

**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, 2024

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

(State or other jurisdiction of
incorporation or organization)

490 Arsenal Way, Suite 120
Watertown, MA

(Address of principal executive offices)

47-5617627

(I.R.S. Employer
Identification No.)

02472

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 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 October 24, 2024, the registrant had 70,588,959 shares of common stock, \$0.0001 par value per share, outstanding.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q, or 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 may 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;
 - 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 of time over which we anticipate our existing cash and cash equivalents, and marketable securities 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, including the possibility for reduced pricing of our products, once approved, if they are later subject to mandatory price negotiation with the Centers for Medicare and Medicaid Services under the Inflation Reduction Act of 2022 or other applicable laws;
 - 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® (Target ORiented ProtEin Degrader Optimizer) 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. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc., or Roche, Betta Pharmaceuticals, Co., Ltd., or Betta Pharma, Merck Sharp & Dohme, LLC, or Merck, and Merck KGaA, Darmstadt, Germany, or MKDG, 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.
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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 titled “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.

SUMMARY OF RISK FACTORS

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 Part II, Item 1A - Risk Factors in this Form 10-Q. These risks include, among others:

- We are a clinical-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 \$70.7 million and \$97.7 million for the nine months ended September 30, 2024 and 2023, respectively.
 - 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 and likelihood of successfully developing any products.
 - While we are a clinical-stage company and have commenced clinical trials of several product candidates, we have never completed a clinical trial of any of our product candidates. Our business could be harmed if we are unable to develop, obtain regulatory approval for and/or commercialize our product candidates, or if we 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 and efficacy of any of our product candidates, which would prevent, delay, or require additional research or analysis to proceed with development, regulatory approval, and commercialization of our current and future product candidates.
 - We have ongoing collaborations with Roche, Betta Pharma, Merck, and MKDG. We may also seek to enter into additional collaborations in the future with third parties for the discovery, development and/or commercialization of certain of our product candidates. However, we may never realize the full potential benefits under these existing or potential collaboration arrangements.
 - We face substantial competition, which may result in others discovering, developing or commercializing products for the same indication and/or patient population 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 or enforceable, our competitors could develop and commercialize technology, product candidates, and products similar or identical to ours, and our ability to successfully commercialize our technology, product candidates, and products may be impaired.
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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 ®, ™ or ℠ 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.

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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

C4 Therapeutics, Inc.
Condensed Consolidated Balance Sheets
(in thousands, except share and per share amounts)
(Unaudited)

	September 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	\$ 59,649	\$ 126,590
Marketable securities, current	195,992	127,091
Accounts receivable	10,341	11,799
Prepaid expenses and other current assets	7,246	5,709
Total current assets	273,228	271,189
Marketable securities, non-current	28,759	28,008
Property and equipment, net	6,206	7,132
Right-of-use asset	59,167	63,956
Restricted cash	3,443	3,443
Other assets	5,257	2,723
Total assets	<u>\$ 376,060</u>	<u>\$ 376,451</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 1,504	\$ 1,446
Accrued expenses and other current liabilities	15,388	20,630
Deferred revenue, current	20,769	15,471
Operating lease liability, current	5,632	5,219
Total current liabilities	43,293	42,766
Deferred revenue, net of current	28,648	21,814
Operating lease liability, net of current	61,463	65,757
Total liabilities	133,404	130,337
Commitments and contingencies (see Note 11)		
Stockholders' equity:		
Preferred stock, par value of \$0.0001 per share; 10,000,000 shares authorized, and no shares issued or outstanding as of September 30, 2024 and December 31, 2023, respectively	—	—
Common stock, par value of \$0.0001 per share; 150,000,000 shares authorized, and 70,562,901 and 60,467,188 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively	7	6
Additional paid-in capital	841,320	774,618
Accumulated other comprehensive income (loss)	455	(127)
Accumulated deficit	(599,126)	(528,383)
Total stockholders' equity	242,656	246,114
Total liabilities and stockholders' equity	<u>\$ 376,060</u>	<u>\$ 376,451</u>

See accompanying notes to unaudited condensed consolidated financial statements.

C4 Therapeutics, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Revenue from collaboration agreements	\$ 15,362	\$ 11,072	\$ 30,407	\$ 17,495
Operating expenses:				
Research and development	31,838	28,347	78,124	87,315
General and administrative	11,768	10,533	31,751	31,784
Restructuring	—	—	2,437	—
Total operating expenses	43,606	38,880	112,312	119,099
Loss from operations	(28,244)	(27,808)	(81,905)	(101,604)
Other income (expense), net:				
Interest expense and amortization of long-term debt – related party	—	(167)	—	(1,373)
Loss on early extinguishment of debt	—	(621)	—	(621)
Interest and other income, net	3,578	2,562	11,162	6,862
Total other income, net	3,578	1,774	11,162	4,868
Loss before income taxes	(24,666)	(26,034)	(70,743)	(96,736)
Income tax expense	—	(1,003)	—	(1,003)
Net loss	\$ (24,666)	\$ (27,037)	\$ (70,743)	\$ (97,739)
Net loss per share – basic and diluted	\$ (0.35)	\$ (0.55)	\$ (1.03)	\$ (1.99)
Weighted-average shares outstanding – basic and diluted	69,627,190	49,212,126	68,958,938	49,103,351
Other comprehensive loss:				
Unrealized gain on marketable securities	895	870	582	3,233
Comprehensive loss	\$ (23,771)	\$ (26,167)	\$ (70,161)	\$ (94,506)

See accompanying notes to unaudited condensed consolidated financial statements.

C4 Therapeutics, Inc.
Condensed Consolidated Statements of Stockholders' Equity
(in thousands, except share amounts)
(Unaudited)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance as of December 31, 2023	60,467,188	\$ 6	\$ 774,618	(127)	\$ (528,383)	\$ 246,114
Issuance of common stock pursuant to the Beta Pharma Stock Purchase Agreement	5,567,928	1	19,999	—	—	20,000
Issuance of common stock pursuant to the at-the-market equity program, net	2,500,601	—	14,089	—	—	14,089
Issuance of common stock upon exercise of stock options	80,936	—	519	—	—	519
Issuance of common stock upon vesting of restricted stock units, net of shares repurchased for tax withholding	121,516	—	(109)	—	—	(109)
Issuance of common stock under 2020 ESPP	34,902	—	84	—	—	84
Stock-based compensation	—	—	6,215	—	—	6,215
Change in unrealized loss, net on marketable securities	—	—	—	(253)	—	(253)
Net loss	—	—	—	—	(28,361)	(28,361)
Other	5,520	—	(16)	—	—	(16)
Balance as of March 31, 2024	68,778,591	\$ 7	\$ 815,399	(380)	\$ (556,744)	\$ 258,282
Exercise of stock options and release of stock units	32,607	—	135	—	—	135
Stock-based compensation	—	—	6,381	—	—	6,381
Change in unrealized loss, net on marketable securities	—	—	—	(60)	—	(60)
Net loss	—	—	—	—	(17,716)	(17,716)
Other	4,444	—	36	—	—	36
Balance as of June 30, 2024	68,815,642	\$ 7	\$ 821,951	(440)	\$ (574,460)	\$ 247,058
Issuance of common stock pursuant to the at-the-market equity program, net	1,631,521	—	10,280	—	—	10,280
Exercise of stock options and release of stock units	1,714	—	13	—	—	13
Issuance of common stock upon vesting of restricted stock units, net of shares repurchased for tax withholding	31,363	—	(85)	—	—	(85)
Issuance of common stock under 2020 ESPP	75,993	—	298	—	—	298
Stock-based compensation	—	—	8,831	—	—	8,831
Change in unrealized loss, net on marketable securities	—	—	—	895	—	895
Net loss	—	—	—	—	(24,666)	(24,666)
Other	6,668	—	32	—	—	32
Balance as of September 30, 2024	70,562,901	\$ 7	\$ 841,320	455	\$ (599,126)	\$ 242,656

See accompanying notes to unaudited condensed consolidated financial statements.

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance as of December 31, 2022	48,966,216	\$ 5	\$ 689,256	\$ (4,137)	\$ (395,890)	\$ 289,234
Issuance of common stock upon exercise of stock options	11,759	—	56	—	—	56
Issuance of common stock upon vesting of restricted stock units, net of shares repurchased for tax withholding	48,730	—	(94)	—	—	(94)
Issuance of common stock under 2020 ESPP	20,748	—	104	—	—	104
Stock-based compensation	—	—	6,251	—	—	6,251
Change in unrealized loss, net on marketable securities	—	—	—	1,667	—	1,667
Net loss	—	—	—	—	(34,780)	(34,780)
Other	5,056	—	32	—	—	32
Balance as of March 31, 2023	49,052,509	\$ 5	\$ 695,605	\$ (2,470)	\$ (430,670)	\$ 262,470
Exercise of stock options and release of stock units	1,337	—	2	—	—	2
Stock-based compensation	—	—	6,425	—	—	6,425
Change in unrealized loss, net on marketable securities	—	—	—	696	—	696
Net loss	—	—	—	—	(35,922)	(35,922)
Other	11,252	—	36	—	—	36
Balance as of June 30, 2023	49,065,098	\$ 5	\$ 702,068	\$ (1,774)	\$ (466,592)	\$ 233,707
Exercise of stock options and release of stock units	—	—	—	—	—	—
Issuance of common stock upon vesting of restricted stock units, net of shares repurchased for tax withholding	69,015	—	(16)	—	—	(16)
Issuance of common stock under 2020 ESPP	113,036	—	264	—	—	264
Stock-based compensation	—	—	8,200	—	—	8,200
Change in unrealized loss, net on marketable securities	—	—	—	870	—	870
Net loss	—	—	—	—	(27,037)	(27,037)
Other	12,721	—	36	—	—	36
Balance as of September 30, 2023	49,259,870	\$ 5	\$ 710,552	\$ (904)	\$ (493,629)	\$ 216,024

See accompanying notes to unaudited condensed consolidated financial statements.

C4 Therapeutics, Inc.
Condensed Consolidated Statements of Cash Flows
(in thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2024	2023
Cash flows used in operating activities:		
Net loss	\$ (70,743)	\$ (97,739)
Adjustments to reconcile net loss to cash used in operating activities:		
Stock-based compensation expense	21,427	20,876
Depreciation and amortization expense	1,338	1,450
Reduction in carrying amount of right-of-use asset	4,790	4,596
Net accretion of discounts on marketable securities	(4,315)	(2,817)
Amortization of debt discount – related party	—	405
Loss on early extinguishment of debt	—	621
Other	53	120
Changes in operating assets and liabilities:		
Accounts receivable	1,458	973
Prepaid expenses and other current and long-term assets	(4,300)	1,404
Accounts payable	57	104
Accrued expenses and other current liabilities	(5,242)	(3,866)
Operating lease liability	(3,881)	(3,489)
Deferred revenue	12,133	(5,467)
Net cash used in operating activities	(47,225)	(82,829)
Cash flows (used in) provided by investing activities:		
Proceeds from maturities of marketable securities	178,781	219,975
Purchases of marketable securities	(243,537)	(92,020)
Purchases of property and equipment, net	(184)	(1,551)
Net cash (used in) provided by investing activities	(64,940)	126,404
Cash flows provided by (used in) financing activities:		
Proceeds from issuance of common stock pursuant to the at-the-market equity program, net	24,370	—
Proceeds from issuance of common stock pursuant to the Betta Pharma Stock Purchase Agreement	20,000	—
Proceeds from exercise of stock options	667	58
Payments for repurchase of common stock for tax withholding	(194)	(110)
Payment of long-term debt – related party	—	(12,500)
Other	381	369
Net cash provided by (used in) financing activities	45,224	(12,183)
Net change in cash, cash equivalents and restricted cash	(66,941)	31,392
Cash, cash equivalents and restricted cash at beginning of period	130,033	33,033
Cash, cash equivalents and restricted cash at end of period	\$ 63,092	\$ 64,425
Reconciliation of cash, cash equivalents and restricted cash:		
Cash, cash equivalents and restricted cash at end of period	\$ 63,092	\$ 64,425
Less: restricted cash	(3,443)	(3,454)
Cash and cash equivalents at end of the period	\$ 59,649	\$ 60,971

C4 Therapeutics, Inc.
Condensed Consolidated Statements of Cash Flows - Continued
(in thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2024	2023
Supplemental disclosures of cash flow information:		
Cash paid for leases	\$ 6,614	\$ 6,421
Cash paid for income taxes	\$ —	\$ 1,003
Cash paid for interest – related party	\$ —	\$ 990

See accompanying notes to unaudited condensed consolidated financial statements.

C4 THERAPEUTICS, INC.

Notes to Condensed Consolidated Financial Statements

(Unaudited)

Note 1. Nature of the business and basis of presentation

C4 Therapeutics, Inc., or, together with its subsidiary, the Company, is a clinical-stage biopharmaceutical company dedicated to the advancement of targeted protein degradation science to develop a new generation of small-molecule medicines to transform how disease is treated. The Company leverages its proprietary technology platform, TORPEDO (Target ORiented ProtEIn DegradEr Optimizer), to efficiently design and optimize small-molecule medicines that harness the body's natural protein recycling system to rapidly degrade disease-causing protein, offering the potential to overcome drug resistance, drug undruggable targets, and improve patient outcomes. The Company uses its TORPEDO platform to advance multiple targeted oncology programs to the clinic while expanding its research platform to deliver the next wave of medicines for difficult-to-treat diseases. The Company was incorporated in Delaware on October 7, 2015 and has its principal office in Watertown, Massachusetts.

Liquidity and capital resources

Since its inception, the Company's primary activities have been focused on research and development activities, building the Company's intellectual property, recruiting and retaining personnel, and raising capital to support these activities. To date, the Company has funded its operations primarily with proceeds received from the sales of redeemable convertible preferred stock, public offerings of the Company's common stock, private placement of the Company's common stock, through its collaboration agreements, and debt financing.

The Company has incurred recurring losses since its inception, including net losses of \$70.7 million and \$97.7 million for the nine months ended September 30, 2024 and 2023, respectively. In addition, as of September 30, 2024, the Company had an accumulated deficit of \$599.1 million. To date, the Company has not generated any revenue from product sales as none of its product candidates have been approved for commercialization. The Company expects to continue to generate operating losses for the foreseeable future.

The Company expects that its cash, cash equivalents, and marketable securities of \$284.4 million as of September 30, 2024 will be sufficient to fund its operations for at least the next twelve months from the date of issuance of these consolidated financial statements. 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.

Risks and uncertainties

The Company is subject to risks common to other life science companies in the early development stage including, but not limited to, uncertainty of ability to raise additional financing, product development and commercialization, development by its competitors of new technological innovations, dependence on key personnel, market acceptance of products, lack of marketing and sales history, product liability, protection of proprietary technology and intellectual property, and compliance with regulations from the Food and Drug Administration, or the FDA, and other government agencies. If the Company does not successfully advance its programs into and through human clinical trials and commercialize any of its product candidates either directly or through collaborations with other companies, the Company may be unable to produce product revenue or achieve profitability. There can be no assurance that the Company's research and development efforts will be successful, adequate protection for the Company's intellectual property will be obtained, any products developed will obtain necessary government regulatory approval, or any approved products will be commercially viable. Even if the Company's product development efforts are successful, it is uncertain when, if ever, the Company will generate significant revenue from product sales. The Company operates in an environment of rapid change in technology and substantial competition from pharmaceutical and biotechnology companies.

Note 2. Summary of significant accounting policies

Basis of presentation and consolidation

The accompanying unaudited interim condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America, or U.S. GAAP, and applicable rules and regulations of the Securities and Exchange Commission, or 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 U.S. 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, 2024, the condensed consolidated statements of operations and comprehensive loss for the three and nine months ended September 30, 2024 and 2023, the condensed consolidated statements of stockholders' equity for the three and nine months ended September 30, 2024 and 2023, and the condensed consolidated statements of cash flows for the nine months ended September 30, 2024 and 2023, 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 as of and for year ended December 31, 2023, and notes thereto, which are included in the Company's 2023 Annual Report on Form 10-K that was filed with the SEC on February 22, 2024, or the 2023 Annual Report.

Use of estimates

The preparation of condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities as of the date of the condensed consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. The Company bases its estimates and assumptions on historical experience when available and on various factors that it believes to be reasonable under the circumstances. This process may result in actual results differing materially from those estimated amounts used in the preparation of the condensed consolidated financial statements if these results differ from historical experience or other assumptions do not turn out to be substantially accurate, even if such assumptions are reasonable when made. Significant estimates and assumptions reflected in these condensed consolidated financial statements include, but are not limited to, amounts and timing of revenues recognized under the Company's research and development collaboration arrangements, prepaid and accrued research and development expense, incremental borrowing rate used in the measurement of lease liabilities, and estimated volatility used in fair valuation of stock options. The Company assesses estimates on an ongoing basis; however, actual results could materially differ from those estimates.

Significant accounting policies

The Company's significant accounting policies are disclosed in the audited condensed consolidated financial statements for the year ended December 31, 2023, which are included in the Company's 2023 Annual Report on Form 10-K that was filed with the SEC on February 22, 2024. Since the date of those condensed consolidated financial statements, there have been no material changes to the Company's significant accounting policies.

In November 2023, the FASB issued ASU 2023-07, Segment Reporting (Topic 280): Improvements to Report Segment Disclosures ("ASU 2023-07"). ASU 2023-07 requires enhanced disclosures about significant segment expenses, enhanced interim disclosure requirements, clarifies circumstances in which an entity can disclose multiple segment measures of profit or loss, provides new segment disclosure requirements for entities with a single reportable segment, and contains other disclosure requirements. ASU 2023-07 is effective for the Company's annual reporting period beginning after December 15, 2023, and subsequent interim periods, with early adoption permitted. ASU 2023-07 requires retrospective application to all prior periods presented in the financial statements. The Company is currently evaluating the effect that adoption of ASU 2023-07 will have on its consolidated financial statements.

Note 3. Fair value measurements

The following table presents 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 such fair values as of September 30, 2024 (in

thousands):

	Fair Value	Level 1	Level 2	Level 3
Cash equivalents:				
Money market funds	\$ 46,987	\$ 46,987	\$ —	\$ —
Corporate debt securities	6,225	—	6,225	—
U.S. Treasury securities	6,221	—	6,221	—
Marketable securities:				
Corporate debt securities	188,972	—	188,972	—
U.S. Treasury securities	23,261	—	23,261	—
U.S. government debt securities	12,518	—	12,518	—
Total cash equivalents and marketable securities	\$ 284,184	\$ 46,987	\$ 237,197	\$ —

There have been no transfers between fair value levels during the nine months ended September 30, 2024.

The following table sets forth the fair value of the Company's financial assets by level within the fair value hierarchy at December 31, 2023 (in thousands):

	Fair Value	Level 1	Level 2	Level 3
Cash equivalents:				
Money market funds	\$ 103,564	\$ 103,564	\$ —	\$ —
U.S. Treasury securities	14,972	—	14,972	—
Corporate debt securities	7,588	—	7,588	—
Marketable securities:				
Corporate debt securities	128,705	—	128,705	—
U.S. government debt securities	20,428	—	20,428	—
U.S. Treasury securities	5,966	—	5,966	—
Total cash equivalents and marketable securities	\$ 281,223	\$ 103,564	\$ 177,659	\$ —

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.

Marketable securities consist of U.S. Treasury securities, U.S. government debt securities, and corporate debt securities, all of which are classified as available-for-sale pursuant to ASC 320, *Investments – Debt and Equity Securities*. Marketable securities are classified within Level 2 of the fair value hierarchy because pricing inputs are other than quoted prices in active markets, which are either directly or indirectly observable as of the reporting date, and fair value is determined using models or other valuation methodologies on a recurring basis.

Note 4. Marketable securities

Marketable securities as of September 30, 2024 consisted of the following (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Marketable securities, current:				
Corporate debt securities	\$ 161,256	\$ 342	\$ (33)	\$ 161,565
U.S. Treasury securities	23,233	28	—	23,261
U.S. government debt securities	11,160	9	(2)	11,167
Marketable securities, non-current:				
Corporate debt securities	27,297	120	(10)	27,407
U.S. government debt securities	1,350	1	—	1,351
Total marketable securities, current and non-current	\$ 224,296	\$ 500	\$ (45)	\$ 224,751

Marketable securities as of December 31, 2023 consisted of the following (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Marketable securities, current:				
Corporate debt securities	\$ 100,903	\$ 16	\$ (221)	\$ 100,698
U.S. government debt securities	20,457	14	(43)	20,428
U.S. Treasury securities	5,965	1	—	5,966
Marketable securities, non-current:				
Corporate debt securities	27,901	120	(14)	28,007
Total marketable securities, current and non-current	\$ 155,226	\$ 151	\$ (278)	\$ 155,099

Marketable securities classified as current have maturities of less than one year and are classified as available-for-sale. Marketable securities classified as non-current are those that: (i) have a maturity of greater than one year, and (ii) are not intended to be liquidated within the next twelve months, although these funds are available for use and, therefore, are classified as available-for-sale. No available-for-sale debt securities held as of September 30, 2024 or December 31, 2023 had remaining maturities greater than five years.

Based on factors such as historical experience, market data, issuer-specific factors, and current economic conditions, the Company did not record an allowance for credit losses at September 30, 2024 and December 31, 2023, related to these securities.

Note 5. Property and equipment

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

	September 30, 2024	December 31, 2023
Property and equipment:		
Laboratory equipment	\$ 8,213	\$ 8,042
Leasehold improvements	4,712	4,712
Furniture and fixtures	1,435	1,422
Office equipment	621	621
Computer equipment	98	98
Total property and equipment	15,079	14,895
Less: accumulated depreciation	(8,873)	(7,763)
Total property and equipment, net	\$ 6,206	\$ 7,132

Depreciation expense related to property and equipment is as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Depreciation expense	\$ 365	\$ 447	\$ 1,109	\$ 1,450

Note 6. Leases

The Company leases office and laboratory space under a non-cancelable operating lease. In addition, the Company subleases a portion of its office and laboratory space. There have been no material changes to the Company's lease or sublease during the nine months ended September 30, 2024. For additional information, please read Note 6, *Leases*, to the audited condensed consolidated financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2023.

Note 7. Accrued expenses and other current liabilities

Accrued expenses and other current liabilities consisted of the following (in thousands):

	September 30, 2024	December 31, 2023
Accrued expenses and other current liabilities:		
Accrued research and development	\$ 8,325	\$ 11,243
Accrued compensation and benefits	5,247	7,344
Other	1,816	2,043
Total accrued expenses and other current liabilities	<u>\$ 15,388</u>	<u>\$ 20,630</u>

Note 8. Collaboration and license agreements***MKDG Collaboration and License Agreement***

On March 1, 2024, the Company entered into a license and collaboration agreement with MKDG, or the MKDG Agreement, to discover two targeted protein degraders against critical oncogenic proteins.

Under the terms of the MKDG Agreement, the Company grants MKDG a worldwide, exclusive license under certain of the Company's intellectual property rights to develop, manufacture, and commercialize two targeted protein degraders against critical oncogenic proteins. MKDG is responsible for all development, regulatory approval, manufacturing and commercialization costs. Under the terms of the MKDG Agreement, MKDG agreed to make an upfront cash payment of \$16.0 million and to fund the Company's discovery research efforts. The Company is eligible to receive approximately \$740 million in the aggregate in discovery, regulatory, and commercial milestone payments across the collaboration, plus tiered royalties on net sales. Royalties payable from MKDG to the Company range from mid-single digit to low-double digit percent, subject to reductions under certain circumstances as described in the MKDG Agreement.

The collaboration is managed by a joint research committee, or MKDG JRC, and a joint steering committee, or MKDG JSC, each of which is comprised of representatives of MKDG and the Company. Under the MKDG Agreement, MKDG has final decision-making authority over the MKDG JSC, which has the authority to decide matters that cannot be resolved by the MKDG JRC. MKDG may terminate the MKDG Agreement on a project-by-project basis or in its entirety upon 60 days' prior written notice. Each party also has various termination rights under certain circumstances, including but not limited to patent challenges, insolvency, or a material breach by the other party, subject to certain conditions.

MKDG Agreement Accounting

The Company identified two performance obligations at the outset of the MKDG Agreement, represented by the two potential research and development targets. While the Company is obligated under the MKDG Agreement to provide the exclusive license and perform certain research activities, the Company determined that the license, the research activities, and participation on the MKDG JRC and MKDG JSC are considered promised services. Participation on the MKDG JRC and MKDG JSC to oversee the research activities contemplated under the MKDG Agreement were determined to be quantitatively and qualitatively immaterial and, therefore, were excluded from the performance obligations. The total transaction price of the MKDG Agreement is allocated to the performance obligations based on their relative standalone selling price. The Company recognizes the transaction price allocated to the performance obligations as the research and development services are provided, using an input method, in proportion to costs incurred to date for each research development target as compared to total costs incurred and expected to be incurred in the future to satisfy the underlying obligation. Incremental fees for research and development services are paid at agreed upon FTE rates and recognized as revenue in the period incurred.

As of September 30, 2024, the total transaction price of \$16.0 million is allocated to the two performance obligations and \$14.4 million remains unsatisfied.

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 condensed consolidated balance sheet.

Merck License and Collaboration Agreement

On December 11, 2023, the Company entered into an exclusive license and collaboration agreement with Merck, or the Merck Agreement, to develop degrader-antibody conjugates, or DACs, an emerging modality designed to selectively target and neutralize disease-causing proteins in cancer cells.

Under the terms of the Merck Agreement, the Company received a \$10.0 million upfront payment. The Company and Merck will collaborate to develop DACs directed to an initial undisclosed oncology target that is exclusive to the collaboration. For DACs directed to this initial target, the Company is eligible to receive milestone payments totaling approximately \$600 million, as well as tiered royalties on future sales. The Merck Agreement also provides Merck with the option to extend the collaboration to include three additional targets that would be exclusive to the collaboration, which could yield option exercise payments as well as potential milestones and royalties. If Merck exercises all of its options to extend the collaboration, the Company would be eligible to receive up to approximately \$2.5 billion in potential payments across the entire collaboration.

The collaboration is managed by a joint research committee, or Merck JRC, which is comprised of representatives from both Merck and the Company. Merck may terminate the Merck Agreement, in its entirety or as to a given target, for convenience upon at least 60 days' prior notice. Each party also has various termination rights under certain circumstances, including but not limited to regulatory safety stoppages, patent challenges, insolvency, or a material breach by the other party, subject to certain conditions.

Merck Agreement Accounting

The Company identified one performance obligation at the outset of the Merck Agreement, which consists of: (1) the exclusive license and (2) the research activities for the initial undisclosed oncology target and the joint research plan. 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 Merck JRC to oversee the research activities and the technology transfer associated with the Merck Agreement were determined to be quantitatively and qualitatively immaterial and therefore are excluded from performance obligations. The Company recognizes the transaction price allocated to this performance obligation as the research and development services are provided, using an input method, in proportion to costs incurred to date for each research development target as compared to total costs incurred and expected to be incurred in the future to satisfy the underlying obligation. The transfer of control occurs over this period and, in management's judgment, is the best measure of progress towards satisfying the performance obligation.

As of September 30, 2024, the total transaction price of \$10.0 million is allocated to the research and development services performance obligation and \$6.6 million of the allocated transaction price remains unsatisfied.

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 as deferred revenue on the Company's consolidated balance sheet.

Betta Pharma License and Collaboration Agreement - Related Party

On May 29, 2023, the Company entered into a license and collaboration agreement, or the Betta Pharma License Agreement, with Betta Pharma to collaborate on the development, manufacturing, and commercialization of CFT8919 in Greater China, comprised of mainland China, Hong Kong SAR, Macau SAR and Taiwan, with the Company retaining rights to CFT8919 in the rest of the world other than Greater China, or the C4T Territory.

Under the terms of the Betta Pharma License Agreement, the Company grants Betta Pharma an exclusive license under certain of the Company's intellectual property rights to develop, manufacture and commercialize CFT8919 for all uses in humans in Greater China. Betta Pharma is responsible for all development, regulatory approval, manufacturing and commercialization costs in Greater China except where Betta Pharma acts as the Company's agent in Greater China in connection with a global trial sponsored by the Company. As part of the collaboration, Betta Pharma made an upfront cash payment of \$10.0 million to the Company and has agreed to make up to \$357.0 million in aggregate milestone payments, plus tiered royalties on net sales of CFT8919 in Greater China. These payments are subject to a withholding tax by the State Taxing Authority of the People's Republic of China. Royalties payable from Betta Pharma to the Company range from low to mid double-digit percent, subject to certain reductions under certain circumstances as described in the Betta Pharma License Agreement. In addition, as part of the collaboration, the Company has agreed to make milestone payments to Betta Pharma of up to \$40.0 million following the Company's receipt of approval of a New Drug Application for CFT8919 from the FDA, with the milestone amount based on the percentage of patients in contemplated clinical trials that were enrolled by Betta Pharma and the line of therapy of the approval. In addition, the Company has agreed to pay Betta Pharma tiered royalties on net sales of CFT8919 in the C4T Territory in the low single digit percent range, subject to reductions under certain circumstances as described in the Betta Pharma License Agreement.

In connection with the execution of the Betta Pharma License Agreement, the Company, Betta Pharma, and an affiliate of Betta Pharma, (Betta Investment (Hong Kong) Limited, or Betta Investment), entered into a stock purchase agreement dated May 29, 2023, or the Betta Stock Purchase Agreement, and together with the Betta Pharma License Agreement, the Betta Agreements, pursuant to which Betta Investment agreed to purchase 5,567,928 shares of the Company's common stock, or the Shares, for an aggregate purchase price of approximately \$25.0 million, or \$4.49 per share, which represented

a 25% premium over the 60-trading-day volume weighted average closing price as of two trading days prior to the effective date of the Betta Stock Purchase Agreement. The Betta Stock Purchase Agreement has certain restrictions customary to agreements of this nature. The closing under the Betta Stock Purchase Agreement occurred on January 4, 2024. Due to Betta Investment's purchase of shares of the Company's common stock in January 2024 under the Betta Stock Purchase Agreement, its subsequent filing of a Schedule 13G on January 12, 2024, and its relationship with Betta Pharma as an affiliate, Betta Pharma is considered a related party to the Company.

The collaboration is managed by a joint steering committee, which is composed of representatives from both Betta Pharma and the Company. Following the completion of the dose escalation phase of the Phase 1 trial of CFT8919, Betta Pharma may terminate the Betta Pharma License Agreement for convenience upon at least 90 days' prior written notice. Each party also has various termination rights under certain circumstances, including but not limited to regulatory safety stoppages, patent challenges, insolvency, or a material breach by the other party, subject to certain conditions.

Betta Agreements accounting

The Company expects to recognize revenue under the Betta Agreements from one type of arrangement, the licensing agreement. The Betta Agreements will consist of the following activities: (1) license of intellectual property, (2) clinical supply agreement, (3) manufacturing technology transfer, and (4) commercial manufacturing supply agreement. The clinical supply agreement, or the Betta Pharma Supply Agreement, was signed on August 31, 2024. The Company recognizes the transaction price allocated to the performance obligation as the costs related to manufactured clinical supply are incurred, using an input method, in proportion to costs incurred to date as compared to total costs incurred and expected to be incurred in the future to satisfy the underlying obligation. The clinical manufacturing costs are paid at agreed upon rates and included in the estimated transaction price. The estimated transaction price as of September 30, 2024 is \$135.7 million, consisting of the \$10.0 million upfront cash consideration, \$5.0 million from the closing of the Betta Stock Purchase Agreement, a \$2.0 million milestone achieved in December 2023 under the Betta Pharma License Agreement, and the estimated consideration expected to be received from the manufactured clinical supply of \$118.7 million. This estimate includes a number of assumptions, including but not limited to the duration and total volume of clinical supply to be provided by the Company pursuant to the Betta Pharma Supply Agreement. In the event there are fluctuations in the Company's assumptions, the estimates of consideration expected to be received pursuant to the Betta Pharma Supply Agreement will also change. Due to scientific and technical uncertainties of the clinical trials, the Company cannot be certain that this amount will be recognized as revenue in future periods.

During the three months ended September 30, 2023, the Company made the related withholding tax payment, related to the upfront payment, of \$1.0 million to the Chinese tax authorities (See Note 12).

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 as deferred revenue on the Company's consolidated balance sheet.

Roche Collaboration and License Agreement

In March 2016, the Company entered into a license agreement with Roche, which was amended in June 2016 and again in March 2017. The Company and Roche amended and restated that agreement (as so amended) in December 2018. This amended and restated agreement is referred to as the Roche Agreement. Under the Roche Agreement, the Company and Roche agreed to collaborate in the research, development, manufacture and commercialization of target-binding degrader medicines using the Company's proprietary TORPEDO platform for the treatment of cancers and other indications. Under the Roche Agreement, the Company may elect to opt into certain co-development rights, in which case the Company will receive an increased royalty rate on future product sales from products directed to that target. In addition, if the Company opts into certain co-detailing rights, it is also entitled to reimbursement of certain commercialization costs. Upon entry into the Roche Agreement, the Company received additional upfront consideration of \$40.0 million.

In November 2020, the Company signed a further amendment, the effect of which was to provide that the parties would develop up to five potential targets, with Roche maintaining its option rights to license and commercialize products directed to those targets. The November 2020 amendment also provides a mechanism through which the Company and Roche can mutually agree to terminate the Roche Agreement on a target-by-target basis by the entry into a Mutual Target Termination Agreement. Upon the entry into a Mutual Target Termination Agreement, the Roche Agreement provides that all rights and responsibilities for know-how and other intellectual property in support of products that use inhibition as their mode of action revert to Roche and all rights and responsibilities for know-how and other intellectual property in support of products that use degradation as their mode of action revert to the Company. In support of this allocation of rights, Roche provides the Company, and the Company provides Roche, with a perpetual irrevocable, fully paid up, exclusive (even as to party granting the license), sublicensable (including in multiple tiers) license to the patents and know-how that are allocated to a party under a Mutual Target Termination Agreement. As the research activities with Roche have progressed and

evolved over time, there are now two targets on which the parties continue to collaborate, with Roche maintaining its option rights to license and commercialize products directed to those two targets. In December 2023, the Company signed a second amendment to the Roche Agreement, the effect of which was to update the terms of the agreement as it pertains to the two targets on which the parties continue to collaborate. Under the second amendment to the Roche Agreement, Roche retains its option rights to license and commercialize products directed to those targets but the timing of its option rights are adjusted to begin upon Roche's receipt of the dose range finding data package. There was no material impact to the accounting in 2023 as a result of the second amendment to the Roche Agreement.

Under the Roche Agreement, as amended, the Company receives annual research plan payments of \$1.0 million for each active research plan. For the two targets that remain under collaboration among the parties, Roche is required to pay the Company fees of \$2.0 million upon the progression of targets to the lead series identification achievement phase. In the event Roche exercises its option rights as to one of these targets, Roche is required to pay the Company an option exercise fee of \$8.0 million.

Under the Roche Agreement, as amended, for each target option exercised by Roche, the Company is eligible to receive milestone payments up to \$273.0 million upon the achievement of certain development milestones with respect to corresponding products, subject to certain reductions and exclusions based on intellectual property coverage. Roche is also required to pay the Company up to \$150.0 million per target in one-time sales-based milestone payments upon the achievement of specified levels of net sales of a product directed to such target. Finally, Roche is required to pay the Company tiered royalties ranging from the mid-single digits to mid-teen percentages on net sales of products sold by Roche pursuant to its exercise of its option rights, subject to certain reductions. For sales of products for which the Company exercises its co-development right, the applicable royalty rates will be increased by a low-single digit percentage.

The collaboration is managed by a joint research committee, or Roche JRC. The Company has control over the Roche JRC prior to Roche's exercise of its option rights as to a particular target, with Roche assuming control of the Roche JRC thereafter, Roche may terminate the Roche Agreement on a target-by-target or product-by-product basis under several scenarios, upon at least 90 days' prior written notice. Each party also has various termination rights under certain circumstances, including but not limited to insolvency or a material breach by the other party, subject to certain conditions.

Roche Agreement accounting

At commencement, the Company identified twelve performance obligations within the Roche Agreement, represented by the six potential research and development targets then included in the collaboration and the option rights held by Roche for each of those six targets. A non-exclusive royalty-free license to use the Company's intellectual property to conduct research and development activities and participation on Roche JRC were identified as promised services. However, the Company determined that the research and development license and research and development services were not distinct from one another, and participation on the Roche JRC was determined to be quantitatively and qualitatively immaterial.

The total transaction price of the Roche Agreement is allocated to the performance obligations based on their relative standalone selling price. The allocated transaction price is recognized as revenue from collaboration agreements in one of two ways:

- Research and development targets: The Company recognizes 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, in proportion to costs incurred to date for each research development target as compared to total costs incurred and expected to be incurred in the future to satisfy the underlying obligation related to said research and development target. The transfer of control occurs over this period and, in management's judgment, is the best measure of progress towards satisfying the performance obligation.
- Option rights: The transaction price allocated to the options rights, which are considered material rights, is recognized in the period that Roche elects to exercise or elects to not exercise its option right to license and commercialize the underlying research and development target.

The following table summarizes the allocation of the total transaction price to the identified performance obligations under the arrangement, and the amount of the transaction price unsatisfied as of September 30, 2024 (in thousands):

	Transaction Price Allocated	Transaction Price Unsatisfied
Performance obligations:		
Research and development targets	\$ 16,688	\$ 13,823
Option rights	2,376	2,376
Total	<u>\$ 19,064</u>	<u>\$ 16,199</u>

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 as deferred revenue on the Company's condensed consolidated balance sheet.

Biogen Collaboration Research and License Agreement

In December 2018, the Company entered into a collaboration research and license agreement, or the Biogen Agreement, with Biogen. In February 2020, the Company and Biogen amended the Biogen Agreement to provide further clarity around Biogen's ownership of target binding moieties (which are portions of molecules), and any related intellectual property that are directed at or bind to collaboration targets. This amendment further provided that Biogen licenses to the Company rights to use these Biogen target binding moieties and any related intellectual property as needed in order to conduct the research and development activities contemplated under the Biogen Agreement. Pursuant to the terms of the Biogen Agreement, the Company and Biogen agreed to collaborate on research activities to develop novel treatments for neurological conditions such as Alzheimer's disease and Parkinson's disease through medicines that rely on target protein degradation, or TPD, as their mode of action, all of which are created using the Company's degrader technology. Under the terms of the Biogen Agreement, the Company was engaged to develop TPD therapeutics that utilize degrader technology for up to five target proteins over a period of 54 months, ending in June 2023. On a target-by-target basis, after successful completion of a defined target evaluation period, Biogen assumes full rights and responsibility for continued development of each target. As of June 30, 2024, the research term of the Biogen Agreement has been fully satisfied.

In exchange for the non-exclusive research license from Biogen, as well as a \$45.0 million nonrefundable upfront payment, the Company has granted a license to develop, commercialize, and manufacture products related to each of the targets (which is contingent on not cancelling the agreement), performs initial research services for drug discovery, has provided a non-exclusive research and commercial license to its intellectual property, and participates on the joint steering committee, or the Biogen JSC. The Company was also 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 is reimbursed by Biogen, and Biogen reimburses the Company for certain full-time equivalent, or FTE, costs. The Company's obligations under the sandbox activities were completed as of August 31, 2021. For any target, following the achievement of development candidate criteria and prior to any IND-enabling study, 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 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. All milestone and sales-based payments are made after the Company has met the defined criteria in the joint research plan for that target, at which time Biogen will have control of the products related to the targets for commercialization; the receipt of these payments is contingent on the further development of products directed to the targets to commercialization by Biogen, without any additional research and development efforts from the Company.

Biogen Agreement accounting

As of September 30, 2024, the total transaction price of the Biogen Agreement of \$55.0 million was allocated to the research and development services performance obligation, and the transaction price has been fully allocated and satisfied.

In April 2024, the Company earned an \$8.0 million milestone payment from Biogen after the Company accepted delivery of a development candidate in an undisclosed indication. In September 2024, the Company earned an additional \$8.0 million milestone payment from Biogen after Biogen accepted delivery of a development candidate in a separate undisclosed indication. The Company's performance obligation under the Biogen Agreement is fully satisfied, and the Company has recognized the full amount as revenue during the three and nine months ended September 30, 2024. Biogen is responsible for all future clinical development and commercialization for this program.

Calico Collaboration and License Agreement

In March 2017, the Company entered into a collaboration and license agreement, or the Calico Agreement, with 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. In August 2021, the Company provided an extension option to Calico, which Calico exercised in September 2021, resulting in a \$1.0 million extension payment to extend the research term with respect to a certain program for up to a one-year period that ended in March 2023. In addition, Calico reimbursed the Company for a number of FTEs, depending on the stage of the research, at specified market rates. As of March 13, 2023, the research term of the Calico Agreement has expired, and the Company's research activities associated with the agreement are complete.

Under the Calico Agreement, Calico paid an upfront amount of \$5.0 million and certain annual payments totaling \$5.0 million through June 30, 2020 and paid target initiation fees and reimbursed the Company for a number of FTEs, depending on the stage of the research, at specified market rates. For each target, the Company is eligible to receive up to \$132.0 million in potential 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. All milestone and sales-based payments are made after the Company has met the defined criteria in the joint research plan for that target, at which time Calico will have control of the products related to targets for commercialization; the receipt of these payments by the Company is contingent on the further development of the targets to commercialized products by Calico, without any additional research and development efforts required by the Company.

Summary of revenue recognized from collaboration agreements

Revenue from collaboration agreements for the three and nine months ended September 30, 2024 and 2023 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,	
	2024	2023	2024	2023
Revenue from collaboration agreements:				
MKDG Agreement	\$ 2,368	\$ —	\$ 4,317	\$ —
Merck Agreement	1,684	—	3,431	—
Betta Agreements	2,896	—	2,896	—
Roche Agreement	414	8,223	2,865	8,736
Biogen Agreement	8,000	2,849	16,898	7,689
Calico Agreement	—	—	—	1,070
Total revenue from collaboration agreements	<u>\$ 15,362</u>	<u>\$ 11,072</u>	<u>\$ 30,407</u>	<u>\$ 17,495</u>

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, 2024 (in thousands):

	Accounts Receivable	Deferred Revenue, Current	Deferred Revenue, Net of Current	Deferred Revenue, Total
Supplemental information:				
MKDG Agreement	\$ 1,572	\$ 4,770	\$ 9,652	\$ 14,422
Merck Agreement	—	6,569	—	6,569
Betta Agreements	769	4,203	11,107	15,310
Roche Agreement	—	5,227	7,889	13,116
Biogen Agreement	8,000	—	—	—
Total	<u>\$ 10,341</u>	<u>\$ 20,769</u>	<u>\$ 28,648</u>	<u>\$ 49,417</u>

Financial information related to the collaboration and license agreements consisted of the following in the Company's condensed consolidated balance sheet as of December 31, 2023 (in thousands):

	Accounts Receivable	Deferred Revenue, Current	Deferred Revenue, Net of Current	Deferred Revenue, Total
Supplemental information:				
Merck Agreement	\$ 10,000	\$ 8,000	\$ 2,000	10,000
Betta Agreement	1,799	4,000	8,000	12,000
Roche Agreement	—	2,667	11,814	14,481
Biogen Agreement	—	804	—	804
Total	\$ 11,799	\$ 15,471	\$ 21,814	\$ 37,285

Supplemental financial information related to the collaboration and license agreements for the three and nine months ended September 30, 2024 and 2023 are (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Revenue recognized that was included in the contract liability at the beginning of the period	\$ 4,994	\$ 2,664	\$ 9,996	\$ 5,895

As of September 30, 2024, the aggregate amount of the transaction price allocated to performance obligations under the MKDG Agreement, Merck Agreement, Betta Agreements, and Roche Agreement that were partially unsatisfied was \$170.0 million. The vast majority of the remaining transaction price to be recognized as revenue is based on the estimated manufactured clinical supply costs under the Betta Pharma collaboration. Due to scientific and technical uncertainties of the clinical trials, the Company cannot be certain that this amount will be recognized as revenue in future periods.

Note 9. Stockholders' equity

At-The-Market Equity Program

In November 2021, the Company filed an automatically effective registration statement on Form S-3, or the Registration Statement, with the SEC that registers the offering, issuance and sale of an unspecified amount of common stock, preferred stock, debt securities, warrants, and/or units of any combination thereof. Simultaneously, the Company entered into an equity distribution agreement with Cowen and Company, LLC, as sales agent, to provide for the issuance and sale by the Company of up to \$200.0 million of common stock from time to time in "at-the-market" offerings under the Registration Statement and related prospectus filed with the Registration Statement, or the ATM Program. During the three and nine months ended September 30, 2024, the Company settled 1,631,521 and 4,132,122 shares for net proceeds of \$10.3 million and \$24.4 million. No amounts were settled under the ATM Program during the three and nine months ended September 30, 2023. As of September 30, 2024, a total of 15,318,264 shares of the Company's common stock at an average purchase price of \$5.54 had been sold through the ATM Program, resulting in net proceeds of \$82.3 million.

Note 10. Stock-based compensation

Stock-based compensation expense for the three and nine months ended September 30, 2024 and 2023 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,	
	2024	2023	2024	2023
Stock-based compensation expense:				
Research and development	\$ 3,341	\$ 3,906	\$ 8,043	\$ 9,133
General and administrative	5,490	4,294	13,384	11,743
Total stock-based compensation expense	\$ 8,831	\$ 8,200	\$ 21,427	\$ 20,876

Stock options

During the nine months ended September 30, 2024, the Company granted stock options for the purchase of 3,382,967 shares of common stock with a weighted average exercise price of \$6.86 per share and a weighted average grant-date fair

value of \$5.62 per shares. As of September 30, 2024, the unrecognized compensation cost related to outstanding stock options was \$41.9 million, which is expected to be recognized over a weighted-average period of 2.3 years.

On March 7, 2024, the Company approved an option repricing program applicable to outstanding option awards granted to current employees of the Company under the Company's 2020 Stock Option and Incentive Plan, or the 2020 Plan, with an exercise price per share greater than or equal to \$22.00. The repriced awards have new exercise prices of \$11.88 per share for awards held by employees generally and \$19.00 per share for awards held by members of the Company's senior leadership team. To receive the benefit of this reduced exercise price, holders of repriced option awards must not, prior to March 7, 2025, (i) voluntarily leave employment with the Company or (ii) exercise the repriced options. The repriced options otherwise remain on their existing terms and conditions as set forth in the 2020 Plan and applicable award agreements. During the three and nine months ended September 30, 2024, the Company recorded an incremental non-cash charge of \$0.4 million and \$0.9 million related to this option repricing. On October 7, 2024, the 2020 Plan was amended to prohibit the plan's administrator from reducing the exercise price of outstanding stock options or stock appreciation rights or effecting repricing through cancellation and re-grant or cancellation in exchange for cash or other awards without prior stockholder approval.

Performance-based restricted stock units

During the nine months ended September 30, 2024, the Company did not grant any performance-based restricted stock units, or PSUs. In addition, 21,000 PSUs vested during the nine months ended September 30, 2024 upon their respective achievement of performance-based vesting criteria. Upon vesting, each PSU automatically converts into one share of the Company's common stock. The Company withheld 6,634 shares of its common stock through net-share settlement as consideration for employee tax withholding obligations arising upon vesting of the PSUs, which tax amounts were remitted to the applicable revenue authorities in cash. As of September 30, 2024, the unrecognized compensation cost related to outstanding PSUs with performance-based vesting criteria that are considered not probable of achievement was \$2.4 million.

Time-based restricted stock units

During the nine months ended September 30, 2024, the Company issued 1,013,350 restricted stock units, or RSUs, that were subject to time-based vesting conditions to its employees. These RSUs are valued on the grant date using the grant date market price of the underlying shares. A total of 161,862 RSUs vested during the nine months ended September 30, 2024 upon their respective vesting schedules. Upon vesting, each RSU automatically converts into one share of the Company's common stock. The Company indirectly repurchased 23,349 shares of its common stock through net-share settlement as consideration for employee tax withholding obligations arising upon vesting of the RSUs, which tax amounts were remitted to the applicable revenue authorities by the Company in cash on behalf of the RSU holders. As of September 30, 2024, the unrecognized compensation cost related to outstanding RSUs was \$8.9 million, which is expected to be recognized over a weighted-average period of 3.1 years.

Note 11. Commitments and contingencies

Legal proceedings

The Company is not currently party to any material legal proceedings. At each reporting date, the Company evaluates whether or not a potential loss amount or a potential range of loss is probable and reasonably estimable under the provisions of the authoritative guidance that addresses accounting for contingencies. The Company expenses as incurred the costs related to such legal proceedings.

Note 12. Loss per share

For periods in which the Company reports a net loss attributable to common stockholders, potentially dilutive securities have been excluded from the computation of diluted net loss per share as their effects would be anti-dilutive. Therefore, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share is the same. For purposes of the dilutive net loss per share calculation, stock options, and restricted stock units for which the performance or market vesting conditions have been met are considered to be common stock equivalents, while restricted stock units with performance or market vesting conditions that were not met as of September 30, 2024 are not considered to be common stock equivalents. The Company excluded the following potential common shares presented based on

amounts outstanding at period end from the computation of diluted net loss per share for the periods indicated because including them would have had an anti-dilutive effect:

	As of September 30,	
	2024	2023
Anti-dilutive common stock equivalents:		
Options to purchase common stock	11,849,611	9,868,099
Total anti-dilutive common stock equivalents	11,849,611	9,868,099

Basic and diluted loss per share is computed by dividing net loss by the weighted-average common shares outstanding for the three and nine months ended September 30, 2024 and 2023 (in thousands, except share and per share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Numerator:				
Net loss	\$ (24,666)	\$ (27,037)	\$ (70,743)	\$ (97,739)
Denominator:				
Weighted-average number of shares used in computed net loss per share – basic and diluted	69,627,190	49,212,126	68,958,938	49,103,351
Net loss per share – basic and diluted	\$ (0.35)	\$ (0.55)	\$ (1.03)	\$ (1.99)

Note 13. Restructuring

In January 2024, the Company implemented a restructuring plan to better align its workforce with the needs of its business and reduce operating costs that included a reduction in the Company's workforce by 30%. The resulting restructuring expense recognized during the nine months ended September 30, 2024 was \$2.4 million, which has all been substantially paid as of June 30, 2024.

Note 14. Income taxes

For the three and nine months ended September 30, 2024, the Company recorded no income tax provision or benefit due to losses generated where no benefit was recorded due to the valuation allowance. The Company continues to maintain a full valuation allowance for its U.S. federal and state deferred tax assets as of September 30, 2024 due to uncertainty regarding future taxable income.

The Company's effective tax rate in the nine months ended September 30, 2023 was impacted by the Chinese withholding tax obligation related to the upfront payment received in connection with the Beta License Agreement, as described in Note 8, Collaboration and license agreement, to the unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q, which resulted in a tax provision of \$(1.0) million and an effective tax rate of (1.0)%.

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 unaudited interim condensed consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q and our audited condensed consolidated financial statements and notes and Management’s Discussion and Analysis of Financial Condition and Results of Operations, included in our Annual Report on Form 10-K for the year ended December 31, 2023, filed with the SEC on February 22, 2024. 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 Annual Report on Form 10-K for the year ended December 31, 2023.

Business overview

We are a clinical-stage biopharmaceutical company dedicated to delivering on the promise of targeted protein degradation, or TPD, science to create a new generation of small-molecule medicines that transforms patients’ lives. By leveraging our proprietary TORPEDO platform, we have the capability to efficiently design and optimize small molecule protein degraders that are highly active against their desired targets by harnessing the body’s natural process for destroying unwanted proteins. We believe our novel oral product candidates have the potential to overcome drug resistance often seen with inhibitors, target currently “undruggable” targets and improve patient outcomes. To date, we have successfully designed and advanced several protein degraders into the clinic across a range of target classes and, based on data from our clinical trials, our product candidates have demonstrated robust target degradation.

One of our most advanced product candidates, cemsidomide (CFT7455), is an orally bioavailable MonoDAC degrader of protein targets called IKZF1 and IKZF3, currently in clinical development for multiple myeloma, or MM, and non-Hodgkin lymphomas, or NHLs. The United States Food and Drug Administration, or FDA, has granted orphan drug designation to cemsidomide (CFT7455) for the treatment of MM. In December 2023, we presented positive clinical data from the dose escalation portion of the cemsidomide (CFT7455) Phase 1/2 trial as a monotherapy and in combination with dexamethasone in MM. We continue to progress the ongoing Phase 1/2 clinical trial of cemsidomide in MM and NHL.

Our other most advanced product candidate, CFT1946, is an orally bioavailable BiDAC degrader designed to be potent and selective against BRAF V600X mutant targets to treat melanoma, non-small cell lung cancer, or NSCLC, colorectal cancer, or CRC, and other malignancies that harbor this mutation. In January 2023, we initiated a first-in-human Phase 1/2 clinical trial of CFT1946 for the treatment of BRAF V600X mutant solid tumors including NSCLC, colorectal cancer and melanoma. In September 2024, we presented initial monotherapy CFT1946 data demonstrating proof of mechanism and early evidence of proof of concept in BRAF V600 mutant solid tumors at the European Society for Medical Oncology (ESMO) Congress 2024. We continue to progress the ongoing Phase 1/2 clinical trial of CFT1946.

Additionally, we are developing CFT8919, an orally bioavailable, allosteric, mutant-selective BiDAC degrader of epidermal growth factor receptor, or EGFR, with an L858R mutation in NSCLC. In May 2023, we entered into an exclusive licensing agreement for the development and commercialization of CFT8919 in Greater China, including Hong Kong SAR, Macau SAR and Taiwan, with Betta Pharmaceuticals, Co., Ltd, or Betta Pharma. Additionally, the FDA cleared the investigational new drug, or IND, application for CFT8919 and Betta Pharma received clinical trial application clearance for CFT8919 from China’s National Medical Product Administration. We expect to initiate clinical trial activities outside Greater China following the completion of Betta Pharma’s Phase 1 dose escalation trial in Greater China.

Beyond these initial product candidates, we are further diversifying our pipeline by developing new degraders against both clinically validated and currently undruggable targets for our own proprietary programs, as well as for programs we are developing in collaboration with MKDG, Merck, and Roche.

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 the 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.

For a description of our collaboration agreements with Roche, Biogen, Calico, Betta Pharma, Merck and MKDG, please see Note 8, *Collaboration and license agreements*, to the unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

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 contract research organizations and other third parties that conduct research, preclinical, and clinical activities on our behalf as well as third parties that manufacture our product candidates for use in our preclinical and clinical trials;
- cost of outside consultants, including their fees and related travel expenses;
- 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 condensed 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.

We expect that our research and development expenses will continue to increase substantially in connection with our planned preclinical and clinical development activities.

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 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 potentially increase in the future to support increased research and development activities. These increases will likely include higher costs related to the hiring of additional personnel; fees to outside consultants, lawyers and accountants; and investor and public relations costs.

Other income (expense), net

Other income (expense), net primarily consists of the following:

- interest expense and amortization of our long-term debt, which is discussed in greater detail in Note 9, *Long-term debt – related party*, to the unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q; and
- interest income earned on our cash, cash equivalents, and marketable securities and accretion of discount on marketable securities.

Results of operations

Comparison of the three and nine months ended September 30, 2024 and 2023

Revenue

Revenue from our collaboration and license agreements consisted of the following for the three and nine months ended September 30, 2024 and 2023 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Revenue from collaboration agreements:				
MKDG Agreement	\$ 2,368	\$ —	\$ 4,317	\$ —
Merck Agreement	1,684	—	3,431	—
Betta Pharma Agreement	2,896	—	2,896	—
Roche Agreement	414	8,223	2,865	8,736
Biogen Agreement	8,000	2,849	16,898	7,689
Calico Agreement	—	—	—	1,070
Total revenue from collaboration agreements	\$ 15,362	\$ 11,072	\$ 30,407	\$ 17,495

The \$4.3 million increase in revenue in the three months ended September 30, 2024, as compared to the three months ended September 30, 2023 is primarily driven by the \$8.0 million milestone earned under the Biogen Agreement for the accepted delivery of a development candidate in an undisclosed indication and a total of \$6.9 million of revenue recognized related to the MKDG, Merck and Betta Pharma collaborations that had activities commence in 2024. This was offset by a \$7.8 million decrease in revenue related to the Roche collaboration as a result of our September 2023 completion of research activities for a nominated target.

The \$12.9 million increase in revenue in the nine months ended in September 30, 2024, as compared to the nine months ended September 30, 2023 is primarily driven by the \$10.6 million increase from start of collaboration activities in 2024 for the MKDG, Merck, and Betta Pharma Agreements, and two milestones earned under the Biogen Agreement. This was offset by a \$5.9 million decrease under the Roche Agreement as a result of our September 2023 completion of research activities for a nominated target.

Research and development expense

The following table summarizes our research and development expense for the three and nine months ended September 30, 2024 and 2023 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Research and development expenses:				
Personnel expenses	\$ 9,147	\$ 12,066	\$ 25,904	\$ 32,977
Preclinical development and discovery expenses	9,582	5,303	20,461	21,644
Clinical expenses	7,138	4,549	14,506	12,136
Facilities and supplies	2,950	3,222	9,336	10,277
Professional fees	1,761	2,119	5,282	6,729
Intellectual property and other expenses	1,260	1,088	2,635	3,552
Total research and development expenses	\$ 31,838	\$ 28,347	\$ 78,124	\$ 87,315

The \$3.5 million increase in research and development expense in the three months ended September 30, 2024 as compared to the three months ended September 30, 2023 is primarily driven by:

- a \$4.3 million increase in preclinical expenses as a result of the progress made on our collaboration programs; and
- a \$2.6 million increase in clinical expenses due to continued progress on our cemsidomide and CFT1946 programs.

These amounts were partially offset by a \$2.9 million decrease in personnel costs as a result of our restructuring activities in January 2024.

The \$9.2 million decrease in research and development expense in the nine months ended September 30, 2024 as compared to the nine months ended September 30, 2023 is primarily driven by:

- a \$7.1 million decrease in personnel costs as a result of our restructuring activities;
- a \$1.4 million decrease in professional fees; and
- a \$1.2 million decrease in preclinical expenses as a result of prioritization of our business towards programs that are in clinical stages.

These amounts were partially offset by a \$2.4 million increase in clinical expenses as a result of continued progress on our cemsidomide and CFT1946 programs.

General and administrative expense

The following table summarizes our general and administrative expense for the three and nine months ended September 30, 2024 and 2023 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
General and administrative expenses:				
Personnel expenses	\$ 8,929	\$ 8,086	\$ 23,912	\$ 23,151
Professional fees	1,715	1,493	4,773	5,517
Facilities and other expenses	1,124	954	3,066	3,116
Total general and administrative expenses	<u>\$ 11,768</u>	<u>\$ 10,533</u>	<u>\$ 31,751</u>	<u>\$ 31,784</u>

The \$1.2 million increase in general and administrative expense in the three months ended September 30, 2024 as compared to the three months ended September 30, 2023 is primarily driven by a \$0.9 million increase in personnel expenses related to our hiring of key personnel.

General and administrative expense in the nine months ended September 30, 2024 as compared to the nine months ended September 30, 2023 remained relatively flat as a result of an increase of \$0.8 million for personnel expenses offset by a \$0.7 million decrease in professional fees and other expenses.

Restructuring expense

The \$2.4 million increase of restructuring expense in the nine months ended September 30, 2024 compared to the nine months ended September 30, 2023 is driven by the restructuring plan implemented in January 2024 to better align the

Company's workforce with the needs of the business and reduce operating costs, which resulted in a reduction in the Company's workforce of 30%.

Other income (expense), net

The following table summarizes our other income (expense), net for the three and nine months ended September 30, 2024 and 2023 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Other income (expense), net:				
Interest and other income, net	\$ 3,578	\$ 2,562	\$ 11,162	\$ 6,862
Loss on extinguishment of long-term debt	—	(621)	—	(621)
Interest expense and amortization of long-term debt – related party	—	(167)	—	(1,373)
Total other income, net	\$ 3,578	\$ 1,774	\$ 11,162	\$ 4,868

The \$1.8 million increase in other income (expense), net in the three months ended September 30, 2024 as compared to the three months ended September 30, 2023 is primarily driven by a \$1.0 million increase in interest and other income resulting from higher interest earned on our investments during the three months ended September 30, 2024 and a \$0.6 million decrease in loss on extinguishment of long-term debt.

The \$6.3 million increase in other income (expense), net in the nine months ended September 30, 2024 as compared to the nine months ended September 30, 2023 is primarily driven by a \$4.3 million increase in interest and other income resulting from higher interest earned on our investments during the three months ended September 30, 2024 and a \$1.4 million decrease in interest expense from long-term debt.

Liquidity and capital resources

Sources of liquidity

Since inception, we have incurred significant operating losses. We expect to incur significant expenses and operating losses for the foreseeable future as we advance the preclinical programs and our product candidates through clinical development. 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, public offerings of our common stock, private placements of our common stock, and through payments from collaboration partners. As of September 30, 2024, we had cash, cash equivalents and marketable securities of approximately \$284.4 million.

Cash flows

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

	Nine Months Ended September 30,	
	2024	2023
Net change in cash, cash equivalents and restricted cash:		
Net cash used in operating activities	\$ (47,225)	\$ (82,829)
Net cash (used in) provided by investing activities	(64,940)	126,404
Net cash provided by (used in) financing activities	45,224	(12,183)
Total net change in cash, cash equivalents and restricted cash	\$ (66,941)	\$ 31,392

Operating activities

Net cash used in operating activities for the nine months ended September 30, 2024 was driven primarily by the following uses of cash:

- net loss of \$70.7 million;
- \$5.2 million change in accrued expenses and other current liabilities;
- \$4.3 million change in prepaid expenses and other current and long-term assets; and
- \$3.9 million change in our operating lease liability.

These were offset by:

- \$12.1 million change in deferred revenue due to the upfront payment related to the MKDG Agreement and the allocated transaction price that remains unsatisfied related to the Betta Pharma License Agreement, partially offset by the recognition of revenue under our collaboration agreements;
- \$1.5 million change in accounts receivable, primarily a result of the Merck upfront payment; and
- non-cash expenses of \$23.2 million, which primarily consisted of stock-based compensation expense of \$21.4 million.

Investing activities

Net cash used in investing activities for the nine months ended September 30, 2024 was driven primarily by \$64.8 million of purchases of marketable securities, net of maturities.

Financing activities

Net cash provided by financing activities for the nine months ended September 30, 2024 was driven primarily by:

- \$20.0 million in net proceeds for the execution of the Betta Stock Purchase Agreement; and
- \$24.4 million in net proceeds from our at-the-market equity program.

Funding requirements

Since our inception, we have incurred significant operating losses, and we expect to continue to incur significant expenses and increasing operating losses for the foreseeable future as we advance the preclinical programs and our product candidates through clinical development. In addition, we expect to continue to incur costs associated with operating as a public company.

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

- continue our ongoing first-in-human Phase 1/2 trials and initiate and conduct planned first-in-human Phase 1/2 trials for our other product candidates;
- advance additional product candidates into preclinical and clinical development;
- continue to invest in our proprietary TORPEDO platform;
- advance, expand, maintain, and protect our intellectual property portfolio;
- hire additional clinical, regulatory, quality, and scientific personnel;
- add operational, financial 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 roles;
- 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 preclinical and clinical development. Our future capital requirements will depend on many factors, including:

- the progress, costs, and results of ongoing and 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 progress and success of our existing and any future collaborations with third-party partners, including whether or not we receive additional research support or milestone payments from our existing 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, that we can generate substantial revenue from product sales, we expect to finance our cash needs through a combination of equity offerings, private placements of equity securities, 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, Calico, Biogen, Betta Pharma, Merck, and MKDG, we do not have any committed external sources of funds as of September 30, 2024.

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.

If we raise additional capital through the sale of equity securities, each investor's ownership interest will be diluted, and the terms of any securities we may issue could include liquidation or other preferences that adversely affect the rights of holders of our common stock. 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.

At-the-market equity program

In November 2021, we filed an automatically effective registration statement on Form S-3, or the Registration Statement, with the SEC that registers the offering, issuance and sale of an unspecified amount of common stock, preferred stock, debt securities, warrants, and/or units of any combination thereof. Simultaneously, we entered into an equity distribution agreement with Cowen and Company, LLC, as sales agent, to provide for the issuance and sale by of up to \$200.0 million of common stock from time to time in "at-the-market" offerings under the Registration Statement and related prospectus and any prospectus supplement filed with the Registration Statement, or the ATM Program. In February 2023, we filed a post-effective amendment to convert the automatic shelf registration statement into a conventional shelf registration statement and that registration statement became effective in May 2023. As of September 30, 2024, the Company has sold 15,318,264 shares of our common stock at an average purchase price of \$5.54 under the ATM Program, resulting in net proceeds of \$82.3 million.

Contractual obligations

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

During the nine months ended September 30, 2024, except for the minimum rental commitments disclosed in Note 6, *Leases*, to the unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q, there were no significant changes to our contractual obligations and commitments described under "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the year ended December 31, 2023.

Critical accounting policies and use of estimates

Our critical accounting policies are those policies that require the most significant judgments and estimates in the preparation of our unaudited condensed consolidated financial statements. We have determined that our most critical accounting policies are those relating to revenue recognition from collaborations, research and development expense recognition, lease liability measurement, and stock-based compensation. There have been no significant changes to our

existing critical accounting policies discussed in our Annual Report on Form 10-K for the year ended December 31, 2023, which was filed with the SEC on February 22, 2024.

Off-balance sheet arrangements

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

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, cash equivalents, and marketable securities. Our interest income is sensitive to changes in the general level of interest rates, primarily United States interest rates. As of September 30, 2024, we had marketable securities of \$224.8 million, which consisted of corporate debt securities, U.S. government debt securities, and U.S. Treasury securities. Our marketable securities are short term in nature with a weighted-average maturity date of 0.6 years. As such, while these interest-earning instruments carry a degree of interest rate risk, historical fluctuations in interest income have not been significant for the Company.

Item 4. Controls and Procedures.

Evaluation of disclosure controls and procedures

Our management, with the participation of our principal executive officer and our principal financial officer 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, or the Exchange Act, as of September 30, 2024. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits 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, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Based on the evaluation of our disclosure controls and procedures as of September 30, 2024, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures as of such date are effective at the reasonable assurance level.

Changes in internal control over financial reporting

We continuously seek to improve the efficiency and effectiveness of our internal controls. This results in refinements to processes throughout the company. There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended September 30, 2024 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. See “Risk Factors—*We will continue to incur additional 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.*”

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 together with all the other information in this Quarterly Report on Form 10-Q, including the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our financial statements and related notes appearing at the end of this Quarterly Report on Form 10-Q, in evaluating our company. The risks and uncertainties described below and in our other filings with the SEC, may not be the only ones that we face. The occurrence of any of the events or developments described below, if they actually occur, 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 a clinical-stage biopharmaceutical company 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 a clinical-stage biopharmaceutical company with limited operating history. Our net loss was \$24.7 million and \$27.0 million for nine months ended September 30, 2024 and 2023, respectively. As of September 30, 2024, we had an accumulated deficit of \$599.1 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 public offerings or other issuances of our common stock, proceeds from our collaborations and debt financing. We are still in the early stages of development of our product candidates. As a result, 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, conduct, and successfully complete first-in-human and later-stage clinical trials of our product candidates and as we expand the scope of our proprietary research and development portfolios;
- leverage our TORPEDO platform to identify and then advance additional product candidates into preclinical and clinical development;
- expand the capabilities of our TORPEDO platform;
- 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 expect to obtain marketing approval;
- advance, expand, maintain, and protect our intellectual property portfolio; and
- manage staffing needs to meet the changing needs of the business as we advance additional product candidates and/or continue to develop existing product candidates.

Further, we expect to continue to incur additional costs associated with operating as a public company, including significant legal, accounting, insurance, investor relations, and other expenses.

Our expenses could increase beyond our expectations if we are required by the FDA, the European Medicines Agency, or other regulatory authorities to perform trials in addition to those that we currently expect, or if we experience any delays in

either establishing appropriate manufacturing arrangements for or 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, 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, conduct, and complete our ongoing and planned first-in-human Phase 1/2 clinical trials of our product candidates, advance our TORPEDO platform and continue research and development activities, expand our proprietary research and development portfolios and initiate and continue 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 continue 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, cash equivalents, and marketable securities of approximately \$284.4 million as of September 30, 2024. We believe that these funds and the anticipated cost savings from our restructuring in January 2024 will be sufficient to fund our planned operating expenses into 2027. We have based this estimate on assumptions that may prove to be wrong, and we could deplete our current capital resources sooner than we currently expect. Our future capital requirements will depend on many factors, including:

- the timing, progress, costs, and results of our ongoing and planned first-in-human Phase 1/2 clinical trials for our product candidates and any future clinical development of those product candidates;
- the scope, progress, costs, and results of clinical development stage programs and 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;
- 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 or expect to 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 delays due to any global health epidemics, that we experience in our preclinical studies, 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 or access to our TORPEDO platform.

Our current cash, cash equivalents, and marketable securities 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 several 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.

We remain early in the development lifecycle, which may make it difficult for you to evaluate the success of our business to date and assess our future viability.

We commenced operations in late 2015 and initiated our first Phase 1/2 clinical trial in 2021. Our activities 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, establishing arrangements with third parties for the manufacture of initial quantities of our product candidates, and preparing for and conducting early-stage clinical trials. While we have ongoing clinical trials and anticipate the commencement of an additional clinical trial through our partner Betta Pharma, all of our other product candidates are still in the discovery stage. We have not yet demonstrated our ability to successfully 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 the past.

In addition, as a 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.

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, share issuances, private placements, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. Although we may receive potential future payments under our collaborations, we do not currently have any committed external source of funds. If 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.

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 and none of the product candidates developed through our TORPEDO platform have been approved in the United States, Europe, or any other jurisdiction. 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 targeted protein degraders, 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 product 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 would prevent or diminish their clinical benefit, as would be the case if the scientific research that forms the basis of our efforts proves to be contradicted.

While we have ongoing clinical trials, at this time, we have not yet completed a clinical trial of any product candidate. As a result, we are only starting to assess the safety of our lead product candidates in patients, and we have not yet assessed the safety of any of our other earlier-stage product candidates in humans. Although some of our earlier-stage 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 a clinical stage biotechnology company and, while we have commenced clinical trials of certain of our product candidates, our other product candidates are still in the discovery stage. 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 a clinical-stage biotechnology company and, while we have ongoing clinical trials, our other product candidates are currently in the discovery stage. As a result, their risk of failure is high. We have invested substantially all of our efforts and financial resources into building our TORPEDO platform and identifying and conducting preclinical development of our current product candidates, including our lead programs. Our ability to generate revenue from product sales, which we do not expect will occur for several 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 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 suitable 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 our products and maintaining that profile following approval;
- effectively competing with other therapies; and
- the skill and success of our third-party collaboration partners in accomplishing any of the aforementioned in the markets in which they are developing our product candidate(s) in a timely manner.

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.

Relative to companies that are more established than we are or that have a larger footprint than we do, we have relatively limited experience as a company in completing preclinical studies to enable the filing of INDs, submitting INDs or commencing, enrolling and conducting clinical trials.

Our experience as a company in completing IND-enabling preclinical studies comes from our work in commencing clinical development of four product candidates. While this work represents a substantial amount of progress, to date, we still have relatively limited experience as a company in commencing, enrolling and conducting clinical trials. In part because of this, while we continue to make strides in this area, we cannot be certain that our planned clinical trials will begin, enroll or be completed on time, if at all. Additionally, even if the applicable regulatory authorities agree with the design and implementation of the clinical trials set forth in our INDs upon initial IND submission, we cannot guarantee that those regulatory authorities will not change their requirements in the future. These considerations apply to the INDs described above, additional INDs that we may submit in the future and also to new clinical trials we may submit as amendments to existing or new INDs.

Further, large-scale clinical trials would require significant additional financial and management resources and reliance on third-party clinical investigators, contract research organizations, or CROs, and consultants. Relying on third-party clinical investigators, CROs and consultants may cause us to encounter delays that are outside of our control and, for each of the product candidates that is currently in clinical development, we have engaged a CRO to lead our first-in-human Phase 1/2 clinical trial. Relying on third parties in the conduct of our preclinical studies or clinical trials exposes us to a risk that they may not adequately adhere to study or trial protocols or comply with good laboratory practice or good clinical practice, or GCP, as required for any studies or trials we plan to submit to a regulatory authority. We may also be unable to identify and contract with sufficient investigators, CROs, and consultants on a timely basis or at all, and we may also determine and have in the past determined after a clinical trial has commenced that a change in CRO is warranted. There can be no assurance that we will be able to negotiate and enter into appropriate contractual arrangements without current or potential future CROs, if and when necessary for our other product candidates, 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 and efficacy of any of our product candidates, which would prevent or delay development, regulatory approval, and commercialization. Further, the results of preclinical studies may not be predictive of future results in later studies or trials and initial success in clinical trials may not be indicative of results obtained when these trials are completed or in later stage clinical trials.

Before obtaining regulatory approval for the commercial sale of any of our product candidates, 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. This testing is expensive and can take many years to complete. Further, the outcome of these activities is inherently uncertain. Failure can occur at any time during the clinical development process and, because many of 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 targeted protein degraders 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. 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. Although product candidates may demonstrate promising results in preclinical studies and early clinical trials, they may not prove to be effective or safe in subsequent clinical trials. The results of the dose escalation portion of our ongoing and planned first-in-human Phase 1/2 clinical trials of our product candidates may not be predictive of the results of further clinical trials of these product candidates or any other product candidates and may not be sufficient to enable us to progress to the Phase 2 portion of a Phase 1/2 clinical trial. 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. As was the case for our CFT8634 product candidate, which was the subject of a Phase 1/2 clinical trial that we ultimately elected to shut down, product candidates in clinical trials may fail to show the desired safety and efficacy profile despite having progressed successfully through preclinical studies and/or initial or earlier stage clinical trials. Likewise, early, smaller-scale clinical trials may not be predictive of eventual safety or effectiveness in large-scale pivotal clinical trials. In particular, the small number of patients in our planned early clinical trials or the designs of these trials may make the results of these trials less predictive of the outcome of later clinical trials. Many companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy, insufficient durability of 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 marketable products. Any setbacks of this nature in our clinical development could materially harm our business, financial condition, results of operations and prospects.

Additionally, we expect that the first clinical trials for our product candidates will 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. This is the case with our ongoing first-in-human clinical trials and will be the case in the first-in-human clinical trials of the additional product candidates we presently expect to advance into clinical development. Open-label clinical trials often test only the investigational product 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 or have conducted may not demonstrate the safety and efficacy necessary to obtain regulatory approval to market our product candidates. If the results of our ongoing or future preclinical studies or clinical trials are inconclusive with respect to the safety and efficacy of our product candidates, if evidence of target degradation does not correlate with clinical efficacy, 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 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 commenced clinical trials of several of our product candidates, some of which remain ongoing, we have not yet initiated clinical trials for the remainder of our product candidates. As is the case with all drugs, it is likely that there may be side effects associated with the use of our product candidates related to on-target toxicity, off-target toxicity, or other mechanisms of drug toxicity including chemical-based toxicity. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects of this nature. If unacceptable levels of toxicity are observed or if our product candidates have other characteristics that are unexpected, we may need to abandon their development, modify our development plans as to dose level and/or dose schedule or otherwise, 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. For example, due to observed safety signals, we previously modified the dosing

schedule in our ongoing Phase 1/2 clinical trial of cemsidomide (CFT7455) as we continue to advance this clinical trial. Further, if we were to observe unacceptable levels of side effects, or if other developers of similar targeted protein degraders were to find an unacceptable severity or prevalence of side effects with their drug 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. 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. Any of these occurrences may significantly harm our business, financial condition, and prospects.

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 or top-line preliminary data from our clinical trials. Interim data from clinical trials that we may conduct 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 remains 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.

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.

While we have commenced clinical trials of several product candidates, one of which we elected to shut down, and anticipate the commencement of a clinical trial of CFT8919 through our partner Betta Pharma, the remainder of our product candidates are still in the discovery stage at this time and the risk of failure for all of our product candidates remains 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.

Clinical testing is expensive, difficult to design and implement, can take many years to enroll and 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 or CROs;
- 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 we may be unable 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, modify our development plans as to dose level and/or dose schedule or otherwise, or abandon product development programs;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- staffing shortages, including but not limited to the lack of appropriately trained or experienced clinical research associates or medical staff at the institutions where we conduct our clinical trials or the lack of sufficient support personnel at these institutions involved in site contracting and activation, may cause delays or create other challenges to the timely and efficient conduct of our clinical trials;
- 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 any global health epidemics, such as the recent COVID-19 pandemic, which may increase the likelihood that we encounter these types of difficulties or cause other delays in initiating, enrolling, conducting, or completing our planned clinical trials.

We also may encounter challenges in our clinical development programs due to evolving regulatory policy in the United States or other jurisdictions. For example, in 2021, the FDA's Oncology Center of Excellence launched Project Optimus, an initiative to reform dose selection in oncology drug development. If the FDA believes we have not sufficiently established that the selected dose or doses for our product candidates maximize efficacy as well as safety and tolerability, the FDA may require us to conduct additional clinical trials or generate additional dosing-related information, which could significantly delay and/or increase the expense of our clinical development programs.

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 enroll or 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 related to our product candidates, 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 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. While we have commenced clinical trials of several product candidates and anticipate the commencement of a clinical trial of CFT8919 through our partner Beta Pharma, we do not know whether any of our other clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant 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 systemic anti-cancer therapy (e.g., chemotherapy), surgery, radiation therapy 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 has been shown to not be effective. Our ongoing and planned early-stage clinical trials will be with patients who have received one or more prior treatments, and we expect that we would initially seek regulatory approval of our lead product candidates as 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 for the same indication and/or patient population 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 developing product candidates based on chimeric small molecules for targeted protein degradation including Arvinas, Inc., Astellas Pharma Inc., BioTheryX, Inc., Captor Therapeutics, Inc., Cullgen Inc., Foghorn Therapeutics, Inc., Frontier Medicines Corporation, Glubio Therapeutics, Inc., Kymera Therapeutics, Inc., Monte Rosa Therapeutics, Inc., Nurix Therapeutics, Inc., Orum Therapeutics, Inc., PhoreMost, Ltd., Plexium, Inc., Salaris Pharmaceuticals, Inc., Seed Therapeutics, Inc., SK Life Science Labs., Ltd. (a subsidiary of SK Biopharmaceuticals), and Vividion Therapeutics, Inc. (a subsidiary of Bayer AG). Further, several large pharmaceutical companies and academic institutions 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.

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. 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, 2023, we had \$214.9 million federal net operating loss carryforwards and \$315.3 million gross in U.S. state net operating loss carryforwards, portions of which expire at various dates through 2043. Under current law, federal net operating losses generated in tax years beginning after 2017, if any, will not expire and may be carried forward indefinitely, but our ability to deduct such federal net operating losses in tax years beginning after December 31, 2020 will be limited to the lesser of the net operating loss carryover or 80% of the corporation's adjusted taxable income (subject to Section 382 of the Internal Revenue Code of 1986, as amended). It is uncertain if and to what extent various states will conform to the federal tax laws. In addition, at the state level, there may be periods during which the use of net operating losses is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

As of December 31, 2023, we also had U.S. federal and state research and development tax credit carryforwards of \$12.6 million and \$5.2 million, respectively, which expire at various dates through 2043. 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 2021, we completed a study of ownership changes from inception through December 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 have not updated the study to assess whether a change of ownership has occurred during 2023 and through 2024. We may have experienced additional ownership changes that have not been identified that could result in the expiration of our net operating loss and tax credit carryforwards before utilization and we may experience subsequent shifts in our stock ownership, some of which are outside our control. As a result, if we earn net taxable income and 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 will harm our future operating results by effectively increasing our future tax obligations.

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

While we have commenced clinical trials of several product candidates, and anticipate the commencement of a clinical trial of CFT8919 through our partner Betta Pharma, all of our other product candidates are still in the discovery stage at this time, which means that we have not yet evaluated any of our other product candidates in human clinical trials. 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 or results. 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 or results that are unexpected, we may choose or need to abandon their development, modify our development plans as to dose level and/or dose schedule or otherwise, 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 types 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.

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

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 have progressed three product candidates, cemsidomide (CFT7455), CFT8634, and CFT1946, into first-in-human clinical trials in June 2021, May 2022, and December 2022, respectively, with clinical trials currently ongoing for cemsidomide (CFT7455) and CFT1946 and a clinical trial planned for CFT8919 through our partner, Betta Pharma. While we believe that we or our partner will be able to enroll a sufficient number of patients into each ongoing or planned clinical trials, we cannot predict with certainty how difficult it will be to enroll patients for trials, some of which are in rare indications. Our ability to identify and enroll eligible patients for clinical trials of our product candidates 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 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 availability of suitable and sufficient staffing at clinical trial sites;
- 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 any global health epidemics, such as the recent 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 or by interfering with patients' ability to return to the clinical trial site for required monitoring, procedures, or follow-up.

Our inability to enroll a sufficient number of patients for our 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.

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 or our partners may develop our product candidates in combination with other drugs. 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 our product candidates, we may be unable to obtain approval of or market our product candidates.

Based on the study design for a number of our product candidates, once a recommended dose is identified from the dose escalation portion of our first-in-human Phase 1/2 clinical trial, we often plan to conduct a portion of that clinical trial in

combination with one or more other medicines. 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 our product candidates. 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 our product candidates, we will not be able to market our product candidates 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 our product candidates, 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 our product candidates, we may not be able to complete clinical development of our product candidates on our current timeline or at all.

Even if our product candidates 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 drugs used in combination with our product candidates 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 current clinical-stage 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 or 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 or failing to comply with regulatory requirements or our clinical protocols.

We currently rely on CROs to conduct our clinical trials, and we currently do not plan to independently conduct clinical trials of any of our product candidates. Additionally, we must contract with third-party research sites for the conduct of our clinical trials. Just as we rely on Beta Pharma to develop CFT8919 in Greater China in an efficient and effective manner, we may also similarly rely on other third-party collaboration partners in the future to develop one or more of our products in various territories on certain timelines. Our agreements with these CROs, sites, and other third parties 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 or if we were to need to change a CRO for an ongoing clinical trial, which we have done in the past, we might experience delays in our clinical 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, safety and confidentiality of trial participants are protected. GCP compliance extends not only to sponsors of clinical research but also to third parties including CROs and sites involved in the conduct of clinical research. Similarly, other regulators throughout the world require compliance with similar standards that are also applicable to clinical trial sponsors and other third parties like CROs and clinical trial sites.

Further, these CROs or sites may have relationships with other entities, some of which may be our peers or competitors. If the CROs or sites 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, for any reason, 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. Our failure or the failure of these third parties to comply with applicable regulatory requirements or our stated protocols could also subject us to enforcement action. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

We also currently rely on certain foreign or foreign-owned third-party vendors to manufacture certain materials used in clinical trials of our product candidates or to provide services in connection with certain clinical trials or certain discovery activities. Our engagement with these foreign and foreign-owned vendors may be subject to new U.S. legislation or investigations, sanctions, trade restrictions and other foreign regulatory requirements, which could cause us to need to identify alternate service providers, increase the cost or reduce the supply of materials available to us, delay the procurement or supply of these materials, delay or impact clinical trials, have an adverse effect on our ability to secure significant commitments from governments to purchase our potential therapies, any of which could adversely affect our financial condition and business prospects.

Manufacturing pharmaceutical products is complex and subject to product delays or 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, including where a pre-approval inspection or an inspection of manufacturing sites is required and FDA is unable to complete those required inspections during the review period for any reason.

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, quality assurance, and manufacturing success;

- the possible breach of the manufacturing agreement by the third-party CMO;
- the possible risk that the CMO will cease offering the services we require or shut down operations altogether, either temporarily or permanently, due to a regulatory concern, financial insolvency, non-compliance with applicable law or another reason;
- 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 or the inability of the CMO to provide us with a manufacturing slot when we need it.

We have only limited supply 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 anticipate receiving or receive marketing approval for any of our product candidates, we will need to establish or have established an agreement for commercial manufacture with one or more third parties. In addition, new U.S. legislation or investigations, as well as possible sanctions, trade restrictions and/or other foreign regulatory requirements, could serve to limit the third parties we could engage, increase the cost or reduce the supply of materials available to us, or otherwise adversely affect our financial condition and business prospects.

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. Some of 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 containment and other precautions that must be taken as part of the manufacture of our product candidates and, for molecules with high OEB designations, serve to limit the number of CMOs who are qualified to manufacture our molecules. 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, particularly, in some cases, given the potency or OEB of our compounds.

Any performance failure or delay in performance on the part of our existing or future manufacturers could delay clinical development or marketing authorization. While our CMOs have experienced performance issues in the past that have not ultimately delayed our clinical development efforts, we could experience a manufacturing issue in the future 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 drug substance or drug product. If our current CMOs cannot perform as agreed, we may be required to replace them. While we have identified several potential alternative vendors who could manufacture some or all of our product candidates, switching vendors could result in significant additional costs and delays to our operations as we select and qualify a replacement manufacturer, we may be constrained in the vendors we can select, particularly for compounds that have high OEB designations, or we may not be able to reach agreement with an alternative manufacturer on acceptable terms.

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 a portion of our supply chain for our preclinical and clinical trial supplies. If our current or future suppliers, whether for raw materials, drug substance, or drug product, are unable to supply us with sufficient materials for our preclinical studies and clinical trials, we may experience delays in our development efforts as we locate and qualify new suppliers or manufacturers.

The third-party manufacturers on whom we rely may incorporate their own proprietary processes into our product candidate manufacturing processes. We have limited control and oversight of a third party's proprietary manufacturing processes. If a third-party manufacturer were to modify its processes, those 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 product development and manufacturing process will evolve in an effort to optimize processes and results. Some of those product and manufacturing process changes may involve the use of third-party proprietary technology, which could then cause us to need to obtain a license from third parties. In addition, 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 demonstrate analytical comparability and/or conduct additional bridging studies or trials, all of which would require additional time and expense.

We have existing collaborations with third parties under which we are engaged in the research, development and commercialization of certain product candidates. If any of these collaborations are not successful, we may not be able to capitalize on the market potential of those product candidates. In addition, these collaborations could impact our intellectual property rights.

Currently, we have three collaborations involving our ongoing research programs:

- a collaboration agreement with Roche that we entered into in December 2015, which we amended and restated in December 2018 and further amended periodically thereafter, with collaboration activities ongoing as to two targets;
- a collaboration agreement with Merck that we entered into in December 2023, which is for the development and commercialization of degrader-antibody conjugates, or DACs, with respect to one initial target, with the option for Merck to add up to three additional targets over a stated period of time; and
- a collaboration agreement with MKDG that we entered into in March 2024, which is for the development and commercialization of two targeted protein degraders against critical oncogenic proteins that the Company has progressed within its internal discovery pipeline.

Under these collaboration agreements, we are generally responsible for developing drug candidates leveraging our TORPEDO platform based on partner-selected targets. Further, these agreements as well as our agreements with prior research collaboration partners provide that our current and past collaboration partners have exclusive rights to develop degraders for their selected and reserved targets. As a result, we are not permitted to pursue a target of potential interest – either alone or with another partner – while that target is bound by these restrictions.

Further, 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 that were to happen, we might decide to abandon the program or to move the program forward on our own, which would require us to devote additional resources to the program on a going-forward basis. In addition, if one of our collaborators terminates its agreement with us generally, which they are permitted to do for convenience with between 60 and 270 days' notice, or with respect to a specific target or in connection with a material breach of the agreement by us that remains uncured for a specified period of time, we may find it more difficult to 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.

It is also possible that our current and past collaborators may not properly obtain, maintain, enforce, or defend the intellectual property or proprietary rights arising out of our licensed programs or may use our proprietary information in a way that could jeopardize or invalidate our proprietary information or expose us to potential litigation. Generally, our collaborators have the first right to enforce and 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 these intellectual property rights if our collaborator does not, our ability to do so may be compromised by their actions. In addition, if any licensed program were later to revert to us, our ability to protect any intellectual property or other proprietary rights associated with that program would be impacted by the intellectual property filings made or other steps taken by our collaborator prior to program reversion. Further, our 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.

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.

In May 2023, we entered into the Betta Pharma License Agreement with Betta Pharma under which Betta Pharma receives an exclusive license for the development, manufacturing, and commercialization of CFT8919 in Greater China, while we retain the rights to develop and commercialize CFT8919 in the rest of the world. Similarly, in the future, we may form or seek strategic alliances, create joint ventures, or other 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. Our likely collaborators in any other collaboration arrangements we may enter into include large and mid-size pharmaceutical companies and biotechnology companies. However, it is possible that we will not be able to enter into a collaboration agreement of this nature or that the terms of any potential new collaboration arrangement may not be favorable.

For example, we may seek to enter into collaboration arrangements to advance our cemsidomide (CFT7455) product candidate in MM or other indications or we may form or seek to form collaboration arrangements to enable our development and commercialization of a product candidate in a specified geographic area, as we have done in the case of CFT8919 and our collaboration with Betta Pharma. In addition, as we did in our more recent collaboration agreements with Merck and MKDG, we may seek to enter into collaboration agreements that enable other companies to access and leverage our TORPEDO platform to develop medicines directed at targets selected by our collaboration partners. 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 and efficacy and obtain marketing approval. Additionally, our existing partners may decide to acquire or partner with other companies developing targeted protein degraders or directed at the targets or indications to which our product candidates are directed, 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.

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 and the ability of governmental authorities to require that we negotiate the pricing of our products, as well as the timing of these mandatory negotiations;
- 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 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 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 other approved treatments or have failed prior treatments. In addition, our estimates of the prevalence of our target patient populations may be inaccurate.

We are developing product candidates to 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 later-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 or out of date. 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 or, in the case of CFT8919, Beta Pharma, 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, any of which would impact 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 or, in the case of CFT8919, Betta Pharma, might obtain marketing approval for a product candidate in a particular country, but then be subject to price regulations that delay the 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, therefore, hinder our ability to recoup our investment in one or more of our product candidates, even if our product candidates obtain marketing approval.

Our and, in the case of CFT8919, Betta Pharma's 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. The Medicare Drug Price Negotiation Program, administered by CMS as part of the Inflation Reduction Act of 2022, commonly referred to as the IRA, may apply to our products if they are selected for negotiation, which could materially reduce the amount of revenue we can generate from our products if they are approved. 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 coverage and 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. In addition, in light of the requirements of the IRA, we may be required to negotiate pricing for our product candidates, if approved, with Medicare, with those negotiated prices going into effect nine years after product approval. 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.

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. 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, product 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 and/or increased product liability insurance costs;
- 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.

We currently maintain product liability insurance coverage to support our clinical development activities. We may need to purchase additional product liability insurance coverage 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, product candidates, and products or if the scope of the patent protection obtained is not sufficiently broad or enforceable, our competitors could develop and commercialize technology, product candidates, and products similar or identical to ours, our ability to successfully commercialize our technology, product candidates, and products may be impaired or 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 platform technologies, our pipeline drug product candidates, any future drug product candidates we may develop and their use or manufacture.

Our commercial success depends in part on our ability to obtain and maintain patents and other proprietary protection in the United States and other countries with respect to our proprietary technology, product candidates 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, prosecute, and maintain 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 and patent applications, covering technology that we license from third parties or that we license to our collaborators. 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 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 those inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights or those of our collaborators are highly uncertain. Our pending and future patent applications may not result in patents being issued that protect our technology, product candidates or products, in whole or in part, or that effectively prevent others from commercializing competitive technologies, product candidates and products.

Changes in either the patent laws or interpretation of the patent or other laws in the United States and other countries may diminish the value of our patents and potential applications, narrow the scope of our patent protection, or cause us to be required to pay royalties to third parties. 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, product candidates, 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, product candidates, and products or limit the duration of the patent protection of our technology, product candidates 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 U.S. patent law. These changes include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The U.S. 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, as there is always a risk that a third party could file a patent application that could be blocking to our patent filings. 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 federal courts of the United States. The USPTO issued a Final Rule on November 11, 2018 announcing that it will now use the same claim construction currently used in the federal courts of the United States—which is the ordinary and customary 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 of this legislation, 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 collaborators or our 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 or actually invalidated, held unenforceable or interpreted narrowly. In addition, the U.S. Supreme Court's June 2024 *Loper Bright Enterprises v. Raimondo* decision, which overturned a long-established doctrine of courts giving deference to administrative agencies' interpretations of statutory language and related rules and regulations, has introduced uncertainty regarding the extent to which courts will exercise independent judgement over the interpretation of patent statutes and regulations in future litigation proceedings involving the enforceability or validity of patents and USPTO regulations, policies, and decisions. Even if we successfully assert our patents, a court may not award remedies that sufficiently compensate us for our losses. In addition, we may not have sufficient financial or other resources to seek to enforce our patents adequately against perceived infringers, which could have a material and adverse effect on the profitability of our products.

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 or manufacture of our products or our collaborators' 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 or those of our collaborators, in which case we or our collaborators 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 reexamination, post-grant review, *inter partes* review, derivation proceedings, or interference 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 product candidates and technology, including derivation, reexamination, post-grant review, *inter partes* review, or interference 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 our product candidates or 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 product candidates, 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, or our platform technologies 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 small molecule pharmaceuticals, which degrade specific proteins. A number of companies and institutions have patent applications and issued patents in this general area, such as, for example, Accutar Biotechnology, Inc., Amgen Inc., Amphista Therapeutics, Ltd., Araxes Pharma, LLC, Arvinas, Inc., Astellas Pharma Inc., AstraZeneca PLC, Aurigen Discovery Technologies, Ltd., Bayer AG (and its subsidiary Vividion Therapeutics, Inc.), BeiGene Co. Ltd., BioTheryX, Inc., Boehringer Ingelheim International GmbH, Bristol Myers Squibb Company (and its subsidiary Celgene Corporation), Captor Therapeutics Inc., Cullgen Inc., the Dana-Farber Cancer Institute and its Center for Protein Degradation, Dialectic Therapeutics, Inc., Foghorn Therapeutics, Inc., Frontier Medicines Corporation, GlaxoSmithKline PLC, Genentech, Inc., Glubio Therapeutics, Inc., Hinoa Pharmaceuticals, Inc., Janssen Biotech, Inc., Kymera Therapeutics, Inc., Monte Rosa Therapeutics, Inc., Novartis International AG, Nurix Therapeutics, Inc., Orum Therapeutics, Inc., Otsuka Pharmaceuticals, Inc., Phoremest, Ltd., Plexium, Inc., Prelude Therapeutics, Inc., Inc., Roche AG, Salarius Pharmaceuticals Inc., Salarius Pharmaceuticals, Inc., Seed Therapeutics, Inc., Sichuan Haisco Pharmaceutical Co., Ltd., SK Life Science Labs, Inc. (a subsidiary of SK Biopharmaceuticals Co. Ltd.), the University of Michigan School of Medicine, Vertex Pharmaceuticals, Inc., 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 candidate or 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 typically 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 product candidates or products or their methods of use or manufacture. If that were to occur and as we have done in the past in certain circumstances, we or our collaborators, as applicable, may have to take steps to try to invalidate the applicable patent or application, which steps might include, for example, third-party submissions or oppositions before the relevant patent office, or adversarial proceedings or litigation, such as post-grant review or *inter partes* review before the USPTO Patent Trial and Appeal Board, or declaratory judgment actions before a court, 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, which could prevent us or our collaborators from selling a product or using our proprietary technologies.

Our product candidates, if and when approved, will be 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 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 the Hatch-Waxman Act, we will list 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 Orange Book.

There are detailed rules and requirements regarding the patents that may be submitted to the FDA for listing in the Orange Book. We may be unable to obtain patents covering our product candidates that contain one or more claims that satisfy the requirements for listing in the Orange Book. Even if we submit a patent for listing in the Orange Book, the FDA may decline to list the patent or a generic drug manufacturer, the U.S. Federal Trade Commission or another entity may challenge the listing. If one of our product candidates is approved and a patent covering that product candidate is not listed in the Orange Book, with respect to any unlisted patent, a generic drug manufacturer would not have to provide advance notice to us of any ANDA filed with the FDA to obtain permission to sell a generic version of that product candidate.

Currently, in the United States, the FDA may grant five years of data 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 new drug application, or NDA. We expect that all of our products will qualify as NCEs; however, the FDA will not conduct an assessment for NCE status until it is reviewing a marketing application for that drug. A generic company can submit an ANDA to the FDA four years after approval of any of our drug products designated as an NCE. 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. If a lawsuit is brought, the FDA is prevented from issuing a final approval of an ANDA for the generic drug until 30 months from our receipt of the generic manufacturer's certification notice, or such shorter or longer time as the presiding court might order based on certain behaviors of the parties, 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 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 the date of 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. In addition, the regulatory review period of an FDA-approved product may not serve as the basis for a patent term extension if the active ingredient of such product was subject to regulatory review and approval in an earlier product approved by the FDA. 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 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 that may be subject to contractual confidentiality and non-use obligations. 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 a patent application and any resulting 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, maintaining, 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, maintaining, 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

Receiving regulatory approval from the FDA and foreign regulatory authorities is 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 amount of 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 standards, 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 (independently or with one of our collaboration partners), will ever obtain marketing approval.

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

- the FDA or foreign regulatory authority, each referred to here as a health authority, may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the health authority that a product candidate is safe and effective for its proposed indication, or that it is of sufficient strength, identity, or quality in accordance with the health authority's standards;
- results of clinical trials may not meet the level of statistical significance required by the health authority for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the health authority 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 valid or of sufficient quality to support the submission of an NDA to the FDA or other submission to a foreign regulatory authority or to obtain marketing approval in the United States or any other country or jurisdiction;
- the health authority 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 standards, policies, or regulations of a health authority may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy drug development process, as well as the unpredictability of future clinical trial results, may result in our failing to obtain regulatory approval to allow us to market any of our product candidates, which would significantly harm our business, results of operations, and prospects. The FDA and other health authorities have substantial discretion in the approval process and determining when or whether regulatory approval will be obtained for any of our product candidates, including in the context of accelerated approvals. Even if we believe the data collected from clinical trials of our product candidates are promising, that data may not be sufficient to support approval by the FDA or any other health authority.

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 as a company 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 may be required to conduct post-approval studies in special populations that are difficult to conduct or complete. We will also 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 and applicable product tracking and tracing requirements. As such, we and our CMOs 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 CMOs 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 manufacturers' 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. In addition, the U.S. Supreme Court's June 2024 decision to overturn established case law giving deference to regulatory agencies' interpretations of ambiguous statutory language has introduced uncertainty regarding the extent to which the FDA's regulations, policies and decisions may become subject to increasing legal challenges, delays, and/or changes. 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 some or all of our current and future product candidates, including cemsidomide (CFT7455) and CFT1946. 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 a designation. In any event, although Breakthrough Therapy designation is designed to expedite the development and review of drugs that receive such designation, 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 of a product candidate. 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 our lead product candidates 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 designations.

A Fast Track designation by the FDA, even if granted for one or all of our lead product candidates, 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.

At various times, we may seek Fast Track designation for one or more of our product candidates. If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical

needs for this condition, the drug sponsor may apply for FDA Fast Track designation for a particular indication. We may seek Fast Track designation for one or all of our lead product candidates and/or 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 and we might only be successful in receiving a Fast Track designation from the FDA for a product candidate after applying on more than one occasion. 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 receipt of a 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 a 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 a Fast Track designation, and even though Fast Track designation is designed to expedite the development and review of drugs that receive such 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 a 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.

We have obtained Orphan Drug Designation for cemsidomide (CFT7455), and if we decide to seek Orphan Drug Designation for any other 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.

In August 2021, the FDA granted Orphan Drug Designation to cemsidomide (CFT7455) for the treatment of MM. We may seek Orphan Drug Designation for one or more of our other current or future product candidates. Regulatory authorities in some jurisdictions, including the United States and the European Union, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may grant an Orphan Drug 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, receipt of an 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. Although Orphan Drug Designation is intended to incent drug development for rare diseases or conditions, Orphan Drug Designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. In addition, while receipt of Orphan Drug Designation may result in a waiver of any obligation by FDA to conduct studies in pediatric populations, such waiver may not apply to oncology drugs

If a product that has an 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 drug 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 drug exclusivity if we are unable to manufacture sufficient supply of our product.

We may also seek Orphan Drug Designations for our other lead candidates and/or 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 an 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, even if we 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 FDCA and its orphan drug regulations, in a way that limits or blocks our ability to obtain an Orphan Drug Designation or orphan drug exclusivity, if our product candidates are approved, for our targeted indications.

We may seek approval of our product candidates, where applicable under the FDA's accelerated approval pathway. This pathway 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 our lead product candidates and may seek approval of future product candidates, where applicable, 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, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, or IMM, that is reasonably likely to predict an effect on IMM or other clinical benefit. Under the Food and Drug Omnibus Reform Act, commonly referred to as FDORA, the FDA is permitted to require, as appropriate, that a post-approval confirmatory study or studies be underway prior to approval or within a specified time period after the date of approval for a product that is granted accelerated approval. FDORA also requires sponsors to send updates to the FDA every 180 days on the status of these studies, including progress towards enrollment targets, and the FDA must promptly post this information publicly. FDORA also gives the FDA increased authority to withdraw accelerated approval on an expedited basis if the sponsor fails to conduct such activities in a timely manner, send the necessary updates to the FDA, or if such post-approval studies fail to verify the drug's predicted clinical benefit; and to take action, such as issuing fines, against companies that fail to conduct with due diligence any post-approval confirmatory study or submit timely reports to the agency on their progress. In addition, the FDA generally requires pre-approval of promotional materials for products receiving accelerated approval, which could adversely impact the timing of the commercial launch of the product. Thus, even if we seek to utilize the accelerated approval pathway for any of our product candidates, we may not be able to obtain accelerated approval, and even if we do, that product may not experience a faster development or regulatory review or approval process. In addition, receiving accelerated approval does not assure the product's accelerated approval will eventually be converted to a traditional approval.

The FDA may identify in a written request that pediatric information would be beneficial for a product candidate for which we obtained approval and request that we conduct pediatric studies. We may elect not to perform these studies or, if we opted to conduct these studies, we may not be able to complete them or the data generated from these studies may not be acceptable to the FDA.

Section 505A of the Food, Drug, and Cosmetic Act, or the FDC Act, provides incentives to drug manufacturers who conduct studies of drugs in children. Referred to as the "pediatric exclusivity provision," this law provides an additional six months of non-patent exclusivity to pharmaceutical manufacturers that conduct acceptable pediatric studies of new and currently-marketed drug products for which pediatric data would be beneficial pursuant to a written request by the FDA. As a result, if we received a written request for pediatric studies from the FDA, conducted pediatric clinical studies and submitted reports that were accepted by the FDA within the statutory time limits, we could receive an additional six-months of regulatory exclusivity beyond all other types of patent and non-patent exclusivity then in effect for all our approved drug products that contain the active moiety for which pediatric exclusivity was granted. However, even if we received a written request for pediatric studies from the FDA for one or more of our drug products, we may determine not to or be unable to carry out pediatric studies that comply with Section 505A of the FDC Act, or we may carry out studies that are not accepted by the FDA for this purpose. If this situation were to arise, we would not receive this six-month regulatory exclusivity extension.

Our relationships with customers, healthcare providers, and third-party payors are or will be subject, directly or indirectly, to foreign, 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 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: (i) prevent fraud, kickbacks, self-dealing and other abusive practices, (ii) guarantee the security and privacy of health information, and (iii) increase transparency around the financial relationships between physicians, teaching hospitals and manufacturers of drugs, medical devices and biologics. 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. See the sections entitled "*Business — Other Healthcare Laws*" and "*Business — Healthcare Reform*" in our 2023 Annual Report.

Ensuring that our business arrangements and practices 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 comply 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 and abroad 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 in the United States), 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. See the section entitled “Coverage and Reimbursement” in our 2023 Annual Report.

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 and other countries 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. The principal decisions about reimbursement for new medicines in the United States

are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the United States Department of Health and Human Services, or HHS. CMS will decide 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 considered by payors 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.

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 EU do not follow price structures of the United States and generally prices in the EU 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. 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. See the section entitled “*Business — Government Regulation - Healthcare Reform*” in our 2023 Annual Report.

We expect that additional state and federal healthcare reform measures will be adopted in the future, such as the proposed BIOSECURE Act, any of which could limit the extent to which state and federal governments cover particular healthcare products and services, limit the amounts that the federal and state governments will pay for healthcare products and services, or cause us to need to identify or engage alternate service providers. This could result in reduced demand for any product candidate we develop, additional pricing pressures, delayed or limited supply of materials needed for our research or development activities, or other adverse effects to our financial condition and business prospects.

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.

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. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our product candidates, if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our approved products;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

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 applicable privacy laws, in the United States as well as other jurisdictions, 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. Depending on the facts and circumstances, we could be subject to civil, criminal, and administrative penalties if we obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA. In addition, 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.

In the United States, the California Consumer Privacy Act of 2018, or the CCPA, went into effect in January 2020. The CCPA provides data privacy rights for consumers and imposes operational requirements on companies, including placing increased privacy and security obligations on entities handling certain personal data of consumers or households in California. 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.

Additionally, the CCPA was amended by the California Privacy Rights Act, or CPRA, which became effective on January 1, 2023. The CPRA significantly modified the CCPA, including by imposing additional obligations on covered businesses, expanding consumers' rights and imposing new obligations with respect to certain sensitive personal information. The CPRA also created a new state agency that is vested with authority to implement and enforce the CCPA. The effects of the CCPA, as amended, are potentially significant and may require us to modify our data collection or processing practices and policies and to incur substantial costs and expenses in an effort to comply and increase our potential exposure to regulatory enforcement and/or 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.

Furthermore, numerous states have passed broad consumer privacy laws that are similar in many respects to the CCPA and with many other states proposing similar laws, it is quite possible that other states will follow suit and also pass

comprehensive privacy-focused legislation. If enacted, this type of legislation may add additional complexity, further variation in requirements, restrictions and potential legal risk, require additional investment of resources in compliance programs, impact data collection strategies and the availability of previously useful data and could result in increased compliance costs and/or changes in business practices and policies. The existence of comprehensive privacy laws in different states within the United States will make our compliance obligations more complex and costly and may increase the likelihood that we may be subject to enforcement actions or otherwise incur liability for noncompliance. Further, in addition to comprehensive laws at the state level, some states have been proposing or passing laws that target particular aspects of privacy. For example, in the state of Washington, the My Health My Data Act, which went into effect in March 2024, protects the privacy of medical and health-related information that is not covered by HIPAA. In addition, a small number of states have passed laws specifically focused on biometric information.

The increasing number and complexity of privacy and data protection laws, and other changes in laws or regulations across the globe, especially those associated with the enhanced protection of certain types of sensitive data, such as healthcare data or other personal information from our clinical trials, could lead to government enforcement actions and significant penalties against us and could have a material adverse effect on our business, financial condition or results of operations.

Outside of the United States, we also face the challenge of stringent privacy and data protection laws. For example, legislators in the European Economic Area, or EEA, adopted the European Union, or EU, General Data Protection Regulation, or EU GDPR, and the EU GDPR, as transposed into the laws of the United Kingdom, the UK GDPR, collectively referred to as the GDPR. The GDPR imposes more stringent data protection compliance requirements on controllers and processors of personal data of subjects located in the EEA and UK, including special protections for "special category data," which includes health, biometric, and genetic information and provides for significant penalties for noncompliance. Further, the GDPR provides a broad right for EEA Member States to create supplemental national laws, as laws relating to the processing of health, genetic, and biometric data, which could further limit our ability to use and share such data or could cause our costs to increase, and harm our business and financial condition. The GDPR includes compliance obligations that may be applicable to our business, which could cause us to change our business practices, and increases financial penalties for noncompliance (including possible fines of up to the greater of €20 million (£17.5 million under the UK GDPR) and 4% of our global annual turnover for the preceding financial year for the most serious violations, as well as the right to compensation for financial or non-financial damages claimed by any individuals under Article 82 of the GDPR). In addition to such fines, we may be subject to litigation and/or adverse publicity, which could have a material adverse effect on our reputation and business.

The 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.

The GDPR requires us to inform data subjects of how we process their personal data and how they can exercise their rights, ensure we have a valid legal basis to process personal data (if this is consent, the requirements for obtaining consent carries a higher threshold), and appoint a data protection officer where sensitive personal data (i.e., health data) is processed on a large scale. In addition, the GDPR introduces mandatory data breach notification requirements throughout the EEA and UK, requires us to maintain records of our processing activities and to document data protection impact assessments where there is high risk processing, imposes additional obligations on us when we are contracting with service providers, requires appropriate technical and organizational measures be put in place to safeguard personal data and requires us to adopt appropriate privacy governance including policies, procedures, training and data audit. We are taking steps to comply with the GDPR as appropriate and as and when applicable to us, but this is an ongoing compliance process. 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. If our efforts to comply with GDPR or other applicable EEA and UK laws and regulations are not successful, or are perceived to be unsuccessful, it could adversely affect our business in the EEA and/or the UK.

Significantly, the GDPR imposes strict rules on the transfer of personal data out of the EEA and UK to other regions outside the EEA/UK, or third countries, that have not been deemed to offer "adequate" privacy protections by the competent data protection authorities, including the United States in certain circumstances, unless a derogation exists or adequate international transfer safeguards (for example, the European Commission approved Standard Contractual Clauses, or the EU SCCs, and the UK International Data Transfer Agreement/Addendum, or the UK IDTA) are put in place. Where relying on the EU SCCs or UK IDTA for data transfers, we may also be required to carry out transfer impact assessments on the transfers made pursuant to the EU SCCs and UK IDTA, on a case-by-case basis, to ensure the law in the recipient country provides "essentially equivalent" protections to safeguard the transferred personal data as provided in the EEA and

UK, and may be required to adopt supplementary measures if this standard is not met. The international transfer obligations under the EEA and UK data protection regimes will require significant effort and cost, and may result in us needing to make strategic considerations around where EEA and UK personal data is located and which service providers we can utilize for the processing of EEA and UK personal data. Any inability to transfer personal data from the EEA to the United States in compliance with data protection laws may impede our ability to conduct trials and may adversely affect our business and financial position.

Although the UK is regarded as one of the third countries under the EU GDPR, the European Commission has adopted an adequacy decision in favor of the UK, enabling data transfers from EEA member states to the UK without additional safeguards. The UK government has confirmed that personal data transfers from the UK to the EEA remain free flowing. The relationship between the UK and the EU in relation to certain aspects of data protection law remains unclear, and it is unclear how UK data protection laws and regulations will develop in the medium to longer term, and how data transfers to and from the UK will be regulated in the long term. Further, the UK government has introduced a Data Protection and Digital Information Bill, or the UK Bill, into the UK legislative process. The aim of the UK Bill is to reform the UK's data protection regime following Brexit. If passed, the final version of the UK Bill may have the effect of further altering the similarities between the UK and EEA data protection regime and threaten the UK adequacy decision from the European Commission. In addition, EEA Member States have adopted national laws to implement the GDPR that may partially deviate from the GDPR. Further, the competent authorities in the EEA Member States may interpret GDPR obligations slightly differently from country to country and therefore we do not expect to operate in a uniform legal landscape in the EEA. The potential of the respective provisions and enforcement of the EU GDPR and UK GDPR further diverging in the future creates additional regulatory challenges and uncertainties for us. This lack of clarity on future UK laws and regulations and their interaction with EU laws and regulations could add legal risk, complexity and cost to our handling of personal data and our privacy and data security compliance programs and could require us to implement different compliance measures for the UK and the EEA.

Outside of the United States and Europe, many jurisdictions in which we have CROs or otherwise do business are also considering and/or have enacted comprehensive data protection legislation. We may, however, incur liabilities, expenses, costs and other operational losses under the GDPR and applicable EEA Member States and the UK privacy laws in connection with any measures we take to comply with them.

We may be subject to the supervision of local data protection authorities in those jurisdictions where we are processing personal data in the EEA and UK, including where our business activities involve monitoring the behavior of individuals in the EEA or UK (for example, when undertaking clinical trials). We depend on a number of third parties in relation to the provision of our services, a number of which process personal data of EEA and/or UK individuals on our behalf. With each such provider we enter or intend to enter into contractual arrangements under which they are contractually obligated to only process personal data according to our instructions, and conduct or intend to conduct diligence to ensure that they have sufficient technical and organizational security measures in place.

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 CMOs 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 United States 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. In the future, 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, Chief Scientific Officer, Chief Medical Officer, Chief Financial Officer, Chief Legal Officer, Chief People Officer, and Chief Business Officer. 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. For example, we recently appointed Paige Mahaney, Ph.D., as our Chief Scientific

Officer, effective October 28, 2024, following the decision of Stewart Fisher, Ph.D., to retire from that position. While we expect to engage in an orderly transition process as we integrate Dr. Mahaney and would do the same for any other new officers or managers who we may appoint in the future, 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.

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.

To encourage valuable employees to remain at our company, in addition to salary and cash incentives, we have provided stock options and other equity awards that vest over time or based on the achievement of milestones. The value to our employees of equity awards 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. The same may be true in respect of equity awards that vest based on the achievement of milestones. 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.

Our internal computer systems, or those of any of our collaborators, vendors, contractors, or consultants, may fail or suffer security breaches, incidents or compromises, which could result in a material disruption of our product development programs and could harm our reputation or subject us to liability, and adversely affect our business and financial results.

Our internal computer systems and those of any collaborators, vendors, 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, security breach, incident or compromise 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.

Any actual or perceived security breach, incident or compromise of our platform, systems, and networks could damage our reputation and brand, expose us to a risk of litigation and possible liability, and require us to expend significant capital and other resources to respond to and alleviate problems caused by the security breach. Our ability to maintain adequate cyber-crime and liability insurance may be reduced. Some jurisdictions have enacted laws requiring companies to notify individuals of data security breaches involving certain types of personal data and our agreements with certain partners require us to notify them in the event of a security incident. These types of mandatory disclosures are costly, could lead to negative publicity, and may cause our partners to lose confidence in the effectiveness of our data security measures. Any of these events could harm our reputation or subject us to liability, and materially and adversely affect our business and financial results. Although we maintain cyber liability insurance, we cannot be certain that its coverage will be adequate for liabilities actually incurred or that insurance will continue to be available to us on economically reasonable terms, or at all.

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, CMOs, 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 that violate study and trial protocols or the regulations of the FDA or similar foreign regulatory authorities;
- violations of healthcare fraud and abuse laws and regulations in the United States and abroad;
- violations of U.S. 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 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/or 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 were to 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.

Currently, our common stock is listed on the Nasdaq Global Select Market. However, there may not be enough liquidity in that market to enable you to sell your shares of our common stock.

Currently, our common stock is listed on the Nasdaq Global Select Market. If an active trading market for our shares is not sustained, you may not be able to sell your shares quickly or at the market price. We cannot predict the extent to which investor interest in us will lead to sustaining an active, liquid trading market. 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 or cease publishing 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 is and will continue to 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 have control over these analysts. There can be no assurance that existing analysts will continue to provide research coverage or that new analysts will begin to provide coverage. Although we have obtained 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 has been and may continue 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 or changes in standard of care regimens;
- results of preclinical studies and clinical trials of our product candidates or those of our competitors;
- the timing and progress of our clinical development activities and the timing of our release of data from our clinical trials;
- 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 and the value of the cash, cash equivalents, and marketable securities we hold;
- 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 the recent COVID-19 pandemic;
- general economic, industry, and market conditions; and
- the other factors described in this “Risk Factors” section.

If any of the foregoing factors were viewed as likely to have a negative impact on our business, prospects or operations 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 our capital effectively.

Our management has broad discretion in the application of the net proceeds from our prior financings, including our initial and follow-on public offerings, 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 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 a significant percentage of our shares. 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. These stockholders, if acting together, will consequently 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 by-laws 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 by-laws 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 anti-takeover provisions and other provisions in our amended and restated certificate of incorporation and amended and restated by-laws 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.

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

As a public company, we will continue to incur significant legal, accounting, and other expenses that we would not have to 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 devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations increase our legal and financial compliance and insurance costs and make some activities more time-consuming and costly. For example, these rules and regulations 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 continually evaluate these rules and regulations and cannot always predict or estimate the amount of additional costs we may incur or the timing of these costs. These rules and regulations are also 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 are required to furnish a report by our management on our internal control over financial reporting. However, as a "smaller reporting company," we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm until we are no longer a smaller reporting company. As of the end of our fiscal year ended December 31, 2023, we qualified as a "non-accelerated filer" as defined in the Securities Exchange Act of 1934, as amended, or the Exchange Act and as a "smaller reporting company." Our compliance with Section 404 necessitates that we incur substantial accounting expense and expend significant management efforts.

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 we will 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. 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 condensed consolidated financial statements.

Our amended and restated by-laws 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 by-laws, 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 (i) any derivative action or proceeding brought on our behalf; (ii) 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; (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law or our amended and restated certificate of incorporation or amended and restated by-laws; (iv) any action to interpret, apply, enforce, or determine the validity of our amended and restated certificate of incorporation or amended and restated by-laws; or (v) any action asserting a claim governed by the internal affairs doctrine. We refer to this provision in our amended and restated by-laws 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 by-laws further provide that unless we consent in writing to the selection of an alternative forum, the U.S. 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 amended and restated by-laws as the Federal Forum Provision. In addition, our amended and restated by-laws 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.

The Delaware Forum Provision and the Federal Forum Provision in our amended and restated by-laws 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, and 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 U.S. 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. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

Business disruptions, including due to natural disasters, global conflicts or political unrest, and unstable market conditions and downturns in economic and market conditions, may have serious adverse consequences on our business, financial condition and stock price.

Our operations and those of any CMOs, CROs and other contractors and consultants that we may engage could be impacted by earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption.

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 significant volatility associated with recent geopolitical tensions, including with China, and global conflicts, such as those between Russia and Ukraine and Israel and Hamas, have caused significant instability and disruptions in the capital and credit markets. Global economic conditions continue to be volatile and uncertain in the United States and abroad. Our operations could be adversely affected by economic and political changes in the markets, including higher inflation rates, increasing interest rates, supply chain disruptions, recessions, trade restrictions, tariff increases or potential new tariffs, and economic embargoes imposed by the United States. 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, or not available at all.

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, modify, 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.

Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults, or non-performance by financial institutions or transactional counterparties, could adversely affect the Company's current and projected business operations and its financial condition and results of operations.

Adverse developments that affect financial institutions, such as events involving liquidity that are rumored or actual, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation as receiver.

We periodically assess our banking and other relationships as we believe necessary or appropriate, including to ensure that we have appropriate diversification in these relationships. Nonetheless, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect the Company, the financial institutions with which the Company has credit agreements or arrangements directly, or the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of

financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could involve financial institutions or financial services industry companies with which the Company has financial or business relationships, but could also include factors involving financial markets or the financial services industry generally.

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

On September 30, 2024, the Company granted an employee an option to purchase 146,880 shares of the Company's common stock (the "Inducement Grant") in a transaction exempt from registration under Section 4(a)(2) of the Securities Act. The Inducement Grant was granted as inducement material to this employee's entering into employment with the Company in accordance with Nasdaq Listing Rule 5635(c)(4). The Company received no cash proceeds and no commissions were paid to any person in connection with the issuance of the Inducement Grant.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Rule 10b5-1 Trading Plans

During the fiscal quarter ended on September 30, 2024, none of our directors and officers (as defined in Rule 16a-1(f) under the Exchange Act) adopted, modified or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as those terms are defined in Item 408(a) of Regulation S-K.

Item 6. Exhibits.

Exhibit Number	Description	Form	File Number	Date of Filing	Exhibit/Annex	Filed Herewith
3.1	Fifth Amended and Restated Certificate of Incorporation of the Registrant	8-K	001-39567	10/06/2020	3.1	
3.2	Certificate of Amendment to the Fifth Amended and Restated Certificate of Incorporation of the Registrant	DEF14A	001-39567	04/28/2023	A	
3.3	Second Amended and Restated By-laws of the Registrant	S-1	333-248719	09/10/2020	3.5	
4.1	Amended and Restated Investors' Rights Agreement among the Registrant, its warrant holder and certain of its stockholders	S-1	333-248719	09/10/2020	4.1	
4.2	Stock Purchase Agreement, dated May 29, 2023, by and among C4 Therapeutics, Inc., Beta Pharmaceuticals Co., Ltd. and Beta Investment (Hong Kong) Limited.	8-K	001-39567	05/30/2023	10.2	
10.1	Amendment No. 1 to C4 Therapeutics, Inc. 2020 Stock Option and Incentive Plan	8-K	001-39567	10/11/2024	10.1	
10.2	Consulting Agreement dated as of October 15, 2024, between C4 Therapeutics, Inc. and Stewart Fisher	8-K	001-39567	10/16/2024	10.1	
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
101.INS	XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document					
101.SCH	Inline XBRL Taxonomy Extension Schema Document					
101.CAL	Inline XBRL Taxonomy Calculation Linkbase Document					
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document					

Exhibit Number	Description	Form	File Number	Date of Filing	Exhibit/Annex	Filed Herewith
101.LAB	Inline XBRL Taxonomy Label Linkbase Document					
101.PRE	Inline XBRL Taxonomy Presentation Linkbase Document					
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)					

* Exhibits 32.1 and 32.2 are being furnished herewith and shall not be deemed to be “filed” for purposes of Section 18 of the Exchange Act, or otherwise subject to the liability of that section, nor shall such exhibit be deemed to be incorporated by reference in any registration statement or other document filed under the Securities Act, or the Exchange Act, except as otherwise stated in such filing.

SIGNATURES

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

C4 THERAPEUTICS, INC.

Date: October 31, 2024

By: /s/ Andrew J. Hirsch

Andrew J. Hirsch

President and Chief Executive Officer (Principal Executive Officer)

Date: October 31, 2024

By: /s/ Kendra R. Adams

Kendra R. Adams

Chief Financial Officer and Treasurer (Principal Financial Officer)

Date: October 31, 2024

By: /s/ Mark Mossler

Mark Mossler

Chief Accounting Officer (Principal Accounting Officer)

**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: October 31, 2024

By: /s/ Andrew J. Hirsch

Andrew J. Hirsch
Chief Executive Officer

**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, Kendra R. Adams, 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: October 31, 2024

By: /s/ Kendra R. Adams

Kendra R. Adams
Chief Financial Officer and Treasurer

**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, 2024, 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 results of operations of the Company.

Date: October 31, 2024

By: /s/ Andrew J. Hirsch

Andrew J. Hirsch
Chief Executive Officer

**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, 2024, 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 results of operations of the Company.

Date: October 31, 2024

By: /s/ Kendra R. Adams

Kendra R. Adams
Chief Financial Officer and Treasurer