Company has cash and cash equivalents and short-term investments of $199.4 million as of September 30, 2020. Management considers that there are no conditions or events, in the aggregate, that raise substantial doubt about the entity’s ability to continue as a going concern for a period of at least one year from the date the condensed consolidated financial statements are issued. Accordingly, the condensed consolidated financial statements have been prepared on a basis that assumes the Company will continue as a going concern and contemplates the realization of assets and satisfaction of liabilities and commitments in the ordinary course of business.

Reverse Stock Split

On September 25, 2020, the Company’s effected a one-for-8.4335 reverse stock split of its issued and outstanding common stock and stock options, and a proportional adjustment to the existing conversion ratios for the Company’s convertible preferred stock. Accordingly, all issued and outstanding common stock, options to purchase common stock and per share amounts contained in the condensed consolidated financial statements have been retroactively adjusted to give effect to the reverse stock split for all periods presented except as otherwise stated.

COVID-19 Pandemic

The impact of the COVID-19 coronavirus outbreak on the Company’s financial performance will depend on future developments, including the duration and spread of the outbreak and related governmental advisories and restrictions. These developments and the impact of COVID-19 on the financial markets and the overall economy are highly uncertain and cannot be predicted. If the financial markets and/or the overall economy are impacted for an extended period, the Company’s results may be materially adversely affected. The Company is currently unable to determine the extent of the impact of the pandemic to its operations and financial condition, as the Company has not yet started any clinical trials. Once the Company begins its clinical trials, it will assess any potential delays as a result of the pandemic, as well as their financial impact.

(2) Summary of Significant Accounting Policies

Basis of Presentation and Consolidation

The accompanying interim unaudited condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United Stated ("US GAAP") and applicable rules and regulations of the Securities and Exchange Commission (the "SEC") regarding interim financial reporting, and the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. These condensed consolidated financial statements include the accounts of C4 Therapeutics, Inc. and its subsidiary C4T Securities Corporation. All intercompany balances and transactions have been eliminated in consolidation.

Unaudited Interim Financial Information

The accompanying condensed consolidated balance sheet as of September 30, 2020, the condensed consolidated statements of operations and comprehensive loss for the three and nine months ended September 30, 2020 and 2019, the condensed consolidated statements of redeemable convertible preferred stock and stockholders' deficit for the three and nine months ended September 30, 2020 and 2019, the condensed consolidated statements of cash flows for the nine months ended September 30, 2020 and 2019, and the related interim disclosures are unaudited. These unaudited condensed consolidated financial statements include all adjustments necessary, consisting of only normal recurring adjustments, to fairly state the financial position and the results of the Company's operations and cash flows for interim periods in accordance with U.S. GAAP. Interim period results are not necessarily indicative of results of operations or cash flows for a full year or any subsequent interim period. The accompanying condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements and unaudited condensed consolidated statements included in the Company's prospectus related to the Company's IPO effective on October 1, 2020, pursuant to Rule 424(b) under the Securities Act (the "Prospectus").

Significant Accounting Policies

The Company's significant accounting policies are disclosed in the audited consolidated financial statements for the year ended December 31, 2019, which are included in the Prospectus. An update and supplement to these accounting policies follows.

Short-Term Investments

The Company classifies all short-term investments with an original maturity when purchased of greater than three months as available-for-sale. Available-for-sale securities are carried at fair value, with the unrealized gains and losses reported in other comprehensive loss. The amortized cost of debt securities in this category is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization is included in interest income. Realized gains and losses and declines in value judged to be other than temporary on available-for-sale securities, are included in interest income.

The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are included in interest income. To determine whether an other-than-temporary impairment exists, the Company considers whether it has the ability and intent to hold the investment until a market price recovery, and whether evidence indicating the recoverability of the cost of the investment outweighs evidence to the contrary.

The Company's short-term investments as of September 30, 2020 of $136.0 million consisted entirely of US Treasury securities.

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 offering costs until such financings are consummated. After consummation of the equity financing, these costs are recorded in stockholders' (deficit) equity 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 as a charge to operating expenses in the condensed consolidated statements of operations and comprehensive loss. The Company had $2.9 million of deferred offering costs related to the IPO as of September 30, 2020.

Warrant Liability

In connection with the Company's completion of a financing involving the sale of shares of Series B redeemable convertible preferred stock (the "Series B Financing") in June and July 2020 and the entry into the Term Loan (see note 8), the Company issued a warrant to purchase shares of its Series B Preferred Stock. The Company classified the warrant as a liability on its consolidated balance sheet. The Company remeasures this warrant liability to fair value at each reporting date and recognizes changes in the fair value of the warrant liability as a component of other income (expense), net in the consolidated statement of operations and comprehensive loss.

The Company utilized the Black-Scholes option-pricing model, which incorporates assumptions and estimates, to value these warrants. The Company assesses these assumptions and estimates on a quarterly basis. Estimates and assumptions impacting the fair value measurement include the fair value per share of the underlying redeemable convertible Series B Preferred Stock or common stock issuable upon exercise of the warrant, remaining contractual term of the warrant, risk-free interest rate, expected dividend yield and expected volatility of the price of the underlying redeemable convertible preferred stock or common stock. See Note 13.

(3) Fair Value Measurements

In accordance with authoritative guidance on fair value measurements and disclosures under U.S. GAAP, the Company discloses and recognizes the fair value of its assets and liabilities using a hierarchy that distinguishes between assumptions based on market data (observable inputs) and our own assumptions (unobservable inputs). The hierarchy consists of three levels:

Level 1 – Unadjusted quoted prices in active markets for identical assets or liabilities

Level 2 – Quoted prices for similar assets and liabilities in active markets, quoted prices in markets that are not active, or inputs which are observable, directly or indirectly, for substantially the full term of the asset or liability.

Level 3 – Unobservable inputs that reflect our own assumptions about the assumptions market participants would use in pricing the asset or liability in which there is little, if any, market activity for the asset or liability at the measurement date.

The following tables present information about the Company's financial assets measured at fair value on a recurring basis and indicates the level of the fair value hierarchy utilized to determine these fair values as of September 30, 2020 and December 31, 2019 (in thousands):

DESCRIPTION	SEPTEMBER 30, 2020	QUOTED PRICES IN ACTIVE MARKETS FOR IDENTICAL ASSETS (LEVEL 1)	SIGNIFICANT OTHER OBSERVABLE INPUTS (LEVEL 2)	SIGNIFICANT OTHER OBSERVABLE INPUTS (LEVEL 3)
Asset				
Cash and cash equivalents (money market funds)	$ 63,434	$ 63,434	$ —	$ —
Short-term investments	135,979	135,979	—	—
Total financial assets	$ 199,413	$ 199,413	$ —	$ —
Liability				
Warrants	$ 5,465	$ —	$ —	$ 5,465
Total financial liabilities	$ 5,465	$ —	$ —	$ 5,465

DESCRIPTION	DECEMBER 31, 2019	QUOTED PRICES IN ACTIVE MARKETS FOR IDENTICAL ASSETS (LEVEL 1)	SIGNIFICANT OTHER OBSERVABLE INPUTS (LEVEL 2)	SIGNIFICANT OTHER OBSERVABLE INPUTS (LEVEL 3)
Asset				
Cash and cash equivalents (money market funds)	$ 90,549	$ 90,549	$ —	$ —
Total financial assets	$ 90,549	$ 90,549	$ —	$ —

The Company's warrant liability represented a Level 3 investment as of September 30, 2020 (see Note 8).

The Company classifies its money market funds, which are valued based on quoted market prices in active markets, with no valuation adjustment, as Level 1 assets within the fair value hierarchy.

Short-term investments consist of U.S. Treasury securities, are classified as available-for-sale pursuant to ASC 320, Investments – Debt and Equity Securities, and are valued based on quoted market prices in active markets, with no valuation adjustment.

As of September 30, 2020 and December 31, 2019, none of the Company's available-for-sale investments that were in an unrealized loss position had been in an unrealized loss position for more than 12 months. During the three and nine months ended September 30, 2020, the Company did not recognize any other-than-temporary impairment losses.

There have been no transfers between fair value levels during the three and nine months ended September 30, 2020 and 2019.

(4) Property and Equipment

Property and equipment consisted of the following (in thousands):

	SEPTEMBER 30, 2020	DECEMBER 31, 2019
Laboratory equipment	$ 7,038	$ 6,766
Computer equipment	223	167
Furniture and fixtures	805	797
Office equipment	179	167
Leasehold improvements	541	520
Total	8,786	8,417
Less: accumulated depreciation	(5,207)	(3,954)
Property and equipment, net	$ 3,580	$ 4,463

Total depreciation and amortization expense for the nine-month periods ended September 30, 2020 and 2019 was $1.3 million and $1.2 million respectively. Primarily all of the depreciation and amortization expense was recorded in research and development expenses for the three and nine months ended September 30, 2020 and 2019.

(5) Leases

In July 2017, the Company entered into a lease of office and laboratory space for its headquarters at 490 Arsenal Way in Watertown, Massachusetts (the “Watertown Lease”). The Watertown Lease commenced in April 2018 with rent commencing in May 2018. The Company recognized operating lease costs of $3.1 million and $3.0 million for the nine months ended September 30, 2020 and 2019, respectively.

The Company incurred approximately $0.5 million in costs for leasehold improvements for the nine months ended September 30, 2019. The Company incurred no costs for leasehold improvements for the nine months ended September 30, 2020. The Watertown Lease required the Company to provide collateral in the amount of $2.6 million, which is recorded as restricted cash on the accompanying condensed consolidated balance sheets.

As of December 31, 2019, assets under the Watertown Lease classified as right-of-use assets on the Company’s condensed consolidated balance sheet were $14.5 million, net of accumulated amortization. Liabilities under the Watertown Lease were $13.8 million, of which $0.9 million were classified as operating lease liability, current, and $12.9 million were classified as operating lease liability, net of current, on the Company’s condensed consolidated balance sheet.

As of September 30, 2020, assets under the Watertown Lease classified as right-of-use assets on the Company’s condensed consolidated balance sheet were $13.5 million, net of accumulated amortization. Liabilities under the Watertown Lease were $13.1 million, of which $1.0 million were classified as operating lease liability, current, and $12.1 million were classified as operating lease liability, net of current, on the Company’s condensed consolidated balance sheet.

Additionally, the Company recorded right-of-use amortization of $0.9 million for the nine months ended September 30, 2020 and 2019.

The elements of lease costs under the Watertown Lease were as follows (in thousands):

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2020	2019	2020	2019
Lease cost:				
Operating lease cost	$ 637	637	$ 1,912	$ 1,912
Variable lease cost	419	366	1,207	1,087
Total lease cost	1,056	1,003	3,119	2,999
Other information:				
Operating cash flows for operating liabilities	$ 551	535	$ 1,654	$ 1,606
Operating lease liabilities arising from obtaining right-of-use assets	—	—	—	—
Weighted average remaining lease term	7.5 years	8.5 years	7.5 years	8.5 years
Weighted average discount rate	10%	10%	10%	10%

As of September 30, 2020, undiscounted minimum future lease payments under non-cancelable leases were as follows: (in thousands):

FUTURE OPERATING LEASE PAYMENTS		
2020(1)	$	551
2021		2,272
2022		2,340
2023		2,410
2024		2,483
Thereafter		8,833
Total lease payments		18,889
Less imputed interest		(5,792)
Total operating lease liabilities at September 30, 2020	$	13,097

(1) For the three months ended December 31, 2020.

(6) Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following as of September 30, 2020 and December 31, 2019 (in thousands):

	SEPTEMBER 30, 2020		DECEMBER 31, 2019
Accrued research and development	5,387	$	2,615
Accrued compensation and benefits	2,727		3,048
Accrued professional fees	1,552		728
Other	164		280
Total accrued expenses and other current liabilities	$ 9,830	$	6,671

(7) Collaboration and License Agreements

Roche Collaboration and License Agreement

Original Roche Agreement Structure

In March 2016, the Company entered into a license agreement (the “Original Roche Agreement”) with Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc. (“Roche”). Pursuant to the terms of the Original Roche Agreement, the Company and Roche agreed to collaborate on research activities to develop novel treatments in the field of targeted protein degradation (“TPD”) using the Company’s degrader technology. Under the terms of the Original Roche Agreement, the Company initially developed TPD therapeutics that utilize degrader technology for up to ten target proteins until the earlier of the exercise of the option right or termination for the last available target. On a target-by target basis, after successful completion of a defined preclinical development phase, Roche had an exclusive option to pursue further clinical development and commercialization.

In exchange for a $15.0 million nonrefundable upfront payment and additional fees for dedicated personnel, the Company performed initial research and development services for drug discovery and preclinical development, provided a non-exclusive research and development license to its technology and participated on the joint research committee (the “Roche JRC”). For each target option exercised by Roche, the Company was eligible to receive up to $277.0 million in research, development and commercial milestone payments, with the commercial milestones being dependent on underlying net sales. Roche was also required to pay the Company up to $150.0 million in one-time sales-based payments for the first product to achieve certain levels of net sales. In addition, Roche was required to pay the Company royalties, at percentages from the mid-single digits to the low double-digits, on a licensed product-by licensed product basis, on worldwide net product sales. The research and development was to be performed by the Company over an estimated period of approximately 42 months per target according to the research plan. Roche also reimbursed the Company for up to five full-time equivalents (“FTEs”) (“FTE Funding”) per target unless otherwise agreed upon by the Roche JRC.

Restated Roche Agreement Structure

On December 22, 2018, the Company and Roche executed the Amended and Restated Roche License Agreement (the “Restated Roche Agreement”). Under the Restated Roche Agreement, the Company has a more active role in the manufacturing and commercialization of the targets, whereby if certain co-development and co-detailing rights are opted into by the Company, the parties will split future development costs in return for the rights to a larger share of future earnings from commercialization of the target. The target structure was revised to six potential targets, three of which were nominated as of the execution of the Restated Roche Agreement and represent continuations of the initial preclinical research and development efforts begun under the Original Roche Agreement and three additional targets that were not nominated as of the execution of the Restated Roche Agreement. Roche maintained its option rights to license and commercialize these six targets. For certain

targets, Roche is required to pay the Company fees of $2.0 million and $3.0 million upon the progression of targets to the lead series identification achievement and good laboratory practice ("GLP") toxicology ("Tox") study phase, respectively. For each target option exercised by Roche, the Company is eligible to receive up to $275.0 million in research and development milestones per target and commercial milestone payments, with the commercial milestones being dependent on underlying net sales. Roche is also required to pay the Company up to $150.0 million per target in one-time sales-based payments if the target achieves certain levels of net sales. In addition, Roche is required to pay the Company royalties, at percentages from the mid-single digits to the low double-digits, on a licensed product-by licensed product basis, on worldwide net product sales.

Under the Restated Roche Agreement:

- the Company received additional upfront consideration of $40.0 million from Roche;
- the Company has an option for co-development and co-detailing rights, whereby it would be required to provide additional financial support in return for the rights to a larger share of future earnings from commercializing one or more of the six targets;
- Roche will no longer provide FTE reimbursement; rather, it will make annual research plan payments of $1.0 million for each active research plan; and
- Adjustments were made to the option exercise fees, whereby certain targets now have option exercise fees of $7.0 million to $12.0 million (those progressed up to Phase 1 or through the GLP Tox studies, respectively) and others have $20.0 million (those progressed through clinical trials).

The collaboration is managed by a joint research committee. The Company has control over the committee and may terminate the Restated Roche Agreement on a target-by-target or product-by-product basis under several scenarios, upon at least 90 days' prior written notice.

Restated Roche Agreement Accounting

The Restated Roche Agreement is a modification of the Original Roche Agreement under Accounting Standards Codification (ASC) 606, Revenue from Contracts with Customers, or ASC 606 as both the scope and price of the contract were changed under the Restated Roche Agreement and new, distinct performance obligations were created for targets that have different standalone selling prices based on the Company's revised obligations. The Restated Roche Agreement was not determined to be a separate contract for accounting purposes. The modification was accounted for as if it were a termination of the existing contract and the creation of a new contract, for which the unrecognized consideration from the Original Roche Agreement is added to the new transaction price promised as part of the Restated Roche Agreement and will be recognized as revenue prospectively, as the new performance obligations are satisfied. The Company made this determination after considering the performance obligations under the Restated Roche Agreement. When the amendment was signed, the contract was restructured such that the Company would pursue some of the same targets, but would have additional material responsibility to potentially develop the targets beyond the option exercise point, to either Phase 1 completion or to a point where the Company will exercise its co-development and co-detailing options and more fully share in the costs and future revenues. The $40.0 million upfront payment, $13.5 million of expected research plan funding payments, plus $6.4 million of remaining deferred revenue from the Original Roche Agreement represent the transaction price as of the outset of the arrangement.

The Company assessed this arrangement in accordance with ASC 606 and concluded that the contract counterparty, Roche, is a customer. The Company identified the following promises at the outset of the Restated Roche Agreement: (1) a non-exclusive royalty-free license to use the Company's intellectual property to conduct research and development activities; (2) research and development services under the research plan for the three initial targets; (3) participation on the Roche JRC; (4) option rights to initiate a research plan for three additional targets; (5) an option to obtain a non-exclusive commercial license to intellectual property and know-how generated from the collaboration, subject to certain exclusivity requirements; (6) option rights to develop, commercialize and manufacture products related to any of the six targets; and (7) rights for Roche to substitute targets prior to completion of a research plan, limited to six exchanges in total across the arrangement and subject to approval by the Roche JRC. The Roche JRC has equal representation from both parties, but the Company holds final decision-making authority in the event of a disagreement until the time at which Roche licenses a target and leads development efforts.

The six potential targets were determined to be distinct from one another, as Roche can derive benefit from each target independent of the others. For each target, the Company determined that the research and development license and research and development services were not distinct from one another, because the research and development services are essential to the license. Roche would receive little to no economic benefit from the license if it did not obtain the research services. Participation on the Roche JRC to oversee the research and development activities and the technology transfer associated with the Original Roche Agreement were determined to be quantitatively and qualitatively immaterial. The Company evaluated Roche's option rights to initiate a research plan for three additional targets as well as the option rights to license and commercialize each target to determine whether they provide Roche with any material rights. The Company concluded that each of the options were issued with an option exercise fee that represented a significant and incremental discount and therefore provide material rights for six of the six targets—three material rights from the option to license the three initial targets at the end of their research terms and three material rights from the option to initiate a research plan for the three additional targets along with the option to license such at the end of their research terms. The consideration allocated to the option rights to initiate the three additional targets is deferred until the underlying option is exercised, at which point the Company will begin recognizing revenue for these targets. The non-exclusive, limited commercial license to the intellectual property and know-how generated from the collaboration was determined to be immaterial and, as such, no consideration was allocated to it.

Based on these assessments, the Company identified twelve performance obligations, including three research services performance obligations, six material rights for the options to purchase a commercial license for six targets and three material rights for the option to initiate research services for the uninitiated three targets as of the outset of the arrangement. The first three performance obligations primarily comprise: (1) the non-exclusive research and development license and (2) the research and development services for the target, including the related substitution rights.

The Company included the $40.0 million upfront payment, $13.5 million of expected research plan funding payments ($1.0 million per active target per year, for a maximum of $3.0 million per target), and $6.4 million of remaining deferred revenue from the Original Roche Agreement in the transaction price as of the outset of the arrangement. The Company also achieved a milestone for the identification of lead series for target 2 in April 2019, resulting in a milestone payment of $2.0 million, which was added to the transaction price and recognized cumulatively. The transaction price of $61.9 million was allocated to the performance obligations based on the estimated stand-alone selling prices at the time of the amendment. For each performance obligation, the stand-alone selling price was determined considering the expected cost of the research and development services and a reasonable margin for the respective services. The material rights from the option rights were valued based on the estimated discount at which the option is priced and the Company's estimated probability of the options' exercise as of the time of the amendment.

The Company allocated the following amounts of the total transaction price to the performance obligations as of the amendment date, including the $2.0 million milestone achieved in April 2019:

- $28.6 million to the research and development performance obligations for targets 1-3; and
- $4.7 million to the three material rights, related to the three targets initiated at the outset of the Restated Roche Agreement, which will not begin revenue recognition until the option is exercised or expires.
- $28.6 million to the option to nominate targets 4-6 and the three material rights related to these options.

The Company will recognize the portion of the transaction price allocated to each of the research and development performance obligations as the research and development services are provided, using an input method, according to costs incurred as related to the research and development activities for each individual program and the costs expected to be incurred in the future to satisfy that individual performance obligation. The transfer of control occurs over this time period and, in management's judgment, is the best measure of progress towards satisfying the performance obligation.

Amounts due to the Company that have not yet been received are recorded as accounts receivable and amounts received that have not yet been recognized as revenue are recorded in deferred revenue on the Company's consolidated balance sheet.

Biogen Collaboration Research and License Agreement

In December 2018, the Company entered into a collaboration research and license agreement (the "Biogen License Agreement") with Biogen MA, Inc. ("Biogen"). Pursuant to the terms of the Biogen License Agreement, the Company and Biogen agreed to collaborate on research activities to develop novel treatments in the field of TPD using the Company's degrader technology. Under the terms of the Biogen License Agreement, the Company will initially develop TPD therapeutics that utilize degrader technology for up to five target proteins over a period of 54 months. On a target-by-target basis, after successful completion of a defined target evaluation period, Biogen assumes full rights and responsibility to each degrader to meet certain criteria against a target. Biogen also has the option to pay an additional $62.5 million to extend the contract and select up to five additional targets for development.

In exchange for the non-exclusive research license from Biogen as well as a $45.0 million nonrefundable upfront payment, the Company will grant a license to develop, commercialize and manufacture products related to each of the targets (which is contingent on not cancelling the contract), will perform initial research services for drug discovery, provide a non-exclusive research and commercial license to its intellectual property and will participate on the joint steering committee (the "Biogen JSC"). The Company will also be obligated to participate in early research activities for other potential targets or "sandbox activities," at Biogen's election up to a maximum amount; any work performed for these services will be reimbursed by Biogen, and Biogen will reimburse the Company for certain FTE costs. Biogen is also required to pay the Company up to $35.0 million per target in development milestones and $26.0 million per target in one-time sales-based payments for the first product to achieve certain levels of net sales. In addition, Biogen is required to pay the Company royalties on a licensed product-by-licensed product basis, on worldwide net product sales.

The collaboration is managed by the Biogen JSC, which Biogen has control over, and Biogen may terminate the Biogen License Agreement on a target-by-target or product-by-product basis under several scenarios, upon at least 90 days' prior written notice.

The nonrefundable upfront cash payment of $45.0 million is not creditable against any of the target development milestone fees. The research will be performed by the Company over 54 months according to the research plan approved by the Biogen JSC.

Biogen License Agreement Accounting

The Company assessed this arrangement in accordance with ASC 606 and concluded that the contract counterparty, Biogen, is a customer. The Company identified the following promises under the arrangement: (1) a non-exclusive, royalty-free license to use the Company's intellectual property to conduct research activities; (2) an upfront license to develop, commercialize and manufacture products related to each of the targets (which is contingent on not cancelling the contract); (3) research services for preclinical activities under the research plan; (4) participation on the Biogen JSC; and (5) substitution rights for Biogen via "sandbox activities" to replace targets prior to a program reaching completion of a research plan, limited to five exchanges in total. Substitution is dependent on the original target failing to meet certain criteria; Biogen may only replace a target in this specific scenario. The Company also determined that Biogen's ability to terminate the Agreement at-will with 90 days' notice is not representative of a substantive purchase option to continue to the research and does not provide a material right in the form of a continuous renewal option.

The Company determined that the licenses and research activities were not distinct from one another, as the licenses have limited value without the performance of the research activities by the Company. Participation on the Biogen JSC to oversee the research activities and the technology transfer associated with the Biogen License Agreement were determined to be quantitatively and qualitatively immaterial and therefore are excluded from performance obligations.

Based on these assessments, the Company identified one performance obligation at the outset of the Biogen License Agreement, representing a combined performance obligation consisting of (1) the licenses, (2) the research activities for the target evaluation phase for all five targets and (3) the joint research plan phase for each target.

The Company will recognize the transaction price as the research and development services are provided, using an input method, according to costs incurred as related to the research and development activities for the costs expected to be incurred in the future to satisfy that individual performance obligation. The transfer of control occurs over this time period and, in management's judgment, is the best measure of progress towards satisfying the performance obligation.

Biogen also has the option to fund sandbox activities in exchange for consideration, whereby the Company will perform discovery-type research at Biogen's election to develop other potential targets that may be used as replacement targets for the initially nominated targets or two additional targets under the Biogen Agreement. Revenues earned under this option, if initiated, will be recognized as services are performed and are not included in the transaction price. Sandbox research activities will be reimbursed on an FTE basis at market rates, which is adjusted for changes in the "Consumer Price Index" each year. The sandbox activities constitute additional research that can be purchased on an a la carte basis at an amount consistent with standalone selling price. The Company recognizes revenue as the services performed for the sandbox activities are performed and recognized $0.6 and $0.2 million of revenue for the three months ended September 30, 2020 and 2019, respectively, and $2.0 and $0.2 million of revenue for the nine months ended September 30, 2020 and 2019, respectively, related to the sandbox activities.

The Company recognizes FTE reimbursement related to sandbox activities as revenue as the hours are incurred each quarter. Amounts due to the Company that have not yet been received are recorded as accounts receivable and amounts received that have not yet been recognized as revenue are recorded in deferred revenue on the Company's consolidated balance sheet.

Calico Collaboration and License Agreement

In March 2017, the Company entered into a collaboration and license agreement (the "Calico License Agreement") with Calico Life Sciences LLC ("Calico") whereby the Company and Calico agreed to collaborate to develop and commercialize small molecule protein degraders for diseases of aging, including cancer for a five-year period ending in March 2022 (the "research term").

Under the terms of the Calico License Agreement, the Company will initially develop and commercialize small molecule protein degraders for up to five target proteins over the research term. On a target-by-target basis, after successful completion of a defined target evaluation period, Calico has an exclusive option to pursue further pre-clinical development and commercialization via a joint research plan for each target.

Under the Calico License Agreement, Calico paid an upfront amount of $5.0 million and certain annual payments totaling $5.0 million through June 30, 2020, and pays target initiation fees and reimburses the Company for a number of FTEs, depending on the stage of the research, at specified market rates. Upon completion of the required discovery research and development services on any target, Calico is entitled to pursue commercial development of that target. The Company will perform initial research services for drug discovery and preclinical development, provide a non-exclusive research and commercial license to its IP and will participate on the Calico joint research committee (the "CJRC"). For each target, the Company is eligible to receive up to $132.0 million in potential research, development and commercial milestone payments, on sales of all products resulting from the collaboration efforts. Calico is also required to pay the Company up to $65.0 million in one-time sales-based payments for the first product to achieve certain levels of net sales. In addition, Calico is required to pay the Company royalties, at percentages in the mid-single digits, on a licensed product-by-licensed product basis, on worldwide net product sales.

The Calico License Agreement is managed by a joint research committee (the "CJRC"). Calico has control over the CJRC and may terminate the Calico License Agreement on a target-by-target or product-by-product basis under several scenarios, upon prior written notice.

The nonrefundable upfront and certain annual payments are not creditable against any other payments. Calico will reimburse the Company for a contractually defined number of FTEs ("Calico FTE Funding") per target depending on the phase of development, unless otherwise agreed upon by the CJRC. The research will be performed by the Company over the research term in accordance with the research plan.

Calico License Agreement Accounting

The Company assessed this arrangement in accordance with ASC 606 and concluded that the contract counterparty, Calico, is a customer. The Company identified the following promises under the arrangement: (1) the non-exclusive, royalty-free research license and commercial license, which function for purposes of the arrangement as a license and are therefore analyzed together; (2) the target evaluation research services for all five targets; (3) the joint research plan research services related to targets 1 and 2, which were nominated at the execution of the Calico License Agreement; (4) the target initiation rights/options associated with targets 3, 4 and 5, subject to nomination; and (5) the joint research plan services associated with targets 3, 4 and 5, subject to nomination and payment of the target initiation fees from (4). The Company determined that the license and research activities were not distinct from one another, as the license has limited value without the performance of the research activities by the Company. Participation on the CJRC to oversee the R&D activities and the technology transfer associated with the Calico License Agreement were determined to be quantitatively and qualitatively immaterial and therefore are excluded from performance obligations. The Company determined that the option rights to nominate the targets were not distinct from one another or from the other promises in the arrangement, specifically the research license and research services. The Company evaluated the target initiation rights for targets 3, 4 and 5 and the research services associated with the joint research plan nomination for these targets to determine whether they provide Calico with any material rights. The Company concluded that these options were not issued at a significant and incremental discount and therefore do not provide material rights.

Based on these assessments, the Company identified one performance obligation at the outset of the Calico License Agreement, which consists of: (1) the non-exclusive license and (2) the research activities for the target evaluation phase for all five targets and the joint research plan phase for targets 1 and 2.

Under the Calico License Agreement, the transaction price determined by the Company is the upfront amount plus the committed anniversary payments and the target initiation fees related to the targets nominated at the execution of the Calico License Agreement. Based on the ability of Calico to cancel the arrangement for any reason, Calico effectively has an option for continued access to the Company's research license and procurement of research services that they can cancel at any time. Under the Calico License Agreement, the Company amortized the upfront fee received on a straight-line basis over the period services are available to the counterparty (i.e. the contractual term of five years). Straight-line amortization of the upfront payment was considered the best measure of progress because the customer has access to research and development services throughout the period. Incremental fees for research and development services are paid at agreed upon FTE rates and recognized in the period incurred.

Amounts due to the Company that have not yet been received are recorded as accounts receivable and amounts received that have not yet been recognized as revenue are recorded in deferred revenue on the Company's consolidated balance sheet.

The following tables summarize the impact of the collaboration and license agreements on the Company's condensed consolidated statements of operations and comprehensive loss for the three and nine months ended September 30, 2020 and 2019 and the Company's condensed consolidated balance sheet as of September 30, 2020 and December 31, 2019.

Revenue from collaboration agreements for the three and nine months ended September 30, 2020 and 2019 in the condensed consolidated statements of operations and comprehensive loss was as follows (in thousands):

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2020	2019	2020	2019
Restated Roche Agreement	$ 1,395	1,762	$ 7,424	$ 3,875
Biogen License Agreement	3,525	642	6,827	1,707
Calico License Agreement	3,527	2,960	10,682	7,590
	$ 8,447	$ 5,364	$ 24,933	$ 13,172

The Company achieved $4.0 million in milestones under the Biogen Agreement in June 2020, which was recorded as accounts receivable and deferred revenue at that time. The Company received payment of these milestones from Biogen in August 2020.

Financial information related to the collaboration and license agreements consisted of the following in the Company's condensed consolidated balance sheet as of September 30, 2020 and December 31, 2019 (in thousands):

DESCRIPTION	AS OF SEPTEMBER 30, 2020 (unaudited) ACCOUNTS RECEIVABLE	DEFERRED REVENUE, CURRENT	DEFERRED REVENUE, NET OF CURRENT	DEFERRED REVENUE, TOTAL
Restated Roche Agreement	$ 583	$ 7,821	$ 31,286	$ 39,107
Biogen License Agreement	631	13,694	28,597	42,291
Calico License Agreement	2,927	2,400	1,200	3,600
	$ 4,141	$ 23,915	$ 61,083	$ 84,998

DESCRIPTION	AS OF DECEMBER 31, 2019 ACCOUNTS RECEIVABLE	DEFERRED REVENUE, CURRENT	DEFERRED REVENUE, NET OF CURRENT	DEFERRED REVENUE, TOTAL
Restated Roche Agreement	$ —	$ 12,164	$ 32,784	$ 44,948
Biogen License Agreement	275	6,141	36,934	43,075
Calico License Agreement	4,348	2,400	3,000	5,400
	$ 4,623	$ 20,705	$ 72,718	$ 93,423

(8) Long-term Debt and Warrant Liability

On June 5, 2020, contemporaneously with the completion of the Series B Financing (see Note 9), the Company entered into a Credit Agreement with Perceptive Life Sciences Master Fund LTD., an affiliate of Perceptive Credit Holdings III, LP (“Perceptive”) that provides for an aggregate principal borrowing amount of up to $20.0 million, available in two tranches of $12.5 million and $7.5 million (such arrangement, the “Term Loan”). The Company drew down on the first tranche of $12.5 million in June 2020, bearing interest at a variable rate of 11.25%, which was calculated based on the one-month LIBOR rate, which, per the Credit Agreement, can never be below 1.75%, plus an applicable margin, which was initially determined to be 9.5%. The Term Loan matures on September 5, 2024, unless it is accelerated in accordance with its terms. The Company will make interest-only payments until December 5, 2022, at which point the Company will make payments of principal equal to 2% of the Term Loan until maturity. If the Company pays off the Term Loan prior to the Maturity Date, it will be required to pay a $5.0 million prepayment fee. In connection with the Term Loan, the Company is required to maintain a balance of at least $3.0 million in C4 Therapeutics, Inc. parent companies bank account while the Term Loan is outstanding.

The Credit Agreement allows for prepayment in full of the outstanding principal of the Term Loan at any time. Any prepayment shall be in a minimum principal amount of $0.5 million and in multiples of $0.1 million in excess of that amount, plus accrued interest and a prepayment fee, which would be calculated based on the terms of the Credit Agreement. The Company paid a closing fee of $0.3 million in connection with its entry into the Credit Agreement.

The aggregate principal amount of debt outstanding as of September 30, 2020 was $12.5 million. As of September 30, 2020, the unamortized debt discount was $2.6 million. The carrying value of the long-term debt, net of issuance costs and the debt discount related to the warrants to purchase shares of the Company’s equity securities (as discussed below) that were issued in connection with the entry into the Credit Agreement, was $9.7 million.

In connection with the Term Loan, the Company issued a warrant to purchase up to 2,857,142 shares of the Company's Series B preferred stock to Perceptive at an exercise price per share of $1.05. The warrants are exercisable at any time prior to the ten-year anniversary of the closing date under the Credit Agreement. The Company determined that the warrant is liability-classified and will be remeasured to fair value each reporting period, with changes recorded in the statement of operations and comprehensive loss. The Company determined the fair value of this warrant to be $5.5 million using the Black-Scholes model based on the following assumptions as of September 30, 2020:

	AS OF SEPTEMBER 30, 2020
Stock price	$ 2.26
Exercise price	$ 1.05
Expected term (in years)	9.75
Volatility	75%
Risk-free interest rate	0.69%
Dividend yield	—

(9) Stockholder's Equity

Certificate of Incorporation

As of September 30, 2020, the terms of the Company's equity securities were defined in the Company's Fourth Amended and Restated Certificate of Incorporation, which was filed with the Secretary of the State of Delaware on June 3, 2020 (the "Fourth Charter"). Under the Fourth Charter, the Company was authorized to issue Series Seed Preferred Stock, Series A Preferred Stock and Series B Preferred Stock, each of which had a par value of $0.0005 per share and which are referred to collectively as Preferred Stock. On October 6, 2020, in connection with the consummation of the IPO, the Company filed its Fifth Amended and Restated Certificate of Incorporation with the Secretary of the State of Delaware. The summary below relates to the Company's Fourth Charter.

Reverse Stock Split

As described in Note 1, on September 25, 2020 the Company effected a one-for-8.4335 reverse stock split of its issued and outstanding common stock, stock options and common stock warrants and a proportional adjustment to the existing conversion ratios for the Company's convertible preferred stock. Accordingly, all issued and outstanding common stock, options to purchase common stock and per share amounts contained in the condensed consolidated financial statements have been retroactively adjusted to give effect to the reverse stock split for all periods presented.

Common Stock

Features of the Common Stock

Under the Fourth Charter, the Company's common stock had a par value of $0.0001 and the holders of common stock were entitled to one vote for each share held at all meetings of stockholders and written actions in lieu of meetings provided. The Fourth Charter also provided that all dividends shall be declared and paid pro rata according to the number of shares held by each holder of common stock. In the event of a liquidation, dissolution or winding up of the Company, the common stock ranks behind the Preferred Stock in terms of distribution of assets. The holders of the common stock have no preemptive or other subscription rights, and there are no redemption or sinking fund provisions with respect to such stock.

Preferred Stock

In June and July 2020, the Company closed a $150.0 million Series B Financing with existing and new investors. As part of the Series B Financing, the Company issued 142,857,142 shares of its Series B preferred stock at a purchase price of $1.05 per share, for aggregate gross proceeds of $150.0 million. Of the amounts above, 138,571,428 shares were issued for gross proceeds of $145.5 million, less related offering costs of $4.5 million in June 2020, and 4,285,714 shares were issued for proceeds of $4.5 million in July 2020.

As of September 30, 2020 and December 31, 2019, Preferred Stock consisted of the following (in thousands, except share data):

	SEPTEMBER 30, 2020				
	PREFERRED STOCK AUTHORIZED	PREFERRED STOCK ISSUED AND OUTSTANDING	CARRYING VALUE	LIQUIDATION VALUE	COMMON STOCK ISSUABLE UPON CONVERSION
Series Seed Preferred Stock	4,000,000	4,000,000	$ 1,000	$ 1,000	474,298
Series A Preferred Stock	110,000,000	109,145,900	109,995	109,995	12,941,857
Series B Convertible Preferred Stock	150,000,000	142,857,142	145,525	145,525	16,939,224
	264,000,000	256,003,042	$ 256,520	$ 256,520	30,355,379

	DECEMBER 31, 2019				
	PREFERRED STOCK AUTHORIZED	PREFERRED STOCK ISSUED AND OUTSTANDING	CARRYING VALUE	LIQUIDATION VALUE	COMMON STOCK ISSUABLE UPON CONVERSION
Series Seed Preferred Stock	4,000,000	4,000,000	$ 1,000	$ 1,000	474,298
Series A Preferred Stock	110,000,000	109,145,900	109,995	109,995	12,941,857
FF Preferred Stock	32,760,000	—	—	—	—
	146,760,000	113,145,900	$ 110,995	$ 110,995	13,416,155

The following is a summary of the rights and privileges of the holders of Preferred Stock as of September 30, 2020 and December 31, 2019, which is comprised of shares of Series Seed preferred stock, Series A preferred stock and Series B preferred stock, each of which has a par value of $0.0005 per share:

Conversion

As of September 30, 2020, all outstanding shares of Preferred Stock were convertible into common stock on a 8.4335-to-one basis at any time at the option of the holder and were mandatorily convertible upon the consummation of a qualified initial public offering, which was defined as an underwritten public offering resulting in at least $50.0 million in gross proceeds to the Company (see Note 13).

Voting

All shares of Preferred Stock have voting rights that provide for voting on an as-converted to common stock basis, with each share entitled to the number of votes equal to the number of whole shares into which such share is then convertible. As a result, under the Fourth Charter, as of September 30, 2020, every 8.4335 shares of Preferred Stock was entitled to one vote.

Redemption

The Preferred Stock was not redeemable except in the event of a liquidation. The Series Seed Preferred Stock, Series A Preferred Stock, and Series B Preferred Stock were entitled to receive liquidation payments at their respective issuance prices together with any accrued but unpaid dividends in preference to the common stock. Because the Series Seed Preferred Stock, Series A Preferred Stock, and Series B Preferred Stock were only mandatorily redeemable upon the occurrence of a liquidation event and the preferred stockholders had control of the Company's board of directors, they are classified in the mezzanine section of the Company's condensed consolidated balance sheet.

Dividends

The Series B Preferred Stock had dividend preference over all shares of common stock or Preferred Stock. Under the Fourth Charter, the holders of the Series B Preferred Stock then outstanding were entitled to receive, first or simultaneously, a dividend on each outstanding share of Series B Preferred Stock in an amount at least equal to the greater of the amount of accrued dividends on the Series B Preferred Stock and the amount that would be paid to holders of Series B Preferred Stock on an as-converted to common stock basis or other shares pursuant to the dividend granted. The Series A Preferred Stock had similar dividend preference over the common stock.

The Series Seed Preferred Stock is eligible to receive dividends on a pro rata as-converted basis in proportion to the number of shares of common stock that would be held upon conversion to common stock. Series A Preferred Stock and Series B Preferred Stock accrue dividends at a rate of $0.08 and $0.084 per annum, respectively, and are payable only if and when declared by the Company's board of directors or in the event of a liquidation.

(10) Stock-based Compensation

On December 28, 2015, the Company's board of directors adopted the C4 Therapeutics, Inc. 2015 Incentive Stock Option and Grant Plan (the "2015 Plan") and reserved 2,525,327 shares of common stock for issuance under this plan. As of April 2019, the shares reserved increased to 3,614,753. On June 3, 2020, the number of shares reserved for issuance under the 2015 Plan was increased to 5,058,203. As of September 30, 2020, 2,364,975 shares remained available for future grant under the 2015 Plan. Following the IPO, no further awards will be granted under the 2015 Plan, though this plan does remain in effect as to previously granted awards.

The 2015 Plan authorizes the board of directors or a committee of the board of directors to grant incentive stock options, nonqualified stock options and restricted stock awards to eligible employees, outside directors and consultants of the Company. Options generally vest over a period of five or eight years, with a cliff vesting at one year and quarterly vesting thereafter and options that lapse or are forfeited are available to be granted again. The contractual life of all options is generally ten years from the date of grant.

In connection with the issuance of stock options, the Company recorded stock-based compensation expense of $0.4 million and $0.6 million for the three months ended September 30, 2020 and 2019, respectively and $0.7 million and $0.9 million for the nine months ended September 30, 2020 and 2019, respectively.

Stock-based compensation expense for the three and nine months ended September 30, 2020 and 2019 was classified in the Company's condensed consolidated statement of operations and comprehensive loss as follows (in thousands):

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2020	2019	2020	2019
Research and development	$ 345	$ 118	$ 620	$ 272
General and administrative	91	509	93	641
Total stock-based compensation expense	$ 436	$ 627	$ 713	$ 913

Stock option activity under the 2015 Plan is summarized as follows:

	NUMBER OF OPTIONS	WEIGHTED-AVERAGE EXERCISE PRICE	WEIGHTED-AVERAGE REMAINING CONTRACTUAL TERM (IN YEARS)	AGGREGATE INTRINSIC VALUE
Outstanding as of December 31, 2019	2,368,950	$ 4.35	8.11	$ 10,309
Granted	1,467,424	4.98		
Exercised	(251,466)	3.17		2,442
Cancelled or forfeited	(1,229,054)	4.52		
Outstanding as of September 30, 2020	2,355,854	4.82	8.89	$ 11,367
Options exercisable as of December 31, 2019	733,310	3.40	7.41	$ 2,275
Options exercisable as of September 30, 2020	365,732	4.04	7.28	$ 6,949

President and Chief Executive Officer Termination

On March 3, 2020 ("Separation Date"), the employment of the Company's then current president and chief executive officer ("CEO") terminated. The Company repurchased all of the CEO's outstanding shares of common stock, which had been issued upon his exercise of previously granted stock options, for total consideration of $0.1 million. The CEO also relinquished his right to purchase shares of common stock upon the exercise of stock options that were vested as of his termination date, in exchange for total consideration paid by the Company of $0.8 million. The Company recorded the repurchase liability once the termination was deemed probable on March 3, 2020. The Company recognized the repurchase price of these shares of common stock and the relinquishment of these vested options in additional-paid-in-capital.

2020 Stock Option and Incentive Plan

On September 8, 2020, the Company's board of directors adopted the C4 Therapeutics, Inc. 2020 Stock Option and Incentive Plan (the "2020 Plan"), which became effective on September 30, 2020. There are 6,567,144 shares of common stock reserved for issuance under the 2020 Plan. Under the 2020 Plan, the compensation committee of the Company's board of directors (or its designee) is authorized to grant a broad range of equity-based awards, including stock options, stock appreciation rights ("SARs"), restricted stock awards ("RSAs"), restricted stock units ("RSUs"), performance awards and stock bonus awards to the Company's officers, employees, directors and other key persons, including consultants.

Following the effectiveness of the 2020 Plan, the Company ceased making grants under the 2015 Plan. However, the 2015 Plan continues to govern the terms and conditions of the outstanding awards granted under it. Shares of common stock subject to awards granted under the 2015 Plan that cease to be subject to such awards by forfeiture or otherwise after the termination of the 2015 Plan will be available for issuance under the 2020 Plan. As of September 30, 2020, no awards had been made under the 2020 Plan.

On September 8, 2020, the Company's board of directors adopted the C4 Therapeutics, Inc. 2020 Employee Stock Purchase Plan (the "2020 ESPP"), which became effective on September 30, 2020 for use by the Company following the IPO. There are 437,809 shares of common stock reserved for issuance under the 2020 ESPP. All employees meeting eligibility requirements defined in the plan may participate in the 2020 ESPP by purchasing shares of the Company's common stock. To participate in the 2020 ESPP, eligible employees will authorize payroll deductions of up to 15% of their eligible compensation during an offering period. The Company may hold one of more offering periods each year during which employees will be able to purchase shares under the 2020 ESPP. As of September 30, 2020, the Company had not held any offering periods and no shares had been issued under the 2020 ESPP.

(11) Income Taxes

During the nine months ended September 30, 2020 and 2019, the Company recorded a full valuation allowance on federal and state deferred tax assets since management does not forecast the Company to be in a profitable position in the near future.

As a result of the COVID-19 pandemic, the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act") was enacted on March 27, 2020 to provide relief for taxpayers. The CARES Act contain a significant number of provisions that may impact on the Company's accounting for income taxes. The Company has considered several key corporate provisions within the CARES Act, has evaluated its potential impact and as a result recorded a tax benefit of $0.2 million and $0.5 million for the three and nine month periods ended September 30, 2020, respectively, related to an anticipated refund to be received for federal taxes incurred for the year ending December 31, 2019. The refund is expected to be received when the Company files its fiscal year 2020 tax returns which are due October 15, 2021. Accordingly, the Company has recorded the receivable of $0.5 million in other long-term assets on the Company's unaudited condensed consolidated balance sheet as of September 30, 2020.

(12) Loss Per Share

Basic and diluted loss per share is computed by dividing net loss attributable to common stockholders by the weighted-average common shares outstanding (in thousands, except share and per share data):

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2020	2019	2020	2019
Numerator:				
Net loss	$ (21,835)	$ (10,094)	$ (44,540)	$ (24,076)
Accrual of preferred stock dividends	(5,212)	(2,201)	(10,363)	(6,531)
Net loss attributable to common stockholders	$ (27,047)	$ (12,295)	$ (54,903)	$ (30,607)
Denominator:				
Weighted-average common stock outstanding	1,540,902	1,376,365	1,493,521	1,354,734
Net loss per share attributable to common stockholders	$ (17.55)	$ (8.93)	$ (36.76)	$ (22.59)

(13) Subsequent Events

The Company has evaluated subsequent events from the balance sheet date through the issuance date of these condensed consolidated financial statements and has not identified any events requiring disclosure, except as noted below.

IPO

On October 1, 2020, the SEC declared the Company's registration statement on Form S-1, as amended (the "Registration Statement") effective. On October 6, 2020, the Company closed the IPO, at which time the Company issued 11,040,000 shares of its common stock at a price to the public of $19.00 per share (which number includes 1,440,000 shares of common stock that were issued to the underwriters for the IPO when they exercised in full their overallotment option). Upon the closing of the IPO, all outstanding shares of the Company's Preferred Stock automatically converted into 30,355,379 shares of common stock. Net proceeds from the IPO, including the exercise in full of the underwriters' option to purchase additional shares, were $191.1 million, after deducting underwriting discounts and commissions of $14.7 million and expenses of approximately $4.0 million.

Subsequent to the closing of the IPO, there were no shares of Preferred Stock outstanding. In connection with the closing of the IPO, the Company filed its Fifth Amended and Restated Certificate of Incorporation, which provides that the Company's authorized capital stock consists of 150,000,000 shares designated as common stock and 10,000,000 shares designated as preferred stock, all of which have a par value of $0.0001 per share.

Conversion of Preferred Stock and Series B Warrant

Upon on the completion of the Company's IPO on October 6, 2020, all outstanding shares of the Company's Preferred Stock were converted into shares of common stock using the exchange rate set forth in the Fourth Charter, as amended, which provided that every 8.4335 shares of Preferred Stock converted into one share of common stock. As a result, no shares of preferred stock are presently outstanding and the Company does not have any present plans to issue any shares of preferred stock.

In addition, as described in Note 8, in June 2020, the Company issued a warrant to purchase 2,857,142 shares of its Series B Preferred Stock to its lender, Perceptive Credit Holdings III, LP. Upon completion of the Company's IPO, this warrant was automatically converted into a warrant exercisable for 338,784 shares of the Company's common stock.

Stock Options

In September 2020, the Company approved the issuance of stock options under the 2020 Plan to Marc A. Cohen, the Company's Co-Founder, Executive Chairman and (at that time) interim Chief Executive Officer, and Andrew Hirsch, the Company's President, Director and Chief Executive Officer-elect, representing 1.5% and 3.5%, respectively, of the Company's fully-diluted shares measured at the time of Company's IPO (calculated to include the shares sold in the IPO but to exclude the shares reserved for future awards under the 2020 Plan and the 2020 ESPP following the IPO). Upon the IPO, the Company determined that Mr. Cohen's award was for 725,002 shares and Mr. Hirsch's award was for 1,691,672 shares. These grants, were approved in September 2020. Upon the effectiveness of the Registration Statement on October 1, 2020, these awards were deemed granted and the exercise price was established at $19.00 per share. These options vest quarterly over four years subject to cliff vesting after six months. Mr. Cohen's award is subject to full acceleration upon a sale of the Company and Mr. Hirsch's award is subject to full acceleration upon a sale of the Company and the termination of his employment thereafter pursuant to the terms of his employment agreement, subject to Mr. Hirsch's execution of an effective release of claims in favor of the Company.

In addition to these awards, in September 2020, the Company also approved the grant of 192,681 stock options to the Company's directors and certain employees. Ultimately, when the Registration Statement was declared effective on October 1, 2020, these awards were deemed granted and the exercise price was established at $19.00 per share. These shares will vest over one- to four-year periods, subject to the recipient maintaining a business relationship with the Company through the applicable vesting date.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our interim condensed consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q and our final prospectus filed with the U.S. Securities and Exchange Commission (the "SEC") pursuant to Rule 424(b) under the Securities Act of 1933, as amended (the "Securities Act") on October 1, 2020. As discussed in the section titled "Special Note Regarding Forward-Looking Statements," the following discussion and analysis contains forward-looking statements that involve risks and uncertainties, as well as assumptions that, if they never materialize or prove incorrect, could cause our results to differ materially from those expressed or implied by such forward-looking statements. Factors that could cause or contribute to these differences include, but are not limited to, those identified below and those discussed in the section titled "Risk Factors" in Part II, Item 1A of this Quarterly Report on Form 10-Q and in our Prospectus.

We are a biopharmaceutical company focused on transforming the treatment of cancer, serious neurodegenerative conditions and other diseases by developing novel therapeutic candidates engineered to harness the body's natural regulation of protein levels to target and destroy disease-causing proteins. We leverage our proprietary technology platform, TORPEDO (Target ORiented ProtEin Degrader Optimizer), to synthesize a new class of small molecule protein degraders that selectively and efficiently destroy disease-causing proteins. We are using our TORPEDO platform to build a robust pipeline of orally administered protein degradation drug candidates, with an initial focus on oncology indications. Our approach to medicine harnesses the innate machinery of the cell to attack disease and potentially bring deep and durable responses to patients.

We commenced operations in October 2015, and our operations to date have been limited to organizing and staffing our company, business planning, raising capital, establishing development collaborations with Roche, Biogen and Calico, conducting discovery and research activities, filing patent applications, identifying potential product candidates, undertaking preclinical studies and establishing arrangements with third parties for the manufacture of initial quantities of our product candidates. To date, we have not generated any revenue from product sales and have financed our operations primarily through sales of our equity interests and proceeds from our collaborations. Through September 30, 2020, we had raised approximately $224.0 million in gross proceeds from the sale of Series seed redeemable convertible preferred stock, Series A redeemable convertible preferred stock and Series B redeemable convertible preferred stock and have received an aggregate of $163.4 million in payments from collaboration partners. In October 2020, we completed an initial public offering, or IPO, pursuant to which we issued 11,040,000 shares of our common stock (including 1,440,000 shares that were issued upon the exercise by the underwriters of their over-allotment option), at a price to the public of $19.00. Net proceeds from the IPO, including the exercise of the underwriter's overallotment option, were $191.1 million after deducting underwriting discounts and commissions of $14.7 million and expenses of $ 4.0 million.

Our ability to generate revenue from product sales sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our product candidates. Since inception, we have incurred significant operating losses. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. Our net losses were $21.8 million and $44.5 million for the three and nine months ended September 30, 2020, respectively, and $10.1 million and $24.1 million for the three and nine months ended September 30, 2019, respectively. As of September 30, 2020, we had an accumulated deficit of $162.0 million.

We anticipate that our expenses will increase substantially due to costs including those associated with the following:

- our preclinical activities for our lead product candidates and the advancement of these candidates into first-in-human Phase 1/2 clinical trials in the United States, which we expect to initiate in the first half of 2021 for CFT7455 and by the end of 2021 for CFT8634;
- development activities associated with our other product candidates;
- research activities in oncology, neurological and other disease areas to expand our pipeline;
- hiring additional personnel in research, clinical trials, quality and other functional areas;
- increased activities by our contract manufacturing organizations, or CMOs, to supply us with product for our preclinical studies and clinical trials;
- the management of our intellectual property portfolio; and
- operating as a public company.

In addition, our net losses and cash flows may fluctuate significantly from period to period depending on, among other things, variations in the level of expense related to the ongoing development of our product candidates, our TORPEDO platform or future development programs; the delay, addition or termination of clinical trials; and the execution of any additional collaboration, licensing or similar arrangements, and the timing of payments we may make or receive under such arrangements.

We will not generate any revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for one or more of our product candidates. If we obtain regulatory approval for any of our product candidates, to the extent we decide to commercialize that product ourselves, we would expect to incur significant expenses related to developing our internal commercialization capability to support product sales, marketing and distribution.

As a result, we will need substantial additional funding to support our operating activities as we advance our product candidates through clinical development, seek regulatory approval and prepare for and, if any of our product candidates are approved, proceed to commercialization. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operating activities through a combination of equity offerings, debt offerings, reimbursements and potential milestones earned under our existing collaboration agreements and potential license and development agreements with third parties, including but not limited to our existing collaboration partners. Adequate funding may not be available to us on acceptable terms, or at all.

If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research, product development or future commercialization efforts, 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. Although we continue to pursue these capital raising plans, there is no assurance that we will be successful in obtaining sufficient funding on terms acceptable to us to fund continuing operations, if at all.

As of September 30, 2020, we had cash and cash equivalents and short-term investments of $199.4 million. We expect that our existing cash and cash equivalents, short-term investments and the net proceeds of our IPO will be sufficient to fund our operations for at least the next twelve months. The impact of the COVID-19 coronavirus outbreak on our financial performance will depend on future developments, including the duration and spread of the outbreak and related governmental advisories and restrictions. There are multiple causes of these delays, including laboratory closures, reluctance of patients to enroll or continue in trials for fear of exposure to COVID-19, local and regional shelter-in-place and work from home orders and regulations that discourage, hamper or prohibit patient visits, healthcare providers and health systems shifting away from clinical trials toward the acute care of COVID-19 patients and the FDA and other regulators making product candidates for the treatment of COVID-19 a priority over product candidates unrelated to the pandemic.

In terms of the impact on our operations, we have seen increased risk of delays in production of components used to manufacture our lead degrader candidates due to previous delays at one of our China-based manufacturers, and one of our clinical research organizations, or CROs, in India was forced to temporarily shut down due to local lockdown orders. In addition, earlier this year, we temporarily closed the office and laboratory spaces at our corporate headquarters in Watertown, Massachusetts and transitioned our employees to work from home. While we have had a subset of our employees back in our office and lab facilities since June 2020, the majority of our employees currently continue to work from home and we expect this situation will continue into next year. We are working closely with our CROs, manufacturers, investigators and preclinical and clinical trial sites to assess the full impact of the COVID-19 pandemic on the timelines and expected costs for each of our programs. While the ongoing impact of the pandemic is uncertain, we believe our CRO redundancies in China, India and Boston and the transition of the majority of our employees to remote work arrangements have mitigated the impact of these types of disruptions on our business.

We note the high level of difficulty in projecting the effects of COVID-19 on our programs and our company, given the rapid and dramatic evolution in the course and impact of the pandemic and the societal and governmental response to it.

Financial Operations Overview

Revenues

To date, we have not generated any revenue from product sales and do not expect to generate any revenue from the sale of products for the foreseeable future. Our revenues to date have been generated through research collaboration and license agreements. We recognize revenue over our expected performance period under each agreement. We expect that our revenue for the next several years will be derived primarily from our current collaboration agreements and any additional collaborations that we may enter into in the future. To date, we have not received any royalties under any of our existing collaboration agreements.

Roche Collaboration and License Agreement

In March 2016, we entered into a collaboration and license agreement, or the Original Roche Agreement, with Roche, whereby Roche provided us with a non-refundable upfront payment of $15.0 million, which was creditable against our target initiation fees of either $1.0 million or $4.0 million, depending on the compound selected. Pursuant to the terms of the Original Roche Agreement, we collaborated on research activities to develop novel treatments in the field of targeted protein degradation using our degrader technology. We initially developed therapeutics that utilize degrader technology for up to ten target proteins. On a target-by-target basis, after successful completion of a defined preclinical development phase, Roche had an exclusive option to pursue a license from us for further clinical development and commercialization.

On December 22, 2018, we amended and restated the Original Roche Agreement, or the Restated Roche Agreement. Under the Restated Roche Agreement, we have a more active role in the manufacturing and commercialization of the targets included in the collaboration, such that if we opt into certain co-development and co-detailing rights, the parties will split future development costs in return for our having rights to a larger share of future earnings from commercialization of the relevant target. The target structure was revised to nine potential targets, three of which had been nominated as of the execution of the Restated Roche Agreement and represent continuations of the initial preclinical research and development efforts begun under the Original Roche Agreement, and three additional targets that were not nominated as of the date of execution of the Restated Roche Agreement. At the time of entry into the Restated Roche Agreement, Roche maintained its option rights to license and commercialize these nine targets.

Under the Restated Roche Agreement, we received additional upfront consideration of $40.0 million from Roche. In addition, under the Restated Roche Agreement, will make annual research plan payments of $1.0 million for each active research plan. Finally, adjustments were made to the option exercise fees such that targets that have progressed through GLP toxicology studies at the time of exercise now have option exercise fees of $7.0 million to $12.0 million and those progressed through Phase 1 trials have option exercise fees of $20.0 million.

For certain targets, Roche is required to pay us fees of $2.0 million and $3.0 million upon the identification of a lead series and the commencement of GLP toxicology studies, respectively. For each target option exercised by Roche, we are eligible to receive up to $275 million in research, development and commercial milestone payments. Roche is also required to pay us up to $150 million per target in one-time sales-based payments if the target achieves certain levels of net sales. Roche is also required to pay us royalties, at percentages from the mid-single digits to the low double-digits, on a licensed product-by licensed product basis, on worldwide net product sales.

Biogen Collaboration Research and License Agreement

On December 28, 2018, we entered into a Collaboration Research and License Agreement, or the Biogen Agreement, with Biogen, pursuant to which we agreed to collaborate on research and development efforts for up to five targets to discover and develop potential new treatments for neurological conditions such as Alzheimer's disease and Parkinson's disease. The Biogen Agreement also has an option for Biogen to nominate additional targets and extend the Biogen Agreement. We granted Biogen a non-exclusive research license under our intellectual property to perform research activities, select and optimize degraders and develop products including the degraders, as well as a commercial license to manufacture and commercialize the targets once the initial research and development work is complete. The research under the Biogen Agreement will take place over a 54-month research term with Biogen having an option to extend the Biogen Agreement for up to four additional years in exchange for the payment by Biogen of an additional $62.5 million. If Biogen were to elect to extend the term of the Biogen Agreement, Biogen would be entitled to nominate up to five additional targets.

The Biogen Agreement provides for three initial targets, with Biogen having the right to initiate up to an additional two targets and to control all post-discovery activities. Biogen paid us a nonrefundable upfront payment of $45.0 million for access to our technology and research services through the discovery research phase. The nonrefundable upfront cash payment of $45.0 million is not creditable against any of the target development milestone fees.

Following the achievement of development candidate criteria, prior to any IND-enabling study, for any target, Biogen will bear all costs and expenses of and will have sole discretion and decision-making authority with respect to the performance of further activities with respect to any degrader under development under the Biogen Agreement and all products that incorporate that degrader. Biogen is also required to pay us up to $35.0 million per target in development milestones and $26.0 million per target in one-time sales-based payments for the first product to achieve certain levels of net sales. In addition, Biogen is required to pay us royalties on a licensed product-by-licensed product basis, on worldwide net product sales, at percentages in the mid-single digits. All milestone and sales-based payments are made after we have met the defined criteria in the joint research plan for that target, at which time Biogen will have control of the targets for commercialization. Under the Biogen Agreement, the receipt of these payments is contingent on the further development of the targets to commercialization by Biogen, without any additional research and development efforts from us.

Biogen also has the option to fund additional discovery activities, in which case we will perform discovery-type research at Biogen's election to develop other potential targets that may be used as replacement targets for the initially nominated targets or two additional targets under the Biogen Agreement. Revenues earned under this option, if initiated, will be recognized as services are performed and are not included in the transaction price at the outset of the arrangement. These research activities will be reimbursed on a full-time equivalent, or FTE, basis at specified market rates. These additional discovery activities can be purchased up to a maximum amount by Biogen on an à la carte basis at an amount consistent with standalone selling price. If Biogen were to exercise these options, we would recognize revenue as those options are exercised.

Calico License Agreement

In March 2017, we entered into a Collaboration and License Agreement, or the Calico Agreement, with Calico whereby we agreed to collaborate to develop and commercialize a set number of targets for small molecule protein degraders for diseases of aging, including cancer, for a five-year period ending in March 2022, or the research term.

We provided Calico with a non-exclusive research license under our intellectual property to perform research activities and select and optimize degraders and develop products including the degraders. We also granted Calico a commercial license for any licensed products resulting from the development candidates supplied by us. We are required to perform research and development activities for the nominated targets over the research term, with the intent to provide a development candidate for each target to Calico once the agreed-upon research is complete.

Calico is obligated to reimburse us for our research and development activities for each target at specified levels through the identification of a development candidate, after which time Calico shall assume full responsibility for candidate development.

After the initiation of each target, the Calico Agreement does not contain any options for Calico to license the individual targets. Instead, once we complete the initial research and development activities required, Calico controls and directs the targets with no additional work required to be performed by us. There is no exercise price or incremental fee payable to us to progress the research further, though Calico is required to pay an initiation fee with the commencement of each research plan. Once Calico

nominates a target and pays the applicable target initiation fee, we will commence research and development activities for that target. The Calico Agreement provides for up to five initial targets. Research activities performed are reimbursed at specified levels for the five-year term of the Calico Agreement.

Under this agreement, Calico paid us a nonrefundable upfront amount of $5.0 million and certain annual payments of $5.0 million through September 30, 2020. Upon our completion of the required discovery research and development services on any target, Calico is entitled to pursue commercial development of that target. For each target, we are eligible to receive potential research, development and commercial milestone payments aggregating up to $132.0 million. Calico is also required to pay one-time sales-based payments aggregating up to $65.0 million for the first product to achieve certain levels of net sales. In addition, Calico is required to pay us royalties, on a licensed product-by-licensed product basis, on worldwide net product sales, at percentages in the mid-single digits. All milestone and sales-based payments are made after we have met the defined criteria in the joint research plan for that target, at which time Calico will have control of the targets for commercialization; the receipt of these payments by us is contingent on the further development of the targets to commercialization by Calico, without any additional research and development efforts required by us.

Operating Expenses

Our operating expenses since inception have consisted solely of research and development costs and general and administrative costs.

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for our research activities, including our discovery efforts and the development of our product candidates, and include:

- salaries, benefits and other related costs, including stock-based compensation expense, for personnel engaged in research and development functions;
- expenses incurred under agreements with third parties, including CROs and other third parties that conduct research and preclinical activities on our behalf, as well as third parties that manufacture our product candidates for use in our preclinical and potential future clinical trials;
- costs of outside consultants, including their fees, unit-based compensation and related travel expenses;
- the costs of laboratory supplies and acquiring materials for preclinical studies and clinical trials;
- facility-related expenses, which include direct depreciation costs of equipment and allocated expenses for rent and maintenance of facilities and other operating costs; and
- third-party licensing fees.

We expense research and development costs as incurred. Costs for external development activities are recognized based on an evaluation of the progress to completion of specific tasks using information provided to us by our vendors. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and are reflected in our consolidated financial statements as prepaid or accrued research and development expenses. Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses and expensed as the related goods are delivered or the services are performed.

Research and development activities are central to our business model. We expect that our research and development expenses will continue to increase for the foreseeable future as we continue to discover and develop additional product candidates and advance our lead product candidates into clinical trials, including our first-in-human Phase 1/2 trials. If any of our product candidates enter into later stages of clinical development, they will generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We cannot reasonably estimate or determine with certainty the duration and costs of future clinical trials of CFT7455, CFT8634 or any other product candidate we may develop or if, when or to what extent we will generate revenue from the commercialization and sale of any product candidate for which we obtain marketing approval. We may never succeed in obtaining marketing approval for any product candidate.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation, for personnel in our executive, finance, legal, business development and administrative functions. General and administrative expenses also include legal fees relating to intellectual property and corporate matters; professional fees for accounting, auditing, tax and consulting services; insurance costs; travel expenses; and facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs.

We expect that our general and administrative expenses will increase in the future as we increase our headcount to support our growing operations, including additional personnel to support our operations as a publicly traded company. We also expect to incur increased expenses associated with being a public company, including higher costs of accounting, audit, legal, regulatory and tax-related services associated with maintaining compliance with Nasdaq and SEC requirements, director and officer insurance costs and investor and public relations costs.

Interest Income

Interest income consists of interest income earned on our cash and cash equivalents and short-term investments. We expect interest income to vary each reporting period depending on our average bank deposit, money market fund and investment balances during the period and market interest rates.

Interest Expense

Interest expense consists of interest due under our credit agreement and the amortization of debt discount.

Other (Expense) Income, Net

Other (expense) income, net primarily consists of accretion of discount on short-term investments.

Provision (benefit) for income taxes

The provision for income taxes primarily consists of reserves for unrecognized tax benefits and minimum state taxes. The benefit for income taxes consists of a discrete tax benefit arising from the provisions of the CARES Act, that permits net operating loss carryovers and carrybacks to offset 100% of taxable income for taxable years beginning before 2021. We have generated net operating losses since inception and have established a full valuation allowance against our deferred tax assets due to the uncertainty surrounding the realization of such assets.

Results of Operations

Comparison of the Three Months Ended September 30, 2020 and 2019

The following table summarizes our results of operations for the three months ended September 30, 2020 and 2019 (in thousands):

	THREE MONTHS ENDED SEPTEMBER 30,	
	2020	2019
Revenue from collaboration agreements	$ 8,447	$ 5,364
Operating expenses:		
Research and development	23,935	12,948
General and administrative	2,861	2,417
Total operating expenses	26,796	15,365
Operating loss	(18,349)	(10,001)
Other income (expense), net:		
Change in fair value of warrant liability	(3,141)	-
Other income (expense), net	(512)	557
Total other income (expense), net	(3,653)	557
Loss before income taxes	(22,002)	(9,444)
Income tax expense (benefit)	(167)	650
Net loss	$ (21,835)	$ (10,094)

Revenue

Revenue from our collaboration and license agreements consisted of the following for the three months ended September 30, 2020 and 2019 (in thousands):

	THREE MONTHS ENDED SEPTEMBER 30,	
	2020	2019
Restated Roche Agreement	$ 1,395	$ 1,762
Biogen License Agreement	3,525	642
Calico License Agreement	3,527	2,960
	$ 8,447	$ 5,364

Revenue was $8.4 million, for the three months ended September 30, 2020 compared with $5.4 million for the three months ended September 30, 2019. The increase in revenue of $3.0 million primarily relates primarily to increased FTE reimbursement revenue from Calico and increased revenue recognized in connection with the Biogen Agreement due to progress in programs and sandbox related revenue, offset by lower revenue recognized under the Restated Roche Agreement.

Research and Development Expenses

The following table summarizes our research and development expenses for the three months ended September 30, 2020 and 2019 (in thousands):

	THREE MONTHS ENDED SEPTEMBER 30,		
	2020	2019	INCREASE (DECREASE)
Preclinical and development expenses	$ 14,454	$ 6,392	$ 8,062
Personnel expenses	5,436	3,648	1,788
Facilities and supplies	2,653	2,292	361
Consulting	1,129	402	727
Intellectual property	242	117	125
Other expenses	21	97	(76)
	$ 23,935	$ 12,948	$ 10,987

Research and development expenses were $23.9 million for the three months ended September 30, 2020, compared with $12.9 million for the three months ended September 30, 2019. The increase of $11.0 million was primarily due to an increase in the use of FTE resources for chemistry and biology of $5.7 million, an increase in preclinical studies for our product candidates of $2.4 million, an increase of $1.8 million in personnel expenses to support our growing clinical development activities and an increase in consulting costs of $0.7 million to support our clinical development activities.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the three months ended September 30, 2020 and 2019 (in thousands):

	THREE MONTHS ENDED SEPTEMBER 30,		
	2020	2019	INCREASE (DECREASE)
Legal and professional fees	$ 1,636	$ 425	$ 1,211
Personnel expenses	912	1,611	(699)
Facilities and supplies	166	191	(25)
Other expenses	147	190	(43)
	$ 2,861	$ 2,417	$ 444

General and administrative expenses were $2.9 million for the three months ended September 30, 2020, compared with $2.4 million for the three months ended September 30, 2019. The increase of $0.4 million was primarily due to an increase in legal and professional fees of $1.2 million due to the utilization of external counsel and consultants offset by a decrease in personnel expenses of $0.7 million, primarily resulting from the termination of the senior executives in March 2020.

Other Income (Expense), Net

Other income (expense), net was $3.7 million in expense for the three months ended September 30, 2020, compared with $0.6 million in income for the three months ended September 30, 2019. The decrease of $4.3 million was primarily due to the change in fair value of warrant liability of $3.1 million, decreased interest income of $0.6 million resulting from lower market interest rates earned on cash and short-term investments and interest expense and amortization of the debt discount related to the Perceptive Debt Agreement of $0.6 million.

Income Taxes

The provision for income taxes was a benefit during the three months ended September 30, 2020 as compared to an expense for the three months ended September 30, 2019. For the three months ended September 30, 2020, we recognized an income tax benefit of $0.2 million resulting from the expected tax benefit to be recognized as a result of the full-year 2020 projected tax loss carryback to fiscal year 2019 allowed under the CARES Act, which was signed into law in March 2020.

For the nine months ended September 30, 2019, we recognized income tax expense of $0.7 million for the pro-rated annual tax estimated as of September 30, 2019.

We will recognize interest and/or penalties related to uncertain tax benefits in income tax expense as they arise. As of December 31, 2018 and 2019 and September 30, 2019 and 2020, we had no accrued interest or penalties related to uncertain tax benefits.

Comparison of the Nine Months Ended September 30, 2020 and 2019

The following table summarizes our results of operations for the nine months ended September 30, 2020 and 2019 (in thousands):

	NINE MONTHS ENDED SEPTEMBER 30,	
	2020	2019
Revenue from collaboration agreements	$ 24,933	$ 13,172
Operating expenses:		
General and administrative	58,007	32,042
Research and development	8,472	6,083
Total operating expenses	66,479	38,125
Operating loss	(41,546)	(24,953)
Other income (expense), net:		
Change in fair value of warrant liability	(3,141)	-
Other income (expense), net	(355)	1,777
Total other income (expense), net	(3,496)	1,777
Loss before income taxes	(45,042)	(23,176)
Income tax expense (benefit)	(502)	900
Net loss	$ (44,540)	$ (24,076)

Revenue

Revenue from our collaboration and license agreements consisted of the following for the nine months ended September 30, 2020 and 2019 (in thousands):

	NINE MONTHS ENDED SEPTEMBER 30,	
	2020	2019
Restated Roche Agreement	$ 7,424	$ 3,875
Biogen License Agreement	6,827	1,707
Calico License Agreement	10,682	7,590
	24,933	13,172

Revenue was $24.9 million for the nine months ended September 30, 2020, compared with $13.2 million for the nine months ended September 30, 2019. The increase in revenue of $11.7 million reflects a $3.5 million increase in the revenue related to the Restated Roche Agreement due to additional progress made on the three active targets, a $5.1 million increase in the revenue related to the Biogen Agreement due to the additional progress made on the initial three targets nominated and an increase in Sandbox related revenue of $1.9 million, and a $3.1 million increase in the revenue related to the Calico Agreement primarily related to additional FTE reimbursement received in 2020.

Research and Development Expenses

The following table summarizes our research and development expenses for the nine months ended September 30, 2019 and 2020 (in thousands):

	NINE MONTHS ENDED SEPTEMBER 30,		
	2020	2019	INCREASE (DECREASE)
Personnel expenses	$ 14,605	$ 10,331	$ 4,274
Preclinical and development expenses	32,225	13,399	18,826
Facilities and supplies	7,155	6,419	736
Intellectual property	886	570	316
Consulting	2,969	978	1,991
Other expenses	167	345	(178)
	$ 58,007	$ 32,042	$ 25,965

Research and development expenses for the nine months ended September 30, 2020 were $58.0 million, compared to $32.0 million for the nine months ended September 30, 2019. The increase of $26.0 million was primarily due to an increase in the use of FTE resources for chemistry and biology of $14.8 million, an increase in preclinical studies for our product candidates of $4.0 million, an increase of $4.3 million in personnel expenses to support our growing clinical development activities and
an increase in consulting costs of $2.0 million also to support our clinical development activities.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the nine months ended September 30, 2020 and 2019 (in thousands):

	NINE MONTHS ENDED SEPTEMBER 30,		
	2020	2019	INCREASE (DECREASE)
Personnel expenses	$ 4,012	$ 3,979	$ 33
Facilities and supplies	472	488	(16)
Legal and professional fees	3,609	1,255	2,354
Other expenses	379	361	18
	$ 8,472	$ 6,083	$ 2,389

General and administrative expenses were $8.5 million for the nine months ended September 30, 2020, compared with $6.1 million for the nine months ended September 30, 2019. The increase of $2.4 million was primarily due to a $2.4 million increase in legal and professional costs due to the utilization of external counsel and consultants.

Other Income (Expense), Net

Other income (expense), net was $3.5 million expense for the nine months ended September 30, 2020, compared with $1.8 million income for the nine months ended September 30, 2019. The decrease of $5.3 million was primarily due to the change in fair value of warrant liability of $3.1 million, lower interest earned on short-term investments in 2020 of $1.5 million and interest expense and amortization of debt discount related to the Perceptive Debt Agreement of $0.7 million.

Income Taxes

For the nine months ended September 30, 2020, we recognized an income tax benefit of $0.5 million resulting from the expected tax benefit to be recognized as a result of the full-year 2020 projected tax loss carryback to fiscal year 2019 allowed under the CARES Act, which was signed into law in March 2020. For the nine months ended September 30, 2019, we recognized income tax expense of $0.9 million for the pro-rated annual tax estimated as of September 30, 2019.

We will recognize interest and/or penalties related to uncertain tax benefits in income tax expense as they arise. As of and September 30, 2020 and 2019, we had no accrued interest or penalties related to uncertain tax benefits.

Liquidity and Capital Resources

Sources of Liquidity

We do not currently have any approved products and have never generated any revenue from product sales. To date, we have financed our operations primarily through the sale of preferred stock and through payments from collaboration partners. We had cash and cash equivalents and short-term investments of $199.4 million as of September 30, 2020.

In June 2020 and July 2020, we closed a financing in which we sold shares of our Series B preferred stock with both existing and new investors, which we refer to as the Series B Financing. As part of the Series B Financing, we issued 142,857,142 shares of redeemable convertible Series B preferred stock, or Series B Preferred Stock, at a purchase price of $1.05 per share, for aggregate gross proceeds of $150.0 million or net proceeds of $145.5 million when taking into account offering costs of $4.5 million. All shares of our preferred stock were automatically converted into shares of our common stock on October 6, 2020 upon the completion of the IPO at a conversion rate of 8.4335 shares of preferred stock to one share of common stock. In addition, we secured a $20.0 million credit arrangement with Perceptive Credit Holdings III, LP, or Perceptive Credit, an affiliate of one of the investors who participated in the Series B Financing , which we refer to as the Credit Agreement ,pursuant to which we borrowed an initial amount of $12.5 million, bearing a variable interest rate of 11.25%. We have the opportunity to draw down another $7.5 million under the Credit Facility, subject to the satisfaction of certain milestones relating to the filing of an Investigational New Drug application for certain of our pipeline targets. The loans extended under the Credit Agreement will be repaid beginning in December 2022 in monthly installments of interest plus principal equal to 2.0% of the initial principal amount through September 2024. We paid a closing fee of $0.3 million related to the establishment of the Credit Agreement and Perceptive Credit's issuance of the loan and have the right to prepay the loan in its entirety prior to the maturity date by paying the applicable prepayment fee. If we do not prepay the loan, the entire unpaid principal balance becomes due on the maturity date, September 5, 2024. We are also subject to customary financial covenants in the Credit Agreement that dictate accelerated repayment upon the occurrence of certain events of default, none of which are expected to occur based on our current liquidity.

On October 1, 2020, the Securities and Exchange Commission declared our registration statement on Form S-1 (Registration No. 333–248719) for our IPO effective. The IPO closed on October 6, 2020, at which time we issued 11,040,000 shares of our common stock at a price to the public of $19.00, which total includes 1,440,000 shares of our common stock issued to the underwriters for the IPO to the public when they exercised in full their overallotment option. The proceeds from our IPO, including the full exercise of the underwriter's overallotment option, were approximately $191.1 million after deducting underwriting discounts and commissions of $14.7 million and expenses of $4.0 million.

Funding Requirements

We believe that our cash and cash equivalents and short-term investments of $199.4 million as of September 30, 2020, combined with the net proceeds from our IPO of $191.1 million, which closed on October 6, 2020, will be sufficient to fund our operating expenses and capital expenditure requirements for at least the next twelve months.

Since our inception, we have incurred significant operating losses. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future as we advance the preclinical and clinical development of our product candidates

Specifically, we anticipate that our expenses will increase substantially in the future, if and as we:

- initiate planned first-in-human Phase 1/2 trials of our lead product candidates, CFT7455 and CFT8634;
- Advance additional product candidates into preclinical and clinical development;
- continue to invest in our proprietary TORPEDO platform;
- expand, maintain and protect our intellectual property portfolio;
- hire additional clinical, regulatory and scientific personnel;
- add operational, financial, legal and management information systems and personnel to support our ongoing research, product development, potential future commercialization efforts, operations as a public company and general and administrative responsibilities;
- seek marketing approvals for any product candidates that successfully complete clinical trials; and
- ultimately establish a sales, marketing and distribution infrastructure and scale up external manufacturing capabilities to commercialize any products for which we may obtain marketing approval.

Because of the numerous risks and uncertainties associated with development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital and operating costs associated with our current and anticipated pre-clinical studies and clinical trials. Our future capital requirements will depend on many factors, including:

- the progress, costs and results of our planned first-in-human Phase 1/2 trials for our lead product candidates and any future clinical development of those lead product candidates;
- the scope, progress, costs and results of preclinical and clinical development for our other product candidates and development programs;
- the number and development requirements of other product candidates that we pursue;
- the success of our collaborations with Roche, Biogen and Calico, including whether or not we receive additional research support or milestone payments from our collaboration partners upon the achievement of milestones;
- the costs, timing and outcome of regulatory review of our product candidates;
- 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;
- our willingness and ability to establish additional collaboration arrangements with other biotechnology or pharmaceutical companies on favorable terms, if at all, for the development or commercialization of current or additional future 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; and
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval.

As a result of the anticipated expenditures described above, we will need to obtain substantial additional financing to support our continuing operations and pursue our long-term business plan. Until such time, if ever, as we can generate substantial revenue from product sales, we expect to finance our cash needs through a combination of equity offerings, debt offerings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. Although we may receive potential future milestone and royalty payments under our collaborations with Roche, Biogen and Calico, we do not have any committed external source of funds, as of September 30, 2020, other than an additional $7.5 million under our Credit Agreement. Adequate additional funds may not be available to us on acceptable terms, or at all. If we are unable to raise capital when needed or on attractive terms, we may be required to delay, limit, reduce or terminate our research, product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

To the extent that we raise additional capital through the sale of equity securities, each investor's ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as making acquisitions or capital expenditures or declaring dividends.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing 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.

Cash Flows

The following table summarizes our sources and uses of cash for the period presented (in thousands):

	NINE MONTHS ENDED SEPTEMBER 30,	
	2020	2019
Net cash provided by (used in) by operating activities	$ (45,710)	$ 65,918
Net cash used in investing activities	(136,284)	(1,422)
Net cash provided by financing activities	154,879	166
Net increase (decrease) in cash and cash equivalents and restricted cash	$ (27,115)	$ 64,662

Operating Activities

Net cash used in operating activities for the nine months ended September 30, 2020 was $45.7 million, primarily consisting of our net loss of $44.5 million, an increase in deferred revenue of $8.4 million, due to the recognition of revenue under our collaboration agreements offset in part by non-cash change in fair value of warrant liability of $3.1 million and timing of working capital.

Net cash provided by operating activities for the nine months ended September 30, 2019 was $65.9 million, primarily consisting of a decrease of $83.8 million in accounts receivable, primarily from the receipt of upfront payments from Roche and Biogen of $85.0 million, partially offset by our net loss of $24.1 million.

Investing Activities

Net cash used in investing activities for the nine months ended September 30, 2020 was $136.3 million, primarily attributable to the purchase of short-term investments.

Net cash used in investing activities for the nine months ended September 30, 2019 was $1.4 million, attributable to purchases of property and equipment.

Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2020 was $154.9 million, primarily attributable to the net proceeds received from the issuance of Series B redeemable convertible preferred stock in June and July, 2020 of $145.5 million and the net proceeds from the issuance of long-term debt of $12.0 million. Net cash provided by financing activities for the nine months ended September 30, 2020 is also comprised of financing costs paid related to the IPO of $2.5 million, repurchases of $0.1 million related to common stock issued upon the exercise of our former Chief Executive Officer's stock options and $0.8 million related to a settlement with our former Chief Executive Officer related to his vested but unexercised stock options.

Net cash provided by financing activities for the nine months ended September 30, 2019 was $0.2 million, primarily attributable to the proceeds from the issuance of common stock in conjunction with the exercise of stock options.

Contractual Obligations

The following is a summary of our significant contractual obligations as of September 30, 2020 (in thousands):

	PAYMENTS DUE BY PERIOD				
	TOTAL	LESS THAN 1 YEAR	1 TO 3 YEARS	4 TO 5 YEARS	MORE THAN 5 YEARS
Operating lease commitments (1)	$ 18,889	$ 2,255	$ 4,715	$ 5,003	$ 6,916
Long-term debt	12,500	—	12,500	—	—
Total	$ 31,389	$ 2,255	$ 17,215	$ 5,003	$ 6,916

(1) Represents future minimum lease payments under our operating leases and equipment for office and lab space in Watertown, Massachusetts that expires in April 2028.

We enter into contracts in the normal course of business with third-party CROs and CMOs for clinical trials, preclinical studies, manufacturing and other services and products for operating purposes. These contracts generally provide for termination following a certain period after notice and therefore we believe that our non-cancelable obligations under these agreements are not material and they are not included in the table above. We have not included milestone or royalty payments or other contractual payment obligations in the table above if the timing and amount of such obligations are unknown or uncertain.

Critical Accounting Policies and Use of Estimates

This management's discussion and analysis of financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of our consolidated financial statements and related disclosures requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, revenues, costs and expenses and the disclosure of contingent assets and liabilities in our consolidated financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

Our significant accounting policies are described in more detail in the notes to our condensed consolidated financial statements elsewhere in Form 10-Q. Our critical accounting policies and more significant areas involving management's judgements and estimates used in the preparation of our condensed consolidated financial statements are discussed in the section titled " Management's Discussion and Analysis of Financial Condition and Results of Operations in our prospectus related to our initial public offering ("IPO"), filed with the SEC on October 2, 2020, pursuant to Rule 424(b) under the Securities Act (the "Prospectus").

New Accounting Pronouncements

For information on new accounting standards, see Note 2 to our consolidated audited financial statements appearing in our prospectus.

Off-Balance Sheet Arrangements

We have not entered into any off-balance sheet arrangements and do not have any holdings in variable interest entities.

Internal control over financial reporting

In the preparation of our consolidated financial statements, we determined that a material weakness in our internal control over financial reporting existed as of December 31, 2019. This identified material weakness in our internal control over financial reporting arose because we did not maintain effective segregation of duties in the process and recording of journal entries. We have undertaken a plan to remediate the material weakness during 2020, including additional system controls that prevent one person from initiating and approving the same journal entry. In addition, we have performed additional reviews and other post-closing procedures but until such measures have been validated and tested, we cannot assure you that this material weakness has been resolved or that these measures will be sufficient to prevent future material weaknesses or significant deficiencies in our internal control over financial reporting from occurring. See "Risk Factors—*We will incur increased costs as a result of operating as a public company and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices*."

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate sensitivities. Our interest-earning assets consist of cash and cash equivalents and short-term investments. Interest income earned on these assets was $1.8 million and $0.6 million for the years ended December 31, 2019 and 2018, respectively, and $0.3 million and $1.5 million for the nine months ended September 30, 2020 and 2019, respectively. Our interest income is sensitive to changes in the general level of interest rates, primarily U.S. interest rates. As of September 30, 2020, our cash equivalents consisted of bank deposits and money market funds. We did not hold any marketable securities as of December 31, 2019, but we made purchases and sales of marketable securities during 2019 that included interest-earning securities. As of September 30, 2020, we had marketable securities of $136.0 million which consisted entirely of US Treasury securities. These interest-earning instruments carry a degree of interest rate risk; however, historical fluctuations in interest income have not been significant for us.

Emerging Growth Company Status

As an "emerging growth company," the JOBS Act allows us to delay adoption of new or revised accounting standards applicable to public companies until such standards are made applicable to private companies. We have elected to avail ourselves of this extended transition period for complying with new or revised accounting standards until the earlier of the date that we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of this extended transition period. Accordingly, the information contained herein may be different from the information you receive from other public companies that are not emerging growth companies. in which you hold stock.

In addition, as an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include:

- being permitted to only provide two years of audited financial statements in addition to any required unaudited interim financial statements with correspondingly reduced “Management’s Discussion and Analysis of Financial Condition and Results of Operations” disclosure;
- reduced disclosure about the compensation paid to our executive officers;
- not being required to submit to our stockholders’ advisory votes on executive compensation or golden parachute arrangements; and
- an exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002.

We may take advantage of these exemptions for up to the last day of 2025 or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company on the date that is the earliest of (1) the last day of the fiscal year in which we have total annual gross revenues of $1.07 billion or more; (2) the last day of 2025; (3) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years; or (4) the date on which we are deemed to be a large accelerated filer under the rules of the Securities and Exchange Commission. We may choose to take advantage of some but not all of these exemptions.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our President and Chief Executive Officer and our Chief Financial Officer, who serve as our principal executive officer and our principal financial officer, respectively, have evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act)) as of September 30, 2020.

Disclosure controls and procedures are controls and other procedures that are designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include controls and procedures designed to ensure that information required to be disclosed in our company’s reports filed under the Exchange Act is accumulated and communicated to management, including our President and Chief Executive Officer and our Chief Financial Officer, to allow timely decisions regarding required disclosure. Based on the evaluation of our disclosure controls and procedures, our President and Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were not effective as of September 30, 2020 due to the material weakness in our internal control over financial reporting described below. In light of this fact, our management has implemented additional system controls and performed additional reviews and other post-closing procedures and has concluded that, notwithstanding the material weakness in our internal control over financial reporting, the condensed consolidated financial statements for the periods covered by and included in this Quarterly Report on Form 10-Q fairly present, in all material respects, our financial position, results of operations and cash flows for the periods presented in conformity with U.S. GAAP.

Previously Reported Material Weakness

As disclosed in the section titled “MD&A” in Part I, Item 2 of this Quarterly Report on Form 10-Q, we previously identified a material weakness in our internal control over financial reporting. Specifically, we did not maintain adequate segregation of duties over the review and approval of journal entries. This material weakness could result in a misstatement of account balances or disclosures that would result in a material misstatement to the annual or interim financial statements that would not be prevented or detected. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis.

Remediation Plan

To address our material weakness, we have undertaken a plan to remediate the material weakness during 2020, including additional system controls that prevent one person from initiating and approving the same journal entry. In addition, we have performed additional reviews and other post-closing procedures. We intend to continue to take steps to remediate the material weakness through hiring additional accounting and financial reporting personnel, formalizing documentation of policies and procedures and further evolving our accounting processes. The actions that we are taking are subject to audit committee oversight.

While we believe that these efforts have improved our internal control over financial reporting, we will not be able to conclude whether the steps we have taken will fully remediate the material weakness in our internal control over financial reporting until we have validated our remediation efforts and confirmed their effectiveness.

Changes in Internal Control Over Financial Reporting

We have taken actions to remediate the material weaknesses relating to our internal control over financial reporting, as described above. Except as described above, there were no changes in our internal controls over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the three months ended September 30, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitation on the Effectiveness Over Financial Reporting

The effectiveness of any system of internal control over financial reporting, including ours, is subject to inherent limitations, including the exercise of judgment in designing, implementing, operating, and evaluating the controls and procedures, and the inability to eliminate misconduct completely. Accordingly, any system of internal control over financial reporting, including ours, no matter how well designed and operated, can only provide reasonable, not absolute assurances. In addition, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. We intend to continue to monitor and upgrade our internal controls as necessary or appropriate for our business, but there can be no assurance that such improvements will be sufficient to provide us with effective internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. As of the date of this quarterly report on Form 10-Q, we were not a party to any material legal matters or claims.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this quarterly report on Form 10-Q, including our financial statements and the related notes and the section of this quarterly report on Form 10-Q titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" before you make an investment decision. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. As a result, the market price of our common stock could decline, and you may lose all or part of your investment in our common stock.

Risks Related to Our Financial Position and Need for Additional Capital

We are an early stage biopharmaceutical company with a limited operating history and have incurred significant losses since our inception. We expect to incur losses over at least the next several years and may never achieve or maintain profitability.

We are an early stage biopharmaceutical company with limited operating history. Our net loss was $44.5 million for the nine months ended September 30, 2020, and $34.1 million and $15.7 million for the years ended December 31, 2019 and 2018, respectively. As of September 30, 2020, we had an accumulated deficit of $162.0 million. To date, we have not generated any revenue from product sales and have financed our operations primarily through sales of our equity interests, including our initial public offering, proceeds from our collaborations and debt financing. We are still in the early stages of development of our product candidates and expect to initiate our first clinical trial in the first half of 2021. As such, we expect that it will be several years, if ever, before we have a product candidate ready for regulatory approval and commercialization. We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability. To become and remain profitable, we must succeed in developing, obtaining marketing approval for and commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including, without limitation, successfully completing preclinical studies and clinical trials of our product candidates, discovering additional product candidates, establishing arrangements with third parties for the conduct of our clinical trials, procuring clinical- and commercial-scale manufacturing, obtaining marketing approval for our product candidates, manufacturing, marketing and selling any products for which we may obtain marketing approval, identifying collaborators to develop product candidates we identify or additional uses of existing product candidates and successfully completing development of product candidates for our collaboration partners.

We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. We anticipate that our expenses will increase substantially if and as we:

- initiate a planned first-in-human Phase 1/2 clinical trial of our lead product candidate, CFT7455, in patients with multiple myeloma, or MM, or non-Hodgkin lymphomas, or NHLs, such as peripheral T cell lymphoma, or PTCL, and mantle cell lymphoma, or MCL;
- initiate a planned first-in-human Phase 1/2 clinical trial of our second lead product candidate, CFT8634, in patients with synovial sarcoma or SMARCB1-deleted solid tumors;
- leverage our TORPEDO platform to identify and then advance additional product candidates into preclinical and clinical development;
- expand the capabilities of our TORPEDO platform;
- initiate, conduct and successfully complete later-stage clinical trials;
- seek marketing approvals for any product candidates that successfully complete clinical trials;
- ultimately establish a sales, marketing and distribution infrastructure and scale up external manufacturing capabilities to commercialize any products for which we may obtain marketing approval;
- expand, maintain and protect our intellectual property portfolio;
- hire additional clinical, regulatory and scientific personnel; and
- add operational, financial and management information systems and personnel, including personnel to support our ongoing research and development and potential future commercialization efforts.

Further, we expect to incur additional costs associated with operating as a public company, including significant legal, accounting, insurance, investor relations and other expenses that we did not incur as a private company.

Our expenses could increase beyond our expectations if we are required by the U.S. Food and Drug Administration, or the FDA, the European Medicines Agency, or EMA, or other regulatory authorities to perform trials in addition to those that we currently expect, or if we experience any delays in establishing appropriate manufacturing arrangements for, completing our clinical trials or the clinical development of any of our product candidates.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses we will incur or when, if ever, 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. 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 research and development efforts, expand our business or continue operations. A decline in the value of our company, or in the value of our common stock, could also cause you to lose all or part of your investment.

If one or more of the product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing those approved product candidates. Even if we are able to generate revenues from the sale of any approved products, we may not become profitable and may need to obtain additional funding to continue operations.

We will need* substantial *additional funding to pursue our business objectives and continue our operations. If we are unable to raise capital when needed, we may be required to delay, limit, reduce or terminate our research or product development programs or future commercialization efforts.

We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we prepare for and initiate our planned first-in-human Phase 1/2 clinical trials of CFT7455 and CFT8634, advance our TORPEDO platform and continue research and development and initiate clinical trials of, and potentially seek marketing approval for, our current and future preclinical programs. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. Further, we expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we may be required to delay, limit, reduce or terminate our research, product development programs or any future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

We had cash and cash equivalents and short-term investments of approximately $385.0 million as of October 31, 2020. We believe that these funds, combined with the proceeds from the closing of our initial public offering and anticipated payments from collaboration partners, will be sufficient to fund our operating expenses and capital expenditure requirements through the second quarter of 2023. We have based this estimate on assumptions that may prove to be wrong and we could use our capital resources sooner than we currently expect. Our future capital requirements will depend on many factors, including:

- the progress, costs and results of our planned first-in-human Phase 1/2 clinical trials for CFT7455 and CFT8634 and any future clinical development of CFT7455 and CFT8634;
- the scope, progress, costs and results of preclinical and clinical development for our other product candidates and development programs;
- the number and development requirements of other product candidates that we pursue;
- the success of our ongoing collaborations with Biogen, Inc., or Biogen, F. Hoffman-La Roche Ltd., or Roche, and Calico Life Sciences LLC, or Calico;
- the costs, timing and outcomes 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 and the timing of the receipt of any such revenue;
- any delays or interruptions, including due to the COVID-19 pandemic, that we experience in our preclinical studies, future clinical trials and/or supply chain;
- 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
- our ability to establish collaboration arrangements with other biotechnology or pharmaceutical companies on favorable terms, if at all, for the development or commercialization of our product candidates.

Our current cash and cash equivalents and short-term investments will not be sufficient for us to fund any of our product candidates through regulatory approval. As a result, we will need to raise substantial additional capital to complete the development and commercialization of our product candidates. Identifying potential product candidates and conducting preclinical studies and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete. We may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for many years, if at all. Adequate additional funds may not be available to us on acceptable terms, or at all. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans.

If one or more of the product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing those approved product candidates. Even if we are able to generate revenues from the sale of any approved products, we may not become profitable and may need to obtain additional funding to continue operations.

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

We commenced operations in 2015 and our operations to date have been limited to organizing and staffing our company, business planning, raising capital, conducting discovery and research activities, filing patent applications, identifying potential product candidates, developing and advancing our TORPEDO platform, undertaking preclinical studies and establishing arrangements with third parties for the manufacture of initial quantities of our product candidates. All of our product candidates are still in preclinical development. We have not yet demonstrated our ability to successfully initiate or complete any clinical trials, obtain marketing approvals, manufacture a commercial scale product directly or through a third party or conduct sales, marketing and distribution activities necessary for successful product 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 if we had already successfully completed some or all of these types of activities.

In addition, as an early-stage biopharmaceutical company, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown challenges. We will need to transition at some point from a company with a research and development focus to a company capable of supporting commercial activities and we may not be successful in making that transition.

We expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance.

The ongoing global COVID-19 pandemic could continue to adversely impact our business, including our preclinical studies and development programs, supply chain and business development activities.

The COVID-19 pandemic, which began in December 2019, has spread worldwide and caused governments worldwide to implement measures to slow the spread of the outbreak through quarantines, travel restrictions, heightened border scrutiny, business shutdowns and other measures. The outbreak and government measures taken in response have also had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred, supply chains have been disrupted, facilities and production have been suspended and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, such as travel, has fallen. The future progression of the outbreak and its effects on our business and operations remain uncertain. In addition, any delays in foreign shipments coming into the United States could also impact our preclinical study or clinical trial plans.

We and our contract manufacturing organizations, or CMOs, and CROs may face disruptions that could affect our ability to initiate and complete preclinical studies or clinical trials. For example, because of ongoing efforts to address the pandemic, we may face disruptions in procuring items that are essential for our research and development activities, including, due to shortages arising in raw materials used in the manufacturing of our product candidates, laboratory supplies for our preclinical studies and clinical trials or animals that are used for preclinical testing. We and our CROs and CMOs may face disruptions related to our planned future clinical trials arising from potential delays in IND-enabling studies, manufacturing disruptions and/or the ability to obtain necessary institutional review board, or IRB, or other necessary site approvals, as well as other delays at clinical trial sites, including delays related to site staffing.

For example, in March 2020, due to COVID-19, we closed the office and laboratory spaces in our Watertown, Massachusetts facility and transitioned our employees to work from home. During the spring, we also experienced closures at the locations of some of our Indian CROs due to local lockdown requirements. These shutdowns resulted in delays to our preclinical studies. Due to the COVID-19 pandemic, we have also seen the risk of delays in production of components used to manufacture our lead degrader candidates increase due to previous delays at one of our China-based manufacturers, which we believe we have remediated by working with that manufacturer to change the location of future work to another of the manufacturer's sites. In June 2020, we reopened our office location to enable a subset of our employees—those whose work can only be performed in our laboratories—to return to the office, and we have required our remaining employees to continue working from home, an arrangement that we expect will continue for some time. While the ongoing impact of this pandemic is uncertain, we believe the redundancies we have in place between our China and India based CROs and our Watertown, Massachusetts-based laboratory staff, as well as the transition of the majority of our employees to remote work arrangements, have mitigated the impact of these disruptions on our business.

The response to the COVID-19 pandemic may result in the redirection of resources with respect to regulatory and intellectual property matters in a way that would adversely impact our ability to progress regulatory approvals and protect our intellectual property. For example, since March 2020, foreign and domestic inspections by FDA have largely been on hold with FDA announcing plans in July 2020 to resume prioritized domestic inspections. As of June 23, 2020, the FDA also noted that it is continuing to ensure timely reviews of applications for medical products during the COVID-19 pandemic in line with its user fee performance goals, including for oncology product development with its staff teleworking full-time. However, FDA may not be able to continue its current pace and review timelines could be extended. In addition, we may face impediments to regulatory meetings and approvals due to measures intended to limit in-person interactions.

The pandemic has already caused significant disruptions in the financial markets and may continue to cause these types of disruptions, which could impact our ability to raise additional funds through public offerings and may also contribute to volatility in our stock price and otherwise impact trading in our stock. Moreover, it is possible the pandemic will significantly impact

economies worldwide, which could adversely affect our business prospects, financial condition and results of operations. Any significant disruption of global financial markets, reducing our ability to access capital, could negatively affect our liquidity and ability to continue operations.

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 pre-clinical studies or 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 COVID-19 pandemic adversely affects our business prospects, financial condition and results of operations, it may also have the effect of heightening many of the other risks described in this “Risk Factors” section, such as those relating to the timing and results of our planned and future clinical trials and our financing needs.

Our Credit Agreement with Perceptive Credit contains restrictions that limit our flexibility in operating our business.

In June 2020, we entered into a credit agreement and guaranty, or the Credit Agreement, with Perceptive Credit Holdings III, LP, or Perceptive Credit, an affiliate of Perceptive Advisors LLC, or Perceptive Advisors. The Credit Agreement provides for a $20.0 million senior secured delayed draw term loan facility, or the Delayed Draw Loan Facility. The Credit Agreement is secured by a lien on substantially all of our and our subsidiaries’ assets, including, but not limited to, shares of our subsidiaries, our current and future intellectual property, insurance, trade and intercompany receivables, inventory and equipment and contract rights. The Credit Agreement requires us to meet specified minimum cash requirements, as described below, and contains various affirmative and negative covenants that limit our ability to engage in specified types of transactions. These covenants, which are subject to customary exceptions, limit our ability to, without Perceptive Credit’s prior written consent, effect any of the following, among other things:

- sell, lease, transfer or otherwise dispose of certain assets;
- acquire another company or business or enter into a merger or similar transaction with third parties;
- incur additional indebtedness;
- make investments;
- enter into certain inbound and outbound licenses of intellectual property, subject to certain exceptions;
- encumber or permit liens on certain assets; and
- pay dividends and make other restricted payments with respect to our common stock.

In addition, we are required to deposit into controlled accounts all cash or other payments received in respect of any and all of our accounts receivable or any other contract or right and interest and, at all times, to maintain a minimum aggregate balance of $3.0 million in cash in one or more such controlled accounts. These accounts are required to be maintained as cash collateral accounts securing our obligations under the Credit Agreement. Until our obligations under the Credit Agreement have been discharged, our ability to use the cash amounts held in these controlled accounts in the operation of our business will be limited.

Our ability to draw on the Delayed Draw Loan Facility is contingent on our compliance with the covenants described above and certain other covenants, as well as our achievement of designated milestones. If we do not meet these milestones, the inability to draw on the Delayed Draw Loan Facility may adversely affect our business prospects, financial condition and results of operations.

Our board of directors or management team could believe that taking any one of these actions would be in our best interests and the best interests of our stockholders. If that were the case and if we are unable to complete any of these actions because Perceptive Credit does not provide its consent, it could adversely impact our business, financial condition and results of operations. In the event of a default, including, among other things, our failure to make any payment when due or our failure to comply with any provision of the Credit Agreement, subject to customary grace periods, Perceptive Credit could elect to declare all amounts outstanding to be immediately due and payable and terminate all commitments to extend further credit. If we are unable to repay the amounts due under the Credit Agreement, Perceptive Credit could proceed against the collateral granted to it to secure this indebtedness, which could have an adverse effect on our business, financial condition and results of operations.

Perceptive Credit’s interests as a lender may not always be aligned with our interests or with Perceptive Advisor’s interests as a stockholder. If our interests come into conflict with those of Perceptive Credit, including in the event of a default under the Credit Agreement, Perceptive Credit may choose to act in its self-interest, which could adversely affect the success of our current and future collaborative efforts with Perceptive Advisor.

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

Until the time, if ever, when we can generate substantial revenue from product sales, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. Although we may receive potential future payments under our collaborations with Biogen, Roche and Calico, we do not currently have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted and the terms of any securities we may issue in the future may include liquidation or other preferences that adversely affect your rights as a common stockholder. 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 acquisitions or capital expenditures or declaring

dividends. Pursuant to the Credit Agreement, we granted Perceptive Credit a warrant that now enables Perceptive Credit to purchase 338,784 shares of our common stock. Covenants in the Credit Agreement impose certain limitations and obligations on us, including restrictions on our ability to incur additional debt and to enter into certain business combinations without Perceptive Credit's prior written consent.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing 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.

Risks Related to the Discovery and Development of Our Product Candidates

Our approach to the discovery and development of product candidates based on our TORPEDO platform for targeted protein degradation is unproven, which makes it difficult to predict the time, cost of development and likelihood of successfully developing any products.

Treating diseases using targeted protein degradation is a new treatment modality. Our future success depends on the successful development of this novel therapeutic approach. Very few small molecule product candidates using targeted protein degradation, such as those developed through our TORPEDO platform, have been tested in humans. None have been approved in the United States or Europe, and the data underlying the feasibility of developing these types of therapeutic products is both preliminary and limited. If any adverse learnings are made by other developers of chimeric targeting molecules, there is a risk that development of our product candidates could be materially impacted. Discovery and development of small molecules that harness the ubiquitin proteasome pathway to degrade protein targets have been impeded largely by the complexities and limited understanding of the functions, biochemistry and structural biology of the specific components of the ubiquitin-proteasome system, including E3 ligases and their required accessory proteins involved in target protein ubiquitination, as well as by challenges of engineering compounds that promote protein-to-protein interactions.

The scientific research that forms the basis of our efforts to develop our degrader product candidates under our TORPEDO platform is ongoing and the scientific evidence to support the feasibility of developing TORPEDO platform-derived therapeutic treatments is both preliminary and limited. Further, certain cancer patients have shown inherent primary resistance to approved drugs that inhibit disease-causing proteins and other patients have developed acquired secondary resistance to these inhibitors. Although we believe our products candidates may have the ability to degrade the specific mutations that confer resistance to currently marketed inhibitors of disease-causing enzymes, any inherent primary or acquired secondary resistance to our product candidates in patients, or if the research proves to be contradicted, would prevent or diminish their clinical benefit.

We have not yet initiated a clinical trial of any product candidate and we have not yet assessed the safety of any of our product candidates in humans. Although some of our product candidates have produced observable results in animal studies, there is a limited safety data set for their effects in animals. In addition, these product candidates may not demonstrate the same chemical and pharmacological properties in humans and may interact with human biological systems in unforeseen, ineffective or harmful ways. As a result, there could be adverse effects from treatment with any of our current or future product candidates that we cannot predict at this time.

Additionally, the regulatory approval process for novel product candidates such as ours can be more expensive and take longer than for other, better-known or extensively studied product candidates. Although other companies are also developing therapeutics based on targeted protein degradation, no regulatory authority has granted approval for any therapeutic of this nature at this time. As a result, it is more difficult for us to predict the time and cost of developing our product candidates and we cannot predict whether the application of our TORPEDO platform, or any similar or competitive protein degradation platforms, will result in the development of product candidates that make it through to marketing approval. Any development problems we experience in the future related to our TORPEDO platform or any of our research programs may cause significant delays or unanticipated costs or may prevent the development of a commercially viable product. Any of these factors may prevent us from completing our preclinical studies or any clinical trials that we may initiate, as well as from commercializing any product candidates we may develop on a timely or profitable basis, if at all.

We are an early stage biotechnology company and all of our product candidates are currently in preclinical development. If we are unable to advance to clinical development, develop, obtain regulatory approval for and commercialize our product candidates or experience significant delays in doing so, our business may be materially harmed.

We are an early stage biotechnology company and all of our product candidates are currently in preclinical development. As a result, their risk of failure is high. We have invested substantially all of our efforts and financial resources in building our TORPEDO platform and identifying and conducting preclinical development of our current product candidates, including CFT7455 and CFT8634. Our ability to generate revenue from product sales, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of one or more of our product candidates. The success of our product candidates will depend on several factors, including the following:

- sufficiency of our financial and other resources;
- successful initiations and completion of preclinical studies;
- successful submission of INDs and initiation of clinical trials;
- successful patient enrollment in, and conduct and completion of, clinical trials;
- receipt and related terms of marketing approvals from applicable regulatory authorities;

- obtaining and maintaining patent or trade secret protection and regulatory exclusivity for our product candidates;
- making arrangements with third-party manufacturers for both clinical and commercial supplies of our product candidates;
- developing product candidates that achieve the therapeutic properties desired and appropriate for their intended indications;
- establishing sales, marketing and distribution capabilities and launching commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- acceptance of our products, if and when approved, by patients, the medical community and third-party payors;
- obtaining and maintaining third-party coverage and adequate reimbursement;
- establishing a continued acceptable safety profile of the products and maintaining such that a profile following approval; and
- effectively competing with other therapies.

If we do not successfully achieve one or more of these factors in a timely manner, or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which could materially harm our business. Moreover, if we do not receive regulatory approvals, we may not be able to continue our operations.

We have no experience as a company in completing IND-enabling preclinical studies or commencing and conducting clinical trials.

We have no experience as a company in completing IND-enabling preclinical studies and then commencing and conducting clinical trials. In part because of this lack of experience, we cannot be certain that our preclinical studies will be completed on time or if our planned clinical trials will begin or be completed on time, if at all. Large-scale clinical trials would require significant additional financial and management resources and reliance on third-party clinical investigators and consultants. Relying on third-party clinical investigators, clinical research organizations, or CROs, and consultants may cause us to encounter delays that are outside of our control. In addition, relying on third parties in the conduct of our preclinical studies or clinical trials exposes us to a risk that they may not adequately comply with good laboratory practice, or GLP, or good clinical practice, or GCP, as required for any studies or trials we plan to submit to a regulatory authority. We may be unable to identify and contract with sufficient investigators, CROs and consultants on a timely basis or at all. For each of our lead product candidates, CFT7455 and CFT8634, we have entered into a master services agreement with a CRO to lead our planned first-in-human Phase 1/2 clinical trial for the applicable product candidate. There can be no assurance that we will be able to negotiate and enter into additional master services agreement with this or other CROs, as necessary, on terms that are acceptable to us on a timely basis or at all.

Our preclinical studies and clinical trials may fail to demonstrate adequately the safety, potency, purity and efficacy of any of our product candidates, which would prevent or delay development, regulatory approval and commercialization.

Before obtaining regulatory approval for the commercial sale of any of our product candidates, including CFT7455 and CFT8634, we must demonstrate through lengthy, complex and expensive preclinical studies and clinical trials that our product candidates are both safe and effective for use in each target indication. Preclinical and clinical testing is expensive and can take many years to complete and the outcome of these activities is inherently uncertain. Failure can occur at any time during the preclinical study and clinical trial processes and, because our product candidates are in an early stage of development and have never been tested in humans, there is a high risk of failure. In addition, because chimeric targeting molecules are a relatively new class of product candidates, any failures or adverse outcomes in preclinical or clinical testing seen by other developers in this class could materially impact the success of our programs. We may never succeed in developing marketable products.

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

Additionally, we expect that the first clinical trials for our product candidates may be open-label studies, where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. Most typically, open-label clinical trials test only the investigational product candidate and sometimes do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label clinical trials are aware when they are receiving treatment. In addition, open-label clinical trials may be subject to an “investigator bias” where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge.

Any preclinical studies or clinical trials that we may conduct may not demonstrate the safety, potency, purity and efficacy necessary to obtain regulatory approval to market our product candidates. If the results of our ongoing or future preclinical studies and clinical trials are inconclusive with respect to the safety, potency, purity and efficacy of our product candidates, if we do not meet the clinical endpoints with statistical and clinically meaningful significance or if there are safety concerns associated with our product candidates, we may be prevented or delayed in obtaining marketing approval for those product candidates. In some instances, there can be significant variability in safety, potency, purity or efficacy results between different preclinical studies and clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants. While we have not yet initiated clinical trials for any of our product candidates, as is the case with all oncology drugs, it is likely that there may be side effects associated with their use. Results of our trials could reveal a high and unacceptable severity and prevalence of these or other side effects. If that were to occur, or if other developers of similar chimeric targeting molecules were to find an unacceptable severity or prevalence of side effects with their candidates, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. Drug-related side effects could also affect patient recruitment or the ability of enrolled patients to complete an ongoing trial or result in potential product liability claims. Any of these occurrences may significantly harm our business, financial condition and prospects.

Further, our product candidates could cause undesirable side effects in clinical trials related to on-target toxicity. If on-target toxicity is observed or if our product candidates have characteristics that are unexpected, we may need to abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Many compounds that initially showed promise in early stage testing for treating cancer have later been found to cause side effects that prevented further development of the compound.

Drug development is a lengthy and expensive process with an uncertain outcome. We may incur unexpected costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

All of our product candidates are in preclinical development and their risk of failure is high. We are unable to predict when or if any of our product candidates will prove effective or safe in humans or will receive marketing approval. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Before we can commence clinical trials for a product candidate, we must complete extensive preclinical studies that support our planned INDs in the United States or similar applications in other jurisdictions. We cannot be certain of the timely completion or outcome of our preclinical studies and cannot predict if the FDA or similar regulatory authorities outside the United States will allow us to commence our proposed clinical trials or if the outcome of our preclinical studies ultimately will support the further development of any of our product candidates.

Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to the timing and outcome. A failure of one or more clinical trials can occur at any stage of the process. We may experience numerous unforeseen events during or as a result of clinical trials, which could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including:

- delays in reaching, or the failure to reach, a consensus with regulators on clinical trial design or the inability to produce acceptable preclinical results to enable entry into human clinical trials;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials may be insufficient or inadequate, including as a result of delays in the testing, validation, manufacturing and delivery of product candidates to the clinical sites by us or by third parties with whom we have contracted to perform certain of those functions;
- delays in reaching, or the failure to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- the failure of regulators or institutional review boards, or IRBs, to authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- difficulty in designing clinical trials and in selecting endpoints for diseases that have not been well studied and for which the natural history and course of the disease is poorly understood;
- the selection of certain clinical endpoints that may require prolonged periods of clinical observation or analysis of the resulting data;
- 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, participants may drop out of these clinical trials at a higher rate than we anticipate or fail to return for post-treatment follow-up or the failure to recruit suitable patients to participate in our clinical trials;
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or IRBs to suspend or terminate our clinical trials;
- we may have to suspend or terminate clinical trials of our product candidates for various reasons, including a finding that the participants are being exposed to unacceptable health risks;
- the third parties with whom we contract may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;

- the requirement from regulators or IRBs that we or our investigators suspend or terminate clinical trials for various reasons, including noncompliance with regulatory requirements or unacceptable safety risks;
- clinical trials 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 product development programs;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- imposition of a clinical hold by regulatory authorities as a result of a serious adverse event, concerns with a class of product candidates or after an inspection of our clinical trial operations, trial sites or manufacturing facilities;
- occurrence of serious adverse events associated with the product candidate that are viewed to outweigh its potential benefits; and
- disruptions caused by the evolving effects of the COVID-19 pandemic may increase the likelihood that we encounter these types of difficulties or delays in initiating, enrolling, conducting or completing our planned clinical trials.

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 modestly positive or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for our product candidates, if at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be required to perform additional clinical trials to support marketing approval;
- have regulatory authorities withdraw or suspend their approval, or impose restrictions on distribution of a product candidate in the form of a modified risk evaluation and mitigation strategy, or REMS;
- be subject to additional post-marketing testing requirements or changes in the way the product is administered; or
- have our product removed from the market after obtaining marketing approval.

Our product development costs also will increase if we experience delays in preclinical studies or clinical trials or in obtaining marketing approvals. We do not know whether any of our preclinical studies or clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant preclinical study or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates, or could allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates, which may harm our business, results of operations, financial condition and prospects.

Further, cancer therapies sometimes are characterized as first-line, second-line or third-line. The FDA often approves new oncology therapies initially only for third-line or later use, meaning for use after two or more other treatments have failed. When cancer is detected early enough, first-line therapy, usually hormone therapy, surgery, radiation therapy, immunotherapy or a combination of these, is sometimes adequate to cure the cancer or prolong life without a cure. Second-line and third-line therapies are administered to patients when prior therapy is not effective. Our planned clinical trials for our lead product candidates CFT7455 and CFT8634 and other drug candidates will be with patients who have received one or more prior treatments and we expect that we would initially seek regulatory approval of these product candidates for second-line or third-line therapy. Subsequently, for those products that prove to be sufficiently beneficial, if any, we would expect to seek approval potentially as a first-line therapy, but any product candidates we develop, even if approved for second-line or third-line therapy, may not be approved for first-line therapy and, prior to seeking and/or receiving any approvals for first-line therapy, we may have to conduct additional clinical trials.

Targeted protein degradation is a novel modality that continues to attract substantial interest from existing and emerging biotechnology and pharmaceutical companies. As a result, we face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. We face, and will continue to face, competition from third parties that use protein degradation, antibody therapy, inhibitory nucleic acid, immunotherapy, gene editing or gene therapy development platforms and from companies focused on more traditional therapeutic modalities, such as small molecule inhibitors. The competition we face and will face is likely to come from multiple sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions, government agencies and public and private research institutions.

Targeted protein degradation is an emerging therapeutic modality that has the potential to deliver therapies that improve outcomes for patients. As a result, a number of biotechnology and pharmaceutical companies are already working to develop degradation-based therapies and the number of companies entering this space continues to increase. We are aware of several biotechnology companies focused on developing product candidates based on small molecules for targeted protein degradation including Arvinas, Inc., BioTheryX, Inc., Cullgen Inc., Foghorn Therapeutics, Inc., Frontier Medicines Corporation, Lycia Therapeutics, Inc., Monte Rosa Therapeutics, Inc., Nurix Therapeutics, Inc., Vividion Therapeutics, Inc. and Kymera Therapeutics, Inc. Further, several large pharmaceutical companies have disclosed investments and research in this field, including Amgen, AstraZeneca plc, Bristol-Myers Squibb Company (and its subsidiary Celgene Corporation), GlaxoSmithKline plc, Genentech, Inc. and Novartis International AG. In addition to competition from other protein degradation therapies, any products that we develop may also face competition from other types of therapies, such as small molecule, antibody, T cell or

gene therapies. For example, we understand that Adaptimmune Limited and GlaxoSmithKline plc are pursuing the development of therapies for patients with synovial sarcoma.

Many of our current or potential competitors, either alone or with their collaboration 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. 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 product candidates. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors, the scale of which could be difficult to compete against. 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 product candidates. 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 product candidate that we may develop. Our competitors also may obtain FDA or other regulatory approval for their product candidates more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic products. There are generic products currently on the market for certain of the indications that we are pursuing and additional products are expected to become available on a generic basis over the coming years. If our product candidates are approved, we expect that they will be priced at a significant premium over competitive generic products.

Our ability to use our net operating loss carryforwards and research and development tax credit carryforwards may be limited.

As of December 31, 2019, we had no federal net operating loss carryforwards and $8.2 million in state net operating loss carryforwards, which begin to expire in 2038. We may have federal net operating loss carryforwards in future years. Under legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act, as modified by the Coronavirus Aid, Relief and Economic Security Act, or the CARES Act, federal net operating losses generated after 2017, if any, will not expire and may be carried forward indefinitely, but the deductibility of such federal net operating losses (particularly those generated in tax years beginning after December 31, 2020) in tax years beginning after December 31, 2020, is limited. It is uncertain how various states will respond to the Tax Cuts and Jobs Act, the CARES Act or any newly enacted federal tax law. In addition, at the state level, there may be periods during which the use of net operating losses is suspended or otherwise limited, including a recent California franchise tax law change limiting the usability of California state net operating losses to offset taxable income in tax years beginning after 2019 and before 2023.

As of December 31, 2019, we also had federal and state research and development tax credit carryforwards of $0.4 million and $0.1 million, respectively, which begin to expire in 2039. These tax credit carryforwards could expire unused and be unavailable to offset our future income tax liabilities.

In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, and corresponding provisions of state law, if a corporation undergoes an “ownership change,” which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation’s ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. In 2020, the Company completed a study of ownership changes from inception through May 31, 2020, which concluded that we experienced ownership changes as defined by Section 382 of the Code. However, there were no net operating loss carryforwards that were limited or expired unused. We may experience ownership changes in the future as a result of subsequent changes in our stock ownership, including as a result of our recently closed initial public offering, some of which may be outside of our control. If we determine that an ownership change has occurred and our ability to use our historical net operating loss and tax credit carryforwards is materially limited, that would harm our future operating results by effectively increasing our future tax obligations.

We may not be able to file INDs to commence additional clinical trials on the timelines we expect and, even if we are able to, the FDA may not permit us to proceed.

We plan to submit an IND for CFT7455 in the fourth quarter of 2020 and for CFT8634 in the second half of 2021, but we may not be able to file these planned INDs on the timelines we expect. For example, we may experience manufacturing delays or other delays with IND-enabling studies. Moreover, we cannot be sure that submission of an IND will result in the FDA allowing us to commence clinical trials or that, once begun, issues will not arise that lead to the suspension or termination of our clinical trials. Additionally, even if the applicable regulatory authorities agree with the design and implementation of the clinical trials set forth in our INDs, we cannot guarantee that those regulatory authorities will not change their requirements in the future. These considerations apply to the INDs described above and also to new clinical trials we may submit as amendments to existing INDs or as part of new INDs in the future. Any failure to file INDs on the timelines we expect or to obtain regulatory approvals for our trials may prevent us from completing our clinical trials or commercializing our products on a timely basis, if at all.

If serious adverse events, undesirable side effects or unexpected characteristics are identified during the development of any product candidates we may develop, we may need to abandon or limit our further clinical development of those product candidates.

We have not evaluated any product candidates in human clinical trials. Moreover, we are not aware of any clinical trials using small molecules for targeted protein degradation, such as those developed using our TORPEDO platform. It is impossible to predict when or if any product candidates we may develop will prove safe in humans. There can be no assurance that any of the product candidates developed through our TORPEDO platform will not cause undesirable side effects, which could arise at any time during preclinical or clinical development.

A potential risk with product candidates developed through our TORPEDO platform, or in any protein degradation product candidate, is that healthy proteins or proteins not targeted for degradation will be degraded or that the degradation of the targeted protein in and of itself could cause adverse events, undesirable side effects or unexpected characteristics. There is also the potential risk of delayed adverse events following treatment using product candidates developed through our TORPEDO platform.

If any product candidates we develop are associated with serious adverse events or undesirable side effects or have other characteristics that are unexpected, we may need to abandon their development or limit development to certain uses or subpopulations in which the adverse events, undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. The occurrence of any of these sorts of events would have an adverse effect on our business, financial condition, results of operations and prospects. Many product candidates that initially showed promise in early-stage testing for treating cancer or other diseases have later been found to cause side effects that prevented further clinical development of the product candidates or limited their competitiveness in the market. For example, single agent BRAF inhibitors can cause a secondary malignancy called keratocanthoma, which is a skin cancer caused by paradoxical activation of BRAF upon inhibitor binding.

The results of preclinical studies may not be predictive of future results in later studies or trials. Initial success in clinical trials may not be indicative of results obtained when these trials are completed or in later stage clinical trials.

The results of preclinical studies may not be predictive of the results of clinical trials and the results of any early-stage clinical trials we commence in the future may not be predictive of the results of the later-stage clinical trials. In addition, initial success in clinical trials may not be indicative of results obtained when those trials are completed or in later stage clinical trials. In particular, the small number of patients in our planned early clinical trials may make the results of these trials less predictive of the outcome of later clinical trials. For example, even if successful, the results of the dose escalation portion of our future first-in-human Phase 1/2 clinical trials of CFT7455 and CFT8634 may not be predictive of the results of further clinical trials of these product candidates or any of our other product candidates. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. Our future clinical trials may not ultimately be successful or support further clinical development of any of our product candidates. There is a high failure rate for product candidates proceeding through clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in clinical development even after achieving encouraging results in earlier studies. Any setbacks of this nature in our clinical development could materially harm our business, financial condition, results of operations and prospects. In addition, we may conduct some of our clinical trials in a combination Phase 1/2 design and, if the Phase 1 portion of the trial is not successful, we will not be allowed to proceed into the Phase 2 portion of the trial.

If we experience delays or difficulties in the enrollment of patients in our clinical trials, our timelines for submitting for and receiving necessary marketing approvals could be delayed or prevented.

We may not be able to initiate clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials, as required by the FDA or similar regulatory authorities outside of the United States. We are preparing to advance CFT7455 into first-in-human Phase 1/2 clinical trials in MM and NHLs, including PTCL and MCL. In addition, we are planning to advance CFT8634 into first-in-human Phase 1/2 clinical trials in patients with synovial sarcoma or SMARCB1 deleted solid tumors. While we believe that we will be able to enroll a sufficient number of patients into each of these clinical trials, we cannot predict with certainty how difficult it will be to enroll patients for trials in these rare indications generally and during the COVID-19 pandemic, specifically. Our ability to identify and enroll eligible patients for CFT7455 and CFT8634 clinical trials may turn out to be limited or we may be slower in enrolling these trials than we anticipate. In addition, some of our competitors have ongoing clinical trials for product candidates that treat the same indications as our product candidates and, as a result, patients who would otherwise be eligible for our clinical trials may instead elect to enroll in clinical trials of our competitors' product candidates. Patient enrollment in clinical trials is also affected by other factors including:

- the severity of the disease under investigation;
- the eligibility criteria for the trial in question;
- the perceived risks and benefits of the product candidates offered in the clinical trials;
- the efforts to facilitate timely enrollment in clinical trials;
- the patient referral practices of physicians;
- the burden on patients due to the scope and invasiveness of required procedures under clinical trial protocols, some of which may be inconvenient and/or uncomfortable;
- the ability to monitor patients adequately during and after treatment;

- the proximity and availability of clinical trial sites for prospective patients; and
- the impact of the current COVID-19 pandemic, which may affect the conduct of a clinical trial, including by slowing potential enrollment or reducing the number of eligible patients for clinical trials.

Our inability to enroll a sufficient number of patients for our planned clinical trials, or our inability to do so on a timely basis, would result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may also result in increased development costs for our product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing.

The conclusions and analysis drawn from announced or published interim top-line and preliminary data from our clinical trials from time to time may change as more patient data become available. Further, all interim data that we provide remains 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 our clinical trials. 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. In addition, preliminary or top-line data also remain subject to audit and verification procedures that may result in the final data being different, potentially in material ways, from the preliminary data we previously announced or published. As a result, interim and preliminary data should be viewed with caution until final data are available. Adverse differences between preliminary or interim data and final data could significantly harm our reputation, business, financial condition, results of operations and prospects.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on research programs and product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

We may develop CFT7455 in combination with other drugs for MM. If the FDA or similar regulatory authorities outside of the United States do not approve these other drugs, revoke their approval of these other drugs or if safety, efficacy, manufacturing or supply issues arise with the drugs we choose to evaluate in combination with CFT7455, we may be unable to obtain approval of or market CFT7455.

Once a recommended dose is identified from the dose escalation portion of our first-in-human Phase 1/2 clinical trial of CFT7455 for the treatment of MM, we may conduct a portion of that clinical trial in combination with a dexamethasone inhibitor. We did not develop or obtain marketing approval for, nor do we manufacture or sell, any of the currently approved drugs that we may study in combination with CFT7455. If the FDA or similar regulatory authorities outside of the United States revoke their approval of the drug or drugs we intend to deliver in combination with CFT7455, we will not be able to market CFT7455 in combination with those revoked drugs.

If safety or efficacy issues arise with any of these drugs, we could experience significant regulatory delays and the FDA or similar regulatory authorities outside of the United States may require us to redesign or terminate certain of our clinical trials. If the drugs we use are replaced as the standard of care for the indications we choose for CFT7455, the FDA or similar regulatory authorities outside of the United States may require us to conduct additional clinical trials. In addition, if manufacturing or other issues result in a shortage of supply of the drugs with which we determine to combine with CFT7455, we may not be able to complete clinical development of CFT7455 on our current timeline or at all.

Even if CFT7455 were to receive marketing approval or be commercialized for use in combination with other existing drugs, we would continue to be subject to the risks that the FDA or similar regulatory authorities outside of the United States could revoke approval of the drug used in combination with CFT7455 or that safety, efficacy, manufacturing or supply issues could arise with these existing drugs.

Combination therapies are commonly used for the treatment of cancer and we would be subject to similar risks if we were to elect to develop any of our other product candidates for use in combination with other drugs or for indications other than cancer. This could result in our own products being removed from the market or being less successful commercially.

We may not be successful in our efforts to identify or discover additional potential product candidates.

While our two lead programs are focused on oncology targets, a key element of our strategy is to apply our TORPEDO platform to develop product candidates that address a broad array of targets and new therapeutic areas, such as neurodegeneration, diseases of aging and infectious disease. The therapeutic discovery activities that we are conducting may not be successful in identifying product candidates that are useful in treating cancer or other diseases. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for a number of reasons, including:

- potential product candidates may, on further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be drugs that will receive marketing approval or achieve market acceptance;

- potential product candidates may not be effective in treating their targeted diseases; or
- the market size for the target indications of a potential product candidate may diminish over time due to improvements in the standard of care to the point that further development is not warranted.

Research programs to identify new product candidates require substantial technical, financial and human resources. We may choose to focus our efforts and resources on a potential product candidate that ultimately proves to be unsuccessful. If we are unable to identify suitable product candidates for preclinical and clinical development, we will not be able to obtain revenues from sale of products in future periods, which likely would result in significant harm to our financial position and adversely impact our stock price.

If we do not achieve our projected development goals in the timeframes we announce and expect, the commercialization of our products may be delayed and, as a result, our stock price may decline.

From time to time, we may estimate the timing of the anticipated accomplishment of various scientific, clinical, regulatory and other product development goals, which we sometimes refer to as milestones. These milestones may include the commencement or completion of preclinical studies and clinical trials and the submission of regulatory filings. From time to time, we may publicly announce the expected timing of some of these milestones. Each of these milestones is and will be based on numerous assumptions. The actual timing of these milestones can vary dramatically compared to our estimates, in some cases for reasons beyond our control. If we do not meet these milestones as publicly announced, or at all, our revenue may be lower than expected, the commercialization of our products may be delayed or never achieved and, as a result, our stock price may decline.

Risks Related to Dependence on Third Parties

We expect to rely on third parties to conduct our future clinical trials and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials.

We expect to rely on CROs to conduct our planned first-in-human Phase 1/2 clinical trial programs for CFT7455 and CFT8634 and our other clinical trials as we currently do not plan to independently conduct clinical trials of our other product candidates. Our agreements with these CROs might terminate for a variety of reasons, including a failure to perform by the third parties. If we were ever to need to enter into alternative arrangements, we would experience delays in our product development activities.

Our reliance on CROs for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities for how these activities are performed. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols in the applicable IND. Moreover, the FDA requires compliance with standards, commonly referred to as GCPs, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected.

Further, these CROs may have relationships with other entities, some of which may be our peers or competitors. If the CROs with whom we work do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates.

Manufacturing pharmaceutical products is complex and subject to product loss for a variety of reasons. We contract with third parties for the manufacture of our product candidates for preclinical testing and clinical trials and expect to continue to do so for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or that we will not have the quantities we desire or require at an acceptable cost or quality or at the right time, which could delay, prevent or impair our development or commercialization efforts.

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We rely on and expect to continue to rely on contract manufacturing organizations, or CMOs, for both drug substance and finished drug product. This reliance on third parties may increase the risk that we will not have sufficient quantities of our product candidates or products or that we will not have the quantities we desire or require at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

We may be unable to establish agreements with CMOs or to do so on acceptable terms. Even if we are able to establish agreements with CMOs, reliance on third-party manufacturers entails additional risks, including:

- reliance on the third party for regulatory, compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third-party CMO;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how; and
- the possible termination or non-renewal of the agreement by the third party at a time that is costly or inconvenient for us.

We have only limited technology transfer agreements in place with respect to our product candidates and these existing arrangements do not extend to commercial supply. We acquire many key materials on a purchase order basis. As a result, we do not have long-term committed arrangements with respect to our product candidates and other materials. If we receive marketing approval for any of our product candidates, we will need to establish an agreement for commercial manufacture with a third party.

Third-party manufacturers may not be able to comply with current good manufacturing practices, or cGMP, regulations or similar regulatory requirements outside of the United States. Our molecules are highly potent and, in the absence of additional safety data, they receive a high occupational exposure band, or OEB. These assigned OEBs dictate the contaminant and other precautions that must be taken as part of the manufacture of our product candidates. Our failure, or the failure of our CMOs, to comply with applicable regulations, including the ability of our CMOs to work with our highly potent materials and the safety protocols in connection therewith, could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products.

Our product candidates and any products that we may develop may compete with other product candidates and products for access to manufacturing facilities. As a result, we may not obtain access to these facilities on a priority basis or at all. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us.

Any performance failure or delay in performance on the part of our existing or future manufacturers could delay clinical development or marketing approval. For example, our contract fill/finish manufacturer had a mechanical issue arise in connection with a manufacturing step for our CFT7455 product candidate. While we do not believe this issue will have an impact on our development timelines, in the future, we could experience a manufacturing issue that would have a material impact on development of our product candidates and the occurrence of an event of this nature would largely be outside of our control. We do not currently have arrangements in place for redundant supply or a second source for bulk drug substance. If our current CMOs cannot perform as agreed, we may be required to replace them. Although we believe that there are several potential alternative manufacturers who could manufacture our product candidates, we may incur added costs and delays in identifying and qualifying any replacement manufacturers or we may not be able to reach agreement with any alternative manufacturer. While we have identified alternate vendors for CFT7455 and CFT8634, switching vendors could result in significant additional costs of materials and significant delays to our operations.

Our current and anticipated future dependence upon others for the manufacture of our product candidates or products may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis.

Additionally, we currently rely on single source suppliers for certain of the raw materials for our preclinical study and clinical trial supplies. If our current or future suppliers are unable to supply us with sufficient raw materials for our preclinical studies and clinical trials, we may experience delays in our development efforts as we locate and qualify new raw material manufacturers. These third-party manufacturers may incorporate their own proprietary processes into our product candidate manufacturing processes. We have limited control and oversight of a third party's proprietary process and a third-party manufacturer may elect to modify its process without our consent or knowledge. These modifications could negatively impact our manufacturing, including product loss or failure that requires additional manufacturing runs or a change in manufacturer, both of which could significantly increase the cost of and significantly delay the manufacture of our product candidates.

As our product candidates progress through preclinical studies and clinical trials towards approval and commercialization, we expect that various aspects of the manufacturing process will be altered in an effort to optimize processes and results. These types of changes may require that we make amendments to our regulatory applications, which could further delay the timeframes under which modified manufacturing processes can be used for any of our product candidates.

In addition, as we advance our product candidates into later stage clinical trials and plan for the potential commercialization of our product candidates, we may determine that it is necessary or appropriate to bring on additional suppliers of drug product and/or drug substance, which could result in changes to the manufacturing processes for our product candidates and may require us to provide additional information to regulatory authorities. If we were to bring on additional CMOs for our product candidates, we may also be required to conduct additional bridging studies or trials, all of which take would require additional time and expense.

We expect to depend on collaborations with third parties for the research, development and commercialization of certain of the product candidates we may develop. If any of these collaborations are not successful, we may not be able to capitalize on the market potential of those product candidates.

We anticipate seeking third-party collaborators for the research, development and commercialization of some of our product candidates developed using our TORPEDO platform. Previously, we entered into the following collaborations:

- a collaboration agreement with Roche in December 2015, which we amended and restated in December 2018 and further amended in November 2020;
- a collaboration agreement with Calico in March 2017; and
- a collaboration agreement with Biogen in December 2018.

Our likely collaborators in any other collaboration arrangements we may enter into include large and mid-size pharmaceutical companies and biotechnology companies. If we were to enter into any collaboration arrangements with third parties, those arrangements will likely limit our control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of any product candidates we may seek to develop with them. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements. We cannot predict the success of any collaboration in which we have entered or may enter.

Collaborations involving our research programs or any product candidates we may develop, including our existing collaborations with Roche, Calico and Biogen, pose the following risks to us:

- Collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations. For example, our collaborations with Roche, Biogen and Calico are each managed by a joint governance committee, which is composed of representatives from us and the applicable collaborator.
- Collaborators may not pursue development and commercialization of any product candidates we may develop or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborator's strategic focus or market considerations or available funding or external factors such as an acquisition or business combination that diverts resources or creates competing priorities. If this were to happen, we may need additional capital to pursue further development or commercialization of the applicable product candidates. For example, in June 2020, Roche notified us that they will not be electing to pursue further development of our EGFR program and, in November 2020, we entered into an amendment to the Roche collaboration to document the reversion of this program to us.
- Roche, Biogen and Calico have broad rights to select a limited number of targets for protein degradation development, so long as that target is not excluded by us under the terms of each collaboration and may select targets we are considering but have not taken sufficient action (e.g., internal development of, or steps toward partnering, such target) to exclude under the collaboration.
- Collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing.
- Collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours.
- Subject to certain diligence obligations, Collaborators with marketing and distribution rights to one or more products may not commit sufficient resources to the marketing and distribution of such product or products.
- Collaborators may not properly obtain, maintain, enforce or defend our intellectual property or proprietary rights or may use our proprietary information in a way that could jeopardize or invalidate our proprietary information or expose us to potential litigation. For example, Roche, Biogen and Calico have the first right to enforce and Roche also has the first right to defend, certain intellectual property rights under the applicable collaboration arrangement with respect to particular licensed programs and, although we may have the right to assume the enforcement and defense of such intellectual property rights if the collaborator does not, our ability to do so may be compromised by their actions.
- Collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in cases where that applies, we would not have the exclusive right to commercialize the collaboration intellectual property.
- Disputes may arise between our collaborators and us that result in the delay or termination of the research, development or commercialization of our products or product candidates or that result in costly litigation or arbitration that diverts management attention and resources.
- We may lose certain valuable rights under circumstances identified in our collaborations, including if we undergo a change of control.
- Collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates. For example, each of Roche, Biogen and Calico can terminate its agreement with us in its entirety or with respect to a specific target for convenience upon written notice ranging from 90 to 270 days' notice or in connection with a material breach of the agreement by us that remains uncured for a specified period of time.

- Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If a present or future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program under such collaboration could be delayed, diminished or terminated.
- Collaborators may be unable to maintain compliance with GLP and GCP requirements or to secure approval for clinical development plans from the FDA or foreign regulatory authorities.
- The amount of revenue we derive from our collaborations may be volatile on a quarterly basis.

If our collaborations do not result in the successful development and commercialization of products or if one of our collaborators terminates its agreement with us or elects not to pursue a program within a collaboration, we may not receive any future research funding or milestone or royalty payments under that collaboration or in respect of that terminated program. If we do not receive the funding we expect under these agreements, our development of product candidates could be delayed and we may need additional resources to develop our product candidates. In addition, if one of our collaborators terminates its agreement with us, we may find it more difficult to find a suitable replacement collaborator or attract new collaborators and our development programs may be delayed or the perception of us in the business and financial communities could be adversely affected. All of the risks relating to product development, marketing approval and commercialization described in this report apply to the activities of our collaborators.

We may in the future decide to collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of any product candidates we may develop. These and other similar relationships may require us to incur non-recurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. In addition, we could face significant competition in seeking appropriate collaborators and the negotiation process is time-consuming and complex. Our ability to reach a definitive collaboration agreement will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of several factors. If we license rights to any product candidates we or our collaborators may develop, we may not be able to realize the benefit of those transactions if we are unable to successfully integrate them with our existing operations and company culture.

We may form or seek collaborations or strategic alliances or enter into additional licensing arrangements in the future and we may not realize the benefits of those collaborations, alliances or licensing arrangements.

We may form or seek strategic alliances, create joint ventures or collaborations or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. For example, we may seek to enter into out-licensing arrangements to advance our CFT7455 product candidate in MM or other indications. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business.

In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process for these sorts of transactions is time-consuming, complex and expensive. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety, potency, purity and efficacy and obtain marketing approval. Additionally, our existing partners may decide to acquire or partner with other companies developing targeted protein degraders, which may have an adverse impact on our business prospects, financial condition and results of operations.

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

Risks Related to the Commercialization of Our Product Candidates

Even if any of our product candidates receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

If any of our product candidates receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. For example, current cancer treatments, such as chemotherapy and radiation therapy, are well-established in the medical community, and doctors may continue to rely on these treatments. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant revenue from product sales 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 efficacy and potential advantages compared to alternative treatments;

- the prevalence and severity of any side effects, in particular compared to alternative treatments;
- our ability to offer our products for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians treating these patients to prescribe these therapies;
- the strength of marketing, sales and distribution support;
- the availability of third-party insurance coverage and adequate reimbursement;
- the timing of any marketing approval in relation to other product approvals;
- support from patient advocacy groups; and
- any restrictions on the use of our products together with other medications.

As a company, we currently have no marketing and sales organization and have no experience in marketing products. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, if approved, we may not be able to generate product revenue.

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

If we are unable or decide not to establish internal sales, marketing and distribution capabilities, we will pursue arrangements with third-party sales, marketing and distribution collaborators regarding the sales and marketing of our products, if approved. However, there can be no assurance that we will be able to establish or maintain these types of arrangements on favorable terms or if at all, or if we are able to do so, that these third-party arrangements will provide effective sales forces or marketing and distribution capabilities. Any revenue we receive will depend upon the efforts of these third parties, which may not be successful. We may have little or no control over the marketing and sales efforts of these third parties and our revenue from product sales may be lower than if we had commercialized our product candidates ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our product candidates.

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

The market opportunities for our product candidates may be relatively small as we expect that they will initially be approved only for those patients who are ineligible for or have failed prior treatments. In addition, our estimates of the prevalence of our target patient populations may be inaccurate.

Our product candidates may target cancer, but cancer therapies are sometimes characterized as first-line, second-line, third-line or subsequent line, and the FDA often approves new therapies initially only for a particular line of use. When cancer is detected early enough, first-line therapy is sometimes adequate to cure the cancer or prolong life without a cure. Whenever first-line therapy, usually chemotherapy, antibody drugs, tumor-targeted small molecules, immunotherapy, hormone therapy, radiation therapy, surgery, other targeted therapies or a combination of these therapies, proves unsuccessful, second-line therapy may be administered. Second-line therapies often consist of more chemotherapy, radiation, antibody drugs, tumor-targeted small molecules or a combination of these. Third-line therapies can include chemotherapy, antibody drugs and small molecule tumor-targeted therapies, more invasive forms of surgery and new technologies. We expect initially to seek approval of our product candidates in most instances as a second- or third-line therapy, for use in patients with relapsed or refractory cancer. Subsequently, for those product candidates that prove to be sufficiently safe and beneficial, if any, we would expect to seek approval as a second-line therapy and potentially as a first-line therapy, but there is no guarantee that any of our product candidates, even if approved as a second or third or subsequent line of therapy, would subsequently be approved for an earlier line of therapy. Further, it is possible that, prior to getting any approvals for our product candidates in earlier lines of treatment, we might have to conduct additional clinical trials.

Our projections of both the number of people who have the cancers we are targeting, who may have their tumors genetically sequenced, as well as the subset of people with these cancers in a position to receive a particular line of therapy and who have the potential to benefit from treatment with our product candidates, are based on our reasonable beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations or market research and may prove to be incorrect. Further, new therapies may change the estimated incidence or prevalence of the cancers that we are targeting. Consequently, even if our product candidates are approved for a second or third-line of therapy, the number of patients that may be eligible for treatment with our product candidates may turn out to be much lower than expected. In addition, we have not yet conducted market research to determine how treating physicians would expect to prescribe a product that is approved for multiple tumor types if there are different lines of approved therapies for each of those tumor types.

Even if we receive marketing approval of any of our product candidates, our products may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which would harm our business.

The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product candidate in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, which would negatively impact the revenues, if any, we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more of our product candidates, even if our product candidates obtain marketing approval.

Our ability to commercialize any product candidates successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government healthcare programs, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, government authorities and third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Coverage and reimbursement may not be available for any product that we commercialize and, even if these are available, the level of reimbursement may not be satisfactory. Reimbursement may affect the demand for, or the price of, any product candidate for which we obtain marketing approval. Obtaining and maintaining adequate reimbursement for our products may be difficult. We may be required to conduct expensive pharmacoeconomic studies to justify coverage and reimbursement or the level of reimbursement relative to other therapies. If coverage and adequate reimbursement are not available or reimbursement is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs. In addition, coverage may be more limited than the purposes for which the drug is approved by the FDA or similar regulatory authorities outside of the United States. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, intellectual property, manufacture, sale and distribution expenses. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for any approved products that we develop could have an adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if or when we commercially sell any products that we may develop. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- termination of clinical trials;
- withdrawal of marketing approval, recall, restriction on the approval or a “black box” warning or contraindication for an approved drug;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue;
- injury to our reputation and significant negative media attention;
- reduced resources of our management to pursue our business strategy; and
- the inability to commercialize any products that we may develop.

As a preclinical company, we do not currently hold product liability insurance coverage. We will need to purchase product liability insurance coverage as we initiate our clinical trials, as we expand our clinical trials and if and when we commence commercialization of our product candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent protection for our technology and products or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, our ability to successfully commercialize our technology and products may be impaired and we may not be able to compete effectively in our market.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect our intellectual property and prevent others from exploiting our pipeline drug product candidates, any future drug product candidates we may develop and our platform technologies, as well as the use or manufacture of our current or future drug product candidates.

Our commercial success depends in part on our ability to obtain and maintain patent and other proprietary protection in the United States and other countries with respect to our proprietary technology and products. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our novel technologies and product candidates. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market. Moreover, the patent applications we own, co-own or license may fail to result in issued patents in the United States or in other foreign countries.

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. Moreover, in some circumstances, we do not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

The patent position of the biopharmaceutical industry generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Publications of discoveries in the 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, co-owned or licensed patents or pending patent applications, or that we were the first inventors 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 that protect our technology or products, in whole or in part, or that 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. 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.

Our owned, co-owned and licensed patent estate consists principally of patent applications, many of which are at an early stage of prosecution. Even if our owned, co-owned and licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned, co-owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned, co-owned and licensed patents or patents obtained by our collaborators may be challenged in the courts or patent offices in the United States and abroad. These challenges may result in loss of exclusivity or freedom to operate 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. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting our drug product candidates might expire before or shortly after they are commercialized. As a result, our owned, co-owned and licensed patent portfolio, or that of our collaborators, may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Changes in patent laws or patent jurisprudence could diminish the value of our patents in general or increase third party challenges to our patents, thereby impairing our ability to protect our product candidates.

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law and made a number of significant changes to United States patent law. These changes include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The United States Patent and Trademark Office, or the USPTO, developed new regulations and procedures to govern administration of the Leahy-Smith

Act and many of the substantive changes to patent law associated with the Leahy-Smith Act, including the first-inventor-to-file provisions, became effective on March 16, 2013. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have an adverse effect on our business and financial condition. The first-to-file provision of the Leahy-Smith Act requires us to act promptly during the period from invention to filing of a patent application. However, even with the intention to act promptly, circumstances could prevent us from promptly filing or prosecuting patent applications on our inventions. The Leahy-Smith Act also enlarged the scope of disclosures that qualify as prior art, which can impact our ability to receive patent protection for an invention.

The Leahy-Smith Act created, for the first time, new procedures under which third parties may challenge issued patents in the United States, including post-grant review, *inter partes* review and derivations proceedings, all of which are adversarial proceedings conducted at the USPTO. Since the effectiveness of the Leahy-Smith Act, some third parties have been using these types of actions to seek and achieve the cancellation of selected or all claims of issued patents of their competitors. Under the Leahy-Smith Act, for a patent with a priority date of March 16, 2013 or later (which is the case for all of our patent filings), a third party can file a petition for post-grant review at any time during a nine-month window commencing at the time of issuance of the patent. In addition, for a patent with a priority date of March 16, 2013 or later, a third party can file a petition for *inter partes* review after the nine-month period for filing a post-grant review petition has expired. Post-grant review proceedings can be brought on any ground of challenge, whereas *inter partes* review proceedings can only be brought to raise a challenge based on published prior art. Under applicable law, the standard of review for these types of adversarial actions at the USPTO are conducted without the presumption of validity afforded to U.S. patents, which is the standard that applies if a third party were to seek to invalidate a patent through a lawsuit filed in the U.S. federal courts. The USPTO issued a Final Rule on November 11, 2018 announcing that it will now use the same claim construction currently used in the U.S. federal courts—which is the plain and ordinary meaning of words used—to interpret patent claims in these USPTO proceedings. As a result of this regulatory landscape, if any of our patents are challenged by a third party in a USPTO proceeding of this nature, there is no guarantee that we will be successful in defending the challenged patent, which could result in our losing rights under the challenged patent in part or in whole.

As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights, or those of our collaborators, are highly uncertain, which could have an adverse effect on our business, financial condition, results of operations and prospects.

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

Competitors may infringe our issued patents, the patents of our licensors or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive, time-consuming and unpredictable. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents. In addition, in a patent infringement proceeding, a court may decide that a patent of ours or our licensors or collaborators is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or 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. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly. Even if we successfully assert our patents, a court may not award remedies that sufficiently compensate us for our losses.

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

A third party may hold intellectual property, including patent rights, that are important or necessary to the development of our products. It may, therefore, be necessary for us to use the patented or proprietary technology of a third party to commercialize our own technology or products, in which case we would be required to obtain a license from that third party. A license to that intellectual property may not be available or may not be available on commercially reasonable terms, which could have an adverse effect on our business and financial condition.

The licensing and acquisition of third-party intellectual property rights is a competitive practice. Companies that may be more established or have greater resources than we do may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their larger size and cash resources or greater clinical development and commercialization capabilities. We may not be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to acquire.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have an adverse effect on the success of our business.

Our commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. There is considerable intellectual property litigation in the biopharmaceutical industry, as well as administrative proceedings for challenging patents, including interference, reexamination and *inter partes* review proceedings before the USPTO and oppositions and other comparable proceedings in foreign jurisdictions.

We may become party to or threatened with future adversarial proceedings or litigation regarding intellectual property rights with respect to our products and technology, including interference, derivation, reexamination or *inter partes* review proceedings before the USPTO. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. As the bio-pharmaceutical industry expands and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others. There may be third-party patents of which we are currently unaware with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our drug 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 we are found by a court of competent jurisdiction to infringe a third party's intellectual property rights, we could be required to obtain a license from the applicable third party intellectual property holder to continue developing and marketing our products and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

A number of other companies, as well as universities and other organizations, file and obtain patents in the same areas as our products, which are targeted protein degraders, and these patent filings could be asserted against us or our collaborators in the future, which could have an adverse effect on the success of our business and, if successful, could lead to expensive litigation that could affect the profitability of our products and/or prohibit the sale or use of our products.

Our MonoDAC and BiDAC product candidates are pharmaceutical small molecule targeted protein degraders. A number of companies and institutions have patent applications and issued patents in this general area, such as, for example, Arvinas, Inc., Kymera Therapeutics, LLC., the Dana-Farber Cancer Institute and its Center for Protein Degradation, Foghorn Therapeutics, Inc., Nurix Therapeutics, Inc., Roche, Novartis AG, Amgen Inc., AstraZeneca PLC, GlaxoSmithKline PLC and others. If any of these companies or institutions or others not included in this list were to assert that one of its patents is infringed by any product we might develop or its use or manufacture, we or our collaborators may be drawn into expensive litigation, which could adversely affect our business prospects, financial condition and results of operations, require extensive time from and cause the distraction of members of our management team and employees at large. Further, if litigation of this nature were successful, that could have a material and adverse effect on the profitability of our products or prohibit their sale. We may not be aware of patent claims that are currently or may in the future be pending that could affect our business or products. Patent applications are typical published between six and eighteen months from filing and the presentation of new claims in already pending applications can sometimes not be visible to the public, which would include us, for a period of time. In addition, even after a patent application is publicly available, we may not yet have seen that patent application and may, therefore, not be aware of the claims or scope of filed and published patent applications. As a result, we cannot provide any assurance that a third party practicing in the general area of our technology will not present or has not presented a patent claim that covers one or more of our products or their methods of use or manufacture. If that were to occur, we or our collaborators, as applicable, may have to take steps to try to invalidate the applicable patent or application and, in a situation of that nature, we or our collaborators may either choose not to do so or our attempt may not be successful. If we determine that we require a license to a third party's patent or patent application, we may discover that a license may not be available on reasonable terms, or at all.

Our products are subject to The Drug Price Competition and Patent Term Restoration Act of 1984, which is also referred to as the Hatch Waxman Act, in the United States, which can increase the risk of litigation with generic companies trying to sell our products and may cause us to lose patent protection.

Because our clinical candidates are pharmaceutical molecules that will be reviewed by the Center for Drug Evaluation and Research, CDER, of the FDA, after commercialization they will be subject in the United States to the patent litigation process of the Hatch-Waxman Act, as amended to date, which allows a generic company to submit an Abbreviated New Drug Application, or ANDA, to the FDA to obtain approval to sell a generic version of our drug using bioequivalence data only. Under amendments made to the Hatch-Waxman Act, we will have the opportunity to list our patents that cover our drug products or their respective methods of use in the FDA's compendium of "Approved Drug Products with Therapeutic Equivalence Evaluation," sometimes referred to as the FDA's Orange Book.

Currently, in the United States, the FDA may grant five years of exclusivity for new chemical entities, or NCEs, which are drugs that contain no active portion that has been approved by the FDA in any other NDA. We expect that all of our products will qualify as NCEs. A generic company can submit an ANDA to the FDA four years after approval of any of our drug products. The submission of an ANDA by a generic company is considered a technical act of patent infringement. The generic company can certify that it will wait until the natural expiration date of our listed patents to sell a generic version of our product or can certify that one or more of our listed patents are invalid, unenforceable or not infringed. If the generic manufacturer elects the latter, we will have 45 days to bring a patent infringement lawsuit against the generic company. If we were to do so, that would likely initiate a challenge to one or more of our Orange Book listed patents based on arguments from the generic manufacturer that our listed patents are invalid, unenforceable or not infringed. Under amendments to the Hatch-Waxman Act, if a lawsuit is brought, the FDA is prevented from issuing a final approval on the generic drug until 30 months after the end of the data

exclusivity period (7.5 years) or a final decision of a court holding that our asserted patent claims are invalid, unenforceable or not infringed. If we do not properly list our relevant patents in the Orange Book or if we fail to file a lawsuit in response to a certification from a generic company under an ANDA in a timely manner, or if we do not prevail in the resulting patent litigation, we can lose our ability to benefit from a proprietary market based on patent protection covering our drug products and we may find that physicians will switch to prescribing and dispensing generic versions of our drug products. Further, even if we were to list our relevant patents in the Orange Book correctly, bring a lawsuit in a timely manner and prevail in that lawsuit, the generic litigation may come at a significant cost to us, both in terms of attorneys' fees and employee time and distraction over a long period. Further, it is common for more than one generic company to try to sell an innovator's drug at the same time and, as a result, we may face the cost and distraction of multiple lawsuits from generic manufacturers at the same time. We may also determine that it is necessary to settle these types of lawsuits in a manner that allows the generic company to enter our market prior to the expiration of our patent or otherwise in a manner that adversely affects the strength, validity or enforceability of our patents.

A number of pharmaceutical companies have been the subject of intense review by the U.S. Federal Trade Commission or a corresponding agency in another country based on how they have conducted or settled patent litigation related to pharmaceutical products. In fact, certain reviews have led to an allegation of an anti-trust violation, sometimes resulting in a fine or loss of rights. We cannot be sure that we would not also be subject to a review of this nature or that the result of a review of this nature would be favorable to us, or that any review of this nature would not result in a fine or penalty.

The U.S. Federal Trade Commission, or FTC, has brought a number of lawsuits in federal court in the past few years to challenge ANDA litigation settlements reached between innovator companies and generic companies as anti-competitive. As an example, the FTC has taken an aggressive position that anything of value is a payment, whether money is paid or not. Under their approach, if an innovator, as part of a patent settlement, agrees not to launch or delay its launch of an authorized generic during the 180-day period granted to the first generic company to challenge an Orange Book listed patent covering an innovator drug, or negotiates a delay in entry without payment, the FTC may consider it an unacceptable reverse payment. Companies in the pharmaceutical industry have argued that these types of agreements are rational business decisions entered into by drug innovators as a way to address risk and that these settlements should, therefore, be immune from antitrust attack if the terms of the settlement are within the scope of the exclusionary potential of the patent. In 2013, the U.S. Supreme Court in a five-to-three decision in *FTC v. Actavis, Inc.* rejected both the pharmaceutical industry's and FTC's arguments with regard to so-called reverse payments. Instead, the Supreme Court held that whether a "reverse payment" settlement involving the exchange of consideration for a delay in entry is subject to an anti-competitive analysis depends on five considerations: (a) the potential for genuine adverse effects on competition; (b) the justification of payment; (c) the patentee's ability to bring about anti-competitive harm; (d) whether the size of the payment is a workable surrogate for the patent's weakness; and (e) that antitrust liability for large unjustified payments does not prevent litigating parties from settling their lawsuits, for example, by allowing the generic drug to enter the market before the patent expires on the branded drug without the patentee paying the generic manufacturer. Further, whether a reverse payment is justified depends upon its size, scale in relation to the patentee's anticipated future litigation costs, and independence from other services for which it might represent payment (as was the case in *Actavis*), as well as the lack of any other convincing justification. The Supreme Court instead held that reverse payment settlements can potentially violate antitrust laws and are subject to the standard antitrust rule-of-reason analysis, with the burden of proving that an agreement is unlawful on the FTC. In reaching this decision, the Supreme Court left to the lower courts the structuring of this rule of reason analysis.

If we are faced with drug patent litigation, including Hatch-Waxman litigation with a generic company, we could be faced with an FTC challenge of this nature, which challenge could impact how or whether we settle the case and, even if we strongly disagree with the FTC's position, we could face a significant expense or penalty. Any litigation settlements we enter into with generic companies under the Hatch-Waxman Act could also be challenged by third-party payors such as insurance companies, direct purchasers or others who consider themselves adversely affected by the settlement. These kinds of follow-on lawsuits, which may be class action suits, can be expensive and can continue over multiple years. If we were to face lawsuits of this nature, we may not be successful in defeating these claims and we may, therefore, be subject to large payment obligations, which we may not be able to satisfy in whole or in part.

We may not be able to obtain patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984 in the United States and, as a result, our product candidates, if approved, may not have patent protection for a sufficient period.

In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 permits one patent term extension of up to five years beyond the normal expiration of one patent per product, which if related to a method of treatment patent, is limited to the approved indication. The length of the patent term extension is typically calculated as one-half of the clinical trial period plus the entire period of time during the review of the new drug application, or NDA, by the FDA, minus any time of delay by us during these periods. There is also a limit on the patent term extension to a term that is no greater than fourteen years from drug approval. Therefore, if we select and are granted a patent term extension on a recently filed and issued patent, we may not receive the full benefit of a possible patent term extension, if at all. We might also not be granted a patent term extension at all, because of, for example, our failure to apply within the applicable period, failure to apply prior to the expiration of relevant patents or other failure to satisfy any of the numerous applicable requirements. Moreover, 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 extensions of this nature are available and may refuse to grant extensions to our patents or may grant more limited extensions than we request. If this occurs, our competitors may be able to obtain approval of competing products following our patent expiration by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case. If this were to occur, it could have an adverse effect on our ability to generate product revenue.

In 1997, as part of the Food & Drug Administration Modernization Act, or FDAMA, Congress enacted a law that provides incentives to drug manufacturers who conduct studies of drugs in children. The law, which provides six-months exclusivity in return for conducting pediatric studies, is referred to as the “pediatric exclusivity provision.” If we were to conduct clinical trials that comply with the FDAMA, we could receive an additional six-month term added to our regulatory data exclusivity period and on the patent term extension period, if received, on our product. However, if we choose not to carry out pediatric studies that comply with the FDAMA, or carry out studies that are not accepted by the FDA for this purpose, we would not receive this additional six-month exclusivity extension to our data exclusivity or our patent term extension.

In Europe, supplementary protection certificates are available to extend a patent term up to five years to compensate for patent term lost during regulatory review, and this period can be extended to five and a half years if data from clinical trials is obtained in accordance with an agreed Pediatric Investigation Plan. Although all countries in Europe must provide supplementary protection certificates, there is no unified legislation among European countries and, as a result, drug developers must apply for supplementary protection certificates on a country-by-country basis. As a result, a company may need to expend significant resources to apply for and receive these certificates in all relevant countries and may receive them in some, but not all, countries, if at all.

Weakening patent laws and enforcement by courts in the United States and foreign countries may impact our ability to protect our markets.

The U.S. Supreme Court has issued opinions in patent cases in the last few years that many consider may weaken patent protection in the United States, either by narrowing the scope of patent protection available in certain circumstances, holding that certain kinds of innovations are not patentable or generally otherwise making it easier to invalidate patents in court. Additionally, there have been recent proposals for additional changes to the patent laws of the United States and other countries that, if adopted, could impact our ability to obtain patent protection for our proprietary technology or our ability to enforce our proprietary technology. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

The laws of some foreign jurisdictions do not protect intellectual property rights to the same extent as in the United States and many companies have encountered significant difficulties in protecting and defending such rights in foreign jurisdictions. If we encounter such difficulties in protecting or are otherwise precluded from effectively protecting our intellectual property rights in foreign jurisdictions, our business prospects could be substantially harmed. For example, we could become a party to foreign opposition proceedings, such as at the European Patent Office, or patent litigation and other proceedings in a foreign court. If so, uncertainties resulting from the initiation and continuation of such proceedings could have an adverse effect on our ability to compete in the marketplace. The cost of foreign adversarial proceedings can also be substantial, and in many foreign jurisdictions, the losing party must pay the attorney fees of the winning party.

We may be subject to claims by third parties asserting that we, our employees, consultants or contractors have misappropriated the applicable third party’s intellectual property or claiming ownership of what we regard as our own intellectual property.

We employ individuals who were previously employed at universities as well as other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We have received confidential and proprietary information from collaborators, prospective licensees and other third parties. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these employees or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee’s former employer. We may also be subject to claims that former employers or other third parties have an ownership interest in our patents. Litigation may be necessary to defend against these claims. We may not be successful 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, such as exclusive ownership of or right to use valuable intellectual property. Even if we are successful, litigation could result in substantial cost and reputational loss and be a distraction to our management and other employees.

In addition, while it is our policy to require our employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning any resulting intellectual property to us, we may be unsuccessful in executing an agreement to that effect with each party who in fact develops intellectual property that we regard as our own. Assignment agreements of this nature 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. In addition, an employee or contractor could create an invention but not inform us of it, in which case we could lose the benefit of the invention and the employee or contractor may leave to develop the invention elsewhere.

Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

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 have a substantial adverse effect on the price of our common stock. Litigation or proceedings of this nature 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 litigation or proceedings of this nature more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

Obtaining and maintaining patent protection depends on compliance with various procedural, documentary, fee payment and other requirements imposed by governmental patent offices and the protection of our patents could be reduced or eliminated if we fail to comply with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and patent offices in foreign countries in several stages over the lifetime of the patent. The USPTO and patent offices in foreign countries require compliance with many procedural, documentary, fee payment and other requirements 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 a patent or patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market, which would have an adverse effect on our business.

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 some of our technology and 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 these 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. These agreements may not effectively prevent disclosure of confidential information nor result in the effective assignment to us of intellectual property and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information or other breaches of the agreements. In addition, others may independently discover our trade secrets and proprietary information. In that case, we could not assert any trade secret rights against that third party. 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. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming and the outcome of a dispute of this nature is inherently unpredictable. Costly and time-consuming litigation could be necessary to seek to enforce and determine the scope of our proprietary rights and our failure to obtain or maintain trade secret protection could adversely affect our competitive business position. In addition, some courts outside of the United States are less willing or unwilling to protect trade secrets. The Defend Trade Secrets Act of 2016 is a U.S. federal law that allows an owner of a trade secret to sue in federal court when its trade secret has been misappropriated. Congress passed this law in an attempt to strengthen the rights of trade secret owners whose valuable assets are taken without authorization. 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 them, 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.

We only have limited geographical protection with respect to certain of our patents and we may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents covering our product candidates in all countries throughout the world would be prohibitively expensive. As a result, our intellectual property rights in some countries outside the United States can be less extensive than the protection we might have in the United States. In-licensing patents covering our product candidates in all countries throughout the world may similarly be prohibitively expensive, if these in-licensing opportunities are available to us at all. Further, in-licensing or filing, prosecuting and defending patents even in only those jurisdictions in which we develop or commercialize our product candidates may be prohibitively expensive or impractical. Competitors may use our and our licensors' technologies in jurisdictions where we have not obtained patent protection or licensed patents to develop their own products and, further, may export otherwise infringing products to territories where we and our licensors have patent protection, but enforcement is not as strong as that in the United States or the European Union. These products may compete with our product candidates, and our or our licensors' patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

In addition, we may decide to abandon national and regional patent applications while they are still pending. The grant proceeding of each national or regional patent is an independent proceeding that may lead to situations in which applications may be rejected by the relevant patent office, while substantively similar applications are granted by others. For example, relative to other countries, China has a heightened detailed description requirement for patentability. Further, generic drug manufacturers or other competitors may challenge the scope, validity or enforceability of our or our licensors' patents, requiring us or our licensors to engage in complex, lengthy and costly litigation or other proceedings. Generic drug manufacturers may develop, seek approval for and launch generic versions of our products. It is also quite common that depending on the country, the scope of patent protection may vary for the same product candidate or technology.

The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws or regulations in the United States and the European Union, and many companies have encountered significant difficulties in protecting and defending proprietary rights in such jurisdictions. Moreover, the legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets or other forms of intellectual property, which could make it difficult for us to prevent competitors in some jurisdictions from marketing competing products in violation of our proprietary rights generally.

Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, are likely to result in substantial costs and divert our efforts and attention from other aspects of our business and could additionally put our or our licensors' patents at risk of being invalidated or interpreted narrowly, could increase the risk of our or our licensors' patent applications not issuing or could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, while damages or other remedies may be awarded to the adverse party, which may be commercially significant. If we prevail, damages or other remedies awarded to us, 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 or license. Further, while we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our product candidates. Accordingly, our efforts to protect our intellectual property rights in these countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize our product candidates in all of our expected significant foreign markets. If we or our licensors encounter difficulties in protecting or are otherwise precluded from effectively protecting the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished and we may face additional competition in those jurisdictions.

In some jurisdictions, compulsory licensing laws compel patent owners to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors are forced to grant a license to third parties under patents relevant to our business, or if we or our licensors are prevented from enforcing patent rights against third parties, our competitive position may be substantially impaired in such jurisdictions.

Risks Related to Regulatory Matters

The regulatory approval processes of the FDA and foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable and, if we are ultimately unable to obtain marketing approval for our product candidates, our business will be substantially harmed.

The time required to obtain approval by the FDA and foreign regulatory authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained marketing approval for any product candidate and it is possible that none of our existing product candidates, or any product candidates we may seek to develop in the future, will ever obtain marketing approval.

Our product candidates could fail to receive marketing approval for many reasons, including the following:

- the FDA may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA that a product candidate is safe and effective for its proposed indication;
- results of clinical trials may not meet the level of statistical significance required by the FDA for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA may disagree with our interpretation of data from preclinical studies or clinical trials;
- data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA to the FDA or other submission or to obtain marketing approval in the United States;
- the FDA may find deficiencies with or fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, results of operations and prospects. The FDA has substantial discretion in the approval process and determining when or whether regulatory approval will be obtained for any of our product candidates. Even if we believe the data collected from clinical trials of our product candidates are promising, such data may not be sufficient to support approval by the FDA.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

Even if we obtain FDA approval for any of our product candidates in the United States, we may never obtain approval for or commercialize any of them in any other jurisdiction, which would limit our ability to realize their full market potential.

In order to market any products in any particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a country-by-country basis regarding safety and efficacy.

Approval by the FDA in the United States does not ensure approval by regulatory authorities in other countries or jurisdictions. However, the failure to obtain approval in one jurisdiction may negatively impact our ability to obtain approval elsewhere. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country.

Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and increased costs for us and require additional preclinical studies or clinical trials which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. We do not have any product candidates approved for sale in any jurisdiction, including in international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of any product we develop will be unrealized.

Even if we receive regulatory approval of any product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

If any of 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. In addition, we will be subject to continued compliance with cGMP and GCP requirements for any clinical trials that we conduct post-approval.

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 cGMP and adherence to commitments made in any NDA, other marketing application and previous responses to inspection observations. 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.

Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials and surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a REMS program as a condition of approval of our product candidates, which could entail requirements for long-term patient follow-up, a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Comparable foreign regulatory authorities may also have programs similar to REMS. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, we will have to comply with requirements including submissions of safety and other post-marketing information and reports and registration.

The FDA may impose consent decrees or withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals;
- product seizure or detention or refusal to permit the import or export of our product candidates; and
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Products may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses and a company that is found to have improperly promoted off-label uses may be subject to significant liability. However, physicians may, in their independent medical judgment, prescribe legally available products for off-label uses. The FDA does not regulate the behavior of physicians in their choice of treatments, but the FDA does restrict manufacturer's communications on the subject of off-label use of their products. The policies of the FDA and of comparable foreign regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. 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 are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

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 Breakthrough Therapy designation for our CFT7455 and CFT8634 product candidates and some or all of our future product candidates. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For product candidates that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA may also be eligible for other expedited approval programs, including accelerated approval.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if 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 candidate products considered for approval under non-expedited FDA review procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the product no longer meets the conditions for qualification. Thus, even though we intend to seek Breakthrough Therapy designation for CFT7455 and CFT8634 and some or all of our future product candidates for the treatment of various cancers, there can be no assurance that we will receive breakthrough therapy designation.

A Fast Track designation by the FDA, even if granted for CFT7455 and/or CFT8634, or any of our other current or future 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.

We may seek Fast Track designation for one or more of our future 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 FDA Fast Track designation for a particular indication. We may seek Fast Track designation for CFT7455 and/or CFT8634 and certain of our future product candidates, but there is no assurance that the FDA will grant this status to any of our proposed product candidates. Marketing applications filed by sponsors of products in Fast Track development may qualify for priority review under the policies and procedures offered by the FDA, but the Fast Track designation does not assure any such qualification or ultimate marketing approval by the FDA. The FDA has broad discretion whether or not to grant Fast Track designation, so even if we believe a particular product candidate is eligible for this designation, there can be no assurance that the FDA would decide to grant it. Even if we do receive Fast Track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures, and receiving a Fast Track designation does not provide assurance of ultimate FDA approval. In addition, the FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program. In addition, the FDA may withdraw any Fast Track designation at any time.

If we decide to seek Orphan Drug Designation for any of our current or future product candidates, we may be unsuccessful or may be unable to maintain the benefits associated with Orphan Drug Designation, including the potential for supplemental market exclusivity.

We may seek Orphan Drug Designation for one or more of our current or future product candidates. Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may grant orphan designation to a drug intended to treat a rare disease or condition, defined as a disease or condition with a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States when there is no reasonable expectation that the cost of developing and making available the drug in the United States will be recovered from sales in the United States for that drug. In the United States, Orphan Drug Designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. After the FDA grants Orphan Drug Designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan Drug Designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

If a product that has Orphan Drug Designation subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including an NDA, to market the same drug for the same indication for seven years, except in limited circumstances such as a showing of clinical superiority to the product with orphan drug exclusivity or if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. As a result, even if one of our product candidates receives orphan exclusivity, the FDA can still approve other drugs that have a different active ingredient for use in treating the same indication or disease. Further, the FDA can waive orphan exclusivity if we are unable to manufacture sufficient supply of our product.

We may seek Orphan Drug Designation for CFT7455, CFT8634 and some or all of our other current or future product candidates in additional orphan indications in which there is a medically plausible basis for the use of these product candidates. Even when we obtain Orphan Drug Designation, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan designated indication and may be lost if the FDA later determines that the request for designation was materially defective or if we, through our manufacturer, are unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. In addition, although we intend to seek orphan drug designation for other product candidates, we may never receive these designations. For example, the FDA has expressed concerns regarding the regulatory considerations for orphan drug designation as applied to tissue agnostic therapies, and the FDA may interpret the Federal Food, Drug and Cosmetic Act, and regulations promulgated thereunder, in a way that limits or blocks our ability to obtain orphan drug designation or orphan drug exclusivity, if our product candidates are approved, for our targeted indications.

Accelerated approval by the FDA, even if granted for CFT7455 and/or CFT8634, or any other current or future 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 plan to seek accelerated approval of CFT7455 and CFT8634 and may seek approval of future product candidates using the FDA's accelerated approval pathway. A product may be eligible for accelerated approval if it treats a serious or life-threatening condition and generally provides a meaningful advantage over available therapies. In addition, it must demonstrate an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform adequate and well controlled post-marketing clinical trials. These confirmatory trials must be completed with due diligence. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. Even if we do receive accelerated approval, we may not experience a faster development or regulatory review or approval process. Further, receiving accelerated approval does not provide assurance of ultimate full FDA approval.

Our relationships with customers, physicians and third-party payors are subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, health information privacy and security laws and other healthcare laws and regulations. If we are unable to comply or have not fully complied with these laws, we could face substantial penalties.

Healthcare providers, physicians and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors subject us to various federal and state fraud and abuse laws and other healthcare laws that may constrain the business or financial arrangements and relationships through which we research, sell, market and distribute our product candidates, if we obtain marketing approval. In particular, the research of our product candidates, as well as the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business or financial arrangements.

Ensuring that our business arrangements with third parties comply with applicable healthcare laws and regulations will likely be costly. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participating in government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, contractual damages, reputational harm and the curtailment or restructuring of our operations. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

If the physicians or other providers or entities with whom we expect to do business are found not to be in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Even if resolved in our favor, litigation or other legal proceedings relating to healthcare laws and regulations 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. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Litigation or proceedings of this nature could substantially increase our operating losses and reduce the resources available for development, manufacturing, sales, marketing or distribution activities. Uncertainties resulting from the initiation and continuation of litigation or other proceedings relating to applicable healthcare laws and regulations could have an adverse effect on our ability to compete in the marketplace.

The successful commercialization of our product candidates in the United States will depend in part on the extent to which third-party payors, including governmental authorities and private health insurers, provide coverage and adequate reimbursement levels, as well as implement pricing policies favorable for our product candidates. 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.

Significant uncertainty exists as to the coverage and reimbursement status of any products for which we may obtain regulatory approval. In the United States and in other countries, patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. The availability of coverage and adequacy of reimbursement for our products by third-party payors, including government health care programs (e.g., Medicare, Medicaid or TRICARE), managed care providers, private health insurers, health maintenance organizations and other organizations is essential for most patients to be able to afford medical services and pharmaceutical products such as our product candidates. Third-party payors decide which medications they will pay for and establish reimbursement levels.

In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services, or HHS. CMS decides whether and to what extent our products will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. Factors payors consider in determining reimbursement are based on whether the product is:

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

Our ability to successfully commercialize our product candidates will depend in part on the extent to which coverage and adequate reimbursement for our products and related treatments will be available from third-party payors. Moreover, a payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. If coverage and adequate reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment. A decision by a third-party payor not to cover or not to separately reimburse for our medical products or therapies using our products could reduce physician utilization of our products once approved. We cannot be sure that coverage and reimbursement in the United States will be available for our current or future product candidates or for any procedures using our current or future product candidates, and any reimbursement that may become available may not be adequate or may be decreased or eliminated in the future.

In the United States, no uniform policy for coverage and reimbursement for products exists among third-party payors. Therefore, coverage and reimbursement for our products can differ significantly from payor to payor. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the reimbursement rate that the payor will pay for the product. One payor's determination to provide coverage for a product does not assure that other payors will also provide coverage and reimbursement for the product. Third-party payors may also limit coverage to specific products on an approved list, or formulary, which might not include all of the FDA-approved products for a particular indication. We cannot be sure that coverage and reimbursement will be available for or accurately estimate the potential revenue from our product candidates or assure that coverage and reimbursement will be available for any product that we may develop.

Further, increasing efforts by third-party payors in the United States and abroad to cap or reduce healthcare costs may cause payor 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. In order to secure coverage and reimbursement for any product that might be approved for sale, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain FDA or comparable regulatory approvals. Additionally, we may also need to provide discounts to purchasers, private health plans or government healthcare programs. Our product candidates may nonetheless not be considered medically necessary or cost-effective. If third-party payors do not consider a product to be cost-effective compared to other available therapies, they may not cover the product after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow a company to sell its products at a profit. We expect to experience pricing pressures from third-party payors in connection with the potential sale of any of our product candidates.

Lastly, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, countries in the EU Member States can restrict the range of medicinal products for which their national health insurance systems provide reimbursement and they can control the prices of medicinal products for human use. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. An EU Member State may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Approaches between EU Member States are diverging. For example, in France, effective market access will be supported by agreements with hospitals and products may be reimbursed by the Social Security Fund. The price of medicines is negotiated with the Economic Committee for Health Products. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our product candidates. Historically, products launched in the European Union do not follow price structures of the United States and generally prices in the European Union tend to be significantly lower than prices in the United States.

Enacted and future healthcare legislation may increase the difficulty and cost for us to progress our clinical programs and obtain marketing approval of and commercialize our product candidates and may affect the prices we may set.

In the United States and other jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, in March 2010, the Affordable Care Act, or the ACA, was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers. Among the provisions of the ACA, those of greatest importance to the pharmaceutical and biotechnology industries include the following:

- an annual, non-deductible fee payable by any entity that manufactures or imports certain branded prescription drugs and biologic agents (other than those designated as orphan drugs), which is apportioned among these entities according to their market share in certain government healthcare programs;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- a licensure framework for follow-on biologic products;
- creation of a new Patient-Centered Outcomes Research Institute to oversee and conduct comparative clinical effectiveness research, as well as funding for such research; and
- establishment of a Center for Medicare & Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

There remain judicial, Congressional and executive branch challenges to certain aspects of the ACA and we expect there will be additional challenges and amendments to the ACA in the future. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the ACA such as removing penalties, starting January 1, 2019, for not complying with the ACA's individual mandate to carry health insurance and increasing the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D. Further, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. On December 14, 2018, a U.S. District Court Judge in Texas ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Cuts and Jobs Act. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit ruled that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case and has allotted one hour for oral arguments. Oral arguments on this case are yet to be held. It is also unclear how such litigation and other efforts to repeal and replace the ACA will impact the ACA and our business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, led to aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030 unless additional action is taken by Congress. However, pursuant to the CARES Act, these Medicare sequester reductions have been suspended from May 1, 2020 through December 31, 2020 due to the COVID-19 pandemic. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Additionally, the Bipartisan Budget Act of 2018, or BBA, among other things, amended the ACA, effective January 1, 2019, by increasing the point-of-sale discount (from 50% under the ACA to 70%) that is owed by pharmaceutical manufacturers who participate in Medicare Part D and closing the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." These new laws or any other similar laws introduced in the future may result in additional reductions in Medicare and other health care funding, which could negatively affect our customers and accordingly, our financial operations.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as bundled payment models. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare and review the relationship between pricing and manufacturer patient programs. The Trump administration's budget proposal for fiscal year 2021 includes a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the Trump administration sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses and place limits on pharmaceutical price increases. On May 11, 2018, President Trump laid out his administration's "Blueprint" to lower drug prices and reduce out-of-pocket costs of prescription drugs that contained proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. HHS has solicited feedback on some of these measures and has implemented others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage plans the option to use step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. The Trump administration's recent budget proposal for fiscal year 2021 includes a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. Although such measures may require additional authorization to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

Individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could adversely affect our business prospects, financial condition and results of operations. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our product candidates or put pressure on our product pricing.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the extent to which state and federal governments cover particular healthcare products and services and could limit the amounts that the federal and state governments will pay for healthcare products and services. This could result in reduced demand for any product candidate we develop or could result in additional pricing pressures.

In markets outside of the United States, reimbursement and healthcare payment systems vary significantly by country and many countries have instituted price ceilings on specific products and therapies. The price control regulations outside of the United States can have a significant impact on the profitability of a given market, and further uncertainty is introduced if and when these laws change. For example, in Canada, price control legislation for patented medicines is currently undergoing significant change that may have significant effects on profitability for companies selling products in Canada.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the United States or any other jurisdiction. It is possible that additional governmental action will be taken to address the COVID-19 pandemic. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or these third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

We may face potential liability under the applicable privacy laws if we obtain identifiable patient health information from clinical trials sponsored by us.

Most healthcare providers, including certain research institutions from which we may obtain patient health information, are subject to privacy and security regulations promulgated under the Health Insurance Portability and Accountability Act of 1966, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH. We are not currently classified as a covered entity or business associate under HIPAA and thus are not directly subject to its requirements or penalties. However, any person may be prosecuted under HIPAA's criminal provisions either directly or under aiding-and-abetting or conspiracy principles. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a HIPAA-covered healthcare provider or research institution that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information. In addition, in the future, we may maintain sensitive personally identifiable information, including health information, that we receive throughout the clinical trial process, in the course of our research collaborations and/or directly from individuals (or their healthcare providers) who may enroll in patient assistance programs if we choose to implement these types of programs. As a result, we may be subject to state laws requiring notification of affected individuals and state regulators in the event of a breach of personal information, which is a broader class of information than the health information protected by HIPAA.

The global data protection landscape is rapidly evolving and we may be or become subject to or affected by numerous federal, state and foreign laws and regulations, as well as regulatory guidance, governing the collection, use, disclosure, transfer, security and processing of personal data, such as information that we collect about participants and healthcare providers in connection with clinical trials. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, which may create uncertainty in our business, affect our or our service providers' ability to operate in certain jurisdictions or to collect, store, transfer use and share personal data, result in liability or impose additional compliance or other costs on us. Any failure or perceived failure by us to comply with federal, state or foreign laws or self-regulatory standards could result in negative publicity, diversion of management time and effort and proceedings against us by governmental entities or others. Recently, California passed the California Data Privacy Protection Act of 2018, or the CCPA, which went into effect in January 2020. The CCPA provides new data privacy rights for consumers and new operational requirements for companies, including placing increased privacy and security obligations on entities handling certain personal data of consumers or households. These requirements could increase our compliance costs and potential liability. 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 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. While there is currently an exception for protected health information that is subject to HIPAA and clinical trial regulations, as currently written, the CCPA may impact certain of our business activities. The new California law may lead to similar laws in other U.S. states or at a national level, which could increase our potential liability and adversely affect our business, which exemplifies the vulnerability of our business to the evolving regulatory environment related to personal data and protected health information.

The EU General Data Protection Regulation, or GDPR, also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies and obtain compensation for damages resulting from violations of the GDPR. In addition, the GDPR includes restrictions on cross-border data transfers. The GDPR may increase our responsibility and liability in relation to personal data that we process where that processing is subject to the GDPR. In addition, we may be required to put in place additional mechanisms to ensure compliance with the GDPR, including GDPR requirements as implemented by individual countries. Compliance with the GDPR will be a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices. Despite those efforts, there is a risk that we may be subject to fines and penalties, litigation and reputational harm in connection with our European activities.

European data protection laws also generally prohibit the transfer of personal data from Europe, including the European Economic Area, United Kingdom and Switzerland, to the United States and most other countries unless the parties to the transfer have implemented specific safeguards to protect the transferred personal data. One of the primary safeguards used for transfers of personal data from the European Union to the United States, namely, the Privacy Shield framework administered by the U.S. Department of Commerce, was recently invalidated by a decision of the European Union's highest court. The same decision also cast doubt on the ability to use one of the primary alternatives to the Privacy Shield, namely, the European Commission's Standard Contractual Clauses, to lawfully transfer personal data from Europe to the United States and most other countries. At present, there are few if any viable alternatives to the Privacy Shield and the Standard Contractual Clauses. To the extent that we were to rely on the EU-U.S. Privacy Shield Framework or the Standard Contractual Clauses, we may not be able to do so in the future, which could increase our costs and limit our ability to process personal data from the European Union.

Further, Brexit has created uncertainty with regard to data protection regulation in the United Kingdom. In particular, while the Data Protection Act of 2018, that "implements" and complements the GDPR achieved Royal Assent on May 23, 2018 and is now effective in the United Kingdom, it is still unclear whether transfer of data from the EEA to the United Kingdom will remain lawful under the GDPR. During the period of "transition" (i.e., until December 31, 2020), EU law will continue to apply in the United Kingdom, including the GDPR, after which the GDPR will be converted into UK law. Beginning in 2021, the United Kingdom will be a "third country" under the GDPR. We may, however, incur liabilities, expenses, costs and other operational losses under the GDPR and applicable EU Member States and the UK privacy laws in connection with any measures we take to comply with them.

Further, certain health privacy laws, data breach notification laws, consumer protection laws and genetic testing laws may apply directly to our operations and/or those of our collaborators and may impose restrictions on our collection, use and dissemination of individuals' health information. Patients about whom we or our collaborators may obtain health information, as well as the providers who may share this information with us, may have statutory or contractual rights that limit our ability to use and disclose the information. We may be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws. Claims that we have violated individuals' privacy rights 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 harm our business.

If we or third-party CMOs, CROs or other contractors or consultants fail to comply with applicable federal, state/provincial or local regulatory requirements, we could be subject to a range of regulatory actions that could affect our or our contractors' ability to develop and commercialize our therapeutic candidates and could harm or prevent sales of any affected therapeutics that we are able to commercialize, or could substantially increase the costs and expenses of developing, commercializing and marketing our therapeutics. Any threatened or actual government enforcement action could also generate adverse publicity and require that we devote substantial resources that could otherwise be used in other aspects of our business. Increasing use of social media could give rise to liability, breaches of data security or reputational damage.

Additionally, we are subject to state and foreign equivalents of each of the healthcare laws described above, among others, some of which may be broader in scope and may apply regardless of the payor.

If we or our third-party manufacturers and suppliers fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have an adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our research and development activities involve the use of biological and hazardous materials and produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. Upon an event of this nature, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Further, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of any changes of this nature and cannot be certain of our future compliance. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials or other work-related injuries, this insurance may not provide adequate coverage against potential liabilities. We do not carry specific biological waste or hazardous waste insurance coverage, workers compensation or property and casualty and general liability insurance policies that include coverage for damages and fines arising from biological or hazardous waste exposure or contamination.

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, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act of 2001 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 for clinical trials outside of the United States, to sell our products abroad once we enter a commercialization phase and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals. We may also 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 these 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 Employee Matters, Managing Growth and Operational Matters

We are highly dependent on our key personnel and anticipate hiring new key personnel. If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific, medical personnel, sales and marketing and other personnel. We are highly dependent on our management, scientific and medical personnel, including our President and Chief Executive Officer, our Chief Scientific Officer, our Chief Medical Officer, our Chief Financial Officer and our Chief Legal Officer. Our Chief Financial Officer is presently a consultant. While we expect to engage in an orderly transition process as we integrate newly appointed officers and managers, we face a variety of risks and uncertainties relating to management transition, including diversion of management attention from business concerns, failure to retain other key personnel or loss of institutional knowledge. In addition, the loss of the services of any of our executive officers, other key employees and other scientific and medical advisors, and an inability to find suitable replacements could result in delays in product development and harm our business.

We conduct our operations at our facilities in Watertown, Massachusetts. The Massachusetts region is headquarters to many other biopharmaceutical companies and many academic and research institutions. Competition for skilled personnel in our market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all. Changes to U.S. immigration and work authorization laws and regulations, including those that restrain the flow of scientific and professional talent, can be significantly affected by political forces and levels of economic activity. Our business may be materially adversely affected if legislative or administrative changes to immigration or visa laws and regulations impair our hiring processes and goals or projects involving personnel who are not U.S. citizens. For example, the president's Proclamation Suspending Entry of Aliens Who Present a Risk to the U.S. Labor Market Following the Coronavirus Outbreak, which was issued in June 2020, may adversely affect our ability to hire and retain highly qualified personnel who are not U.S. citizens or permanent residents.

To encourage valuable employees to remain at our company, in addition to salary and cash incentives, we have provided stock options that vest over time. The value to our employees of stock options that vest over time may be significantly affected by movements in our stock price that are beyond our control and may, at any time, be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Although we have employment agreements with our executive employees, these employment agreements provide for at-will employment, which means that any of our executive employees could leave our employment at any time, with or without notice. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers, as well as junior, mid-level and senior scientific, medical and general and administrative personnel.

In addition, we have scientific and clinical advisors who assist us in formulating our development and clinical strategies. These advisors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. In addition, our advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with ours.

We will need to grow the size of our organization and we may experience difficulties in managing this growth, which could disrupt our operations.

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, manufacturing, regulatory affairs and, if any of our product candidates receives marketing approval, sales, marketing and distribution. In addition, in connection with our transition to being a publicly traded company, we expect to increase the size of our general and administrative teams to support the growth of our business and the requirements of being a publicly traded company. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical and FDA review process for CFT7455, CFT8634 and any other product candidates we develop, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to advance into clinical development and, if approved, commercialize CFT7455, CFT8634 and any of our other product candidates we develop will depend, in part, on our ability to effectively manage any future growth. Due to our limited financial resources and the limited experience of our management team in managing a company with this type of anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations. Further, research at our Indian CROs also exposes us to various risks, including regulatory, economic and political instability, potentially unfavorable tax, import and export policies, fluctuations in foreign exchange and inflation rates, international and civil hostilities, terrorism, natural disasters and pandemics.

Our internal computer systems, or those of any of our collaborators, contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs.

Our internal computer systems and those of any collaborators, contractors or consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any material system failure, accidents or security breaches of this nature to date, if an event of this nature were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our marketing approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications or the inappropriate disclosure of confidential or proprietary information, we could incur liability, our competitive position could be harmed and the further development and commercialization of our product candidates could be delayed. Additionally, we may have data security obligations with respect to the information of third parties that we store. Unauthorized access or use of any third-party data or information of this nature could result in fines or other penalties that may impact our relationships with these third parties and our operations.

Our employees, independent contractors, vendors, principal investigators, CROs and consultants may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading laws.

We are exposed to the risk that our employees, independent contractors, vendors, principal investigators, CROs and consultants may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include, among other things:

- intentional, reckless or negligent conduct or disclosure of unauthorized activities to us that violate the regulations of the FDA or similar foreign regulatory authorities;
- healthcare fraud and abuse laws and regulations in the United States and abroad;
- violations of United States federal securities laws relating to trading in our common stock; and
- failures to report financial information or data accurately.

In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations regulate a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Other forms of misconduct could involve the improper use of information obtained in the course of clinical trials or creating fraudulent data in our preclinical studies or clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of business conduct and ethics and other corporate governance and compliance documents, policies and charters applicable to all of our employees. However, it is not always possible to identify and deter misconduct by employees and other third parties. Further, the precautions we take to detect and prevent this type of 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 these laws or regulations. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. If any actions of this nature 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, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings and curtailment of our operations, any of which could adversely affect our business prospects, financial condition and results of operations.

Risks Related to Our Common Stock

If we determine to raise additional capital in the future, you would suffer dilution of your investment.

We may choose to raise additional capital in the future through the sale of shares or other securities convertible into shares, depending on market conditions, strategic considerations and operational requirements. To the extent we raise additional capital in this manner, our stockholders will be diluted. Future issuances of our common stock or other equity securities, or the perception that sales of this nature may occur, could adversely affect the trading price of our common stock and impair our ability to raise capital through future offerings of shares or equity securities. No prediction can be made as to the effect, if any, that future sales of common stock or the availability of common stock for future sales will have on the trading price of our common stock.

We do not know whether an active, liquid and orderly trading market will develop for our common stock or what the market price of our common stock will be and, as a result, it may be difficult for you to sell your shares of our common stock.

Prior to our initial public offering, there was no public trading market for shares of our common stock. Although our common stock is listed on The Nasdaq Global Select Market, an active trading market for our shares may never develop or be sustained. You may not be able to sell your shares quickly or at the market price if trading in shares of our common stock is not active. Further, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic partnerships or acquire companies or products by using our shares of common stock as consideration.

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

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us, our business or the targeted protein degradation space. 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 common stock could be impacted negatively. In the event we obtain securities or industry analyst coverage, if any of the analysts who cover us were to issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our preclinical studies and future clinical trials and results of operations fail to meet the expectations of any of these analysts, our stock price would likely decline. If one or more of these covering analysts were to 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 a decline in our stock price or trading volume.

The price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock.

The trading price of shares of our common stock is likely to be volatile and subject to wide fluctuations in response to various factors, some of which we cannot control. The stock market in general, and the market for smaller biopharmaceutical companies in particular, have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your common stock at or above the price at which you acquired it. The market price for our common stock may be influenced by many factors, including:

- the degree of success of competitive products or technologies;
- results of preclinical studies and clinical trials of our product candidates or those of our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire or in-license additional technologies or product candidates;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- effects of public health crises, pandemics and epidemics, such as COVID-19;
- general economic, industry and market conditions; and
- the other factors described in this “Risk Factors” section.

If any of the foregoing matters were to occur or if our operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. In the past, following periods of volatility in the market price of a company’s securities, securities class-action litigation often has been instituted against that company. Litigation of this nature, if instituted against us, could cause us to incur substantial costs to defend these claims and divert management’s attention and resources, which could seriously harm our business, financial condition, results of operations and prospects. Further, our director and officer liability insurance cost may increase as a result of litigation of this nature and our insurance deductible may be significant before our insurers are required to provide any coverage to us.

We have broad discretion in the use of the capital we have raised and may not use them effectively.

Our management will have broad discretion in the application of the net proceeds from our prior financings, including our initial public offering, and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common stock. The failure by our management to apply these funds effectively could result in financial losses that could have an adverse effect on our business, cause the price of our common stock to decline and delay the development of our product candidates. Pending their use, we may invest the net proceeds from our prior financing activities in a manner that does not produce income or that loses value.

Our executive officers, directors and principal stockholders will have the ability to control or significantly influence matters submitted to stockholders for approval.

Our executive officers and directors, combined with our stockholders who have reported through filings made with the Securities and Exchange Commission that they own more than 5% of our outstanding common stock, in the aggregate, beneficially own shares representing approximately 10,324,057 of our capital stock as of the closing of our initial public offering on October 6, 2020. As a result, our executive officers and directors, combined with our greater than 5% stockholders, have the ability to control us through this ownership position. As a result, these stockholders, if acting together, will continue to control matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would control the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of ownership control may:

- delay, defer or prevent a change in control;
- entrench our management and the board of directors; or
- impede a merger, consolidation, takeover or other business combination involving us that other stockholders may desire.

Anti-takeover provisions under our charter documents and Delaware law could delay or prevent a change of control, which could limit the market price of our common stock and may prevent or frustrate attempts by our stockholders to replace or remove our current management.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- a board of directors divided into three classes serving staggered three-year terms, the result of which is that not all members of the board will be elected at one time;

- a prohibition on stockholder action through written consent, the result of which is that all stockholder actions will have to be taken at a meeting of our stockholders;
- a requirement that special meetings of stockholders be called only by the board of directors acting pursuant to a resolution approved by the affirmative vote of a majority of the directors then in office;
- advance notice requirements for stockholder proposals and nominations for election to our board of directors;
- a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two-thirds of all outstanding shares of our voting stock then entitled to vote in the election of directors;
- a requirement of approval of not less than two-thirds of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our certificate of incorporation; and
- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporate Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These antitakeover provisions and other provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors and could also delay or impede a merger, tender offer or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

A significant portion of our total outstanding shares are eligible to be sold into the market in the near future, which could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. As of October 6, 2020, 31,855,560 shares of our outstanding common stock are currently restricted as a result of securities laws or lock-up agreements but will become eligible to be sold at various times in the future. Further, securityholders holding an aggregate of 30,694,163 shares of our common stock outstanding or issuable upon the exercise of outstanding options have rights, subject to specified conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We have also registered all shares of common stock that we may issue under our equity compensation plans, which means that those shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates and the lock-up agreements signed by holdings of our securities prior to our initial public offering.

We are an "emerging growth company" and a "smaller reporting company," and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies or smaller reporting companies will make our common stock less attractive to investors.

We are an "emerging growth company," or EGC, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. We will remain an EGC until the earlier of: (1) the last day of the fiscal year in which we have total annual gross revenue of $1.07 billion or more; (2) the last day of 2025; (3) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years; and (4) the date on which we are deemed to be a large accelerated filer under the rules of the SEC, which means the last day of the first year in which the market value of our common stock that is held by non-affiliates exceeds $700 million as of June 30. For so long as we remain an EGC, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not EGCs. These exemptions include:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure in this report;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- reduced disclosure obligations regarding executive compensation;
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved; and
- an exemption from compliance with the requirement of the Public Company Accounting Oversight Board regarding the communication of critical audit matters in the auditor's report on the financial statements.

We may choose to take advantage of some, but not all, of these available exemptions. We have taken advantage of reduced reporting requirements in this report. In particular, we have not included all of the executive compensation information that would be required if we were not an EGC and we have presented only two years of audited financial statements and correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure. We cannot predict whether investors will find our common stock less attractive if we rely on certain or all of 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.

In addition, the JOBS Act provides that an EGC may take advantage of an extended transition period for complying with new or revised accounting standards. This allows an EGC to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption until the earlier of the date that we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act.

We also are a "smaller reporting company," meaning that either (i) the market value of our stock held by non-affiliates is less than $250 million as of the prior June 30 or (ii) our annual revenue is less than $100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700 million as of the prior June 30. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

We will incur increased costs as a result of operating as a public company and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, and particularly after we are no longer an emerging growth company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002, or Sarbanes-Oxley, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The Nasdaq Stock Market LLC and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance and insurance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, which in turn could make it more difficult for us to attract and retain qualified members of our board of directors.

We are evaluating these rules and regulations and cannot predict or estimate the amount of additional costs we may incur or the timing of these costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Pursuant to Section 404 of Sarbanes-Oxley, or Section 404, we will be required to furnish a report by our management on our internal control over financial reporting. However, while we remain an EGC, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. In the preparation of our consolidated financial statements to meet the requirements for our initial public offering, we determined that a material weakness in our internal control over financial reporting existed as of December 31, 2019. The material weakness identified in our internal control over financial reporting arose because we did not maintain effective segregation of duties in the process and recording of journal entries. We have undertaken a plan to remediate the material weakness during 2020, including additional system controls that prevent one person from initiating and approving the same journal entry. In addition, we have performed additional reviews and other post-closing procedures but until such measures have been validated and tested, we cannot assure you that this material weakness has been resolved or that these measures will be sufficient to prevent future material weaknesses or significant deficiencies in our internal control over financial reporting from occurring. Further, we cannot assure you that the measures we have taken in the past or will take in the future will prevent the occurrence of future material weaknesses or significant deficiencies in our internal control over financial reporting. If we identify one or more material weaknesses in the future, it could result in an adverse reaction in the financial markets and restrict our future access to the capital markets due to a loss of confidence in the reliability of our financial statements.

Our amended and restated bylaws designate specific courts as the exclusive forum for certain litigation that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us.

Pursuant to our amended and restated bylaws, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the sole and exclusive forum for state law claims for (1) any derivative action or proceeding brought on our behalf; (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, or other employees to us or our stockholders; (3) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law or our certificate of incorporation or bylaws; (4) any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or bylaws; or (5) any action asserting a claim governed by the internal affairs doctrine. We refer to this provision in our bylaws as the Delaware Forum Provision. The Delaware Forum Provision will not apply to any causes of action arising under the Securities Act of 1933, as amended, the Securities Act, or the Exchange Act of 1934, as amended, or the Exchange Act. Our amended and restated bylaws further provide that unless we consent in writing to the selection of an alternative forum, the United States District Court for the District of Massachusetts shall be the sole and exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, as our headquarters are located in Watertown, Massachusetts. We refer to this provision in our bylaws as the Federal Forum Provision. In addition, our amended and restated bylaws provide that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock is deemed to have notice of and consented to the Delaware Forum Provision and the Federal Forum Provision; provided, however, that stockholders cannot and will not be deemed to have waived our compliance with the U.S. federal securities laws and the rules and regulations thereunder.

The Delaware Forum Provision and the Federal Forum Provision in our bylaws may impose additional litigation costs on stockholders in pursuing any such claims. Additionally, these forum selection clauses may limit our stockholders' ability to bring a claim in a judicial forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage the filing of lawsuits against us and our directors, officers and employees, even though an action, if successful, might benefit our stockholders. In addition, while the Delaware Supreme Court ruled in March 2020 that federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court are "facially valid" under Delaware law, there is uncertainty as to whether other courts will enforce our Federal Forum Provision. If the Federal Forum Provision is found to be unenforceable, we may incur additional costs associated with resolving such matters. The Federal Forum Provision may also impose additional litigation costs on stockholders who assert that the provision is not enforceable or invalid. The Court of Chancery of the State of Delaware and the United States District Court for the District of Massachusetts may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders.

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

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of our Credit Agreement with Perceptive Credit also preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. For example, the global financial crisis caused extreme volatility and disruptions in the capital and credit markets. Similarly, the recent significant volatility associated with the COVID-19 pandemic has caused significant instability and disruptions in the capital and credit markets. A severe or prolonged economic downturn could result in a variety of risks to our business, including weakened demand for our product candidates, and could also impact our ability to raise additional capital when needed on acceptable terms, if at all. Our general business strategy may be adversely affected by any economic downturn of this nature, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, or do not improve, it may make any necessary debt or equity financing more difficult, costly and dilutive.

Failure to secure any necessary financing in a timely manner and on favorable terms could have an adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive these difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget.

Historically, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and pharmaceutical companies have experienced significant stock price volatility in recent years. If we were to be sued, it could result in substantial costs and a diversion of management's attention and resources, which could adversely affect our business prospects, financial condition and results of operations.

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

Recent Sales of Unregistered Securities

Since July 1, 2020 we have made sales of the following unregistered securities:

1. In July 2020, we issued and sold 4,285,714 shares of our Series B preferred stock at a purchase price of $1.05 per share for an aggregate amount of $4.5 million. The issuances and sales of these securities was deemed to be exempt from registration under the Securities Act in reliance on Section 4(a)(2) of the Securities Act, as a transaction by an issuer not involving a public offering.
2. During the period between July 1, 2020 and September 30, 2020, we issued to employees options to purchase an aggregate of 1,467,424 shares of our common stock at an exercise price of $4.98 per share (which reflects the 8.4335-for-1 reverse stock split we effected on September 25, 2020. In addition, on October 1, 2020, we issued to employees and members of our board of directors options to purchase an aggregate of 2,609,355 shares of our common stock at an exercise price of $19.00 per share. We deemed these issuances to be exempt from registration under the Securities Act either in reliance on Rule 701 of the Securities Act as sales and offers under compensatory benefit plans and contracts relating to compensation in compliance with Rule 701, or in reliance on Section 4(a)(2), as transaction by an issuer not involving a public offering. On October 2, 2020, we filed a registration statement on Form S-8 under the Securities Act to register all of the shares of our common stock subject to outstanding options and all shares of our common stock otherwise issuable pursuant to our equity compensation plans.

Use of Proceeds from our Initial Public Offering of Common Stock

In October 2020, our Registration Statement on Form S-1 (No. 333-248719) was declared effective by the SEC pursuant to which we issued and sold an aggregate of 11,040,000 shares of common stock (inclusive of shares of sold pursuant to the underwriters' exercise of their over-allotment option) at a public offering price of $19.00 per share for aggregate net cash proceeds of $191.1 million, after deducting underwriting discounts, commissions and offering costs. No payments for such expenses were made directly or indirectly to (i) any of our officers or directors or their associates, (ii) any persons owning 10% or more of any class of our equity securities or (iii) any of our affiliates.

The sale and issuance of 11,040,000 shares closed on October 6, 2020. Jefferies LLC, Evercore Group L.L.C., BMO Capital Markets Corp. and UBS Securities LLC acted as joint book-running managers for the offering.

There has been no material change in the planned use of proceeds from our initial public offering from that described in the Prospectus.

Repurchase of Shares of Company Equity Securities

None.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

On November 12, 2020, the Company entered into the First Amendment (the "Amendment") to the Amended and Restated License Agreement, by and among F. Hoffman-La Roche Ltd, Hoffman-La Roche Inc. and the Company, dated as of December 28, 2018 (the "Restated Agreement"). The Amendment provides a mechanism through which the parties can mutually agree to terminate the Restated Agreement on a target-by-target basis by the entry into a mutual target termination agreement. In such a circumstance, as provided in the Amendment, the parties have agreed that all rights in know-how and intellectual property in support of products that use inhibition as their mode of action (referred to as the "Roche Field") will revert to the Roche parties and all rights in respect of know-how and intellectual property in support of products that use degradation as their mode of action (referred to as the "C4T Field") will revert to the Company. The Amendment further states that, following the entry into a mutual target termination agreement, the Roche parties will have rights in and responsibility for any know-how and intellectual property generated as a result of the collaboration that fits within the Roche Field and the Company will have rights in and responsibility for any know-how and intellectual property generated as a result of the collaboration that fits within the C4T Field. In support of this allocation of rights, under the Amendment, the Roche parties provided the Company, and the Company provided the Roche parties, with a perpetual, irrevocable, fully paid up, exclusive (even as to party granting the license), sublicenseable (including in multiple tiers) license to the know-how and intellectual property rights that are allocated to a party under the mutual target termination agreement.

Finally, through the entry into the Amendment, the parties mutually agreed to terminate the Restated Agreement as to the target EGFR. As a result, the Roche parties are now free to pursue the target EGFR in the Roche Field and the Company is free to pursue the target EGFR in the C4T Field and all rights in and responsibility for know-how and intellectual property related to EGFR in the Roche Field reverted to the Roche parties and all rights in and responsibility for know-how and intellectual property related to EGFR in the C4T Field reverted to the Company.

Item 6. Exhibits.

Exhibit Number	Description
3.1	Fifth Amended and Restated Certificate of Incorporation of the Registrant, as currently in effect (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K (File No. 001-39567) filed by the Registrant on October 6, 2020).
3.2	Second Amended and Restated Bylaws of the Registrant, as currently in effect (incorporated by reference to Exhibit 3.5 to the Registration Statement on Form S-1 (File No. 333-248719) filed by the Registrant on September 10, 2020).
4.1	Amended and Restated Investors' Rights Agreement among the Registrant, its warrant holder and certain of its stockholders, dated June 5, 2020 (incorporated by reference to Exhibit 4.1 to the Registration Statement on Form S-1 (File No. 333-248719) filed by the Registrant on September 10, 2020).
4.2	Warrant Certificate issued by the Registrant to Perceptive Credit Holdings III, LP dated June 5, 2020 (incorporated by reference to Exhibit 4.2 to the Registration Statement on Form S-1 (File No. 333-248719) filed by the Registrant on September 10, 2020).
4.3	Form of Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.3 to the Registration Statement on Form S-1 (File No. 333-248719) filed by the Registrant on September 28, 2020).
10.1#	Employment Agreement between the Registrant and Andrew Hirsch, dated September 6, 2020 (incorporated by reference to Exhibit 10.8 to the Registration Statement on Form S-1 (File No. 333-248719) filed by the Registrant on September 10, 2020).
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.
31.2*	Certification of Principal Financial 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.
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.
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.
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document
104*	Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibits 101.*)

* Filed herewith.

\# Indicates a management contract or any compensatory plan, contract or arrangement.

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.

C4 THERAPEUTICS, INC.

Date: November 12, 2020

By: /s/ Andrew J. Hirsch

Andrew J. Hirsch

President and Chief Executive Officer

Date: November 12, 2020

By: /s/ William T. McKee

William T. McKee

Chief Financial Officer (Principal Financial Officer)

Date: November 12, 2020

By: /s/ Laura J. Wahlberg

Laura J. Wahlberg

Vice President, Finance and Corporate Controller (Principal Accounting Officer)

Exhibit 31.1

CERTIFICATION 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

I, Andrew J. Hirsch, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of C4 Therapeutics, Inc.;

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

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

4. 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 control 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 12, 2020

By: /s/ Andrew J. Hirsch
Andrew J. Hirsch
Chief Executive Officer

Exhibit 31.2

CERTIFICATION 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

I, William T. McKee, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of C4 Therapeutics, Inc.;

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

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

4. 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 control 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 12, 2020

By: /s/ William T. McKee
William T. McKee
Chief 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 C4 Therapeutics, Inc. (the "Company") on Form 10-Q for the period ending September 30, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: November 12, 2020

By: /s/ Andrew J. Hirsch
Andrew J. Hirsch
Chief 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 C4 Therapeutics, Inc. (the "Company") on Form 10-Q for the period ending September 30, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: November 12, 2020

By: /s/ William T. McKee
William T. McKee
Chief Financial Officer