

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

**FORM 10-Q**

(Mark One)

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

For the Quarterly Period Ended June 30, 2022

OR

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

Commission File Number 001-37587

**CytomX Therapeutics, Inc.**

(Exact name of Registrant as Specified in its Charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

27-3521219  
(I.R.S. Employer  
Identification No.)

151 Oyster Point Blvd., Suite 400  
South San Francisco, CA 94080  
(Address of principal executive offices, including zip code)  
(650) 515-3185  
(Registrant's telephone number, including area code)

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, \$0.00001 par value per share	CTMX	Nasdaq Global Select Market

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

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

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input checked="" type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input 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 July 29, 2022, the registrant had 65,950,242 shares of common stock, \$0.00001 par value per share, outstanding.

**CYTOMX THERAPEUTICS, INC.**  
**FORM 10-Q FOR THE QUARTER ENDED JUNE 30, 2022**  
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## Forward-Looking Statements

This Quarterly Report on Form 10-Q contains certain forward-looking statements that involve risks and uncertainties. These forward-looking statements reflect our current views with respect to, among other things, future events and our financial performance. These statements are often, but not always, made through the use of words or phrases such as “may,” “might,” “should,” “could,” “predict,” “potential,” “believe,” “expect,” “continue,” “will,” “anticipate,” “seek,” “estimate,” “intend,” “plan,” “projection,” “would,” “annualized” and “outlook,” or the negative version of those words or other comparable words or phrases of a future or forward-looking nature. These forward-looking statements are not historical facts, and are based on current expectations, estimates and projections about our industry, management’s beliefs and certain assumptions made by management, many of which, by their nature, are inherently uncertain and beyond our control. Accordingly, we caution you that any such forward-looking statements are not guarantees of future performance and are subject to risks, assumptions, estimates and uncertainties that are difficult to predict. Although we believe that the expectations reflected in these forward-looking statements are reasonable as of the date made, actual results may prove to be materially different from the results expressed or implied by the forward-looking statements.

A number of important factors could cause our actual results to differ materially from those indicated in these forward-looking statements, including those factors identified in “Risk Factors” or “Management’s Discussion and Analysis of Financial Condition and Results of Operations” or the following:

- the extent to which the COVID-19 or any future pandemic and related governmental regulations and restrictions may impact our business, including our research, clinical trials, which include ongoing site initiation and patient enrollment, manufacturing and financial condition;
- our expectations regarding the potential benefits, activity, effectiveness and safety of our product candidates and therapeutics developed utilizing our Probody® platform technology;
- the initiation, timing, progress and results of our ongoing clinical trials, research and development programs, preclinical studies, and Investigational New Drug Application (“IND”), Clinical Trial Application, New Drug Application (“NDA”), Biologics License Application (“BLA”); and other regulatory submissions;
- the timing of the completion of our ongoing clinical trials and the timing and availability of clinical data from such clinical trials;
- our ability to identify and develop additional product candidates;
- our dependence on collaborators for developing, obtaining regulatory approval for and commercializing product candidates in the collaboration;
- our or a collaborator’s ability to obtain and maintain regulatory approval of any of our product candidates;
- our receipt and timing of any milestone payments or royalties under any research collaboration and license agreements or arrangements;
- our expectations and beliefs regarding the evolution of the market for cancer therapies and development of the immuno-oncology industry;
- the rate and degree of market acceptance of any approved product candidates;
- the commercialization of any approved product candidates;
- our ability to establish and maintain collaborations and retain commercial rights for our product candidates in such collaborations;
- the implementation of our business model and strategic plans for our business, technologies and product candidates;
- our estimates of our expenses, ongoing losses, future revenue and capital requirements, including our estimate of cash flow savings as a result of our recently announced restructuring plan;
- our ability to obtain additional funds for our operations;
- our or any collaborator’s ability to obtain and maintain intellectual property protection for our technologies and product candidates and our ability to operate our business without infringing the intellectual property rights of others;
- our reliance on third parties to conduct our preclinical studies or any future clinical trials;
- our reliance on third-party supply and manufacturing partners to supply the materials and components for, and manufacture, our research and development, preclinical and clinical trial product supplies;
- our ability to attract and retain qualified key management and technical personnel;

- our ability to secure and maintain licenses of intellectual property to protect our technologies and product candidates;
- our financial performance; and
- developments relating to our competitors or our industry or to international conflict and uncertainties.

Any forward-looking statements in this Quarterly Report on Form 10-Q reflect our current views with respect to future events or to our future 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. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under Part II, Item 1A. Risk Factors and discussed elsewhere in this Quarterly Report on Form 10-Q. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

This Quarterly Report on Form 10-Q also contains estimates, projections and other information concerning our industry, our business and the markets for certain drugs and therapeutic biologics, including data regarding the estimated size of those markets, their projected growth rates and the incidence of certain medical conditions. Information that is based on estimates, forecasts, projections or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained these industry, business, market and other data from reports, research surveys, studies and similar data prepared by third parties, industry, medical and general publications, government data and similar sources. In some cases, we do not expressly refer to the sources from which these data are derived.

Except where the context otherwise requires, in this Quarterly Report on Form 10-Q, “we,” “us,” “our” and the “Company” refer to CytomX Therapeutics, Inc.

#### **Trademarks**

This Quarterly Report on Form 10-Q includes trademarks, service marks and trade names owned by us or other companies. All trademarks, service marks and trade names included in this Quarterly Report on Form 10-Q are the property of their respective owners.

## PART I – FINANCIAL INFORMATION

## Item 1. Condensed Financial Statements (Unaudited)

**CYTOMX THERAPEUTICS, INC.**  
**CONDENSED BALANCE SHEETS**  
(in thousands, except share and per share data)

	June 30, 2022 <u>(Unaudited)</u>	December 31, 2021 <u>(1)</u>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 129,290	\$ 205,530
Short-term investments	98,875	99,696
Accounts receivable	1,014	790
Prepaid expenses and other current assets	3,591	4,285
Total current assets	232,770	310,301
Property and equipment, net	5,915	5,960
Intangible assets, net	948	1,021
Goodwill	949	949
Restricted cash	917	917
Operating lease right-of-use asset	17,692	19,362
Other assets	895	901
Total assets	<u>\$ 260,086</u>	<u>\$ 339,411</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 1,920	\$ 2,818
Accrued liabilities	31,732	34,236
Deferred revenue, current portion	65,787	69,262
Total current liabilities	99,439	106,316
Deferred revenue, net of current portion	95,863	125,660
Operating lease liabilities - long term	16,076	18,056
Total liabilities	211,378	250,032
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Convertible preferred stock, \$0.00001 par value; 10,000,000 shares authorized and no shares issued and outstanding at June 30, 2022 and December 31, 2021.	—	—
Common stock, \$0.00001 par value; 150,000,000 shares authorized and 65,756,492 and 65,392,758 shares issued and outstanding at June 30, 2022 and December 31, 2021, respectively	1	1
Additional paid-in capital	631,662	623,344
Accumulated other comprehensive loss	(1,162)	(242)
Accumulated deficit	(581,793)	(533,724)
Total stockholders' equity	48,708	89,379
Total liabilities and stockholders' equity	<u>\$ 260,086</u>	<u>\$ 339,411</u>

(1) The condensed balance sheet as of December 31, 2021 was derived from the audited financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2021.

See accompanying notes to condensed financial statements.

**CYTOMX THERAPEUTICS, INC.**  
**CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**  
(in thousands, except share and per share data)  
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Revenues	\$ 18,165	\$ 16,288	\$ 35,302	\$ 32,259
Operating expenses:				
Research and development	31,159	26,100	61,718	48,472
General and administrative	11,748	9,393	22,292	18,619
Total operating expenses	42,907	35,493	84,010	67,091
Loss from operations	(24,742)	(19,205)	(48,708)	(34,832)
Interest income	262	44	330	112
Other income (expense), net	296	(82)	309	(77)
Net loss	<u>\$ (24,184)</u>	<u>\$ (19,243)</u>	<u>\$ (48,069)</u>	<u>\$ (34,797)</u>
Other comprehensive loss:				
Unrealized gain (loss) on investments, net of tax	(243)	58	(920)	62
Comprehensive loss	<u>\$ (24,427)</u>	<u>\$ (19,185)</u>	<u>\$ (48,989)</u>	<u>\$ (34,735)</u>
Net loss per share:				
Basic and diluted net loss per share	<u>\$ (0.37)</u>	<u>\$ (0.30)</u>	<u>\$ (0.73)</u>	<u>\$ (0.55)</u>
Shares used in computing basic and diluted net loss per share	<u>65,542,762</u>	<u>65,055,998</u>	<u>65,468,638</u>	<u>63,023,349</u>

See accompanying notes to condensed financial statements.

**CYTOMX THERAPEUTICS, INC.**  
**CONDENSED STATEMENTS OF STOCKHOLDERS' EQUITY**  
(in thousands, except share data)  
(Unaudited)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
<b>Balance at December 31, 2021</b>	65,392,758	\$ 1	\$ 623,344	\$ (242)	\$ (533,724)	\$ 89,379
Exercise of stock options	5,597	-	7	-	-	7
Stock-based compensation	-	-	3,370	-	-	3,370
Other comprehensive loss	-	-	-	(677)	-	(677)
Net loss	-	-	-	-	(23,885)	(23,885)
<b>Balance at March 31, 2022</b>	65,398,355	1	626,721	(919)	(557,609)	68,194
Exercise of stock options	95,393	-	91	-	-	91
Issuance of common stock under the ESPP	262,744	-	360	-	-	360
Stock-based compensation	-	-	4,490	-	-	4,490
Other comprehensive loss	-	-	-	(243)	-	(243)
Net loss	-	-	-	-	(24,184)	(24,184)
<b>Balance at June 30, 2022</b>	65,756,492	\$ 1	\$ 631,662	\$ (1,162)	\$ (581,793)	\$ 48,708

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income/(Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
<b>Balance at December 31, 2020</b>	48,251,819	\$ 1	\$ 499,964	\$ (47)	\$ (450,115)	\$ 49,803
Issuance of common stock in follow-on offering, net of issuance costs	16,428,571	-	107,712	-	-	107,712
Exercise of stock options	322,507	-	1,023	-	-	1,023
Stock-based compensation	-	-	3,034	-	-	3,034
Other comprehensive income	-	-	-	4	-	4
Net loss	-	-	-	-	(15,554)	(15,554)
<b>Balance at March 31, 2021</b>	65,002,897	1	611,733	(43)	(465,669)	146,022
Exercise of stock options	68,971	-	173	-	-	173
Issuance of common stock under the ESPP	85,135	-	518	-	-	518
Stock-based compensation	-	-	3,425	-	-	3,425
Other comprehensive income	-	-	-	58	-	58
Net loss	-	-	-	-	(19,243)	(19,243)
<b>Balance at June 30, 2021</b>	65,157,003	\$ 1	\$ 615,849	\$ 15	\$ (484,912)	\$ 130,953

See accompanying notes to condensed financial statements.

**CYTOMX THERAPEUTICS, INC.**  
**CONDENSED STATEMENTS OF CASH FLOWS**  
(in thousands)  
(Unaudited)

	Six Months Ended June 30,	
	2022	2021
<b>Cash flows from operating activities:</b>		
Net loss	\$ (48,069)	\$ (34,797)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization of intangible assets	73	73
Depreciation and amortization	1,139	1,278
Amortization of premium (accretion of discounts) on investments	(33)	281
Stock-based compensation expense	7,860	6,459
Non-cash lease expense	1,670	1,534
Changes in operating assets and liabilities		
Accounts receivable	(290)	(133)
Prepaid expenses and other current assets	694	3,199
Other assets	6	1,271
Accounts payable	(844)	(1,173)
Accrued liabilities and other long-term liabilities	(4,484)	(5,559)
Deferred revenue	(33,272)	(30,572)
Net cash used in operating activities	<u>(75,550)</u>	<u>(58,139)</u>
<b>Cash flows from investing activities:</b>		
Purchases of property and equipment	(1,148)	(1,096)
Purchases of investments	-	(99,898)
Maturities of investments	-	113,994
Net cash provided by (used in) investing activities	<u>(1,148)</u>	<u>13,000</u>
<b>Cash flows from financing activities:</b>		
Proceeds from issuance of common stock, net of issuance costs	-	107,712
Proceeds from employee stock purchase plan and exercise of stock options	458	1,714
Net cash provided by financing activities	<u>458</u>	<u>109,426</u>
Net increase (decrease) in cash, cash equivalents and restricted cash	(76,240)	64,287
Cash, cash equivalents and restricted cash, beginning of period	206,447	192,776
Cash, cash equivalents and restricted cash, end of period	<u>\$ 130,207</u>	<u>\$ 257,063</u>
<b>Supplemental disclosures of noncash investing items:</b>		
Purchases of property and equipment in accounts payable and accrued liabilities	\$ 29	\$ 54

See accompanying notes to condensed financial statements.



**CytomX Therapeutics, Inc.**  
**Notes to Condensed Financial Statements (Unaudited)**

**1. Description of the Business**

CytomX Therapeutics, Inc. (the “Company”) is a clinical-stage, oncology-focused biopharmaceutical company dedicated to destroying cancer differently. The Company aims to build a commercial enterprise to maximize its impact on the treatment of cancer. The Company is advancing potential first-in-class and best-in-class antibody-based therapeutics created using its Probody® therapeutic technology platform that could meaningfully improve outcomes for cancer patients. Its proprietary and unique Probody technology platform is designed to enable “conditional activation” of antibody-based drugs in the tumor microenvironment while minimizing drug activity in healthy tissues and in circulation. The Company is located in South San Francisco, California and was incorporated in the state of Delaware in September 2010.

**2. Basis of Presentation and Summary of Significant Accounting Policies**

***Basis of Presentation***

The accompanying interim condensed financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America (“U.S. GAAP”) and applicable rules and regulations of the U.S. Securities and Exchange Commission (“SEC”) regarding interim financial reporting.

***Unaudited Interim Financial Information***

The accompanying interim condensed financial statements and related disclosures are unaudited, have been prepared on the same basis as the annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for a fair statement of the results of operations for the periods presented.

The condensed results of operations for the three and six months ended June 30, 2022 are not necessarily indicative of the results to be expected for the full year or for any other future year or interim period. The accompanying condensed financial statements should be read in conjunction with the audited financial statements and the related notes thereto included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2021 filed with the SEC.

***Use of Estimates***

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

***Cash, cash equivalents and restricted cash***

The following table provides a reconciliation of cash, cash equivalents, and restricted cash reported within the condensed balance sheets that sum to the total of the amounts shown in the condensed statements of cash flows:

	<u>June 30, 2022</u>	<u>December 31, 2021</u>	<u>June 30, 2021</u>	<u>December 31, 2020</u>
			(in thousands)	
Cash and cash equivalents	\$ 129,290	\$ 205,530	\$ 256,146	\$ 191,859
Restricted cash - non-current assets	917	917	917	917
Total	<u>\$ 130,207</u>	<u>\$ 206,447</u>	<u>\$ 257,063</u>	<u>\$ 192,776</u>

Restricted cash represents a standby letter of credit issued pursuant to an office lease.

***Revenue Recognition***

The Company’s revenues are primarily derived through its license, research, development and commercialization agreements. The terms of these types of agreements may include (i) licenses for the Company’s technology or programs, (ii) research and development services, and (iii) services or obligations in connection with participation in research or steering committees. Payments to the Company under these arrangements typically include one or more of the following: nonrefundable upfront and license fees, research funding, milestone and other contingent payments to the Company for the achievement of defined collaboration objectives and certain preclinical, clinical, regulatory and sales-based events, as well as royalties on sales of any commercialized products.

The Company assesses whether the promises in its arrangements with customers are distinct performance obligations that should be accounted for separately. Judgment is required to determine whether the license to the Company's intellectual property is distinct from the research and development services or participation on steering committees.

The Company's collaboration and license agreements may include contingent payments related to specified research, development and regulatory milestones. Such milestone payments are typically payable under the collaborations when the collaboration partner claims or selects a target, or initiates or advances a covered product candidate in preclinical or clinical development, upon submission for marketing approval of a covered product with regulatory authorities, or upon receipt of actual marketing approvals of a covered product or for additional indications. Milestone payments that are not within the control of the Company or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. At each reporting date, the Company re-evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price by using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price in such period of determination.

The Company's collaboration and license agreements may also include contingent payments related to sales-based milestones. Sales-based milestones are typically payable when annual sales of a covered product reach specified levels. Sales-based milestones are recognized at the later of when the associated performance obligation has been satisfied or when the sales occur. Unlike other contingency payments, such as regulatory milestones, sales-based milestones are not included in the transaction price based on estimates at the inception of the contract; instead, they are included when the sales or usage occur.

The transaction price in each arrangement is allocated to the identified performance obligations based on the relative standalone selling price ("SSP") of each distinct performance obligation, which requires judgment. In instances where SSP is not directly observable, such as when a license or service is not sold separately, SSP is determined using information that may include market conditions and other observable inputs. Due to the early stage of the Company's licensed technology, the license of such technology is typically combined with research and development services and steering committee participation as one performance obligation. In the event that the Company receives non-cash consideration such as consideration in the form of a research license and research support services from the counterparty, the transaction price of a non-monetary exchange that has commercial substance is estimated based on the fair value of the non-cash consideration received, which may be determined through a valuation analysis.

In certain cases, the Company's performance creates an asset that does not have an alternative use to the customer and the Company has an enforceable right to payment at all times for performance completed to date. In these cases, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

AbbVie Ireland Unlimited Company ("AbbVie"), one of the Company's collaboration partners, entered into a license agreement with Seagen Inc., formerly Seattle Genetics, Inc. ("SGEN") to license certain intellectual property rights. As part of the Company's collaboration agreement with AbbVie, the Company is required to pay SGEN sublicense fees for certain milestone achievements and an annual maintenance fee. These sublicense fees are treated as reductions to the transaction price and combined with the performance obligation to which they relate.

### ***Contract Balances***

Customer payments are recorded as deferred revenue upon receipt or when due and may require deferral of revenue recognition to a future period until the Company satisfies its performance obligations under these arrangements. Amounts payable to the Company are recorded as accounts receivable when the Company's right to consideration is unconditional.

### **3. Net Loss Per Share**

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of shares of common stock outstanding for the period. Diluted net loss per share is calculated using the weighted-average number of common shares outstanding, plus potential dilutive common stock during the period. Diluted net loss per share is the same as basic net loss per share since the effect of the potentially dilutive securities is anti-dilutive.

**CYTOMX THERAPEUTICS, INC.**  
**Notes to Condensed Financial Statements (Unaudited)—(Continued)**

The following weighted-average outstanding shares of potentially dilutive securities are excluded from the computation of diluted net loss per share for the periods presented, because including them would have been anti-dilutive:

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2022	2021	2022	2021
Options, RSUs and ESPP to purchase common stock	15,226,820	12,117,149	14,888,352	11,837,707

**4. Fair Value Measurements and Investments**

In accordance with Accounting Standards Codification (“ASC”) 820-10, Fair Value Measurements and Disclosures, the Company determines the fair value of financial and non-financial assets and liabilities using the fair value hierarchy, which establishes three levels of inputs that may be used to measure fair value, as follows:

- Level I: Inputs which include quoted prices in active markets for identical assets and liabilities.
- Level II: Inputs other than Level I that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level III: Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The carrying amounts of the Company’s financial instruments, including restricted cash, accounts receivable, accounts payable and accrued liabilities approximate fair value due to their relatively short maturities. The Company’s financial instruments consist of Level I assets which consist primarily of highly liquid money market funds, some of which are included in restricted cash; and U.S. government bonds that are included in short-term investments.

The following tables set forth the fair value of the Company’s investments subject to fair value measurements on a recurring basis and the level of inputs used in such measurements:

	Valuation Hierarchy	June 30, 2022			
		Amortized Cost	Unrealized Gains	Unrealized Losses	Aggregate Fair Value
		(in thousands)			
<b>Assets</b>					
Money market funds	Level I	\$ 75,878	\$ —	\$ —	\$ 75,878
Restricted cash (money market funds)	Level I	917	—	—	917
U.S. Government bonds	Level I	100,037	—	(1,162)	98,875
Total		\$ 176,832	\$ —	\$ (1,162)	\$ 175,670

	Valuation Hierarchy	December 31, 2021			
		Amortized Cost	Unrealized Gains	Unrealized Losses	Aggregate Fair Value
		(in thousands)			
<b>Assets</b>					
Money market funds	Level I	\$ 165,736	\$ —	\$ —	\$ 165,736
Restricted cash (money market funds)	Level I	917	—	—	917
U.S. Government bonds	Level I	99,938	—	(242)	99,696
Total		\$ 266,591	\$ —	\$ (242)	\$ 266,349

No securities have contractual maturities of greater than twelve months.

As of June 30, 2022, the unrealized losses on the Company’s investment in US Government bonds were caused by interest rate changes and were not attributable to credit losses. The remaining contractual terms of those investments are less than a year. The Company does not intend to sell the investments and it is not more likely than not that the Company will be required to sell the investments before recovery of their amortized cost bases.

## 5. Accrued Liabilities

Accrued liabilities consisted of the following:

	June 30, 2022	December 31, 2021
	(in thousands)	
Research and clinical expenses	\$ 18,377	\$ 18,861
Payroll and related expenses	7,109	9,576
Legal and professional expenses	2,259	1,468
Operating lease liabilities - short term	3,845	3,618
Other accrued expenses	142	713
Total	<u>\$ 31,732</u>	<u>\$ 34,236</u>

## 6. Research and Collaboration Agreements

The following table summarizes the revenue by collaboration partner:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
	(in thousands)		(in thousands)	
AbbVie	\$ 5,377	\$ 2,078	\$ 7,804	\$ 3,306
Amgen	369	1,874	2,657	4,456
Astellas	5,014	4,931	10,031	9,687
Bristol Myers Squibb	7,405	7,405	14,810	14,810
Total revenue	<u>\$ 18,165</u>	<u>\$ 16,288</u>	<u>\$ 35,302</u>	<u>\$ 32,259</u>

### *AbbVie Ireland Unlimited Company*

In April 2016, the Company and AbbVie entered into two agreements, a CD71 Co-Development and Licensing Agreement (the “CD71 Agreement”) and a Discovery Collaboration and Licensing Agreement (as amended and restated in June 2019, the “Discovery Agreement”) and together with the CD71 Agreement the “AbbVie Agreements”). Under the terms of the CD71 Agreement, the Company and AbbVie will co-develop a conditionally activated antibody-drug conjugate (“ADC”) against CD71, with the Company responsible for preclinical and early clinical development. AbbVie will be responsible for later development and commercialization, with global late-stage development costs shared between the two companies. The Company will assume 35% of the net profits or net losses related to later development and commercialization unless it opts-out. If the Company opts-out from participation of co-development of the CD71 conditionally activated ADC, which includes CX-2029, AbbVie will have sole right and responsibility for the further development, manufacturing and commercialization of such CD71 conditionally activated ADC.

Under the CD71 Agreement, the Company received an upfront payment of \$20.0 million in April 2016, and was eligible to initially receive up to \$470.0 million in development, regulatory and commercial milestone payments, a 35% profit split on U.S. sales, and royalties on ex-U.S. sales at percentages in the high teens to low twenties if the Company participates in the co-development of the CD71 conditionally activated ADC subject to a reversion to a royalty on U.S. sales, and reduction in royalties on ex-U.S. sales, if the Company opts-out from the co-development of the CD71 conditionally activated ADC. The Company’s share of later stage co-development costs for each CD71 conditionally activated ADC is capped, provided that AbbVie may offset the Company’s co-development cost above the capped amounts from future payments such as milestone payments and royalties. Inclusive of payments received in 2017, 2018 and 2020, as of June 30, 2022, the Company has received \$100.0 million in milestone payments under the CD71 Agreement.

Under the terms of the Discovery Agreement, AbbVie receives exclusive worldwide rights to develop and commercialize conditionally activated ADCs against up to two targets, one of which was selected in March 2017. The Company shall perform research services to discover the Probody therapeutics and create conditionally activated ADCs for the nominated collaboration targets. From that point, AbbVie shall have sole right and responsibility for development and commercialization of products comprising or containing such conditionally activated ADCs (“Discovery Licensed Products”).

Under the Discovery Agreement, the Company received an upfront payment of \$10.0 million in April 2016 and subsequently earned an additional \$10.0 million milestone payment triggered by selection of the second target by AbbVie in June 2019. The Company is also eligible to receive up to \$265.0 million for each target, in development, regulatory and commercial milestone payments and royalties at percentages

in the high single to low teens from commercial sales of any resulting conditionally activated ADCs. The second target was selected under the Discovery Agreement that allows AbbVie to select a target for developing a conditionally activated ADC or a Probody.

The Company determined that the remaining potential milestone payments of both agreements, if recognized, are probable of significant revenue reversal as their achievement is highly dependent on factors outside the Company's control. Therefore, these payments continue to be fully constrained and are not included in the transaction price as of June 30, 2022.

As of June 30, 2022 and December 31, 2021, deferred revenue related to the CD71 Agreement performance obligation was \$9.5 million and \$16.1 million, respectively, and deferred revenue related to the Discovery Agreement performance obligation was \$4.0 million and \$5.2 million, respectively.

***Amgen, Inc.***

On September 29, 2017, the Company and Amgen, Inc. ("Amgen") entered into a Collaboration and License Agreement (the "Amgen Agreement"). Pursuant to the Amgen Agreement, the Company received an upfront payment of \$40.0 million in October 2017. Concurrent with the Amgen Agreement, the Company and Amgen entered into a Share Purchase Agreement pursuant to which Amgen purchased 1,156,069 shares of the Company's common stock at a price of \$17.30 per share for total proceeds of \$20.0 million.

In October 2021, CytomX and Amgen executed an amendment to the Amgen Agreement primarily to (1) extend the target selection date for Amgen to select its additional targets for research and development, and (2) reduce the total number of milestone events and increase the total amount of milestone payments for EGFR Products.

Under the terms of the Amgen Agreement, as amended, the Company and Amgen will co-develop a conditionally activated T-cell engaging bispecific therapeutic targeting epidermal growth factor receptor (the "EGFR Products"). The Company is responsible for early-stage development of EGFR Products and Amgen will be responsible for late-stage development and commercialization of EGFR Products. Following early-stage development, the Company will have the right to elect to participate financially in the global co-development of EGFR Products with Amgen, during which the Company would bear certain of the worldwide development costs for EGFR Products and Amgen would bear the rest of such costs (the "EGFR Co-Development Option"). If the Company exercises its EGFR Co-Development Option, the Company will share in somewhat less than 50% of the profit and losses from sales of such EGFR Products in the U.S., subject to certain caps, offsets, and deferrals. If the Company chooses not to exercise its EGFR Co-Development Option, the Company will not bear any costs of later stage development. The Company is also eligible to receive up to \$460.0 million in development, regulatory, and commercial milestone payments for EGFR Products, and royalties in the low-double-digit to mid-teen percentage of worldwide commercial sales, provided that if the Company exercises its EGFR Co-Development option, it shall receive a profit and loss split of sales in the United States and royalties in the low-double-digit to mid-teen percentage of commercial sales outside of the United States.

Amgen also has the right to select a total of up to three targets, including the two additional targets discussed below. The Company and Amgen collaborate in the research and development of conditionally activated T-cell engaging bispecifics products directed against such targets. Amgen has selected one such target (the "Amgen Other Product"). If Amgen exercises its option within a specified period of time, it can select two such additional targets (the "Amgen Option Products" and, together with the Amgen Other Product, the "Amgen Products"). Except with respect to preclinical activities to be conducted by CytomX, Amgen will be responsible, at its expense, for the development, manufacture, and commercialization of all Amgen Products. If Amgen exercises all of its options and advances all three of the Amgen Products, CytomX was initially eligible to receive up to \$950.0 million in upfront, development, regulatory, and commercial milestones and tiered high single-digit to low-teen percentage royalties. The Company concluded that, at the inception of the agreement, Amgen's option to select the two additional targets is not a material right and does not represent a performance obligation of the agreement.

At the initiation of the collaboration, CytomX had the option to select, from programs specified in the Amgen Agreement, an existing preclinical stage T-cell engaging bispecific product from the Amgen preclinical pipeline. In March 2018, CytomX selected the program. CytomX is responsible, at its expense, for converting this program to a conditionally activated T-cell engaging bispecific product, and thereafter, will be responsible for development, manufacturing, and commercialization of the product ("CytomX Product"). Amgen is eligible to receive up to \$203.0 million in development, regulatory, and commercial milestone payments for the CytomX Product, and tiered mid-single digit to low double-digit percentage royalties. In January 2022, the IND for the EGFR product (CX-904) was allowed to proceed by the U.S. Food and Drug Administration ("FDA").

As of June 30, 2022 and December 31, 2021, deferred revenue related to the EGFR Products performance obligation was \$19.6 million and \$21.8 million, respectively. As of June 30, 2022 and December 31, 2021, deferred revenue related to the Amgen Other Products performance obligation was \$1.0 million and \$1.4 million, respectively.

***Astellas Pharma Inc.***

The Company and Astellas Pharma, Inc. (“Astellas”) entered into a Collaboration and License Agreement (the “Astellas Agreement”) on March 23, 2020, the effective date, to collaborate on preclinical research activities to discover and develop certain antibody compounds for the treatment of cancer using the Company’s Probody therapeutic technology.

Under the terms of the Astellas Agreement, the Company granted Astellas an exclusive, worldwide right to develop and commercialize Probody therapeutics for up to four collaboration targets including one initial target and three additional targets (“Additional Targets”). In addition, Astellas has the right to expand the number of Additional Targets from three up to five (the “Expansion Option”) before the third anniversary of the effective date. Furthermore, for a specified number of targets, at a pre-specified time prior to the initiation of the first pivotal study of a product against such target, the Company may elect to participate in certain development costs and share in the profits generated in the United States with respect to such product (“Cost Share Option”). The Cost Share Option, if exercised, will also provide the option for the Company to co-commercialize such product in the United States. The Company does not consider the Cost Share Option as a performance obligation at the inception of the agreement as the participation is at the Company’s discretion.

Pursuant to the Astellas Agreement, the consideration from Astellas is comprised of an upfront fee of \$80.0 million and contingent payments for development, regulatory and sales milestones of up to an aggregate of approximately \$1.6 billion. If Astellas exercises its Expansion Option for the two Additional Targets, the Company would be eligible to receive additional upfront and milestone payments aggregating to approximately \$0.9 billion. The Company is also entitled to tiered royalties from high-single digit to mid-teen percentage royalties from potential future sales. Astellas is responsible for all preclinical research costs incurred by either party as set forth in the preclinical research plan and the Company will receive research and development service fees based on a prescribed full time employee (“FTE”) rate.

As of June 30, 2022 and December 31, 2021, deferred revenue relating to the Astellas Agreement was \$43.7 million and \$51.6 million, respectively. The amount due from Astellas under the Astellas Agreement was \$1.0 million and \$0.8 million as of June 30, 2022 and December 31, 2021, respectively.

***Bristol Myers Squibb Company***

On May 23, 2014, the Company and Bristol Myers Squibb Company (“Bristol Myers Squibb”) entered into a Collaboration and License Agreement (the “BMS Agreement”) to discover and develop compounds for use in human therapeutics aimed at multiple immuno-oncology targets using the Company’s Probody therapeutic technology. The effective date of the BMS Agreement was July 7, 2014.

Under the terms of the BMS Agreement, the Company granted Bristol Myers Squibb exclusive worldwide rights to develop and commercialize Probody therapeutics for up to four oncology targets. Bristol Myers Squibb had additional rights to substitute up to two collaboration targets within three years of the effective date of the BMS Agreement. These rights expired in May 2017. Each collaboration target had a two-year research term and the two additional targets had to be nominated by Bristol Myers Squibb within five years of the effective date of the BMS Agreement. The research term for each collaboration target could be extended in one year increments up to three times.

Pursuant to the BMS Agreement, the financial consideration from Bristol Myers Squibb was comprised of an upfront payment of \$50.0 million, and the Company was initially entitled to receive contingent payments of up to \$25.0 million for additional targets and up to an aggregate of \$1,192.0 million for development, regulatory and sales milestones. In addition, the Company was entitled to royalty payments in the mid-single digits to low double-digit percentages from potential future sales. The Company also received research and development service fees based on a prescribed FTE rate that was capped.

On March 17, 2017, the Company and Bristol Myers Squibb entered into Amendment Number 1 to Extend Collaboration and License Agreement (“Amendment 1”). Amendment 1 granted Bristol Myers Squibb exclusive worldwide rights to develop and commercialize Probody therapeutics for up to eight additional targets. The effective date of Amendment 1 was April 25, 2017 (“Amendment Effective Date”). Under the terms of Amendment 1, the Company continued to have obligations to Bristol Myers Squibb to discover and conduct preclinical development of Probody therapeutics against any targets they chose to select during the research period under the terms of Amendment 1.

Pursuant to Amendment 1, the financial consideration from Bristol Myers Squibb was comprised of an upfront payment of \$200.0 million and the Company was initially eligible to receive contingent payments for development, regulatory and sales milestones of up to an aggregate of \$3,586.0 million for the eight targets. The Company was also entitled to tiered mid-single to low double-digit percentage royalties from potential future sales. Amendment 1 did not change the term of the Bristol Myers Squibb’s royalty obligation under the BMS Agreement. Bristol Myers Squibb’s royalty obligation continues on a licensed-product by licensed-product basis until the later of (i) the expiration of the last claim of the licensed patents covering the licensed products in the country, (ii) the twelfth anniversary of the first commercial sale of a

**CYTOMX THERAPEUTICS, INC.**  
**Notes to Condensed Financial Statements (Unaudited)—(Continued)**

licensed product in a country, or (iii) the expiration of any applicable regulatory, pediatric, orphan drug or data exclusivity with respect to such product.

The initial transaction price for the BMS Agreement and Amendment 1, collectively, was \$272.8 million consisting of the upfront fees of \$250.0 million, research and development service fees of \$10.8 million and milestone payments received of \$12.0 million upon the adoption of ASC 606 on January 1, 2018. The Company determined that the remaining potential milestone payments were probable of significant revenue reversal as their achievement was highly dependent on factors outside the Company's control. Therefore, these payments were fully constrained and were not included in the transaction price upon the adoption of ASC 606 on January 1, 2018. The BMS Agreement represents an obligation to continuously make the Probody therapeutic technology platform available to Bristol Myers Squibb. Therefore, the initial transaction price is recognized over the estimated research service period, which ends on April 25, 2025.

In February 2021, the Company and Bristol Myers Squibb entered into Amendment Number 2 to amend the Collaboration and License Agreement ("Amendment 2"), as amended by Amendment 1. Subsequent to Amendment 2, Bristol Myers Squibb has the exclusive worldwide rights to develop and commercialize Probody therapeutics for up to five oncology targets. Under the terms of Amendment 2, the period for target selection has been extended and the Company will continue to collaborate with Bristol Myers Squibb to discover and conduct preclinical development of Probody therapeutics against targets selected by Bristol Myers Squibb over the estimated research period, which ends in April 2025. Pursuant to Amendment 2, the Company is eligible to receive contingent payments for development, regulatory and sales milestones of up to an aggregate of \$1,779.0 million. It is also entitled to tiered mid-single to low double-digit percentage of royalties from potential future sales. In addition, the Company will no longer be entitled to receive the research and development service fee as part of the arrangement.

The Company reevaluated the remaining potential milestone payments and determined that significant revenue reversal was still probable as the achievement of such milestones was highly dependent on factors outside the Company's control. As a result, these payments continued to be fully constrained and are not included in the transaction price as of June 30, 2022.

As of June 30, 2022 and December 31, 2021, deferred revenue relating to the BMS Agreement was \$83.9 million and \$98.8 million, respectively.

**Contract Liabilities**

The following table presents changes in the Company's total contract liabilities during the six months ended June 30, 2022:

	<u>Balance at 12/31/2021</u>	<u>Additions</u>	<u>Deductions</u>	<u>Balance at 6/30/2022</u>
	(in thousands)			
<b>Contract liabilities:</b>				
Deferred revenue	\$ 194,922	\$ —	\$ (33,272)	\$ 161,650

The Company expects that the \$161.7 million of deferred revenue related to the following contracts as of June 30, 2022 will be recognized as revenue as set forth below. However, the timing of revenue recognition could differ from the estimates depending on facts and circumstances impacting the various contracts, including progress of research and development, resources assigned to the contracts by the Company or its collaboration partners or other factors outside of the Company's control.

- The \$9.5 million of deferred revenue related to the CD71 Agreement with AbbVie is expected to be recognized based on actual FTE effort and program progress until 2023.
- The \$4.0 million of deferred revenue related to the second target under the Discovery Agreement with AbbVie is expected to be recognized ratably until 2024.
- The \$19.6 million of deferred revenue related to the Amgen EGFR Products is expected to be recognized based on actual FTE effort and program progress until 2024.
- The \$1.0 million of deferred revenue related to the Amgen Other Products is expected to be recognized ratably until 2023.
- The \$43.7 million of deferred revenue related to the Astellas Agreement is expected to be recognized ratably until 2025.
- The \$83.9 million of deferred revenue related to the BMS Agreement is expected to be recognized ratably until 2025.

## 7. Stock-Based Compensation

### Stock Options

Activities for the Company's stock option plans for the six months ended June 30, 2022 were as follows:

	Options Outstanding	
	Number of Options	Weighted- Average Exercise Price Per Share
<b>Balances at December 31, 2021</b>	12,192,216	\$ 9.42
Options granted	3,416,918	3.55
Options exercised	(100,990)	0.98
Option forfeited/expired	(1,077,318)	8.93
<b>Balances at June 30, 2022</b>	<u>14,430,826</u>	<u>\$ 8.13</u>

The Company recorded \$2.8 million and \$3.3 million of stock-based compensation expense related to the stock options for the three months ended June 30, 2022 and 2021, respectively.

The Company recorded \$5.7 million and \$6.3 million of stock-based compensation expense related to the stock options for the six months ended June 30, 2022 and 2021, respectively.

### Time-based RSUs ("TRSUs")

Activities for the Company's TRSUs for the six months ended June 30, 2022 were as follows:

	Number of Shares	Weighted Average Grant Date Fair Value Per Share
<b>Balance at December 31, 2021</b>	433,250	\$ 5.34
RSU's awarded	655,410	3.89
RSU's vested	—	—
RSU's cancelled	(97,044)	4.75
<b>Balance at June 30, 2022</b>	<u>991,616</u>	<u>\$ 4.44</u>

The Company recorded \$0.4 million and \$0.7 million of stock-based compensation expense related to the TRSUs for the three and six months ended June 30, 2022, respectively. The Company began granting TRSUs in the fourth quarter of 2021.

### Performance-based RSUs ("PSUs")

In October 2021, the Company granted 435,000 PSUs as recognition awards to executive employees with an aggregated grant date fair value of \$2.3 million. 50% of the PSUs granted will vest within one year of the grant date upon achievement of certain specific milestones ("Tranche 1") and the remaining 50% will vest within two years of the grant date upon achievement of additional company objectives ("Tranche 2"). The Company determined that it is not probable that the performance conditions will be satisfied for each of these Tranches and hence no compensation cost was recorded for these awards for the year ended December 31, 2021.

As of June 30, 2022, the Company determined that the achievement of the milestones for Tranche 1 was probable and hence recorded \$1.0 million of stock-based compensation expense for the three and six months ended June 30, 2022. As the achievement of the milestones for Tranche 2 was not considered probable, no compensation cost was recorded for these awards as of and for the three and six months ended June 30, 2022.



**CYTOMX THERAPEUTICS, INC.**  
**Notes to Condensed Financial Statements (Unaudited)—(Continued)**

Activities for the Company's PSUs for the six months ended June 30, 2022 were as follows:

	<u>Number of Shares</u>	<u>Weighted Average Grant Date Fair Value Per Share</u>
<b>Balance at December 31, 2021</b>	435,000	\$ 5.34
PSU's awarded	—	—
PSU's vested	—	—
PSU's cancelled	(47,500)	5.34
<b>Balance at June 30, 2022</b>	<u>387,500</u>	<u>\$ 5.34</u>

**Stock-based Compensation**

Total stock-based compensation recorded related to options, TRSUs, PSUs and the ESPP was as follows:

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2022</u>	<u>2021</u>	<u>2022</u>	<u>2021</u>
	(in thousands)			
Stock-based compensation expense:				
Research and development	\$ 2,091	\$ 1,548	\$ 3,696	\$ 2,885
General and administrative	2,399	1,877	4,164	3,574
Total stock-based compensation expense	<u>\$ 4,490</u>	<u>\$ 3,425</u>	<u>\$ 7,860</u>	<u>\$ 6,459</u>

**8. Commitments and Contingencies**

*Legal Proceedings*

On March 4, 2020, Vytacera Bio, LLC filed a patent infringement lawsuit against the Company in the U.S. District Court for the District of Delaware. The lawsuit alleges that the Company's use, offers to sell, and/or sales of the Probody® technology platform for basic research applications constitutes infringement. The complaint seeks unspecified monetary damages. The Company filed an Answer, Affirmative Defenses, and Counterclaims on May 26, 2020. Vytacera Bio, LLC filed its Answer to CytomX Therapeutics Inc.'s Counterclaims on June 5, 2020. On October 13, 2021, the Court granted the parties' stipulation to stay all pending case deadlines except for certain matters, pending resolution of claim construction. On May 9, 2022, the Court entered a claim construction ruling. Also on May 9, 2022, the case was assigned to the District of Delaware's Vacant Judgeship. No new case deadlines have been set. The Company believes that the lawsuit is without merit and intends to vigorously defend itself, and has not recorded any amount for claims associated with this lawsuit as of June 30, 2022.

**9. Income Taxes**

The Company maintains a full valuation allowance against its net deferred tax assets due to the Company's history of losses as of June 30, 2022 and December 31, 2021.

The Company files income taxes in the U.S. federal jurisdiction, the state of California and various other U.S. states. The Company is currently under examination by the state of California for the years 2017 and 2018. The examination contests the Company's tax position on revenue apportionment for upfront and milestone payments resulting from the Company's collaboration and licensing agreements. As of the date of this filing, the state of California has not proposed adjustments to the tax returns. Due to the ongoing nature of the examination and discussions with the state of California, the Company is unable to estimate a date by which this matter will be resolved or reasonably estimate the potential impact should the tax position be revised. Based on the Company's current expectations and understanding of the reasonably possible outcomes, the Company does not anticipate that the resolution of this matter would result in a material impact on its financial position or results of operations.

**10. Subsequent event**

***Restructuring***

On July 6, 2022 the Company announced Phase 2 topline results for praluzatamab ravtansine in breast cancer and its decision to not advance this program ("praluzatamab ravtansine") alone given the data and financial market conditions. The Company will seek a collaboration partnership to further develop praluzatamab ravtansine in patients with advanced breast cancer. On July 13, 2022, the Company announced a restructuring plan to prioritize its resources on its emerging pre-clinical and early clinical pipeline as well as its existing collaboration partnerships. The restructuring plan will result in a reduction to its workforce by approximately 40%, and is expected to be completed by the fourth quarter of 2022. The Company estimates that it will incur aggregate restructuring charges of approximately \$10.0 million, primarily related to one-time severance payments and other employee-related costs, in the third and fourth quarters of 2022.

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

*You should read the following management’s discussion and analysis of our financial condition and results of operations in conjunction with our unaudited condensed financial statements and notes thereto included in Part I, Item 1 of this Quarterly Report on Form 10-Q and with our audited financial statements and notes thereto for the year ended December 31, 2021, included in our Annual Report on Form 10-K as filed with the U.S. Securities and Exchange Commission (“SEC”) on March 1, 2022. This discussion and other parts of this report contain forward-looking statements that involve risks and uncertainties, such as statements of our plans, objectives, expectations and intentions. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the section of this report titled “Risk Factors.” Except as may be required by law, we assume no obligation to update these forward-looking statements or the reasons that results could differ from these forward-looking statements.*

### Overview

We are a clinical-stage, oncology-focused biopharmaceutical company dedicated to destroying cancer differently. We aim to build a commercial enterprise to maximize our impact on the treatment of cancer. By pioneering a novel class of conditionally activated biologic candidates, powered by our Probody® therapeutic technology platform, we lead the field of conditionally activated oncology therapeutics and have established conditional activation as a strategic area of biologics research and development. Our goal is to transcend the limits of current cancer treatments by successfully leveraging therapeutic targets and strategies that were once thought to be inaccessible.

Our proprietary, unique and versatile Probody technology platform is designed to enable conditional activation of biologic therapeutic candidates within the tumor microenvironment, while minimizing drug activity in healthy tissues and circulation. Our industry-leading platform is built on a strong foundation of tumor biology expertise, including deep knowledge of tumor-associated enzymes known as proteases. Proteases are tightly controlled in normal tissues but often poorly regulated and active in tumor microenvironments where they play important roles in cancer cell migration, invasion and metastasis. Leveraging our deep scientific knowledge, we conceived of and constructed our Probody therapeutic platform which allows us to genetically engineer biologic therapeutic candidates to contain protease-cleavable masks. Our masking strategy is designed to reduce binding of biologic therapeutics to their targets until the mask is removed by proteases in the tumor microenvironment, providing more selective targeting of the tumor. We believe this innovative approach has the potential to improve cancer treatment in three ways:

1. Allowing the pursuit of high potential targets that were previously considered “undruggable” due to their ubiquitous expression on healthy tissues;
2. Enhancing an experimental treatment’s “therapeutic window,” the balance between tolerability and anti-tumor activity; and
3. Enabling the development of new combination therapies, including immunotherapies, by improving tolerability.

We are employing our conditional activation platform technology to address some of the biggest challenges in cancer therapy development today. These include the validation of potential new targets for antibody-drug conjugates (“ADCs”), opening solid tumor opportunities for T-cell engaging bispecific antibodies (“TCBs”), and increasing the therapeutic window for immune modulators such as cytokines and checkpoint inhibitors (“CPIs”).

Our robust portfolio of differentiated, experimental treatments includes the wholly-owned, praluzatamab ravtansine (CX-2009) and the AbbVie-partnered CX-2029, two conditionally activated ADCs directed toward the previously undruggable targets CD166 and CD71, respectively. These cancer targets were considered inaccessible to conventional ADCs due to their ubiquitous expression in many healthy tissues, but we believe they are potentially addressable with our Probody technology. Having demonstrated favorable tolerability and encouraging anti-tumor activity in separate dose-escalation Phase 1 studies, praluzatamab ravtansine and CX-2029 are currently in Phase 2 clinical studies.

Praluzatamab ravtansine is our conditionally activated ADC directed toward CD166 and is being evaluated in a three-arm study in patients with advanced human epidermal growth factor receptor 2 (“HER2”)-non-amplified breast cancer. Arms A and B examined praluzatamab ravtansine monotherapy in patients with hormone receptor-positive/HER2-non-amplified breast cancer and triple-negative breast cancer (“TNBC”), respectively. Arm C studied praluzatamab ravtansine in combination with pacmilimab (CX-072), our wholly-owned PD-L1 inhibitor, in patients with TNBC. In July 2022, Phase 2 topline results were disclosed for Arms A and B as of data cut-off date May 2022. Arm A met the primary endpoint of confirmed objective response rate greater than 10% by central radiology review. The safety profile in Arm A was generally consistent with Phase 1 observations and the DM4 payload, with high-grade toxicities or toxicities resulting in dose modification predominantly ocular or neuropathic in nature. Specifically, 30% of patients in Arm A discontinued treatment for an adverse event. Grade 3 or greater ocular and neuropathic toxicities were 15% and 10%, respectively. All patients in Arm A were treated at the initial starting dose of 7 mg/kg administered every three weeks. Arm B did not pass the protocol-defined futility boundary in patients with advanced TNBC and enrollment into Arms B and C will be discontinued. Arm B evaluated patients at starting doses of 7 mg/kg or 6 mg/kg. The toxicity profile of the 7 mg/kg starting dose in Arm B was consistent with the 7 mg/kg starting dose in Arm A. In the 6 mg/kg cohort in Arm

B, no patients discontinued treatment for an adverse event as of the data cut-off date and Grade 3 or greater ocular or neuropathic related events were 3% and 0%, respectively. Based on these results, the Company was encouraged by the emerging safety profile of 6 mg/kg and will seek a partnership to further develop praluzatamab ravtansine in patients with advanced breast cancer.

CX-2029 is being evaluated as monotherapy in a four-cohort Phase 2 expansion study designed to enroll twenty-five efficacy evaluable patients per cohort in the following malignancies: squamous non-small cell lung cancer (“sqNSCLC”), head and neck squamous cell carcinoma (“HNSCC”), esophageal and gastro-esophageal junction (“E/GEJ”) cancers, and diffuse large B-cell lymphoma (“DLBCL”). Patient enrollment into the study is now complete in all three solid cancer indications, including the E/GEJ cancer cohort. The DLBCL cohort was deprioritized due to strategic and competitive reasons and did not enroll any patients. A data update for the fully enrolled sqNSCLC cohort is expected in the fourth quarter of 2022. Data from the E/GEJ cancer cohort continues to mature.

Our partner, Bristol Myers Squibb, is conducting a randomized Phase 2 study evaluating BMS-986249, a Probody version of ipilimumab, the anti-CTLA-4 antibody, in combination with nivolumab, the anti-PD-1 antibody, in patients with metastatic melanoma. In addition, BMS-986249 is being studied in combination with nivolumab in three additional indications: advanced hepatocellular carcinoma, metastatic castration-resistant prostate cancer and advanced TNBC. Bristol Myers Squibb also continues to evaluate BMS-986288, a Probody version of non-fucosylated ipilimumab, as monotherapy or in combination with nivolumab in a Phase 1 clinical study.

Underscoring our commitment to destroying cancer differently, we have recently introduced a third treatment modality into the clinic from our Probody platform, reinforcing our leadership in the field of conditional activation of biologic therapeutics. As part of our partnership with Amgen, we have advanced CX-904, a conditionally activated TCB candidate against EGFR and CD3. Our investigational new drug application (“IND”) for CX-904 was allowed to proceed by the FDA in January 2022. In May 2022, the first patient was dosed in a Phase 1 study evaluating CX-904 as a treatment for patients with advanced solid tumors.

Our pipeline also includes CX-801, a wholly-owned interferon (“IFN”) alpha-2b Probody. Preclinically, CX-801 demonstrated a wide therapeutic index with an enhanced tolerability profile versus unmasked IFN, without compromising its potent antitumor effects. CX-801 has broad potential applicability in traditionally immuno-oncology sensitive as well as insensitive (cold) tumors. An IND submission for CX-801 is planned in the second half of 2023.

Another wholly-owned emerging product candidate is CX-2051, a conditionally activated ADC paired with a next-generation payload and directed toward EpCAM with potential applicability across multiple EpCAM-expressing epithelial cancers. We plan to submit an IND for this program in the second half of 2023.

We are also continuously engaged in drug discovery efforts towards the generation of new clinical candidates across multiple modalities for the treatment of cancer, including additional ADCs, Cytokines and TCBs, reflecting the versatility of our Probody platform.

We do not have any products approved for sale, and we continue to incur significant research and development and general administrative expenses related to our operations. We are not profitable and have incurred losses in each year since our founding in 2008. Our net loss was \$24.2 million and \$48.1 million for the three and six months ended June 30, 2022, respectively. As of June 30, 2022 and December 31, 2021, we had an accumulated deficit of \$581.8 million and \$533.7 million, respectively. We expect to continue to incur significant losses for the foreseeable future.

Global health authorities, including the FDA, regulate many aspects of a product candidate’s life cycle, including research and development and preclinical and clinical testing. We will need to commit significant time, resources, and funding to develop our wholly-owned and partnered product candidates in clinical trials. We are unable to provide the nature, timing, and estimated costs of the efforts necessary to complete the development of our product candidates because, among other reasons, of regulatory uncertainty, manufacturing limitations, and the pace of enrollment of our clinical trials, which is a function of many factors, including the availability and proximity of patients with the relevant condition.

We currently have no manufacturing capabilities and do not intend to establish any such capabilities in the near term. As such, we are dependent on third parties to supply our product candidates according to our specifications, in sufficient quantities, on time, in compliance with appropriate regulatory standards and at competitive prices.

### ***Restructuring***

On July 6, 2022, we announced Phase 2 topline results for praluzatamab ravtansine in breast cancer and our decision to not advance this program (“praluzatamab ravtansine”) alone given the data and financial market conditions. We will seek a collaboration partnership to further develop praluzatamab ravtansine in patients with advanced breast cancer. On July 13, 2022, we announced a restructuring plan to prioritize its resources on our emerging pre-clinical and early clinical pipeline as well as our existing collaboration partnerships. The restructuring plan will result in a reduction to our workforce by approximately 40%, and is expected to be completed by the fourth quarter of 2022. We estimate

that we will incur aggregate restructuring charges of approximately \$10.0 million, primarily related to one-time severance payments and other employee-related costs, in the third and fourth quarters of 2022.

### **Impact of COVID-19**

In December 2019, a strain of novel coronavirus-caused disease (now commonly known as COVID-19) was reported to have surfaced in Wuhan, China and in March 2020 the World Health Organization declared the outbreak a pandemic. There continues to be uncertainty as to the extent and duration of the COVID-19 pandemic including the ongoing emergence and impact of new variants.

The COVID-19 pandemic continues to impact our ongoing operations, including clinical trials. Any preventative or protective actions that we, our collaboration partners or others have taken, or may take, in respect of the virus may result in further disruption for our clinical trials, including clinical trials for pralutamatav ravtansine, CX-2029 and CX-904, manufacturing, research, financial reporting capabilities and operations generally and could potentially impact our patients, partners, employees and third parties. Any resulting financial impact cannot be reasonably estimated at this time but may materially affect the business and our financial condition and results of operations. The extent to which the COVID-19 pandemic continues to impact our results will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of COVID-19 and the actions necessary to contain the virus or treat its impact, among others. Currently, it is not possible to predict how long the pandemic will last or the extent or degree of its ongoing impact on economic activity, and our business. We do not know the full extent of any impact or delay on our business or our operations, including clinical trial activity, however, we will continue to monitor the COVID-19 situation closely and operate in accordance with all relevant health and safety guidelines as they evolve in response to changing public health conditions.

### **Critical Accounting Policies and Estimates**

The preparation of our Condensed Financial Statements requires us to make estimates and judgments that affect the reported amounts in the financial statements and related disclosures. On an ongoing basis, management evaluates its significant accounting policies and estimates. We base our estimates on historical experience and on various market-specific and other relevant assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ significantly from these estimates. Estimates are assessed each period and updated to reflect current information. A summary of our critical accounting policies and estimates is presented in Part II, Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2021. Except as noted below, there have been no material changes to our critical accounting policies and estimates for the six months ended June 30, 2022.

### **Uncertain Tax Position**

We file income taxes in the U.S. federal jurisdiction, the state of California and various other U.S. states. We are currently under examination by the state of California for the years 2017 and 2018. The examination contests our tax position on revenue apportionment for upfront and milestone payments resulting from our collaboration and licensing agreements. As of the date of this filing, the state of California has not proposed adjustments to the tax returns. Due to the ongoing nature of the examination and discussions with the state of California, we are unable to estimate a date by which this matter will be resolved or reasonably estimate the potential impact should the tax position be revised. Based on our current expectations and understanding of the reasonably possible outcomes, we do not anticipate that the resolution of this matter would result in a material impact on our financial position or results of operations.

### **Components of Results of Operations**

#### **Revenue**

Our revenue to date has been primarily derived from non-refundable license payments, milestone payments and reimbursements for research and development expenses under our research, collaboration, and license agreements. We recognize revenue from upfront payments over the term of our estimated period of performance under the agreement using a cost-based input method or a common measure of progress for the entire performance obligation. In addition to receiving upfront payments, we may also be entitled to milestone and other contingent payments upon achieving predefined objectives. Revenue from milestones and other contingent payments, when it is probable that there will not be a significant revenue reversal, is also recognized over the performance period based on a similar method. Reimbursements from Astellas and Bristol Myers Squibb for research and development costs when incurred under our research, collaboration and license agreements with them are classified as revenue.

For the foreseeable future, we do not expect to generate any revenue from the sale of products unless and until such time as our product candidates have advanced through clinical development and obtained regulatory approval. We expect that any revenue we generate in the foreseeable future will fluctuate from year to year as a result of the timing and amount of milestones and other payments from our collaboration agreements with AbbVie, Amgen, Astellas, Bristol Myers Squibb and any other collaboration partners, and as a result of the fluctuations in the research and development expenses we incur in the performance of assigned activities under these agreements.

AbbVie, one of our collaboration partners, entered into a license agreement with Seagen Inc. (“SGEN”) to license certain intellectual property rights. As part of our collaboration agreement with AbbVie, we received a sublicense to these intellectual property rights and therefore pay SGEN sublicense fees. These sublicense fees are treated as reductions to the transaction price and combined with the performance obligation to which they relate. Milestone payments, when considered probable of being reached and when a significant revenue reversal would not be probable of occurring, are also recorded net of the associated sublicense fees and included in the transaction price.

### **Research and Development Expenses**

Our research and development expenses consist primarily of costs incurred to conduct research, such as the discovery and development of our product candidates, clinical development, including activities with third parties, such as contract research organizations (“CRO”) and contract development and manufacturing organizations (“CMO”), and the manufacture of drug products used in clinical trials, as well as the development of product candidates pursuant to our research, collaboration and license agreements. Research and development expenses include personnel costs, including stock-based compensation expense, contractor services, laboratory materials and supplies, depreciation and maintenance of research equipment, and an allocation of related facilities costs. We expense research and development costs as incurred.

We expect our research and development expenses could vary substantially in the future as we prioritize our pipeline opportunities, advance our product candidates through clinical trials, initiate additional clinical trials, and pursue regulatory approval of our product candidates. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming. The actual probability of success for our product candidates may be affected by a variety of factors including: the safety and efficacy of our product candidates, early clinical data, investment in our clinical program, the ability of collaborators to successfully develop our licensed product candidates, competition, manufacturing capability and commercial viability. We may never succeed in achieving regulatory approval for any of our product candidates. As a result of the uncertainties discussed above, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of our product candidates.

### **General and Administrative Expenses**

General and administrative expenses include personnel costs, expenses for outside professional services and other allocated expenses. Personnel costs consist of salaries, bonuses, benefits and stock-based compensation. Outside professional services consist of accounting and audit services, legal and other consulting fees. Allocated expenses primarily consist of rent expense related to our office and information technology related costs.

### **Interest Income**

Interest income primarily consists of interest income from our cash equivalents and investments, and accretion of discounts or amortization of premiums on our investments.

### **Other income (expense), net**

Other income (expense), net consists primarily of gains and losses resulting from changes to currency exchange rates.

## **Results of Operations For the Three and Six Months Ended June 30, 2022 and 2021**

### **Revenue**

The following table summarizes our revenue by collaboration partner during the respective periods:

	Three Months Ended June 30,			Six Months Ended June 30,		
	2022	2021	Change	2022	2021	Change
	(in thousands)					
AbbVie	\$ 5,377	\$ 2,078	\$ 3,299	\$ 7,804	\$ 3,306	\$ 4,498
Amgen	369	1,874	(1,505)	2,657	4,456	(1,799)
Astellas	5,014	4,931	83	10,031	9,687	344
Bristol Myers Squibb	7,405	7,405	-	14,810	14,810	-
<b>Total revenue</b>	<b>\$ 18,165</b>	<b>\$ 16,288</b>	<b>\$ 1,877</b>	<b>\$ 35,302</b>	<b>\$ 32,259</b>	<b>\$ 3,043</b>

The increase in revenue of \$1.9 million and \$3.0 million for the three and six months ended June 30, 2022, respectively, compared to the corresponding periods of 2021 was primarily due to:

- An increase in revenue from AbbVie under the CD71 Co-Development and Licensing Agreement driven by a higher percentage of project completion in current periods;
- Offset by a decrease in revenue from Amgen under the Amgen Agreement driven by lower percentage of completion of the CX-904 project in the current periods due to the increase in projected hours-to-completion within the same projected research period.

### Operating Costs and Expenses

#### Research and Development Expenses

The following table summarizes our research and development expenses by program incurred during the respective periods presented:

	Three Months Ended June 30,			Six Months Ended June 30,		
	2022	2021	Change	2022	2021	Change
<b>External costs incurred by product candidate (target):</b>		(in thousands)			(in thousands)	
Praluzatamab ravtansine, CX-2009 (CD166)	\$ 3,746	\$ 2,793	\$ 953	\$ 8,619	\$ 5,845	\$ 2,774
CX-2029 (CD71)	3,001	3,349	(348)	5,079	4,836	243
Pacmilimab, CX-072 (PD-L1)	1,037	1,715	(678)	1,036	1,514	(478)
CX-904	845	1,171	(326)	1,512	1,652	(140)
Other wholly owned and partnered programs	4,566	2,229	2,337	8,029	3,558	4,471
General research and development expenses	3,471	3,363	108	7,723	7,160	563
	16,666	14,620	2,046	31,998	24,565	7,433
Internal Costs	14,493	11,480	3,013	29,720	23,907	5,813
<b>Total research and development expenses</b>	<b>\$ 31,159</b>	<b>\$ 26,100</b>	<b>\$ 5,059</b>	<b>\$ 61,718</b>	<b>\$ 48,472</b>	<b>\$ 13,246</b>

The \$5.1 million and \$13.2 million increase in research and development expenses for the three and six months ended June 30, 2022, respectively, compared to the corresponding periods of 2021 was primarily due to an increase in personnel related expenses and laboratory contract services supporting our pre-clinical and clinical stage pipeline. The development expenses are expected to decrease over time due to the restructuring plans announced in July 2022, resulting in a pipeline reprioritization and a reduction to our workforce.

#### General and Administrative Expenses

	Three Months Ended June 30,			Six Months Ended June 30,		
	2022	2021	Change	2022	2021	Change
General and administrative expenses	\$ 11,748	\$ 9,393	\$ 2,355	\$ 22,292	\$ 18,619	\$ 3,673

General and administrative expenses increased by \$2.4 million for the three months ended June 30, 2022, compared to the corresponding period of 2021 primarily due to an increase in personnel related expenses as well as professional expenses driven by outside consulting services.

General and administrative expenses increased by \$3.7 million for the six months ended June 30, 2022, compared to the corresponding period of 2021 primarily due to an increase in personnel related expenses as well as outside consulting, legal and intellectual property services.

General and administrative expenses are expected to decrease over time due to the restructuring plan announced in July 2022, resulting in a reduction to our workforce.

## Liquidity and Capital Expenditures

### Sources of Liquidity

As of June 30, 2022, we had cash, cash equivalents and short-term investments of \$228.2 million and an accumulated deficit of \$581.8 million, compared to cash, cash equivalents and short-term investments of \$305.2 million and an accumulated deficit of \$533.7 million as of December 31, 2021. In January and February 2021, in an underwritten public offering of our common stock, we raised an aggregate net proceeds of approximately \$107.7 million. To date, we have financed our operations primarily through sales of our common stock in conjunction with the IPO, subsequent stock offerings and through our at-market offering, sales of our convertible preferred securities prior to our IPO and payments received under our collaboration agreements.

On July 13, 2022, we announced a restructuring plan to prioritize resources on our emerging pre-clinical and early clinical pipeline as well as our existing collaboration partnerships. The restructuring plan will result in a reduction to our workforce by approximately 40%, and is expected to be completed by the fourth quarter of 2022. We estimate that we will incur aggregate restructuring charges of approximately \$10.0 million, primarily related to one-time severance payments and other employee-related costs, in the third and fourth quarters of 2022.

Based upon our current operating plan, we expect our existing capital resources will be sufficient to fund operations into 2025. However, if the anticipated operating results and future financing are not achieved in future periods, our planned expenditures may need to be reduced in order to extend the time period over which the then-available resources would be able to fund the operations. The amounts and timing of our actual expenditures depend on numerous factors, including the progress of our preclinical and clinical development efforts, the results of any clinical trials and other studies, our operating costs and expenditures and other factors described under the caption "Risk Factors" in this Quarterly Report on Form 10-Q. The cost and timing of developing our product candidates is highly uncertain and subject to substantial risks and changes. As such, we may alter our expenditures as a result of contingencies such as the failure of one or all of our product candidates currently in clinical development, the acceleration of one or all of our product candidates in clinical development, the initiating of clinical trials for additional product candidates, the identification of more promising product candidates in our research efforts or unexpected operating costs and expenditures. We will need to raise additional funds in the future. There can be no assurance, however, that such efforts will be successful; or if they are successful, that the terms and conditions of such financing will be favorable to us.

### Summary Statement of Cash Flows

The following table summarizes our cash flows for the periods indicated:

	Six Months Ended	
	June 30,	
	2022	2021
	(in thousands)	
Net cash used in operating activities	\$ (75,550)	\$ (58,139)
Net cash provided by (used in) investing activities	(1,148)	13,000
Net cash provided by financing activities	458	109,426
Net increase (decrease) in cash and cash equivalents	\$ (76,240)	\$ 64,287

#### Cash Flows from Operating Activities

During the six months ended June 30, 2022, cash used in operating activities was \$75.6 million, which consisted of a net loss of \$48.1 million, adjusted by non-cash charges of \$10.7 million and a net decrease of \$38.2 million relating to the change of our net operating assets and liabilities. The non-cash charges primarily consisted of \$7.9 million in stock-based compensation, \$1.6 million in non-cash lease expense and \$1.2 million in depreciation and amortization.

The change in our net operating assets and liabilities was primarily due to:

- a net decrease of \$33.3 million in deferred revenue resulting from the continued recognition of deferred revenue from existing customers;
- a decrease of \$5.3 million in accounts payable, accrued and other long-term liabilities primarily due to timing of payment; and
- an increase of \$0.4 million in cash flows from accounts receivable and prepaid and other current assets primarily due to decreased advance payments to our third party manufacturing vendors and timing of payments.

During the six months ended June 30, 2021, cash used in operating activities was \$58.1 million, which consisted of a net loss of \$34.8 million and a net decrease of \$33.0 million relating to the change of our net operating assets and liabilities, offset by non-cash charges of \$9.7



million. The non-cash charges primarily consisted of \$6.5 million in stock-based compensation, \$1.5 million in non-cash lease expense, \$1.4 million in depreciation and amortization and \$0.3 million in amortization of premium on investments.

The change in our net operating assets and liabilities was primarily due to:

- a net decrease of \$30.6 million in deferred revenue resulting from the continued recognition of deferred revenue from existing customers;
- a decrease of \$6.7 million in accounts payable, accrued and other long-term liabilities primarily due to timing of payment and a reduction in research and clinical expenses; and
- an increase of \$4.4 million in cash flows from other assets, prepaid and other current assets.

#### *Cash Flows from Investing Activities*

During the six months ended June 30, 2022, cash used in investing activities was \$1.1 million of capital expenditures used to purchase property and equipment.

During the six months ended June 30, 2021, cash provided by investing activities was \$13.0 million, which consisted of \$114.0 million in proceeds received upon the maturity of short-term marketable securities, partially offset by \$99.9 million used in the purchase of long-term investments and \$1.1 million of capital expenditures used to purchase property and equipment.

#### *Cash Flows from Financing Activities*

During the six months ended June 30, 2022, cash provided by financing activities consisted of \$0.5 million of proceeds from the exercise of stock options and employee stock purchases under the employee stock purchase plan.

During the six months ended June 30, 2021, cash provided by financing activities consisted of \$107.7 million of net proceeds from the follow-on public offering and \$1.7 million of proceeds from the exercise of stock options and employee stock purchases under the employee stock purchase plan.

#### **Contractual Obligations**

During the six months ended June 30, 2022, there were no material changes in contractual obligations from the amounts disclosed in our Annual Report on Form 10-K for the year ended December 31, 2021.

#### **Item 3. Quantitative and Qualitative Disclosure About Market Risk**

We are exposed to market risks in the ordinary course of our business. These risks primarily relate to interest rate risks. We had cash, cash equivalents and short-term investments of \$228.2 million and \$305.2 million as of June 30, 2022 and December 31, 2021, respectively, which consists of bank deposits, money market funds and U.S. government bonds. Such interest-bearing instruments carry a degree of interest rate risk; however, historical fluctuations of interest income have not been significant.

We do not enter into investments for trading or speculative purposes and have not used any derivative financial instruments to manage our interest rate exposure. We have not historically been exposed to material risks due to changes in interest rates. Based on our investment positions as of June 30, 2022, a hypothetical 100 basis point change in interest rates would not have material effect in the fair value of the portfolio.

#### **Item 4. Controls and Procedures**

##### *Evaluation of Disclosure Controls and Procedures*

The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act of 1934, as amended (the “Exchange Act”) refers to controls and other procedures of an issuer that are designed to ensure that information required to be disclosed by the issuer 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 an issuer in the reports that it files or submits under the Exchange Act is accumulated and communicated to the issuer’s management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the

cost-benefit relationship of possible controls and procedures. Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their control objectives.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2022, the end of the period covered by this Quarterly Report on Form 10-Q. Management's assessment of internal control over financial reporting was conducted using the criteria defined in the *Internal Control—Integrated Framework (2013 framework)* issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). Based upon such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of such date.

***Changes in Internal Controls Over Financial Reporting***

There was no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during our fiscal quarter ended June 30, 2022 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**Item 1. Legal Proceedings**

We are subject to claims and assessments from time to time in the ordinary course of business but are not aware of any such matters, individually or in the aggregate, that will have a material adverse effect on our financial position, results of operations or cash flows.

On March 4, 2020, Vytacera Bio, LLC filed a patent infringement lawsuit against us in the U.S. District Court for the District of Delaware. The lawsuit alleges that our use, offers to sell, and/or sales of the Probody® technology platform for basic research applications constitutes infringement. The complaint seeks unspecified monetary damages. We filed an Answer, Affirmative Defenses, and Counterclaims on May 26, 2020. Vytacera Bio, LLC filed its Answer to CytomX Therapeutics Inc.'s Counterclaims on June 5, 2020. On October 13, 2021, the Court granted the parties' stipulation to stay all pending case deadlines except for certain matters, pending resolution of claim construction. On May 9, 2022, the Court entered a claim construction ruling. Also on May 9, 2022, the case was assigned to the District of Delaware's Vacant Judgeship. No new case deadlines have been set. We believe that the lawsuit is without merit and intend to vigorously defend ourselves. Accordingly, we cannot reasonably estimate any range of potential future charges, and we have not recorded any accrual for a contingent liability associated with these legal proceedings.

**Item 1A. Risk Factors**

**Risk Factors Summary**

We are providing the following summary of risk factors contained in this Quarterly Report on Form 10-Q to enhance the readability and accessibility of our risk factor disclosures in accordance with SEC rules. Please carefully review the full risk factors pertaining to this summary and to additional general risk factors contained in this Quarterly Report on Form 10-Q in their entirety for additional information regarding the material factors that make an investment in our securities speculative or risky. These risks and uncertainties include, but are not limited to, the following:

- The COVID-19 pandemic or any future pandemic could adversely impact our business, including our research, clinical trials, including clinical trial site initiation and patient enrollment, and financial condition.
- We are a clinical-stage biopharmaceutical company with a limited operating history and have not generated any revenue from product sales.
- We may not achieve the expected cost savings we anticipate from our recent restructuring.
- We expect that we will need to raise substantial additional funds to advance development of our product candidates and we cannot guarantee that this additional funding will be available on acceptable terms or at all.
- Clinical development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.
- Our product candidates are in early stages of development and may fail or suffer delays that materially and adversely affect their commercial viability.
- Interim, "top-line," and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.
- Our product candidates may cause undesirable side effects at any time during or after the clinical trial process that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any, including withdrawal from the market.
- If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.
- Our approach to the discovery and development of our therapeutic treatments is based on novel technologies that are unproven and may not result in marketable products.
- The market may not be receptive to our product candidates based on a novel therapeutic modality, and we may not generate any future revenue from the sale or licensing of product candidates.
- We have entered, and may in the future seek to enter, into collaborations with third parties for the development and commercialization of our product candidates using our Probody platform. If we fail to enter into such collaborations, or such

collaborations are not successful, we may not be able to capitalize on the market potential of our Probody platform and resulting product candidates.

- If we do not achieve our projected development and commercialization goals in the timeframes we announce and expect, the commercialization of any of our product candidates may be delayed, and our business will be harmed.
- We may not successfully engage in strategic transactions, including any additional collaborations we seek, which could adversely affect our ability to develop and commercialize product candidates, impact our cash position, increase our expense and present significant distractions to our management.
- We rely on third parties to conduct all of our clinical trials and certain of our preclinical studies and intend to continue to do so, and if such third parties do not perform as contractually required, fail to satisfy regulatory or legal requirements or miss expected deadlines, our development programs could be delayed with material and adverse effects on our business, financial condition, results of operations and prospects.
- Because we have no long-term contracts with and rely on third-party manufacturing and supply partners, most of which are sole source suppliers, our supply of research and development, preclinical and clinical development materials may become limited or interrupted or may not be of satisfactory quantity or quality.
- We, or third-party manufacturers, may be unable to successfully scale-up manufacturing of our product candidates in sufficient quality and quantity, which would delay or prevent us from developing our product candidates and commercializing approved products, if any.
- We face competition from entities that have developed or may develop product candidates for cancer, including companies developing novel treatments and technology platforms. If these companies develop technologies or product candidates more rapidly than we do or their technologies are more effective, our ability to develop and successfully commercialize product candidates may be adversely affected.
- Our stock price may be volatile and purchasers of our common stock could incur substantial losses.

## **Risk Factors**

*You should consider carefully the risks and uncertainties described below, together with all of the other information in this Quarterly Report on Form 10-Q, including our financial statements and the related notes and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” If any of the following risks are realized, our business, financial condition, results of operations and prospects could be materially and adversely affected. The risks described below are not the only risks facing the Company. Risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition, results of operations and/or prospects.*

### **Risks Related to Our Business**

***The COVID-19 pandemic or any future pandemic could adversely impact our business, including our research, clinical trials, and financial condition.***

In December 2019, a novel strain of coronavirus, COVID-19, was reported to have surfaced in Wuhan, China. Since then, COVID-19 has spread to multiple countries, including the United States and European and Asia-Pacific countries, including countries in which we have planned or active clinical trial sites. As COVID-19 and its variants continue to spread around the globe, we will likely continue to experience disruptions that could severely impact our business, research, including research for our partners or research of our partners, and clinical trials, including ongoing or planned clinical trials for praluzatamab ravtansine, CX-2029, CX-904 and clinical trials of our partners, including Bristol Myers Squibb. These disruptions and impacts may include:

- delays or difficulties in enrolling patients in our clinical trials or the clinical trials of our partners;
- delays or difficulties in clinical site initiation for CX-2029, CX-904 or any other clinical trials we or our partners decide to initiate, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our or our partners’ clinical trial sites and hospital staff supporting the conduct of our or our partners’ clinical trials;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others;
- difficulty in interpreting clinical data due to patients being infected by COVID-19;

- limitations in employee resources that would otherwise be focused on the conduct of our clinical trials or the clinical trials of our partners, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- delays in receiving approval from local regulatory authorities to initiate our or our partners' planned clinical trials;
- delays in clinical sites receiving the supplies and materials needed to conduct our or our partners' clinical trials;
- interruption in manufacturing or global shipping that may affect the timely delivery or transport of research materials or clinical trial materials, such as investigational drug product used in our or our partners' clinical trials;
- changes in local regulations as part of a response to the COVID-19 outbreak which may require us or our partners to change the ways in which clinical trials are conducted, which may result in unexpected costs, or cause us or our partners to discontinue the clinical trials altogether;
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees; and
- refusal of the FDA to accept data from clinical trials in affected geographies outside the United States.

For example, in March 2020, we announced the temporary pause in new patient enrollment and new site activation in our Phase 2 clinical trial of praluzatamab ravtansine as a result of the COVID-19 pandemic, primarily due to delays in patient enrollment and clinical site initiations, and the termination of the Phase 2 clinical trial of pacmilimab (CX-072) in combination with ipilimumab after a re-evaluation of the evolving clinical, competitive and commercial landscapes in immuno-oncology, taken together with impact of the COVID-19 pandemic. Since then, we revised our strategy for developing praluzatamab ravtansine, including redesigning the study. We cannot be certain of the continuing impact of the COVID-19 pandemic, including COVID-19 variants on clinical trial planning, or that site initiation, patient recruitment or other clinical trial activities will not continue to be delayed, discontinued or otherwise impacted.

Furthermore, the COVID-19 pandemic and government limitations on activities may continue to impact our ability to conduct research, including limiting our ability to obtain research materials and equipment, limiting access to our laboratories to conduct research, limiting the ability or willingness of employees to work at our facilities and limiting our ability to complete research and experiments in a timely basis or at all. In March 2020 we initiated a mandatory work-from-home program, limiting onsite activity to a substantially reduced level of laboratory research activities. Although we have gradually increased levels of such laboratory research activities, we continue to operate in a hybrid, work-from-home environment and there can be no assurance that we will be able to continue to increase or maintain current levels of such activity. Furthermore, in March 2022, China implemented additional regional lockdowns which continue to impact our ability to obtain some research materials on a timely basis. The COVID-19 pandemic and government limitations could further impact our ability to conduct business generally, including making timely payments, filing timely governmental and other business reports and filings, and otherwise comply with our obligations.

Any of the potential business, research and clinical impacts arising as a result of the COVID-19 pandemic could cause us to default on our obligations to our collaborative partners, including our specific research and development obligations, potentially resulting in termination of one or more collaborations, and could materially and adversely affect our business, financial condition, results of operation and prospects.

In addition, the spread of COVID-19 may negatively impact the trading price of shares of our common stock and could further severely impact our ability to raise additional capital on a timely basis or at all.

The global outbreak of COVID-19 continues to rapidly evolve, including with the discovery of new variants/mutations of the virus. The extent to which the COVID-19 pandemic continues to impact our business, including our clinical trials, research and financial condition will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the outbreak, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

***We are a clinical-stage biopharmaceutical company with a limited operating history and have not generated any revenue from product sales. We have a history of losses, expect to continue to incur significant losses for the foreseeable future and may never achieve or maintain profitability, which could result in a decline in the market value of our common stock.***

We are a clinical-stage biopharmaceutical company with a limited operating history, developing a novel class of therapeutic antibody product candidates, based on our proprietary biologic Probody technology platform. Since our inception, we have devoted our resources to the development of Probody therapeutics. We have had significant operating losses since our inception. As of June 30, 2022 and December 31, 2021, we had an accumulated deficit of \$581.8 million and \$533.7 million, respectively. Substantially all of our losses have resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations.

Though we have developed our Probody platform, our technologies and product candidates are in early stages of development, and we are subject to the risks of failure inherent in the development of product candidates based on novel technologies. We have not yet demonstrated our ability to successfully complete any mid or late-stage clinical trials, including large-scale, pivotal clinical trials, obtain regulatory approvals, arrange for a third party to manufacture a commercial-scale product candidate, or conduct sales and marketing activities necessary for successful commercialization. Typically, it takes many years to develop one product candidate from the time it enters initial preclinical studies to when it is available for treating patients. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a longer operating history. We will need to transition from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

Furthermore, we have never generated any revenue from product sales, and have not obtained regulatory approval for any of our product candidates. We also do not expect to generate any revenue from product sales for the foreseeable future, and we expect to continue to incur significant operating losses for the foreseeable future due to the cost of research and development, preclinical studies and clinical trials and the regulatory approval process for our product candidates. We expect our net losses to increase substantially over time as we continue the development of our pipeline and advance additional programs into clinical development. However, the amount of our future losses is uncertain. Our ability to achieve profitability, if ever, will depend on, among other things, our, or our collaborators, successfully developing product candidates, obtaining regulatory approvals to market and commercialize product candidates, manufacturing any approved products on commercially reasonable terms, establishing a sales and marketing organization or suitable third-party alternatives for any approved product and raising sufficient funds to finance business activities. If we, or our collaborators, are unable to develop our technologies and commercialize one or more of our product candidates or if sales revenue from any product candidate that receives approval is insufficient, we will not achieve profitability, which could have a material and adverse effect on our business, financial condition, results of operations and prospects.

***We expect that we will need to raise substantial additional funds to advance development of our product candidates and we cannot guarantee that this additional funding will be available on acceptable terms or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our product development and commercialization of our current or future product candidates.***

The development of biopharmaceutical product candidates is capital-intensive. To date, we have used substantial funds to develop our technology and product candidates and will require significant funds to conduct our ongoing clinical trials as well as to further our research and development, preclinical testing and future clinical trials of additional product candidates, to seek regulatory approvals for our product candidates and to manufacture and market any products that are approved for commercial sale. In addition, we have incurred and will continue to incur additional costs associated with operating as a public company. However, financial market conditions, including the public equity markets, may make it difficult for biotechnology companies to raise additional funds. We cannot predict when or if market conditions will change.

As of June 30, 2022, we had \$228.2 million in cash, cash equivalents and investments. We believe that our existing capital resources will be sufficient to fund our planned operations into 2025. Our future capital requirements and the period for which we expect our existing resources to support our operations may vary significantly from what we expect and we may not achieve the expected cash flow savings that we anticipate as a result of our recent restructuring. Our monthly spending levels vary based on our ongoing clinical trials, new and ongoing research and development and other corporate activities. Because the length of time and activities associated with conducting our clinical trials and successfully researching and developing our product candidates is highly uncertain, we are unable to estimate the actual funds we will require for development and, once any product candidate is approved, any subsequent marketing and commercialization activities.

The timing and amount of our operating expenditures will depend largely on:

- the scope, timing and progress of our ongoing clinical trials as well as any other preclinical and clinical development activities which may be affected by, among other things, the COVID-19 pandemic;
- the number, size and type of clinical trials and preclinical studies that we may be required to complete for our product candidates, as well as the cost and time of such studies and trials;
- the number, scope and prioritization of preclinical and clinical programs we decide to pursue;
- the time and cost necessary to produce clinical supplies of our product candidates;
- the time and cost necessary to scale our manufacturing capabilities prior to or following regulatory approval and commercial launch of any product candidates;
- the progress of the development efforts of parties with whom we have entered or may in the future enter into collaborations and research and development agreements;

- the timing and amount of payments we may receive or are obligated to pay under our collaboration agreements and license agreements;
- our ability to maintain our current licenses and research and development programs and to establish new collaboration arrangements;
- the costs involved in prosecuting and enforcing patent and other intellectual property claims, including the ongoing patent infringement lawsuit brought by Vytacera against us;
- the cost of any existing or future litigation to which we are or may become a party;
- the cost and timing of regulatory approvals; and
- our efforts to enhance operational systems and hire additional personnel, including personnel to support development and commercialization of our product candidates and satisfy our obligations as a public company.

If we are unable to obtain funding on a timely basis or on acceptable terms, we may have to delay, reduce or terminate our research and development programs and preclinical studies or clinical trials, limit strategic opportunities or undergo reductions in our workforce or other corporate restructuring activities. We also could be required to seek funds through arrangements with collaborators or others that may require us to relinquish rights to some of our technologies or product candidates that we would otherwise pursue on our own. We do not expect to realize revenue from sales of products or royalties from licensed products in the foreseeable future, if at all, and unless and until our product candidates are clinically tested, approved for commercialization and successfully marketed. To date, we have financed our operations primarily through sales of our common stock, sale of our convertible preferred securities prior to our IPO and payments received under our collaboration agreements, including, most recently, the Collaboration and License Agreement that we entered into with Astellas in March 2020. We will be required to seek additional funding in the future and currently intend to do so through additional collaborations, public or private equity offerings or debt financings, credit or loan facilities or a combination of one or more of these funding sources. Our ability to raise additional funds will depend on financial, economic and other factors, many of which are beyond our control, including the COVID-19 pandemic. Additionally, our stock price has declined and our ability to raise adequate funding through equity offerings, if at all, may be limited. Additional funds may not be available to us on acceptable terms or at all. If we raise additional funds by issuing equity securities, our stockholders will suffer dilution and the terms of any financing may adversely affect the rights of our stockholders. In addition, as a condition to providing additional funds to us, future investors may demand, and may be granted, rights superior to those of existing stockholders. Debt financing, if available, is likely to involve restrictive covenants limiting our flexibility in conducting future business activities, and, in the event of insolvency, debt holders would be repaid before holders of our equity securities received any distribution of our corporate assets.

***Clinical development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.***

As is the case with all oncology drugs, our product candidates in clinical development or preclinical development go through a long process and have a high risk of failure, including termination for strategic reasons. It is impossible to predict when or if any of our or our partner's product candidates will prove safe, pure and potent (or effective) in humans or will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we or our partners must complete extensive clinical trials to demonstrate the safety, purity and potency (or efficacy) of our product candidates in humans. Commencement of clinical trials for programs beyond praluzatamab ravnansine, CX-2029, BMS-986249, BMS-986288, and pacmilimab and CX-904 is subject to finalizing the trial design and submission of an IND or similar submission to the FDA or similar global health authorities. In addition, even if we submit an IND or a comparable submission in other jurisdictions for these or other product candidates, including CX-801 and CX-2051, the FDA or other regulatory authorities could disagree that we have satisfied their requirements to commence our clinical trials or disagree with our study design, which may require us to complete additional preclinical studies or amend our protocols or impose stricter conditions on the commencement of clinical trials and may delay our ability to begin Phase 1 clinical trials, causing an increase in the amount of time and expense required to develop our product candidates, including CX-801 and CX-2051. As a result of the foregoing, the research and development, preclinical studies and clinical testing of any product candidate is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the development process.

Further, we or our collaborators may also experience delays in completing ongoing clinical trials, completing preclinical studies or initiating further clinical trials of our product candidates, including, for example, among other things, as a result of the COVID-19 pandemic. We do not know whether our or our collaborators' ongoing clinical trials or preclinical studies will be completed on schedule or at all, or whether planned clinical trials or preclinical studies will begin on time, need to be redesigned, enroll patients on time or be completed on schedule, if at all. We or our collaborators may have insufficient internal resources to complete ongoing clinical trials or initiate clinical trials for our other product candidates. The development programs for our product candidates may also be delayed for a variety of reasons, including delays related to:

- recruiting suitable patients to participate in a clinical trial, particularly in light of the COVID-19 pandemic;

- developing and validating any companion diagnostic to be used in a clinical trial;
- the FDA or other regulatory authorities requiring us to submit additional data or imposing other requirements before permitting us to initiate a clinical trial;
- obtaining regulatory clearance to commence a clinical trial;
- reaching agreement on acceptable terms with prospective contract research organization (“CROs”) and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- obtaining institutional review board (“IRB”) approval at each clinical trial site;
- having patients complete a clinical trial or return for post-treatment follow-up;
- clinical trial sites deviating from trial protocol or dropping out of a trial;
- adding new clinical trial sites;
- manufacturing our product candidates in sufficient quality and quantity for use in clinical trials; or
- collaborators electing to not pursue development and commercialization of our product candidates.

In addition, 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. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or safety profiles, notwithstanding promising results in earlier trials.

***Our product candidates are in early stages of development and may fail or suffer delays that materially and adversely affect their commercial viability. If we are unable to advance our product candidates through clinical development, obtain regulatory approval and ultimately commercialize such product candidates, or experience significant delays in doing so, our business will be materially harmed.***

We are very early in our development efforts, with only four product candidates, praluzatamab ravtansine (CX-2009), CX-2029, pacmilimab (CX-072), and CX-904 currently in early-stage clinical development. In addition, Bristol Myers Squibb is currently evaluating BMS-986249, a CTLA-4-directed Probody therapeutic in a randomized cohort expansion trial of a Phase 1/2 clinical trial that it initiated in January 2018, and BMS-986288, a second anti-CTLA-4 Probody, in a Phase 1/2 trial it initiated in 2019. We have no products on the market and our ability to achieve and sustain profitability depends on obtaining regulatory approvals for and successfully commercializing our product candidates, either alone or with third parties. Before obtaining regulatory approval for the commercial distribution of our product candidates, we or our collaborator must conduct extensive preclinical tests and clinical trials to demonstrate sufficient safety, purity and potency (or efficacy) of our product candidates in patients.

As a result, we may not have the financial resources to continue development of, or to modify existing or enter into new collaborations for, a product candidate if we experience any issues that delay or prevent regulatory approval of, or our ability to commercialize, product candidates, including:

- negative or inconclusive results from our clinical trials, the clinical trials of our collaborators or the clinical trials of others for product candidates similar to ours, leading to a decision or requirement to conduct additional preclinical testing or clinical trials or abandon a program;
- product-related side effects experienced by participants in our clinical trials, the clinical trials of our collaborators or by individuals using drugs or therapeutic biologics similar to our product candidates;
- delays in submitting INDs or comparable foreign applications or delays or failure in obtaining the necessary approvals from regulators to commence a clinical trial, or a suspension or termination of a clinical trial once commenced;
- conditions imposed by the FDA or comparable foreign authorities regarding the scope or design of our clinical trials;
- delays in enrolling research subjects in clinical trials;
- high drop-out rates of research subjects;
- inadequate supply or quality of product candidate components or materials or other supplies necessary for the conduct of our or our collaborators’ clinical trials;
- greater than anticipated clinical trial costs;
- delay in the development or approval of companion diagnostic tests for our product candidates;



- unfavorable FDA or other regulatory agency inspection and review of a clinical trial site;
- failure of our third-party contractors or investigators to comply with regulatory requirements or otherwise meet their contractual obligations in a timely manner, or at all;
- delays and changes in regulatory requirements, policy and guidelines, including the imposition of additional regulatory oversight around clinical testing generally or with respect to our technology in particular; or
- varying interpretations of data by the FDA and similar foreign regulatory agencies.

We could find that the therapeutics we or our collaborators pursue are not safe, pure, potent (or efficacious). Further, a clinical trial may be suspended or terminated by us, our collaborators, the IRBs of the institutions in which such trials are being conducted, the Data Safety Monitoring Board for such trial or by the FDA or other regulatory authorities due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug or therapeutic biologic, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Furthermore, we expect to rely on our collaborators, CROs and clinical trial sites to ensure proper and timely conduct of our clinical trials and while we expect to enter into agreements governing their committed activities, we have limited influence over their actual performance.

If we or our collaborators experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues or receive royalties from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenues. Furthermore, if one or more of our product candidates or our Probody therapeutic technology generally prove to be ineffective, unsafe or commercially unviable, the development of our entire platform and pipeline could be delayed, potentially permanently. Any of these occurrences may materially and adversely affect our business, financial condition, results of operations and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

For example, in March 2020, we made the strategic decision to terminate our Phase 2 clinical trial evaluating pacmilimab in combination ipilimumab in melanoma. This decision followed a re-evaluation of the evolving clinical, competitive and commercial landscapes in immuno-oncology, taken together with the impact of the COVID-19 pandemic. Additionally, in July 2022, we announced topline results of our Phase 2 clinical trial evaluating praluzatamab ravtansine in patients with breast cancer and that we do not plan to further advance this program alone and will be seeking a partnership.

***Interim, “top-line,” and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.***

From time to time, we may publicly disclose preliminary or top-line data from our preclinical studies and clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. For example, in December 2021 we announced preliminary data on two of the four expansion cohorts for CX-2029. We can make no assurances that the ultimate trial results for these two cohorts will be consistent with or better or worse than that reported data. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. Further, as a result of the COVID-19 pandemic or for other reasons, we may not be able to collect accurate or complete data at the time we collect such preliminary data, including as a result of the inability of sites to properly record data due to staffing limitations or the inability of patients to visit sites at scheduled times, the inability of CROs to access site data or for other reasons. As a result, the top-line or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, top-line data should be viewed with caution until the final data are available.

From time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available or as patients from our clinical trials continue other treatments for their disease. Adverse differences between preliminary, top-line, or interim data and final data could significantly harm our business prospects.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or

commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure.

***Our product candidates may cause undesirable side effects at any time during or after the clinical trial process that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any, including withdrawal from the market.***

Undesirable side effects caused by our product candidates could cause us, our collaborators or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other regulatory authorities. As is the case with all oncology drugs, there may be immediate or late side effects associated with the use of our product candidates (e.g., praluzatamab ravtansine (CX-2009), CX-2029, pacmilimab (CX-072) and CX-904). There can be no assurance that unexpected adverse events will not occur in our ongoing trials or in future trials involving our product candidates or the product candidates of our collaborators. Undesirable side effects may appear in later trials that were not observed in our earlier trials or may be more severe in later trials than earlier trials.

In May 2020, we reported that the administration of monotherapy pacmilimab had been generally well tolerated with the majority of treatment-related adverse events (“TRAEs”) as Grade 1/2. At that time, we also reported that of the 114 monotherapy patients treated with 10 mg/kg every two weeks and who were evaluable for safety, ten (9%) patients experienced a grade  $\geq 3$  TRAE, and two (2%) experienced grade  $\geq 3$  immune-related adverse events (“irAEs”), with two (2%) TRAEs leading to treatment discontinuation. In June 2019, we also reported that at the 10 mg/kg dose, the anti-drug antibody (“ADA”) rate was approximately 62%. While we do not believe this ADA is impacting our ability to reach targeted drug exposures, we cannot provide assurance that the rate will not change or that it will not later limit drug exposure or cause severe adverse events. We also cannot provide assurance that the rates and the types of adverse events will not increase with time as more patients are treated in ongoing or future studies.

Administration of pacmilimab in combination with ipilimumab has been generally well tolerated with the majority of TRAEs as Grade 1/2. In October 2019, we reported that of the 27 patients treated across all combination doses, Grade 3/4 TRAEs were reported in nine (33%) patients and Grade 3/4 irAEs were reported in six (22%) patients. Of the 20 patients treated with ipilimumab at 3 mg/kg at varying doses of pacmilimab, Grade 3/4 TRAEs were reported in five (25%) patients and Grade 3/4 irAEs were reported in three (15%) patients. We cannot provide assurance that these rates and the types of adverse events will not increase over time with more patients being treated in future studies of our product candidates.

Administration of praluzatamab ravtansine has also been generally well tolerated with most reported TRAEs being Grade 1/2. In May 2020, we announced that 34/92 (37%) patients experienced a Grade 3/4 TRAE. The most common adverse event observed was ocular toxicity, an anticipated toxicity associated with the DM4 payload. Other Grade 3/4 TRAEs included liver function test abnormalities, gastrointestinal disorders and nervous system disorders. In July 2022, we announced Phase 2 topline results for praluzatamab ravtansine. The safety profile in Arm A, patients with HR-/HER2 non amplified breast cancer, was generally consistent with toxicities observed in Phase 1 studies. High grade toxicities or toxicities resulting in dose modification were predominantly ocular or neuropathic in nature. Thirty percent of patients discontinued treatment for an adverse event and Grade 3 or greater ocular or neuropathic toxicities were 15 percent and 10 percent respectively. The toxicity profile in Arm B in patients with TNBC with a starting dose of 7 mg/kg was consistent with Arm A. We cannot guarantee that these rates and the types of adverse events will not increase over time with more patients being treated in ongoing or future studies.

In May 2020, we announced that CX-2029 was generally well tolerated at doses up to 3 mg/kg with the most common TRAEs being infusion related reactions, anemia and neutropenia/leukopenia. Grade 3 or greater hematologic TRAEs, anemia and neutropenia, were dose dependent, with anemia being managed with transfusions and supportive care. In December 2021, we announced preliminary data on two of four expansion cohorts for CX-2029, including that the most common Grade 3 TRAEs in 10% or more of patients were anemia (67.3%) and decreased neutrophil count (9.6% (plus one Grade 4 event 1.9%)). The etiology of anemia remains under investigation and is likely to be multi-factorial. While the MMAE payload is known to be associated with anemia, preclinical studies have shown that reduction of red blood cell precursors has been observed in response to targeting CD71, which is known to play a role in early erythroid development. Although we believe these TRAEs are manageable, there can be no assurance that the rate or severity of any of these side effects will not increase over time with more patients being treated in ongoing or future studies.

The results of our or our collaborators’ future clinical trials could reveal a high and unacceptable severity of adverse side effects, including immune system related adverse events or increased toxicity, and it is possible that patients enrolled in such clinical trials could respond in unexpected ways or otherwise have unexpected adverse events. For example, in 2022 we are in the process of initiating a first-in-human Phase 1 clinical trial with CX-904 and, while we believe our preclinical studies indicate the potential to reach a favorable therapeutic index, clinical data will be necessary to specify an acceptable dose. We cannot provide assurance that we will reach an acceptable dose for CX-904.

Additionally, the Phase 2 clinical trial of BMS-986249 being conducted by Bristol Myers Squibb includes the administration of the product candidate at relatively high dosage levels, which could further exacerbate such risks. In our Phase 2 clinical trials with praluzatamab ravtansine and CX-2029, we are targeting CD166 and CD71, respectively, targets that are broadly expressed on normal tissue, which could create unacceptable toxicity or fail to result in anti-tumor activity. For instance, CD71 is a metabolic protein with high levels of expression in healthy tissues, and the consequences of targeting such protein in humans are unknown. Any future clinical trials of our product candidates could face similar or heightened risks depending on the modality. Similarly, the combination of EGFR and CD3 has been shown to induce significant toxicities in preclinical animal studies due to the widespread expression of each target.

In the event that our clinical trials or the clinical trials of our collaborators reveal severe adverse side effects, our or our collaborators' clinical trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could impose a clinical hold, order us to cease further development of or deny approval of our product candidates for any or all targeted indications. Such side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. For example, in our Phase 1/2 clinical trial of praluzatamab ravtansine, some patients stopped treatment due to ocular toxicity. While we are using ocular toxicity prophylactic measures in our Phase 2 clinical trial, we cannot be assured that such measures will be effective. In addition, any of these occurrences with respect to one of our product candidates could negatively affect our or any collaborator's ability to enroll patients and seek regulatory approval for other product candidates that we have developed using our Probody platform, which could also result in a collaborator terminating any program utilizing our Probody platform and the termination of such collaborative relationship. Any of these occurrences may materially and adversely affect our business, financial condition, results of operations and prospects. Further, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of patients and limited duration of exposure, rare and severe side effects of our product candidates may only be uncovered with a significantly larger number of patients exposed to the product candidate.

In the event that any of our product candidates receives regulatory approval and we, our collaborators or others identify undesirable side effects caused by such product or any other Probody therapeutics, any of the following adverse events could occur, which could result in the loss of significant revenue to us and materially and adversely affect our results of operations and business:

- regulatory authorities may withdraw their approval of the product or seize the product;
- we or our collaborators may be required to recall the product or change the way the product is administered to patients;
- additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof;
- we may be subject to fines, injunctions or the imposition of civil or criminal penalties;
- regulatory authorities may require the addition of labeling statements, such as a "black box" warning or a contraindication;
- we may be required to create a Medication Guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- our reputation may suffer.

In addition, adverse side effects caused by any drugs of other companies utilizing the same or similar antibodies of our product candidates, or that are similar in nature to our product candidates could delay or prevent regulatory approval of our product candidates, limit the commercial profile of an approved label for our product candidates, or result in significant negative consequences following marketing approval.

We believe that any of these events could prevent us from achieving or maintaining market acceptance of our product candidates and could substantially increase the costs of commercializing our product candidates, if approved, and significantly impact our ability to successfully commercialize our product candidates and generate revenues.

***If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.***

We may not be able to initiate or continue 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 the United States. Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors, including:

- the ongoing COVID-19 pandemic;
- the size and nature of the target patient population;

- the eligibility criteria for the clinical trial;
- the design of the clinical trial;
- the availability of an appropriate genomic screening test;
- the perceived risks and benefits of the product candidate under study;
- the efforts to facilitate timely enrollment in clinical trials;
- the patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment; and
- the proximity and availability of clinical trial sites for prospective patients.

For example, in March 2020, we announced a temporary pause in new patient enrollment and new site activation in our Phase 2 clinical trial of praluzatamab ravtansine as a result of the COVID-19 pandemic. We revised our strategy for praluzatamab ravtansine and in December 2020, we initiated a new Phase 2 clinical trial of praluzatamab ravtansine, for which we anticipated to report initial clinical data in the fourth quarter of 2021. However, in August 2021, we announced that primarily due to the COVID-19 pandemic, that we anticipated initial clinical data from that trial in 2022. In July 2022, data from the Phase 2 trial were reported. However, there can be no assurances that the COVID-19 pandemic will not continue to have a significant impact on our ability to complete our ongoing clinical trials and enroll patients in any planned or future clinical trials.

In addition, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs or therapeutic biologics that may be approved for the indications we are investigating, could affect our ability to enroll a sufficient number of eligible patients in our clinical trials. There are currently several PD-1 and/or PD-L1 agents approved for a growing list of cancer types along with thousands of clinical trials exploring the use of PD-1 and PD-L1 agents. There can be no assurance that further trials with pacmilimab (CX-072) or our other drug candidates will not be adversely affected by a limited patient population. Our clinical trials of praluzatamab ravtansine and CX-2029 study or have studied patients who have one or a select number of specific tumor types rather than patients suffering from any cancer, which limits the rate of enrollment of the trial. In addition, some of our clinical trials seek to treat indications with small population sizes which could be particularly difficult to enroll. The clinical trials for our molecules also compete with thousands of clinical trials with alternative anti-cancer drugs in similar classes (e.g. antibody-drug conjugates), and certain arms of the clinical trials may be difficult to enroll due to the emerging standard of care for such indications in certain jurisdictions, including the United States. Likewise, our clinical trial of CX-904 is also competing with thousands of other anti-cancer clinical trials. Any clinical trials of our product candidates initiated by our collaborators, including Bristol Myers Squibb's ongoing Phase 2 clinical trial, face similar and additional risks relating to enrollment. We or our collaborators could also encounter delays in the development of any of our product candidates if prescribing physicians encounter unresolved ethical issues associated with enrolling patients in clinical trials of our product candidates in lieu of prescribing existing treatments that have established safety and efficacy profiles. Any delays relating to patient enrollment could cause significant delays in the timing of our or our collaborators' clinical trials, which may materially and adversely affect our business, financial condition, results of operations and prospects.

***Our approach to the discovery and development of our therapeutic treatments is based on novel technologies that are unproven and may not result in marketable products.***

We plan to continue to develop a pipeline of product candidates using our proprietary Probody platform. We believe that product candidates (including cancer immunotherapies, conditionally activated ADCs and bispecific antibodies) identified with our product discovery platform may offer an improved therapeutic approach by taking advantage of unique conditions in the tumor microenvironment, thereby reducing the dose-limiting toxic effects associated with traditional antibody products, which can also attack healthy tissue. However, the scientific research that forms the basis of our efforts to develop product candidates based on our Probody platform is ongoing, including the research resulting from our ongoing clinical trials for praluzatamab ravtansine (CX-2009), CX-2029, pacmilimab (CX-072) and CX-904.

We may ultimately discover that our Probody platform and any product candidates resulting from it do not possess certain properties required for therapeutic effectiveness or protection from toxicity. For example, when Probody therapeutics are administered to human subjects, protease levels in tumors may not be sufficient and the peptide mask may not be cleaved, which would limit the potential efficacy of the antibody. In addition, if the peptide mask is inappropriately released, for example, due to an inflammatory disease, it may reduce the potential to limit toxicity of the anti-cancer agent or result in unforeseen events when administered in humans. Binding of the peptide mask to the antigen-binding domain of the Probody may not be constant, which could lead to intermittent periods when the antigen-binding domain or antibody portion is unmasked. Furthermore, Probody product candidates may not remain stable in the human body for the period of time required for the drug to reach and to bind to the target tissue. In addition, product candidates based on our Probody platform may demonstrate different chemical and pharmacological properties in patients than they do in laboratory studies. Although our Probody platform and certain product candidates have demonstrated successful results in animal studies, they may not demonstrate the same chemical and pharmacological

properties in humans and may interact with human biological systems in unforeseen, ineffective or harmful ways. Our understanding of the molecular pharmacology of Probody therapeutics, that is, the precise manner and sequence in which they are activated and behave in vivo, is incomplete. Probody therapeutics are complex biological molecules and we are evaluating the performance of this new technology in cancer patients for the first time. Many specific elements of Probody therapeutic function may contribute to their overall safety and efficacy profile including, but not limited to, the removal of only one mask from the dually-masked antibody, the removal of both masks from the dually-masked antibody, the binding strength of masks for the underlying antibody, and the binding strength of the underlying antibody for its target. We have limited structural evidence for how masks interact with antibodies. It may take many years before we develop a full understanding of Probody pharmacology, and we may never know precisely how they function in vivo. As with any new biologic or product developed on a novel platform, we have a limited understanding of the immunogenicity profile of Probody therapeutics. As a result, our Probody product candidates may trigger immune responses, such as anti-drug antibody (“ADA”), that may inhibit the ability of the antibody to reach the target tissue, inhibit the ability of the antibody to bind to its target, cause adverse side effects in humans or cause hypersensitivity reactions. For example, we reported in February 2019 that in our pacmilimab trial at the 10 mg/kg dose, the ADA rate was approximately 62%. We do not believe the ADA rate is impacting our ability to reach targeted drug exposures. However, we cannot provide assurance that it will not later limit drug exposure or cause severe adverse events. Problems that are specific to our Probody platform may have an unfavorable impact on all of our product candidates. As a result, we may never succeed in developing a marketable product and we may never become profitable, which would cause the value of our common stock to decline.

In addition, the scientific evidence to support the feasibility of developing product candidates against novel, difficult to drug targets, is both preliminary and limited. For example, our understanding of the expression of CD166 and CD71 in both healthy and diseased tissues is still developing. As a result, we cannot provide any assurance that we will be able to successfully identify and advance any product candidates to target novel, difficult-to-drug targets.

We believe that the FDA and foreign regulatory authorities have limited experience with conditionally activated therapeutics in oncology, such experience primarily coming from praluzatamab ravtansine, CX-2029, BMS-986249, BMS-986288, and pacmilimab. We believe that such limited experience may increase the complexity, uncertainty and length of the regulatory approval process for our product candidates and may keep us from commencing first-in-human trials in certain countries. As there is limited historical precedent for the regulatory clearance of Probody-based therapeutics in oncology, there is a higher degree of risk that the FDA or other regulatory authorities could disagree that we or our collaborators have satisfied their requirements to commence clinical trials for some product candidates or disagree with our study designs, which may require us to complete additional preclinical studies or amend our protocols or impose stricter conditions on the commencement of clinical trials. In addition, local clinical practice in other countries may affect whether we or our collaborators are able to initiate a clinical trial there. As a result, we and our collaborators may never receive approval to market and commercialize any product candidate. Even if we or our collaborators obtain regulatory approval, the approval may be for targets, disease indications or patient populations that are not as broad as we or they intended or desired or may require labeling that includes significant use or distribution restrictions or safety warnings. We or our collaborators may be required to perform additional or unanticipated clinical trials to obtain approval or be subject to post-marketing testing requirements to maintain regulatory approval. If one or more of our product candidates or our Probody technology generally prove to be ineffective, unsafe or commercially unviable, our entire platform and pipeline may have little, if any, value, which would have a material and adverse effect on our business, financial condition, results of operations and prospects.

***The market may not be receptive to our product candidates based on a novel therapeutic modality, and we may not generate any future revenue from the sale or licensing of product candidates.***

Even if regulatory approval is obtained for a product candidate, we may not generate or sustain revenue from sales of the product due to factors such as whether the product can be sold at a competitive cost and whether it will otherwise be accepted in the market. The product candidates that we are developing are based on our Probody platform, which is a new technology and therapeutic approach. Market participants with significant influence over acceptance of new treatments, such as physicians and third-party payors, may not adopt a product or treatment based on our Probody platform and technologies, and we may not be able to convince the medical community and third-party payors to accept and use, or to provide favorable reimbursement for, any product candidates developed by us or our collaborators. This may be particularly true for any of our product candidates (including BMS-986249, BMS-986288, and pacmilimab (CX-072)) for which there are existing approved therapies, such as approved agents targeting PD-L1, PD-1, or CTLA-4. Market acceptance of our product candidates will depend on, among other factors:

- the timing of our receipt of any marketing and commercialization approvals;
- the terms of any approvals and the countries in which approvals are obtained;
- the safety, purity, potency (or efficacy) of our product candidates, including those being developed by our collaborators;
- the prevalence and severity of any adverse side effects associated with our product candidates;
- limitations or warnings contained in any labeling approved by the FDA or other regulatory authority;
- the availability of effective companion diagnostics;

- relative convenience and ease of administration of our product candidates;
- the willingness of patients to accept any new methods of administration;
- the success of our physician education programs;
- the availability of coverage and adequate reimbursement from government and third-party payors;
- the pricing of our products, particularly as compared to alternative treatments; and
- the availability of alternative effective treatments for the disease indications our product candidates are intended to treat and the relative risks, benefits and costs of those treatments.

If any product candidate we commercialize fails to achieve market acceptance, it could have a material and adverse effect on our business, financial condition, results of operations and prospects.

***We have entered, and may in the future seek to enter, into collaborations with third parties for the development and commercialization of our product candidates using our Probody platform. If we fail to enter into such collaborations, or such collaborations are not successful, we may not be able to capitalize on the market potential of our Probody platform and resulting product candidates.***

Since 2013, we have entered into collaborations with AbbVie, Amgen, Astellas, Bristol Myers Squibb, ImmunoGen, Pfizer and others to develop certain Probody therapeutics. We may in the future seek third-party collaborators for development and commercialization of other therapeutic technologies or product candidates. Biopharmaceutical companies are our prior and likely future collaborators for any marketing, distribution, development, licensing or broader collaboration arrangements. With respect to our existing collaboration agreements, and what we expect will be the case with any future collaboration agreements, we have and would expect to have limited control over whether such collaborations pursue the development of our product candidates or the amount and timing of resources that such collaborators dedicate to the development or commercialization of our product candidates. For instance, in March 2018, Pfizer terminated the collaboration agreement we had entered into with them in May 2013. Such collaboration agreement had entitled Pfizer to nominate up to four research targets and since 2013, we had collaborated with Pfizer on three of such targets. However, no program was ever advanced beyond the lead optimization stage pursuant to the agreement, and Pfizer had previously elected not to select a fourth target and had decided to discontinue its epidermal growth factor receptor conditionally activated ADC. In July 2017, ImmunoGen discontinued the preclinical evaluation of one of its two programs being developed under our collaboration and in December 2019, licensed the other program to us, terminating their license agreement from us. In addition, in January 2019, Bristol Myers Squibb terminated its programs for three targets it had selected under our agreement with them. As a result, there can be no assurances that any of the programs covered by our existing or future collaborations will be developed further. Further, our ability to generate revenues from our existing and future arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements. Additionally, some of our collaborations may require us to share in certain development and commercialization expenses. If we cannot afford to share such expenses when required, our rights under such collaborations may be adversely affected, including potentially that our collaborators may terminate the relevant agreement.

Overall, collaborations involving our product candidates currently pose, and will continue to pose, the following risks to us:

- collaborators have significant discretion in determining the amount and timing of efforts and resources that they will apply to these collaborations, including, with respect to Bristol Myers Squibb, BMS-986249 and BMS-986288;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on preclinical or clinical trial results, changes in the collaborators' strategic focus or available funding or resources, or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators have significant discretion in designing any clinical trials they operate pursuant to our collaboration agreements, including Bristol Myers Squibb's ongoing Phase 2 cohort expansion of BMS-986249 and its Phase 1/2 clinical trial of BMS-986288, and may release data from such clinical trials, including with respect to our Probody therapeutics, without consulting us;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing and are not necessarily required to give us information about their clinical data;
- collaborators may independently develop, or develop with third parties, products that compete directly or indirectly with our product candidate if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- collaborators with marketing and distribution rights to one or more products may not commit sufficient resources to the marketing and distribution of such product or products;

- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to litigation or potential liability;
- collaborators may infringe, misappropriate or otherwise violate the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our product candidate or that result in costly litigation or arbitration that diverts management attention and resources; and
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates.

As a result of the foregoing, our current and any future collaboration agreements may not lead to development or commercialization of our product candidates in the most efficient manner or at all and may not result in the realization of the benefits we expected to achieve upon our entry into such agreements. Any failure to successfully develop or commercialize our product candidates pursuant to our current or any future collaboration agreements could have a material and adverse effect on our business, financial condition, results of operations and prospects.

***If our collaborators cease development efforts under our collaboration agreements, or if any of those agreements are terminated, these collaborations may fail to lead to commercial products and we may never receive milestone payments or future royalties under these agreements.***

Substantially all of our revenue to date has been derived from our existing collaboration agreements, including, most recently, the agreement that we entered into with Astellas in March 2020, and a significant portion of our future revenue and cash resources is expected to be derived from these agreements or other similar agreements we may enter into in the future. Revenue from research and development collaborations depend upon continuation of the collaborations, reimbursement of development costs, the achievement of milestones and royalties, if any, derived from future products developed from our research. If our development partners do not select additional targets and we are unable to successfully advance the development of our product candidates or achieve milestones, revenue and cash resources from milestone payments under our collaboration agreements will be substantially less than expected.

In addition, to the extent that any of our collaborators were to terminate a collaboration agreement, we may decide to independently develop these product candidates to the extent we retain development rights. Such development could include funding preclinical or clinical trials, assuming marketing and distribution costs and defending intellectual property rights. Alternatively, in certain instances, we may choose to abandon product candidates altogether. For instance, in March 2018, Pfizer terminated our 2013 collaboration agreement with them, and in January 2019, Bristol Myers Squibb terminated its programs for three targets that it had selected under our agreement with them. The termination of any of our collaboration agreements or individual programs within a collaboration agreement could result in a change to our business plan and may have a material adverse effect on our business, financial condition, results of operations and prospects. If a collaboration is terminated, we would not be eligible to receive the milestone, royalty or other payments that would have been payable under the collaboration agreement. For example, as a result of ImmunoGen's decision to out-license the EpCAM program and our licensing of the program from them in 2019, their license for the program from us ended and we will not receive milestone or other payments from them.

***If we do not achieve our projected development and commercialization goals in the timeframes we announce and expect, the commercialization of any of our product candidates may be delayed, and our business will be harmed.***

For planning purposes, we sometimes estimate the timing of the accomplishment of various scientific, clinical, regulatory and other product development objectives. These milestones may include our expectations regarding the commencement or completion of scientific studies and clinical trials, the submission of regulatory filings, or commercialization objectives. From time to time, we may publicly announce the expected timing of some of these milestones, such as the completion of an ongoing clinical trial, the initiation of other clinical programs, receipt of marketing approval, or a commercial launch of a product. The achievement of many of these milestones may be outside of our control. All of these milestones are based on a variety of assumptions which may cause the timing of achievement of the milestones to vary considerably from our estimates, including:

- our available capital resources or capital constraints we experience;
- the rate of progress, costs and results of our clinical trials and research and development activities, including the extent of scheduling conflicts with participating clinicians and collaborators;
- our ability to identify and enroll patients who meet clinical trial eligibility criteria;
- our receipt of approvals by the FDA and other regulatory authorities and the timing thereof;

- other actions, decisions or rules issued by regulators;
- our ability to access sufficient, reliable and affordable supplies of materials used in the manufacture of our product candidates;
- our ability to manufacture and supply clinical trial materials to our clinical sites on a timely basis;
- the efforts of our collaborators with respect to the commercialization of our products; and
- the securing of, costs related to, and timing issues associated with, product manufacturing as well as sales and marketing activities.

For example, in March 2020, we announced the temporary pause in new patient enrollment and new site activation in our Phase 2 clinical trial of praluzatamab ravtansine (CX-2009) as a result of the COVID-19 pandemic and the termination of the Phase 2 clinical trial of pacmilimab (CX-072) in combination with ipilimumab after a re-evaluation of the evolving clinical, competitive and commercial landscapes in immuno-oncology, taken together with the impact of the COVID-19 pandemic. Further, we continue to see an impact as a result of the COVID-19 pandemic on our efforts, including ongoing clinical trial site activation and patient enrollment activities.

If we fail to achieve announced milestones in the timeframes we expect, the commercialization of any of our product candidates may be delayed, and our business and results of operations may be harmed.

***We may not successfully engage in strategic transactions, including any additional collaborations we seek, which could adversely affect our ability to develop and commercialize product candidates, impact our cash position, increase our expense and present significant distractions to our management.***

Since commencing operations, we have entered into several collaboration agreements. From time to time, we may consider strategic transactions, such as additional collaborations, acquisitions of companies, asset purchases and out- or in-licensing of product candidates or technologies. In particular, we will evaluate and, if strategically attractive, seek to enter into additional collaborations, including with major biotechnology or biopharmaceutical companies. For example, in July 2022, in connection with our announcement of Phase 2 topline results for praluzatamab ravtansine, we communicated our plans to seek collaborators to advance the program further. The competition for collaborators is intense and there can be no assurances that we will be able to secure any collaboration for praluzatamab ravtansine or any other program. The negotiation process for strategic collaborations is time-consuming and complex. Any new collaboration may be on terms that are not optimal for us, and we may not be able to maintain any new collaboration if, for example, development or approval of a product candidate is delayed, sales of an approved product candidate do not meet expectations or the collaborator terminates the collaboration. Any such collaboration, or other strategic transaction, may require us to incur non-recurring or other charges, increase our near- and long-term expenditures and pose significant integration or implementation challenges or disrupt our management or business. These transactions would entail numerous operational and financial risks, including exposure to unknown liabilities, disruption of our business and diversion of our management's time and attention in order to manage a collaboration or develop acquired products, product candidates or technologies, incurrence of substantial debt or dilutive issuances of equity securities to pay transaction consideration or costs, higher than expected collaboration, acquisition or integration costs, write-downs of assets or goodwill or impairment charges, increased amortization expenses, difficulty and cost in facilitating the collaboration or combining the operations and personnel of any acquired business, impairment of relationships with key suppliers, manufacturers or customers of any acquired business due to changes in management and ownership and the inability to retain key employees of any acquired business. Accordingly, although there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, any transactions that we do complete may be subject to the foregoing or other risks and have a material and adverse effect on our business, financial condition, results of operations and prospects. The termination by a collaborator of a collaboration may cause a decrease in the price of our stock. Conversely, any failure to enter any additional collaboration or other strategic transaction that would be beneficial to us could delay the development and potential commercialization of our product candidates and have a negative impact on the competitiveness of any product candidate that reaches market.

***If we are unable to successfully develop companion diagnostic tests for certain of our product candidates, or experience significant delays in doing so, we may not realize the full commercial potential of our product candidates.***

Because we are focused on precision medicine, in which predictive biomarkers will be used to identify the right patients for our product candidates, we believe that our success may depend, in part, on the development of companion diagnostic tests. To successfully develop a companion diagnostic test, we would need to address a number of scientific, technical and logistical challenges. However, we have little experience in the development of companion diagnostic tests and may not be successful in developing appropriate tests to pair with any of our product candidates. Companion diagnostic tests are subject to regulation by the FDA and similar regulatory authorities outside the United States as medical devices and require separate regulatory approval prior to commercialization. Given our limited experience in developing companion diagnostic tests, we could seek to rely on third parties to design, manufacture, obtain regulatory approval for any companion diagnostic tests for our product candidates. However, we and such collaborators may encounter difficulties in developing and obtaining approval for the companion diagnostic tests, including issues relating to selectivity/specificity, analytical validation, reproducibility, or



clinical validation. Any delay or failure by us or our collaborators to develop or obtain regulatory approval of the companion diagnostic tests could delay or prevent approval of our product candidates. As a result, our business would be harmed, possibly materially.

***We rely on third parties to conduct all of our clinical trials and certain of our preclinical studies and intend to continue to do so, and if such third parties do not perform as contractually required, fail to satisfy regulatory or legal requirements or miss expected deadlines, our development programs could be delayed with material and adverse effects on our business, financial condition, results of operations and prospects.***

We do not have the ability to independently conduct clinical trials. As such, we currently rely and intend to continue to rely on third-party clinical investigators, CROs, clinical data management organizations and consultants to help us design, conduct, supervise and monitor clinical trials of our product candidates. As a result, we will have less control over the timing, quality and other aspects of our clinical trials than we would have had we conducted them on our own. These investigators, CROs and consultants are not our employees and we have limited control over the amount of time and resources that they dedicate to our programs. These third parties may have contractual relationships with other entities, some of which may be our competitors, which may draw time and resources from our programs. The third parties with which we contract might not be diligent, careful or timely in conducting our preclinical studies or clinical trials, resulting in the preclinical studies or clinical trials being delayed or unsuccessful. Furthermore, our third-party contractors, including CROs are being and may continue to be impacted in their ability to conduct our work as a result of the COVID-19 pandemic.

If we cannot contract with acceptable third parties on commercially reasonable terms, or at all, or if these third parties do not carry out their contractual duties, satisfy legal and regulatory requirements for the conduct of preclinical studies or clinical trials or meet expected deadlines, our clinical development programs could be delayed and otherwise adversely affected. In all events, we will be responsible for ensuring that each of our preclinical studies and clinical trials are conducted in accordance with the general investigational plan and protocols for the trial. The FDA requires preclinical studies to be conducted in accordance with good laboratory practices (“GLPs”) and clinical trials to be conducted in accordance with good clinical practices (“GCPs”), including for designing, conducting, recording and reporting the results of preclinical studies and clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of clinical trial participants are protected. Our reliance on third parties that we do not control will not relieve us of these responsibilities and requirements. Any adverse development or delay in our clinical trials could have a material and adverse effect on our business, financial condition, results of operations and prospects.

***We are currently conducting and will continue to conduct clinical trials and will contract with third-party manufacturers in foreign countries, which could expose us to risks that could have a material adverse effect on the success of our business.***

We have enrolled or are planning to enroll patients in our clinical trials outside the United States, including in Europe and South Korea. While we generally conduct our clinical trials solely or partially in the U.S., to the extent that clinical trials are conducted outside of the U.S., the FDA may have certain additional requirements. The acceptance of study data from clinical trials conducted outside the U.S. or another jurisdiction by the FDA or comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the U.S., the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. In addition, even where the foreign study data are not intended to serve as the sole basis for approval, the FDA will not accept the data as support for an application for marketing approval unless the study is well-designed and well-conducted in accordance with GCP requirements and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the U.S. or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which could be costly and time-consuming, and which may result in current or future product candidates that we may develop not receiving approval for commercialization in the applicable jurisdiction.

Conducting clinical trials outside the United States also exposes us to additional risks, including risks associated with additional foreign regulatory requirements; foreign exchange fluctuations; patient monitoring and compliance; compliance with foreign manufacturing, customs, shipment and storage requirements; the severity of the COVID-19 pandemic in such jurisdictions; and cultural differences in medical practice and clinical research. We are also subject to risks associated with doing business globally, including commercial, political, and financial risks. In addition, we are subject to potential disruption caused by military conflicts; potentially unstable governments or legal systems; civil or political upheaval or unrest; local labor policies and conditions; possible expropriation, nationalization, or confiscation of assets; problems with repatriation of foreign earnings; economic or trade sanctions; closure of markets to imports; anti-American sentiment; terrorism or other types of violence in or outside the United States; health pandemics; and a significant reduction in global travel. For example, pandemics and public health emergencies, such as the COVID-19 pandemic, have disrupted and delayed and could in the future

disrupt or delay enrollment in our clinical trials in Europe, South Korea and elsewhere. Our success will depend, in part, on our ability to overcome the challenges we encounter with respect to these risks and other factors affecting U.S. companies with global operations. If our global clinical trials or foreign third-party suppliers were to experience significant disruption due to these risks or for other reasons, it could have a material adverse effect on our business, financial condition, results of operations and prospects.

***Because we have no long-term contracts with and rely on third-party manufacturing and supply partners, most of which are sole source suppliers, our supply of research and development, preclinical and clinical development materials may become limited or interrupted or may not be of satisfactory quantity or quality.***

We rely on third-party contract manufacturers to manufacture our clinical trial and preclinical study product supplies which, in addition to having other issues, could be adversely impacted by the COVID-19 pandemic. Most of our clinical trial manufacturing contractors and suppliers are our sole source for their respective manufacturing and supplies. Failure of any of these contractors could put our ability to have clinical trial material available when needed. This could result in a substantial delay of our clinical trials. For each of praluzatamab ravtansine (CX-2009), CX-2029, pacmilimab (CX-072), and CX-904, our manufacturing supply chain includes several contract manufacturers, and failure by any of these manufacturers could result in interruptions of our clinical studies. For example, in November 2019, one of our contract manufacturers that manufactures pacmilimab experienced a production failure. If we had not been able to assure sufficient supplies of clinical trial drug product after the production failure, we may have been required to suspend any ongoing trials and postpone future trials. Although we have taken sufficient steps to assure our current supply of pacmilimab clinical trial drug product for our ongoing clinical trial and planned clinical trials, there can be no assurance that we will not have future production failures, which could affect our ability to conduct our trials for praluzatamab ravtansine, CX-2029, pacmilimab, CX-904 or any other clinical trial drug candidates on our planned timeline or at all. We do not own manufacturing facilities for producing such supplies and do not have any long-term contracts and we do not currently have an alternative to any of our third-party contract manufacturers. There can be no assurance that our preclinical and clinical development product supplies will not be limited, interrupted, or of satisfactory quality or continue to be available at acceptable prices. In particular, any replacement of any of our third-party contract manufacturers could require significant effort and expertise because there may be a limited number of qualified replacements. In addition, we may encounter issues with transferring technology to a new third-party manufacturer, and we may encounter regulatory delays if we need to move the manufacturing of our products from one third-party manufacturer to another. For example, we were dependent on ImmunoGen under our collaboration for certain steps in the manufacturing of clinical quantities of praluzatamab ravtansine. At the end of 2018, ImmunoGen closed their clinical manufacturing facility in Norwood, MA. This site provided clinical manufacturing support for the praluzatamab ravtansine program. We completed transfer of the drug substance manufacturing process from ImmunoGen to a CMO, where we have an existing relationship and which has expertise in the manufacture of antibody-drug conjugates at a clinical and commercial scale. While the manufacturing transfer process has been completed, there can be no assurance that we will not experience a disruption in the supply of praluzatamab ravtansine as a result of such transfer or that we will not experience any other disruption in the manufacture of praluzatamab ravtansine.

The manufacturing process for a product candidate is subject to FDA and foreign regulatory authority review. Suppliers and manufacturers must meet applicable manufacturing requirements and undergo rigorous facility and process validation tests required by regulatory authorities in order to comply with regulatory standards, such as current Good Manufacturing Practices (“cGMPs”). In the event that any of our manufacturers fails to comply with such requirements or to perform its obligations to us in relation to quality, timing or otherwise, such as the pacmilimab manufacturing production failure our contract manufacturer experienced in November 2019, or if our supply of components or other materials becomes limited or interrupted for other reasons, such as one of our manufacturers going out of business, we may be forced to manufacture the materials ourselves, for which we currently do not have the capabilities or resources, or enter into an agreement with another third party, which we may not be able to do on reasonable terms, if at all. In some cases, the technical skills or technology required to manufacture our product candidates may be unique or proprietary to the original manufacturer and we may have difficulty transferring such skills or technology to another third party and a feasible alternative may not exist. These factors would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to have another third party manufacture our product candidates. If we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop product candidates in a timely manner or within budget.

We expect to continue to rely on third-party manufacturers if we receive regulatory approval for any product candidate. To the extent that we have existing, or enter into future, manufacturing arrangements with third parties, we will depend on these third parties to perform their obligations in a timely manner consistent with contractual and regulatory requirements, including those related to quality control and assurance. If we are unable to obtain or maintain third-party manufacturing for product candidates, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our product candidates successfully. We may find that our third-party manufacturer is unable to scale up the process in order to produce commercial quantities of our products. Our or a third party’s failure to execute on our manufacturing requirements and comply with cGMPs could adversely affect our business in a number of ways, including:

- an inability to initiate or continue clinical trials of product candidates under development;
- delay in submitting regulatory applications, or receiving regulatory approvals, for product candidates;

- loss of the cooperation of a collaborator;
- subjecting third-party manufacturing facilities or our manufacturing facilities to additional inspections by regulatory authorities;
- requirements to cease distribution or to recall batches of our product candidates; and
- in the event of approval to market and commercialize a product candidate, an inability to meet commercial demands for our products.

The supply chain for the manufacturing of our product candidates is complicated and can involve many parties. This is especially the case for our clinical-stage conditionally activated ADCs, praluzatamab ravtansine and CX-2029. If we were to experience any supply chain issues, our product supply could be seriously disrupted. In addition, we expect the logistical challenges associated with our supply chain to grow more complex as additional product candidates commence any clinical trials.

***We, or third-party manufacturers, may be unable to successfully scale-up manufacturing of our product candidates in sufficient quality and quantity, which would delay or prevent us from developing our product candidates and commercializing approved products, if any.***

It may prove more challenging than we anticipate to manufacture products that incorporate our Probody therapeutic technology. In order to conduct clinical trials of our product candidates, including our clinical trials for praluzatamab ravtansine (CX-2009), CX-2029, pacmilimab (CX-072), and CX-904 we will need to manufacture them in large quantities. To date, we have generally been able to successfully manufacture praluzatamab ravtansine, CX-2029, and pacmilimab for our ongoing early-stage clinical trials. However, in November 2019, we had a production failure at one of our contract manufacturers that manufactured pacmilimab for our Phase 1/2 clinical trial and for our future trials. If we had not been able to assure sufficient supplies of clinical trial drug product after the production failure, we may have been required to suspend any ongoing trials and postpone future trials. Although we have taken sufficient steps to assure our current supply of pacmilimab clinical trial drug product for our planned clinical trials, there can be no assurance that we will not have future production failures, which could affect our ability to conduct our trials for praluzatamab ravtansine, CX-2029, pacmilimab, CX-904 or any other clinical trial drug candidates on our planned timeline or at all. Furthermore, in order to conduct later stage clinical trials of our product candidates, such as our Phase 2 clinical trial for praluzatamab ravtansine, and eventually, if approved, commercial products, we will need to manufacture them in larger quantities. We, or any manufacturing partners, may be unable to successfully increase the manufacturing scale and capacity for any of our product candidates in a timely or cost-effective manner, or at all. For example, we are currently working with our CMOs to change our manufacturing processes and formulations as well as scaling up for larger drug manufacturing capability, including praluzatamab ravtansine drug product for late-stage clinical trials and commercialization. However, we may have to start late-stage trials with our early clinical trial drug product and switch to late-stage or commercial drug product mid trial. In such event, the FDA will require us to complete bridging studies to compare the earlier stage material with late-stage or commercial material to assure comparability between the earlier trial material and the late-stage or commercial material. Changing formulation and scaling up the process is a complicated and difficult task. While we believe we can complete this process successfully, there can be no assurances that the changes we make to the drug product and manufacturing process will be successful or completed in a timely manner or that the FDA will not require additional development steps or studies from those we believe are necessary. If we are not able to scale up our manufacturing capabilities with respect to praluzatamab ravtansine, pacmilimab or any of our other product candidates, increase the life of drug stability of product candidates, or successfully complete the FDA's bridging requirements, we may not be able to successfully obtain FDA approval and commercialize product candidates in a timely manner or at all.

Additionally, we were dependent on ImmunoGen under our collaboration for certain steps in the manufacturing of clinical quantities of praluzatamab ravtansine. At the end of 2018, ImmunoGen closed their clinical manufacturing facility in Norwood, Massachusetts, which provided clinical manufacturing support for the praluzatamab ravtansine program. We completed the transfer of the drug substance manufacturing process from ImmunoGen to a contract manufacturer, where we have an existing relationship and with expertise in the manufacture of antibody drug conjugates at a clinical and commercial scale. While the manufacturing transfer process has been completed, there can be no assurance that we will not experience a disruption in the supply of praluzatamab ravtansine in connection with such transfer or that we will not experience any other disruption in the manufacturing of praluzatamab ravtansine. In addition, for CX-2029, the manufacturing of additional clinical quantities could be particularly difficult because we are relying on three different parties to manufacture supplies. If we, or any manufacturing partners, are unable to successfully scale up the manufacture of our product candidates in sufficient quality and quantity, the development, testing, and clinical trials of that product candidate may be delayed or infeasible, and regulatory approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business.

***We may expend our limited resources to pursue a particular product candidate and fail to capitalize on product candidates 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 specific product candidates and indications. As a result, we may forgo or delay pursuit of opportunities with those products in other indications or with other product candidates 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 product candidates. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

***We may experience difficulties in managing our growth and expanding when needed.***

Over the last few years we have expanded our workforce and activities to manage our expanding pipeline, including Phase 2 clinical trials. However, in July 2022, we announced we will not advance praluzatamab ravtansine into further clinical trials and will seek a partner for the program. As a result, we announced that we would reduce our workforce, primarily development and general and administrative staff, by approximately 40%. In the future we may need to grow our organization substantially to continue development and pursue the potential commercialization of our product candidates, including CX-801 and CX-2051 as well as function as a public company. As we increase the number of our product candidates entering and advancing through preclinical studies and clinical trials, we will need to expand our development, regulatory and manufacturing capabilities or contract with additional organizations to provide these capabilities for us. In addition, we expect our collaborations to require greater resources as the development of our product candidates under such agreements progresses. In the future, we expect to also have to manage additional relationships with collaborators or partners, suppliers and other organizations. In particular, if the third parties on which we currently rely are not capable of delivering services or supplies in a manner that is sufficient to meet our requirements as we expand our operations, we could be required to contract with new third parties and there can be no assurances that the services or supplies of such third parties will be available on commercially reasonable terms, or at all. Furthermore, our ability to manage our operations and future growth will require us to continue to increase headcount as well as improve our operational, financial and management controls, reporting systems and procedures. We may not be able to implement improvements to our management information and control systems in an efficient or timely manner and may discover deficiencies in existing systems and controls.

***We face competition from entities that have developed or may develop product candidates for cancer, including companies developing novel treatments and technology platforms. If these companies develop technologies or product candidates more rapidly than we do or their technologies are more effective, our ability to develop and successfully commercialize product candidates may be adversely affected.***

The development and commercialization of drugs and therapeutic biologics is highly competitive. We compete with a variety of multinational biopharmaceutical companies and specialized biotechnology companies, as well as technology being developed at universities and other research institutions. Our competitors have developed, are developing or will develop product candidates and processes competitive with our product candidates. Competitive therapeutic treatments include those that have already been approved and accepted by the medical community and any new treatments that enter the market. We believe that a significant number of products are currently under development, and may become commercially available in the future, for the treatment of conditions for which we may try to develop product candidates. Additionally, there is intense and rapidly evolving competition in the biotechnology, biopharmaceutical and antibody and immunoregulatory therapeutics fields, and our competitors include larger and better funded biopharmaceutical, biotechnological and therapeutics companies. In addition, these companies compete with us in recruiting scientific and managerial talent.

We believe that while our Probody platform, its associated intellectual property and our scientific and technical know-how, give us a competitive advantage in this space, competition from many sources remains. The clinical development pipeline for cancer includes small molecules, antibodies and therapies from a variety of groups. In addition, numerous compounds are in clinical development for cancer treatment. As a result, our success will partially depend on our ability to develop and protect therapeutics that are safer and more effective than competing products. Our commercial opportunity and success will be reduced or eliminated if competing products that are safer, more effective, or less expensive than the therapeutics we develop or if we are unable to utilize our Probody therapeutic technology to differentiate our Probody therapeutics from the products of our competitors. For instance, if any of our product candidates, including, praluzatamab ravtansine and CX-2029, are approved, they will compete with a range of therapeutic treatments that are either in development or currently marketed. A variety of oncology drugs and therapeutic biologics are currently on the market or in clinical development. The market for immunotherapies like pacmilimab (CX-072) is, in particular, highly competitive and the field is changing quickly. In March 2020, we made the strategic decision to terminate our Phase 2 study evaluating pacmilimab in combination ipilimumab. This decision followed a re-evaluation of the evolving clinical, competitive and commercial landscapes in immuno-oncology, taken together with the impact of the COVID-19 pandemic. Given the amount of time required to successfully develop and obtain regulatory approval for each of our product candidates, it is therefore possible that by the time we obtain any such approval, if ever, and commence sales, we may no longer be able to differentiate such product candidate from those of our competitors.

We face substantial competition from pharmaceutical companies developing products in oncology, including companies such as Amgen, AstraZeneca PLC, Bristol Myers Squibb, GlaxoSmithKline plc, Merck & Co., Inc. Novartis AG, Pfizer, Roche Holding Ltd. and Sanofi SA. Many large and mid-sized biotech companies, including BeiGene, Incyte, Nektar, and Alkermes have ongoing efforts in cancer immunotherapy. Several companies, including Adagene, Amgen, Sanofi, BioAtla, Halozyme, Harpoon Therapeutics, Revitope, Roche, Seagen, Takeda, Werewolf Therapeutics, and Xilio are exploring antibody masking and/or conditional activation strategies, which could

compete with our Probody platform. We are also aware of several companies that are developing ADCs, such as AbbVie, ADC Therapeutics, Daiichi Sankyo, Gilead, ImmunoGen, Merck & Co., Mersana Therapeutics, Pfizer, Roche Holding Ltd. Seagen and Takeda. Furthermore, several large pharmaceutical companies, including Amgen, Novartis AG and Roche Holding Ltd., are developing T-cell engaging immunotherapies, and we are aware of several mid-sized biotech companies, such as MacroGenics and Xencor, and small companies with ongoing efforts to develop T-cell engaging immunotherapies. Any of these companies may be well capitalized and may have significant clinical experience. In addition, these companies include our collaborators.

Many of our competitors have significantly greater financial, technical, manufacturing, marketing, sales and supply resources or experience than we do. If we successfully obtain approval for any product candidate, we will face competition based on many different factors, including the safety and effectiveness of our products, the ease with which our products can be administered and the extent to which patients accept relatively new routes of administration, the timing and scope of regulatory approvals for these products, the availability and cost of manufacturing, marketing and sales capabilities, price, reimbursement coverage and patent position. Competing products could present superior treatment alternatives, including by being more effective, safer, less expensive or marketed and sold more effectively than any products we may develop. Competitive products may make any products we develop less differentiated or noncompetitive before we recover the expense of developing and commercializing our product candidates. Such competitors could also recruit our employees, which could negatively impact our level of expertise and our ability to execute our business plan.

***Any inability to attract and retain qualified key management and technical personnel would impair our ability to implement our business plan.***

Our success largely depends on the continued service of key management, advisors and other specialized personnel, including Sean A. McCarthy, D.Phil., our chief executive officer and chairman. The loss of one or more members of our management team or other key employees or advisors could delay our research and development programs and have a material and adverse effect on our business, financial condition, results of operations and prospects. The relationships that our key managers have cultivated within our industry make us particularly dependent upon their continued employment with us. We are dependent on the continued service of our technical personnel because of the highly technical nature of our product candidates and technologies and the specialized nature of the regulatory approval process. Because our management team and key employees are not obligated to provide us with continued service, they could terminate their employment with us at any time without penalty. In particular, as a result of the COVID-19 pandemic, the ability of employees to engage in a remote working environment has increased the competitive landscape across the country for us in seeking qualified employees. Employees are now able to consider opportunities across the country and it may be more difficult to hire employees. Furthermore, it is more difficult to engage employees in Company culture and build working rapport when they are working remotely. As a result, it may be more difficult to retain employees on a long-term basis. Our future success will depend in large part on our continued ability to attract and retain other highly qualified scientific, technical and management personnel, as well as personnel with expertise in clinical testing, manufacturing, governmental regulation and commercialization. We face competition for personnel from other companies, universities, public and private research institutions, government entities and other organizations, especially as job opportunities in the biotechnology industry have recently increased significantly in the San Francisco Bay Area and across the country.

***If any of our product candidates are approved for marketing and commercialization and we are unable to develop sales, marketing and distribution capabilities on our own or enter into agreements with third parties to perform these functions on acceptable terms, we will be unable to commercialize successfully any such future products.***

We currently have no sales, marketing or distribution capabilities or experience. If any of our product candidates is approved, we will need to develop internal sales, marketing and distribution capabilities to commercialize such products, which would be expensive and time-consuming, or enter into collaborations with third parties to perform these services. If we decide to market our products directly, we will need to commit significant financial and managerial resources to develop a marketing and sales force with technical expertise and supporting distribution, administration and compliance capabilities. If we rely on third parties with such capabilities to market our products or decide to co-promote products with collaborators, we will need to establish and maintain marketing and distribution arrangements with third parties, and there can be no assurance that we will be able to enter into such arrangements on acceptable terms or at all. In entering into third-party marketing or distribution arrangements, any revenue we receive will depend upon the efforts of the third parties and there can be no assurance that such third parties will establish adequate sales and distribution capabilities or be successful in gaining market acceptance of any approved product. If we are not successful in commercializing any product approved in the future, either on our own or through third parties, our business, financial condition, results of operations and prospects could be materially and adversely affected.

***Price controls imposed in foreign markets may adversely affect our future profitability.***

In some countries, particularly member states of the European Union, the pricing of prescription drugs is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after receipt of marketing approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and

pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various European Union member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. In some countries, we or future collaborators may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of our Probody therapeutic candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If reimbursement of any product candidate approved for marketing is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business, financial condition, results of operations or prospects could be materially and adversely affected. We currently do not know how the exit of the United Kingdom from the European Union will affect the pricing of prescription drugs, either in the United Kingdom or in the remaining European Union member states.

***Our business entails a significant risk of product liability and our ability to obtain sufficient insurance coverage could have a material and adverse effect on our business, financial condition, results of operations and prospects.***

We are exposed to significant product liability risks inherent in the development, testing, manufacturing and marketing of therapeutic treatments, including as a result of the clinical testing of praluzatamab ravtansine (CX-2009), CX-2029, BMS-986249, BMS-986288, pacmilimab (CX-072) and CX-904 and any of our other product candidates or those of our collaborators. Product liability claims could delay or prevent completion of our development programs. If we succeed in marketing product candidates, such claims could result in an FDA investigation of the safety and effectiveness of our product candidates, our manufacturing processes and facilities (or the manufacturing processes and facilities of our third-party manufacturers) or our marketing programs and potentially a recall of our products or more serious enforcement action, limitations on the approved indications for which they may be used or suspension or withdrawal of approvals. Regardless of the merits or eventual outcome, liability claims may also result in decreased demand for our products, injury to our reputation, costs to defend the related litigation, a diversion of management's time and our resources, substantial monetary awards to trial participants or patients and a decline in our stock price. We currently have insurance that we believe is appropriate for our stage of development and may need to obtain higher levels of insurance prior to marketing any of our product candidates. Any insurance we have or may obtain may not provide sufficient coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to obtain sufficient insurance at a reasonable cost to protect us against losses caused by product liability claims that could have a material and adverse effect on our business, financial condition, results of operations and prospects.

***Our employees and independent contractors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.***

We are exposed to the risk of fraud or other misconduct by our employees or independent contractors. Misconduct by these parties could include intentional failures to comply with FDA regulations, provide accurate information to the FDA, comply with manufacturing standards we may establish, comply with federal and state data privacy, security, fraud and abuse, and other healthcare laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws could also involve the improper use or misrepresentation of information obtained in the course of clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a material and adverse effect on our business, financial condition, results of operations and prospects, including the imposition of significant fines or other sanctions.

***Our current operations are concentrated in one location, and we or the third parties upon whom we depend may be adversely affected by earthquakes or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.***

Our current operations are located in our facilities in South San Francisco, California. Any unplanned event, such as flood, fire, explosion, earthquake, extreme weather condition, medical epidemics, power shortage, telecommunication failure or other natural or manmade accidents or incidents that result in us being unable to fully utilize our facilities, or the manufacturing facilities of our third-party contract manufacturers, may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Loss of access to these facilities may result in increased costs, delays in the development of our product candidates or interruption of our business operations. Earthquakes or other natural disasters could further disrupt our operations and have a material and adverse effect on our business, financial condition, results of operations and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that

damaged critical infrastructure, such as our research facilities or the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. For example, in March 2020, the COVID-19 pandemic caused us to restrict access to our facility and initiate a work-from-home program limiting onsite activity to a substantially reduced level of laboratory research activities. Although we have gradually increased levels of our laboratory research activities, we continue to operate in a hybrid, work-from-home environment and there can be no assurance that we will be able to continue to increase or maintain current levels of such activity or that the COVID-19 pandemic will not continue to impact our ability to conduct business.

The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material and adverse effect on our business. As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However, in the event of an accident or incident at these facilities, we cannot assure you that the amounts of insurance will be sufficient to satisfy any damages and losses. If our facilities, or the manufacturing facilities of our third-party contract manufacturers, are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our research and development programs may be harmed. Any business interruption may have a material and adverse effect on our business, financial condition, results of operations and prospects.

***Our reported financial results may be adversely affected by changes in accounting principles generally accepted in the U.S.***

We prepare our financial statements in conformity with accounting principles generally accepted in the U.S. These accounting principles are subject to interpretation by the Financial Accounting Standards Board (“FASB”) and the SEC. A change in these policies or interpretations could have a significant effect on our reported financial results, may retroactively affect previously reported results, could cause unexpected financial reporting fluctuations, and may require us to make costly changes to our operational processes and accounting systems. For example, in May 2014, the FASB issued Accounting Standards Update (“ASU”) 2014-09, *Revenue from Contracts with Customers (Topic 606)*, which requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. The ASU replaced most existing revenue recognition guidance in the U.S. GAAP when it became effective. The new standard was effective at the beginning of our fiscal year 2018 with early adoption permitted for our fiscal year 2017. We evaluated the impact of ASU 2014-09 on our financial statements and adoption of the standard had a significant impact on our financial statements and retroactively affected the accounting treatment of transactions completed before adoption. Additionally, for the purpose of revenue recognition, we are required to estimate research service periods as well as the related cost to completion, of our research development program. Such estimates are inherently uncertain and may result in changes in estimates to financial statements in subsequent periods.

***Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.***

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the “IRC”), if a corporation undergoes an “ownership change” (generally defined as a greater than 50 percentage points change (by value) in the ownership of its equity over a rolling three-year period), the corporation’s ability to use its pre-change net operating loss carryforwards and certain other pre-change tax attributes to offset its post-change income and taxes may be limited. California has similar rules. For example, we performed an IRC Section 382 analysis in 2017 and determined there was an ownership change that resulted in Section 382 limitations. The ownership change limited our ability to utilize net operating losses against taxable income in 2018 for both federal and California tax purposes. The remaining net operating losses and credit will be available in future years before expiration during their respective carryforward periods. We may experience ownership changes in the future as a result of shifts in our stock ownership, some of which are outside our control, and our ability to utilize net operating loss carryforwards could be limited by an “ownership change” as described above, which could result in additional increased tax liability to the Company.

**Risks Related to Intellectual Property**

***If we are not able to obtain and enforce patent protection for our technologies or product candidates, development and commercialization of our product candidates may be adversely affected.***

Our success depends in part on our ability to obtain and maintain patents and other forms of intellectual property rights, including in-licenses of intellectual property rights of others, for our product candidates, methods used to manufacture our product candidates and methods for treating patients using our product candidates, as well as our ability to preserve our trade secrets, to prevent third parties from infringing upon our proprietary rights and to operate without infringing upon the proprietary rights of others. We have a substantial number of issued patents and pending patent applications, some of which are co-owned with a third party, covering our Probody platforms and products as well as methods of use and production thereof; we have exclusively licensed UCSB’s interest in the patent family co-owned with UCSB that covers Probody and other pro-protein technology in the fields of therapeutics, *in vivo* diagnostics and prophylactics. In addition, we have exclusively licensed a patent portfolio of three patent families from UCSB that includes patents and patent applications that cover compositions and methods related to the screening for and identification of the masks and protease-cleavable linkers that we incorporate into our Probody

candidates. We may not be able to apply for patents on certain aspects of our product candidates in a timely fashion or at all. Our existing issued and granted patents and any future patents we obtain may not be sufficiently broad to prevent others from using our technology or from developing competing products and technology. There is no guarantee that any of our pending patent applications will result in issued or granted patents, that any of our issued or granted patents will not later be found to be invalid or unenforceable or that any issued or granted patents will include claims that are sufficiently broad to cover our product candidates or to provide meaningful protection from our competitors. Moreover, the patent position of biotechnology and biopharmaceutical companies can be highly uncertain because it involves complex legal and factual questions. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our current and future proprietary technology and product candidates are covered by valid and enforceable patents or are effectively maintained as trade secrets. If third parties disclose or misappropriate our proprietary rights, it may materially and adversely affect our position in the market.

The U.S. Patent and Trademark Office (“USPTO”) and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case. The standards applied by the USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in biotechnology and biopharmaceutical patents. As such, we do not know the degree of future protection that we will have on our proprietary products and technology. While we will endeavor to try to protect our product candidates with intellectual property rights such as patents, as appropriate, the process of obtaining patents is time-consuming, expensive and sometimes unpredictable.

In addition, there are numerous recent changes to the patent laws and proposed changes to the rules of the USPTO that may have a significant impact on our ability to protect our technology and enforce our intellectual property rights. For example, the America Invents Act (“AIA”) enacted within the last several years involves significant changes in patent legislation. The Supreme Court has ruled on several patent cases in recent years, some of which cases either narrow the scope of patent protection available in certain circumstances or weaken the rights of patent owners in certain situations. The recent decision by the Supreme Court in *Association for Molecular Pathology v. Myriad Genetics, Inc.* precludes a claim to a nucleic acid having a stated nucleotide sequence that is identical to a sequence found in nature and has not been modified. We currently are not aware of an immediate impact of this decision on our patents or patent applications because we are developing product candidates that contain modifications, such as our Probody substrates and masks, that we believe are not found in nature. However, this decision has yet to be clearly interpreted by courts and by the USPTO. We cannot assure you that the interpretations of this decision or subsequent rulings will not adversely impact our patents or patent applications. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

Once granted, patents may remain open to opposition, interference, re-examination, post-grant review, inter partes review, nullification or derivation action in court or before patent offices or similar proceedings for a given period after allowance or grant, during which time third parties can raise objections against such initial grant. In the course of such proceedings, which may continue for a protracted period of time, the patent owner may be compelled to limit the scope of the allowed or granted claims thus attacked, or may lose the allowed or granted claims altogether. In addition, there can be no assurance that:

- Others will not or may not be able to make, use or sell compounds that are the same as or similar to our product candidates but that are not covered by the claims of the patents that we own or license.
- We or our licensors, or our collaborators are the first to make the inventions covered by each of our issued patents and pending patent applications that we own or license.
- We or our licensors, or our collaborators are the first to file patent applications covering certain aspects of our inventions.
- Others will not independently develop similar or alternative technologies or duplicate any of our technologies without infringing, misappropriating or otherwise violating our intellectual property rights.
- A third party may not challenge our patents and, if challenged, a court would hold that our patents are valid, enforceable and infringed.
- Any issued patents that we own or have licensed will provide us with any competitive advantages, or will not be challenged by third parties.
- We may develop additional proprietary technologies that are patentable.



- The patents of others will not have a material or adverse effect on our business, financial condition, results of operations and prospects.
- Our competitors do not conduct research and development activities in countries where we do not have enforceable patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets.

***Other companies or organizations may challenge our or our licensors' patent rights or may assert patent rights that prevent us from developing and commercializing our products.***

Probody therapeutics are a relatively new scientific field. We have obtained grants and issuances of Probody therapeutic patents and have licensed one patent family comprising several of these patents from a third party on an exclusive basis for therapeutics applications. The issued patents and pending patent applications in the United States and in key markets around the world that we own or license claim many different methods, compositions and processes relating to the discovery, development, manufacture and commercialization of antibody and immunoregulatory therapeutics. Specifically, we own and have licensed a portfolio of patents, patent applications and other intellectual property covering Probody compositions of matter as well as their methods of manufacturing and use.

As the field of antibody and immunoregulatory therapeutics matures, patent applications are being processed by national patent offices around the world. There is uncertainty about which patents will issue, and, if they do, as to when, to whom, and with what claims. In addition, third parties may attempt to invalidate our intellectual property rights.

Even if our rights are not directly challenged, disputes could lead to the weakening of our intellectual property rights. Our defense against any attempt by third parties to circumvent or invalidate our intellectual property rights could be costly to us, could require significant time and attention of our management and could have a material and adverse effect on our business, financial condition, results of operations and prospects or our ability to successfully compete.

There are many issued and pending patents that claim aspects of our product candidates and modifications that we may need to apply to our product candidates. There are also many issued patents that claim antibodies or portions of antibodies that may be relevant for Probody products we wish to develop. Thus, it is possible that one or more organizations will hold patent rights to which we will need a license. If those organizations refuse to grant us a license to such patent rights on reasonable terms, we may not be able to market products or perform research and development or other activities covered by these patents.

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

Obtaining a valid and enforceable issued or granted patent covering our technology in the U.S. and worldwide can be extremely costly. In jurisdictions where we have not obtained patent protection, competitors may use our technology to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but where it is more difficult to enforce a patent as compared to the U.S. Competitor products may compete with our future products in jurisdictions where we do not have issued or granted patents or where our issued or granted patent claims or other intellectual property rights are not sufficient to prevent competitor activities in these jurisdictions. The legal systems of certain countries, particularly certain developing countries, make it difficult to enforce patents and such countries may not recognize other types of intellectual property protection, particularly that relating to biopharmaceuticals. This could make it difficult for us to prevent the infringement of our patents or marketing of competing products in violation of our proprietary rights generally in certain jurisdictions. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

For example, in March 2022, Russia adopted a decree allowing local companies and individuals to use inventions from certain countries designated as “unfriendly”, including the U.S. Further, under current U.S. currency restrictions on payments to entities in Russia, we may be unable in the future to pay for the prosecution of patent applications or the maintenance of existing patents in Russia. As a result of these actions, we may not be able to protect our technology from unlicensed use in Russia.

We generally file a provisional patent application first (a priority filing) at the USPTO. An international application under the Patent Cooperation Treaty (“PCT”) is usually filed within twelve months after the priority filing. Based on the PCT filing, national and regional patent applications may be filed in the United States, Europe, Japan, Australia and Canada and, depending on the individual case, also in any or all of, *inter alia*, Brazil, China, Hong Kong, India, Indonesia, Israel, Malaysia, Mexico, New Zealand, Russia or Eurasian Patent Organization, Singapore, South Africa, South Korea and other jurisdictions. We have so far not filed for patent protection in all national and regional jurisdictions where such protection may be available. In addition, we may decide to abandon national and regional patent applications before grant. Finally, the grant proceeding of each national or regional patent is an independent proceeding which may lead to situations in which applications might in some jurisdictions be refused by the relevant registration authorities, while granted by others. It is also quite common that depending on the country, various scopes of patent protection may be granted on the same product candidate or technology.

The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws in the U.S., and many companies have encountered significant difficulties in protecting and defending such rights in such jurisdictions. 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 from others in those jurisdictions. Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many 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 with respect to any patents relevant to our business, our competitive position in the relevant jurisdiction may be impaired and our business and results of operations may be adversely affected.

***We or our licensors, or any future strategic partners may become subject to third party claims or litigation alleging infringement of patents or other proprietary rights or seeking to invalidate patents or other proprietary rights, and we may need to resort to litigation to protect or enforce our patents or other proprietary rights, all of which could be costly, time consuming, delay or prevent the development and commercialization of our product candidates, or put our patents and other proprietary rights at risk.***

We or our licensors, or any future strategic partners may be subject to third-party claims for infringement or misappropriation of patent or other proprietary rights. We are generally obligated under our license or collaboration agreements to indemnify and hold harmless our licensors or collaborators for damages arising from intellectual property infringement by us. For example, in March 2020, Vytacera Bio, LLC filed a patent infringement lawsuit against the Company in the U.S. District Court for the District of Delaware. The lawsuit alleges that the Company's use, offers to sell, and/or sales of the Probody technology platform for basic research applications constitutes infringement. The complaint seeks unspecified monetary damages. The Company believes that the lawsuit is without merit and intends to vigorously defend itself. However, there can be no assurance that a court might not rule against us in these proceedings. Even if we are successful in defending against such claim, this litigation could divert management's attention, as well as our resources, from our business and any claims paid out of our cash reserves would harm our financial condition and operating results.

If we or our licensors, or any future strategic partners are found to infringe a third-party patent or other intellectual property rights, we could be required to pay damages, potentially including treble damages, if we are found to have willfully infringed. In addition, we or our licensors, or any future strategic partners may choose to seek, or be required to seek, a license from a third party, which may not be available on acceptable terms, if at all. Even if a license can be obtained on acceptable terms, the rights may be non-exclusive, which could give our competitors access to the same technology or intellectual property rights licensed to us. If we fail to obtain a required license, we or our collaborators may be unable to effectively market product candidates based on our technology, which could limit our ability to generate revenue or achieve profitability and possibly prevent us from generating revenue sufficient to sustain our operations. In addition, we may find it necessary to pursue claims or initiate lawsuits to protect or enforce our patent or other intellectual property rights. The cost to us in defending or initiating any litigation or other proceeding relating to patent or other proprietary rights, even if resolved in our favor, could be substantial, and litigation would divert our management's attention. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could delay our research and development efforts and limit our ability to continue our operations.

If we were to initiate legal proceedings against a third party to enforce a patent covering one of our products or our technology, the defendant could counterclaim that our patent is invalid or unenforceable. In patent litigation in the U.S., defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. The outcome following legal assertions of invalidity and unenforceability during patent litigation is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on one or more of our products or certain aspects of our platform technology. Such a loss of patent protection could have a material and adverse effect on our business, financial condition, results of operations and prospects. Patents and other intellectual property rights also will not protect our technology if competitors design around our protected technology without legally infringing, misappropriating or otherwise violating our patents or other intellectual property rights.

***Intellectual property rights of third parties could adversely affect our ability to commercialize our product candidates, and we might be required to litigate or obtain licenses from third parties in order to develop or market our product candidates. Such litigation or licenses could be costly or not available on commercially reasonable terms.***

Because the antibody landscape is still evolving, including the masked antibody landscape, it is difficult to conclusively assess our freedom to operate without infringing on third-party rights. There are numerous companies that have pending patent applications and issued patents

broadly covering antibodies generally or covering antibodies directed against the same targets as, or targets similar to, those we are pursuing. There are many issued patents and patent applications covering antibodies targeted against PD-1 and PD-L1, and the intellectual property covering PD-1 and PD-L1 antibodies has been the subject of litigation and licensing, especially regarding how broadly certain claims should be construed. If the claims were to be construed broadly by the courts, we may need to obtain a license to some of such intellectual property, covering PD-1 and/or PD-L1 antibodies, which would decrease the profits we would realize from the sale of such products. An increasing number of third parties are filing masked antibody patent applications, several of which contain claims that are patterned after our own patent claims. Our competitive position may suffer if patents issued to third parties or other third-party intellectual property rights cover our products or product candidates or elements thereof, or our manufacture or uses relevant to our development plans. In such cases, we may not be in a position to develop or commercialize products or product candidates unless we successfully pursue litigation to nullify or invalidate the third-party intellectual property right concerned, or enter into a license agreement with the intellectual property right holder, if available on commercially reasonable terms. There may be issued patents of which we are not aware, held by third parties that, if found to be valid and enforceable, could be alleged to be infringed by our Probody therapeutic technologies. There also may be pending patent applications of which we are not aware that may result in issued patents, which could be alleged to be infringed by our Probody therapeutic technologies. If such an infringement claim should be brought and be successful, we may be required to pay substantial damages, be forced to abandon our product candidates or seek a license from any patent holders. No assurances can be given that a license will be available on commercially reasonable terms, if at all.

It is also possible that we have failed to identify relevant third-party patents or applications. For example, U.S. applications filed before November 29, 2000, and certain U.S. applications filed after that date that will not be filed outside the U.S. remain confidential until patents issue. Patent applications in the U.S. and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our products or platform technology could have been filed by others without our knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our platform technologies, our products or the use of our products. Third-party intellectual property right holders may also actively bring infringement claims against us. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we are unable to successfully settle future claims on terms acceptable to us, we may be required to engage in or continue costly, unpredictable and time-consuming litigation and may be prevented from or experience substantial delays in marketing our products. If we fail in any such dispute, in addition to being forced to pay damages, we may be temporarily or permanently prohibited from commercializing any of our product candidates that are held to be infringing. We might, if possible, also be forced to redesign product candidates so that we no longer infringe the third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

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

Litigation, including the ongoing patent infringement lawsuit brought by Vytacera Bio, LLC (“Vytacera”) against us, or other legal proceedings relating to intellectual property claims, with or without merit, is unpredictable and generally expensive and time consuming and is likely to divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. 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. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities.

We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon, misappropriating or otherwise violating or from successfully challenging our intellectual property rights. For example, although we believe the Vytacera lawsuit is without merit and we intend to vigorously defend ourselves, we cannot provide any assurance that we will be successful. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material and adverse effect on our ability to compete in the marketplace.

***If we fail to comply with our obligations under any license, collaboration or other agreements, we may be required to pay damages and could lose our rights to intellectual property rights that are necessary for developing and protecting our product candidates or we could lose certain rights to grant sublicenses.***

Our licenses from Amgen, ImmunoGen and UCSB impose, and any future licenses we enter into are likely to impose, various development, commercialization, funding, diligence, sublicensing, insurance, patent prosecution and enforcement and/or other obligations on us, including various payment obligations such as milestone and royalty payments and payments based on sublicensing revenues. Our rights under our

agreements with our licensors or collaborators may be limited or modified according to their terms. Additionally, if we breach any of these obligations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages and the licensor may have the right to terminate the license, which could result in us being unable to develop, manufacture and sell products that are covered by the licensed technology or enable a competitor to gain access to the licensed technology. Moreover, our licensors and collaborators may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing, misappropriating or otherwise violating the licensor's rights. In addition, while we cannot currently determine the amount of the royalty or sublicense revenue payment obligations we would be required to pay on development or sales of future products, if any, the amounts may be significant. The amount of our future royalty or sublicense revenue payment obligations will depend on the technology and intellectual property we use in products that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize products, we may be unable to achieve or maintain profitability.

***Our intellectual property agreements with our licensors, collaborators and third parties may be subject to disagreements over contract interpretation, which could narrow the scope of, or result in termination of, our rights to the relevant intellectual property or technology or increase our financial or other obligations to such third parties.***

Certain provisions in our intellectual property agreements may be susceptible to multiple interpretations. For example, we may disagree with our licensors or collaborators regarding whether, when and to what extent various obligations under these agreements apply to certain of our product candidates and products, including various payment, development, commercialization, funding, diligence, sublicensing, insurance, patent prosecution and enforcement and/or other obligations. The resolution of any contract interpretation disagreement that may arise could affect the scope of our rights to the relevant intellectual property or technology, or affect financial or other obligations under the relevant agreement. In either case, such disagreement could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact conceives or develops intellectual property that we regard as our own. Our assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property.

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

In addition to seeking patent protection for certain aspects of our product candidates, we also consider trade secrets, including confidential and unpatented know-how, important to the maintenance of our competitive position. We protect trade secrets and confidential and unpatented know-how, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to such knowledge, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants that obligate them to maintain confidentiality and assign their inventions to us.

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 is unpredictable. In addition, some courts in the U.S. and certain foreign jurisdictions are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them 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 may be subject to claims that we or our employees or consultants have wrongfully used or disclosed alleged trade secrets of our employees' or consultants' former employers or their clients. These claims may be costly to defend and if we do not successfully do so, we may be required to pay monetary damages and may lose valuable intellectual property rights or personnel.***

Many of our employees were previously employed at universities or biotechnology or biopharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. A loss of key research personnel or their work product could hamper our ability to commercialize, or prevent us from commercializing, our product candidates, which could severely harm our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

***If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.***

Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected.

#### **Risks Related to Government Regulation**

***We may be unable to obtain or be delayed in obtaining U.S. or foreign regulatory approval and, as a result, be unable or delayed in being able to commercialize our product candidates.***

Our product candidates that we are currently developing are regulated as therapeutic biologics that are subject to requirements for review and approval of a BLA by the FDA's Center for Drug Evaluation and Research ("CDER"). Therefore, our product candidates are subject to extensive governmental regulations relating to, among other things, research, testing, development, manufacturing, safety, efficacy, approval, recordkeeping, reporting, labeling, storage, packaging, advertising and promotion, pricing, marketing and distribution of drugs and therapeutic biologics. Rigorous preclinical testing and clinical trials and an extensive regulatory approval process are required to be successfully completed in the U.S. and in many foreign jurisdictions before a new drug or therapeutic biologic can be marketed. Satisfaction of these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. For example, at this time it is impossible to predict whether the COVID-19 pandemic will cause regulatory delays in the U.S. or foreign jurisdictions. It is possible that none of the product candidates we may develop will obtain the regulatory approvals necessary for us or our existing or future collaborators to begin selling them.

As a company, we have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approvals, including approval by the FDA. The time required to obtain FDA and other approvals is unpredictable but typically takes many years following the commencement of clinical trials, depending upon the type, complexity and novelty of the product candidate. The standards that the FDA and its foreign counterparts use when regulating us require judgment and can change, which makes it difficult to predict with certainty how they will be applied. Any analysis we perform of data from preclinical and clinical activities is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. We may also encounter unexpected delays or increased costs due to new government regulations, for example, from future legislation or administrative action, or from changes in FDA policy during the period of product development, clinical trials and FDA regulatory review. Further, government shutdowns, such as the partial U.S. federal government shutdown in late 2018 or the United Kingdom's departure from the European Union may impact our ability to access government agencies in a timely manner or otherwise impact our ability to move our product candidates through the regulatory process. It is impossible to predict whether legislative changes will be enacted, or whether FDA or foreign regulations, guidance or interpretations will be changed, or what the impact of such changes, if any, may be.

Moreover, the FDA may respond to our submissions by defining requirements we may not have anticipated. Such responses could lead to significant delays in the clinical development of our product candidates. In addition, because there may be approved treatments for some of the diseases for which we may seek approval, in order to receive regulatory approval, we may need to demonstrate through clinical trials that the product candidates we develop to treat these diseases, if any, are not only safe and effective, but safer or more effective than existing products. Furthermore, in recent years, there has been increased public and political pressure on the FDA with respect to the approval process for new drugs and therapeutic biologics, and the FDA's standards, especially regarding product safety, appear to have become more stringent.

Any delay or failure in obtaining required approvals could have a material and adverse effect on our ability to generate revenues from the particular product candidate for which we are seeking approval. Furthermore, any regulatory approval to market a product may be subject to limitations on the approved uses for which we may market the product or the labeling or other restrictions. In addition, the FDA has the authority to require a REMS as part of a BLA or after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug or biologic, such as limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria and requiring treated patients to enroll in a registry. These limitations and restrictions may limit the size of the market for the product and affect reimbursement by third-party payors.

We are also subject to numerous foreign regulatory requirements governing, among other things, the conduct of clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement. The foreign regulatory approval process varies among countries and may include all of the risks associated with FDA approval described above as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. Moreover, the time required to obtain approval may differ from that required to obtain FDA approval. Approval by the FDA does not ensure approval by regulatory authorities outside the U.S. and vice versa.

***Even if we receive regulatory approval for any of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.***

Any regulatory approvals that we or our collaborators obtain for our product candidates may also be subject to limitations on the approved indicated uses for which a 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. In addition, if the FDA or a comparable foreign regulatory authority approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, import, export, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and good clinical practices for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, 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 our strategic partners;
- suspension or revocation of product approvals;
- product seizure or detention or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

The FDA’s policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. 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, which would adversely affect our business.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action, and we may not achieve or sustain profitability.

***Our product candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated.***

The Affordable Care Act includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 (“BPCIA”), which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a highly similar or “biosimilar” product may not be submitted to the FDA until four years following the date that the reference product was first approved by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first approved. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor’s own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product.

We believe that any of our product candidates approved as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

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

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for therapeutic biologics or modifications to approved therapeutic biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough FDA employees and stop critical activities.

Separately, in response to the COVID-19 pandemic, in March 2020, the FDA announced its intention to postpone most inspections of foreign manufacturing facilities, and on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, in July 2020, the FDA resumed certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA utilized this risk-based assessment system to assist in determining when and where it was the safest to conduct prioritized domestic inspections. Additionally, on April 15, 2021, the FDA issued a guidance document in which the FDA described its plans to conduct voluntary remote interactive evaluations of certain drug manufacturing facilities and clinical research sites, among other facilities. According to the guidance, the FDA may request such remote interactive evaluations where the FDA determines that remote evaluation would be appropriate based on mission needs and travel limitations. In May 2021, the FDA outlined a detailed plan to move toward a more consistent state of inspectional operations, and in July 2021, the FDA resumed standard inspectional operations of domestic facilities and was continuing to maintain this level of operation as of September 2021. More recently, the FDA has continued to monitor and implement changes to its inspectional activities to ensure the safety of its employees and those of the firms it regulates as it adapts to the evolving COVID-19 pandemic. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

***Healthcare legislative reform measures may have a material and adverse effect on our business and results of operations.***

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (together, the "ACA"), was passed, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry. The ACA, among other things, subjected therapeutic biologics to potential competition by lower-cost biosimilars, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs and therapeutic biologics that are inhaled, infused, instilled, implanted or injected, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees and taxes on manufacturers of certain branded prescription drugs and therapeutic biologics, and created a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts, which, through subsequent legislative amendments, was increased to 70% starting in 2019, off negotiated prices of applicable brand drugs and therapeutic biologics to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs and therapeutic biologics to be covered under Medicare Part D.

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden issued an executive order initiating a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare. It is unclear how healthcare reform measures enacted by Congress or implemented by the Biden administration, if any, will impact our business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted to reduce healthcare expenditures. The Budget Control Act of 2011, among other things, included aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030, with the exception of a temporary suspension from May 2, 2020 through March 31, 2022, unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. If federal spending is further reduced, anticipated budgetary shortfalls may also impact the ability of relevant agencies, such as the FDA or the National Institutes of Health to continue to function at current levels. Amounts allocated to federal grants and contracts may be reduced or eliminated.

These reductions may also impact the ability of relevant agencies to timely review and approve research and development, manufacturing, and marketing activities, which may delay our ability to develop, market and sell any products we may develop.

Moreover, payment methodologies, including payment for companion diagnostics, may be subject to changes in healthcare legislation and regulatory initiatives. For example, in March 2018, the Centers for Medicare & Medicaid Services (“CMS”) finalized a national coverage determination extending coverage under the Medicare program for certain diagnostic laboratory tests using next generation sequencing (“NGS”) that are approved by the FDA as a companion *in vitro* diagnostic and used in a cancer with an FDA-approved companion diagnostic indication. Under the national coverage determination, diagnostic tests that meet these criteria are covered only in patients with recurrent, metastatic, relapsed, refractory or stages III or IV cancer if the test has an FDA-approved or cleared indication for use in that patient’s cancer and results are provided to the treating physician for management of the patient using a report template to specify treatment options. Although the Medicare program increasingly is used as a model for how private payors and other governmental payors develop their coverage and reimbursement policies, it is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for any companion diagnostics associated with our product candidates.

In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed bills designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. For example, the 21st Century Cures Act changed the reimbursement methodology for infusion drugs and biologics furnished through durable medical equipment in an attempt to remedy over- and underpayment of certain products. Furthermore, the Build Back Better Act, if enacted, would introduce substantial drug pricing reforms, including the establishment of a drug price negotiation program within the U.S. Department of Health and Human Services that would require manufacturers to charge a negotiated “maximum fair price” for certain selected drugs or pay an excise tax for noncompliance, and the establishment of rebate payment requirements on manufacturers of certain drugs payable under Medicare Parts B and D. If the Build Back Better Act is not enacted, similar or other drug pricing proposals could appear in future legislation. Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or companion diagnostics or additional pricing pressures.

***If we or our collaborators, manufacturers or service providers fail to comply with healthcare laws and regulations, we or they could be subject to enforcement actions, which could affect our ability to develop, market and sell our products and may harm our reputation.***

Although we do not currently have any products on the market, if and when we begin commercializing our product candidates, we will be subject to additional healthcare statutory and regulatory requirements and enforcement by the federal government and the states and foreign governments in which we conduct our business. Healthcare providers, physicians and third-party payors play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our product candidates for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind to induce or reward either the referral of an individual for, or the purchase, or order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the U.S. federal False Claims Act, which imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- the U.S. federal Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services; similar to the federal



Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the U.S. federal legislation commonly referred to as Physician Payments Sunshine Act, enacted as part of the ACA, and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children’s Health Insurance Program to report annually to the CMS information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives) and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members; and
- analogous state laws and regulations, such as state anti-kickback and false claims laws that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; and state laws that require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug and therapeutic biologics manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures and pricing information.

Ensuring that our future business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any such requirements, we may be subject to penalties, including civil or criminal penalties, monetary damages, the curtailment or restructuring of our operations, loss of eligibility to obtain approvals from the FDA, or exclusion from participation in government contracting, healthcare reimbursement or other government programs, including Medicare and Medicaid, any of which could adversely our financial results. Although effective compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, these risks cannot be entirely eliminated. Any action against us for an alleged or suspected violation could cause us to incur significant legal expenses and could divert our management’s attention from the operation of our business, even if our defense is successful. In addition, achieving and sustaining compliance with applicable laws and regulations may be costly to us in terms of money, time and resources.

If we or future collaborators, manufacturers or service providers fail to comply with applicable federal, state or foreign laws or regulations, we could be subject to enforcement actions, which could affect our ability to develop, market and sell our products successfully and could harm our reputation and lead to reduced acceptance of our products by the market. These enforcement actions include, among others:

- adverse regulatory inspection findings;
- warning letters;
- voluntary or mandatory product recalls or public notification or medical product safety alerts to healthcare professionals;
- restrictions on, or prohibitions against, marketing our products;
- restrictions on, or prohibitions against, importation or exportation of our products;
- suspension of review or refusal to approve pending applications or supplements to approved applications;
- exclusion from participation in government-funded healthcare programs;
- exclusion from eligibility for the award of government contracts for our products;
- suspension or withdrawal of product approvals;
- seizures or administrative detention of products;
- injunctions; and
- civil and criminal penalties and fines.

***If we fail to comply with U.S. and foreign regulatory requirements, regulatory authorities could limit or withdraw any marketing or commercialization approvals we may receive and subject us to other penalties that could materially harm our business.***

Even if we receive marketing and commercialization approval of a product candidate, we will be subject to continuing regulatory requirements, including in relation to adverse patient experiences with the product and clinical results that are reported after a product is made commercially available, both in the U.S. and any foreign jurisdiction in which we seek regulatory approval. The FDA has significant post-market authority, including the authority to require labeling changes based on new safety information and to require post-market studies or

clinical trials to evaluate safety risks related to the use of a product or to require withdrawal of the product from the market. The FDA also has the authority to require a REMS plan after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug or therapeutic biologic. The manufacturer and manufacturing facilities we use to make a future product, if any, will also be subject to periodic review and inspection by the FDA and other regulatory agencies, including for continued compliance with cGMP requirements. The discovery of any new or previously unknown problems with our third-party manufacturers, manufacturing processes or facilities may result in restrictions on the product, manufacturer or facility, including withdrawal of the product from the market. If we rely on third-party manufacturers, we will not have control over compliance with applicable rules and regulations by such manufacturers. Any product promotion and advertising will also be subject to regulatory requirements and continuing regulatory review. If we or our collaborators, manufacturers or service providers fail to comply with applicable continuing regulatory requirements in the U.S. or foreign jurisdictions in which we seek to market our products, we or they may be subject to, among other things, fines, warning letters, holds on clinical trials, delay of approval or refusal by the FDA to approve pending applications or supplements to approved applications, suspension or withdrawal of regulatory approval, product recalls and seizures, administrative detention of products, refusal to permit the import or export of products, operating restrictions, injunction, civil penalties and criminal prosecution.

***Actual or perceived failures to comply with applicable data protection, privacy and security laws, regulations, standards and other requirements could adversely affect our business, results of operations, and financial condition.***

The regulatory environment surrounding data privacy and security is increasingly demanding. We are or may in the future be subject to numerous U.S. federal and state laws and non-U.S. regulations governing the collection, use, disclosure, retention, and security of personal and confidential information of our clinical subjects, clinical investigators, employees and vendors/business contacts. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards, or perception of their requirements may have on our business. This evolution may create uncertainty in our business, affect our ability to operate in certain jurisdictions or to collect, store, transfer use and share personal information, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future. Any failure or perceived failure by us to comply with federal, state or foreign laws or regulations, our internal policies and procedures or our contracts governing our processing of personal information could result in negative publicity, government investigations and enforcement actions, claims by third parties and damage to our reputation, any of which could have a material adverse effect on our business, results of operation, and financial condition.

In the United States, HIPAA imposes, among other things, certain standards relating to the privacy, security, transmission and breach reporting of individually identifiable health information. We may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA. Depending on the facts and circumstances, we could be subject to significant penalties if we violate HIPAA. Certain states have also adopted comparable privacy and security laws and regulations, some of which may be more stringent than HIPAA. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners. For example, the California Consumer Privacy Act (“CCPA”) went into effect on January 1, 2020. The CCPA creates individual privacy rights for California consumers, including the expanded right 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. Further, the California Privacy Rights Act (“CPRA”) recently passed in California. The CPRA significantly amends the CCPA and will impose additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It will also create a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions will go into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required. Similar laws have passed in Virginia and Colorado, and have been proposed in other states and at the federal level, reflecting a trend toward more stringent privacy legislation in the United States. The enactment of such laws could have potentially conflicting requirements that would make compliance challenging. In the event that we are subject to or affected by HIPAA, the CCPA, the CPRA or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition.

Our operations abroad may also be subject to increased scrutiny or attention from data protection authorities. For example, the GDPR went into effect in May 2018, and imposes stringent requirements for processing the personal data of individuals within the EEA. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to 4% total worldwide annual turnover or €20 million, whichever is higher. Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States; in July 2020, the Court of Justice of the European Union (“CJEU”) limited how organizations could lawfully transfer personal data from the EU/EEA to the United States by invalidating the EU-US Privacy Shield Framework for purposes of international transfers and imposing further restrictions on the use of standard contractual clauses (“SCCs”). The European Commission issued revised SCCs on June 4, 2021 to account for the decision of the CJEU and recommendations

made by the European Data Protection Board. The revised SCCs must be used for relevant new data transfers from September 27, 2021; existing standard contractual clauses arrangements must be migrated to the revised clauses by December 27, 2022. The new SCCs apply only to the transfer of personal data outside of the EEA and not the United Kingdom; the United Kingdom's Information Commissioner's Office launched a public consultation on its draft revised data transfers mechanisms in August 2021. There is some uncertainty around whether the revised clauses can be used for all types of data transfers, particularly whether they can be relied on for data transfers to non-EEA entities subject to the GDPR. As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the standard contractual clauses cannot be used, or start taking enforcement action, we could suffer additional costs, complaints and/or regulatory investigations or fines, and/or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we provide our products and services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results.

Further, from January 1, 2021, we have had to comply with the GDPR and also the UK GDPR, which, together with the amended UK Data Protection Act 2018, retains the GDPR in UK national law. The UK GDPR mirrors the fines under the GDPR, i.e., fines up to the greater of €20 million (£17.5 million) or 4% of global turnover. The relationship between the United Kingdom and European Union in relation to certain aspects of data protection law remains unclear, including how data transfers between European Union member states and the United Kingdom will be treated. These changes may lead to additional compliance costs and could increase our overall risk. The European Commission has adopted an adequacy decision in favor of the United Kingdom, enabling data transfers from EU member states to the United Kingdom without additional safeguards. However, the UK adequacy decision will automatically expire in June 2025 unless the European Commission re-assesses and renews or extends that decision.

In recent years, U.S. and European lawmakers and regulators have expressed concern over electronic marketing and the use of third-party cookies, web beacons and similar technology for online behavioral advertising. In the European Union, the rules on e-marketing are currently set out in the ePrivacy Directive, which will be replaced by a new ePrivacy Regulation. While the ePrivacy Regulation was originally intended to be adopted on May 25, 2018 (alongside the GDPR), it is still going through the European legislative process. The current draft of the ePrivacy Regulation imposes strict opt-in e-marketing rules with limited exceptions for business to business communications, and significantly increases fines for non-compliance. Regulation of cookies and web beacons may lead to broader restrictions on our online activities, including our efforts to understand our users' internet usage and promote ourselves to them.

Although we work to comply with applicable laws, regulations and standards, our contractual obligations and other legal obligations, these requirements are evolving and may be modified, interpreted and applied in an inconsistent manner from one jurisdiction to another, and may conflict with one another or other legal obligations with which we must comply. Any failure or perceived failure by us or our employees, representatives, contractors, consultants, collaborators, or other third parties to comply with such requirements or adequately address privacy and security concerns, even if unfounded, could result in significant fines, penalties and damage to our reputation, and we may be forced to change the way we operate. This could result in additional cost and liability to us, which could negatively affect our business, results of operation, and financial condition.

***Even if we are able to commercialize any product candidate, such product candidate may become subject to unfavorable pricing regulations or third-party coverage and reimbursement policies, which would harm our business.***

The regulations that govern regulatory approvals, pricing and reimbursement for new drugs and therapeutic biologics vary widely from country to country. Some countries require approval of the sale price of a drug or therapeutic biologic before it can be marketed. In many countries, the pricing review period begins after marketing approval is granted. In some foreign markets, prescription biopharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain regulatory approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods and negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain regulatory approval.

Our ability to commercialize any products successfully also will depend in part on the extent to which coverage and reimbursement for these products and related treatments will be available from government authorities, private health insurers and other organizations. Even if we succeed in bringing one or more products to the market, these products may not be considered cost-effective, and the amount reimbursed for any products may be insufficient to allow us to sell our products on a competitive basis. Because our programs are in the early stages of development, we are unable at this time to determine their cost effectiveness or the likely level or method of reimbursement. Increasingly, the third-party payors who reimburse patients or healthcare providers, such as government and private insurance plans, are requiring that drug companies provide them with predetermined discounts from list prices, and are seeking to reduce the prices charged or the amounts reimbursed for biopharmaceutical products. If the price we are able to charge for any products we develop, or the reimbursement provided for such products, is inadequate in light of our development and other costs, our return on investment could be adversely affected. There may be significant delays in obtaining reimbursement for newly-approved drugs or therapeutic biologics, and coverage may be more limited than the purposes for which the drug or therapeutic biologic is approved by the FDA or similar regulatory authorities outside of the United States.

Moreover, eligibility for reimbursement does not imply that any drug or therapeutic biologic will be reimbursed in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs or therapeutic biologics, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may be based on payments allowed for lower-cost drugs or therapeutic biologics that are already reimbursed, may be incorporated into existing payments for other services and may reflect budgetary constraints or imperfections in Medicare data. Net prices for drugs or therapeutic biologics 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 or therapeutic biologics from countries where they may be sold at lower prices than in the U.S. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement rates. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for new drugs or therapeutic biologics that we develop and for which we obtain regulatory approval could have a material and adverse effect on our operating results, our ability to raise capital needed to commercialize products and our financial condition.

***We may seek and fail to obtain fast track or breakthrough therapy designations for our current or future product candidates. If we are successful, these programs may not lead to a faster development or regulatory review process, and they do not guarantee we will receive approval for any product candidate. We may also seek to obtain accelerated approval for one or more of our product candidates but the FDA may disagree that we have met the requirements for such approval.***

If a product is intended for the treatment of a serious or life-threatening condition and preclinical or clinical data demonstrate the potential to address an unmet medical need for this condition, the product sponsor may apply for fast track designation. Fast track designation provides increased opportunities for sponsor meetings with the FDA during preclinical and clinical development, in addition to the potential for rolling review of a BLA, if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even if we do receive fast track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may rescind the fast track designation if it believes that the designation is no longer supported by data from our clinical development program.

We may also seek breakthrough therapy designation for any product candidate that we develop. 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 currently approved therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Like fast track designation, breakthrough therapy designation is within the discretion of the FDA. Accordingly, even if we believe a product candidate we develop meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of breakthrough therapy designation for a product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if a product candidate we develop qualifies as a breakthrough therapy, the FDA may later decide that the drug no longer meets the conditions for qualification and rescind the designation.

Product candidates may also be eligible for accelerated approval if the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of accelerated approval, the FDA will generally require the sponsor to perform adequate and well-controlled post-marketing clinical studies to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. Products receiving accelerated approval may be subject to expedited withdrawal procedures if the sponsor fails to conduct the required post-marketing studies or if such studies fail to verify the predicted clinical benefit. In addition, the FDA requires pre-approval of promotional materials for accelerated approval products, once approved. We cannot guarantee that the FDA will agree any of our product candidates has met the criteria to receive accelerated approval, which would require us to conduct additional clinical testing prior to seeking FDA approval. Even if any of our product candidates received approval through this pathway, the product may fail required post-approval confirmatory clinical trials, and we may be required to remove the product from the market or amend the product label in a way that adversely impacts its marketing.

***We may seek Orphan Drug Designation for some of our product candidates, and we may be unsuccessful or may be unable to maintain the benefits associated with Orphan Drug Designation, including the potential for market exclusivity.***

As part of our business strategy, we may seek Orphan Drug Designation for our product candidates, and we may be unsuccessful. Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs and therapeutic biologics for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a drug or therapeutic biologic as an orphan drug if it is a drug or therapeutic biologic intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable

expectation that the cost of developing the drug or therapeutic biologic will be recovered from sales in the United States. In the United States, Orphan Drug Designation entitles a party to financial incentives such as opportunities for grant funding toward clinical trial costs, tax advantages and user-fee waivers. In addition, if a product that has Orphan Drug Designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications, including a full BLA, to market the same product 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 where the manufacturer is unable to assure sufficient product quantity.

Even if we obtain Orphan Drug Designation for our product candidates in specific indications, we may not be the first to obtain marketing approval of these product candidates for the orphan-designated indication due to the uncertainties associated with developing pharmaceutical products. In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different biologics can be approved for the same condition. Even after an orphan product is approved, the FDA can subsequently approve the same drug or therapeutic biologic for the same condition if the FDA concludes that the later drug or therapeutic biologic is safer, more effective or makes a major contribution to patient care. Orphan Drug Designation neither shortens the development time or regulatory review time of a drug or therapeutic biologic nor gives the drug or therapeutic biologic any advantage in the regulatory review or approval process. In addition, while we may seek Orphan Drug Designation for our product candidates, we may never receive such designations.

Tax reform legislation passed in 2017 reduced the amount of the qualified clinical research costs for a designated orphan product that a sponsor may claim as a credit from 50% to 25%. Thus, further limiting the advantage and may impact our future business strategy of seeking the Orphan Drug Designation.

### **Risks Related to Ownership of Our Common Stock**

*Our quarterly operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.*

We expect our operating results to be subject to quarterly fluctuations. Our net loss and other operating results will be affected by numerous factors, including:

- variations in the level of expense related to the ongoing development of our Probody platform, our product candidates or future development programs;
- results of clinical trials, or the addition or termination of clinical trials or funding support by us, or existing or future collaborators or licensing partners;
- our execution of any additional collaboration, licensing or similar arrangements, and the timing of payments we may make or receive under existing or future arrangements or the termination or modification of any such existing or future arrangements;
- developments or disputes concerning patents or other proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our products;
- any intellectual property infringement lawsuit or opposition, interference or cancellation proceeding in which we may become involved, including the ongoing patent infringement lawsuit brought by Vytacera against us;
- additions and departures of key personnel;
- strategic decisions by us or our competitors, such as acquisitions, divestitures, spin-offs, joint ventures, strategic investments or changes in business strategy;
- if any of our product candidates receives regulatory approval, the terms of such approval and market acceptance and demand for such product candidates;
- regulatory developments affecting our product candidates or those of our competitors; and
- changes in general market and economic conditions.

If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

***Our stock price may be volatile and purchasers of our common stock could incur substantial losses.***

Our stock price is volatile. Since our initial public offering (“IPO”), our stock had low and high sales prices in the range of \$1.19 and \$35.00 per share. The market price for our common stock may be influenced by many factors, including the other risks described in this section titled “Risk Factors” and the following:

- results of clinical trials and preclinical studies of our product candidates, or those of our competitors or our collaborators;
- regulatory or legal developments in the U.S. and other countries, especially changes in laws or regulations applicable to our products;
- the success of competitive products or technologies;
- introductions and announcements of new products by us, our future commercialization partners, or our competitors, and the timing of these introductions or announcements;
- actions taken by regulatory agencies with respect to our products, clinical studies, manufacturing process or sales and marketing terms;
- the extent to which the COVID-19 pandemic and related governmental regulations and restrictions may impact our business, including our research, clinical trials, manufacturing and financial condition, as well as the impact of other pandemics, natural disasters and other calamities;
- actual or anticipated variations in our financial results or those of companies that are perceived to be similar to us;
- the success of our efforts to acquire or in-license additional technologies, products or product candidates;
- developments concerning any existing or future collaborations, including but not limited to those with our sources of manufacturing supply and our commercialization partners;
- market conditions in the pharmaceutical and biotechnology sectors;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures or capital commitments;
- developments or disputes concerning patents or other proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our products;
- our ability or inability to raise additional capital and the terms on which we raise it;
- the recruitment or departure of key personnel;
- changes in the structure of healthcare payment systems;
- actual or anticipated changes in earnings estimates or changes in stock market analyst recommendations regarding our common stock, other comparable companies or our industry generally;
- our failure or the failure of our competitors to meet analysts’ projections or guidance that we or our competitors may give to the market;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- announcement and expectation of additional financing efforts;
- speculation in the press or investment community;
- trading volume of our common stock;
- sales of our common stock by us or our stockholders;
- the concentrated ownership of our common stock;
- changes in accounting principles;
- terrorist acts, acts of war or periods of widespread civil unrest;
- natural disasters and other calamities; and
- general economic, industry and market conditions.

The stock markets in general, and the markets for pharmaceutical, biopharmaceutical and biotechnology stocks in particular, have experienced extreme volatility, including as a result of the COVID-19 pandemic, that has been often unrelated to the operating performance of the issuer. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance.

In addition, the spread of COVID-19 may negatively impact the trading price of shares of our common stock and could further severely impact our ability to raise additional capital on a timely basis or at all.

***The future issuance of equity or of debt securities that are convertible into equity will dilute our share capital.***

We may choose to raise additional capital in the future, depending on market conditions, strategic considerations and operational requirements. To the extent that additional capital is raised through the issuance of shares or other securities convertible into shares, our stockholders will be diluted. On February 27, 2020, we entered into an Open Market Sale Agreement (the “Sales Agreement”) with Jefferies LLC (“Jefferies”), to sell shares of our common stock, par value \$0.00001 per share, with aggregate gross sales proceeds of up to \$75,000,000, from time to time, through an at the market offering under which Jefferies will act as sales agent. We have issued securities under the Sales Agreement and may do so in the future. In addition, in January and February 2021, we sold 16,428,571 shares of our common stock at \$7.00 per share in an underwritten public offering. Future issuances of our common stock or other equity securities pursuant to the Sales Agreement or otherwise, or the perception that such sales 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.

***The employment agreements with our executive officers may require us to pay severance benefits to officers in connection with termination of employment or upon a change of control of us, which could harm our financial condition.***

Each of our executive officers is entitled to receive a lump sum payment equal to one year or more of his or her base salary as well as continued medical and dental coverage for a period of one year or more plus a prorated portion of his or her target annual bonus for the calendar year in which his or her employment is terminated following his or her termination of employment due to good reason or without cause. In the event of a change in control and a termination of employment without cause or due to good reason, each of our executive officers would similarly receive one year or more of his or her base salary as well as continued medical and dental coverage for a period of one year or more, as well as an additional lump sum payment equal to 100% or more of his or her target annual bonus for the calendar year in which his or her employment is terminated and full vesting of his or her outstanding option awards. The accelerated vesting of options could result in dilution to our existing stockholders and harm the market price of our common stock. Furthermore, the payment of these severance benefits could harm our financial condition. In addition, these potential severance payments may discourage or prevent third parties from seeking a business combination with us.

***An active market for our common stock may not be maintained.***

Prior to our IPO in October 2015, there had been no public market for shares of our common stock. Our stock began trading on the Nasdaq Global Select Market in 2015, and we can provide no assurance that we will be able to maintain an active trading market on The Nasdaq Global Select Market or any other exchange in the future. If an active market for our common stock is not maintained, it may be difficult to sell shares without depressing the market price for the shares or at all. An inactive market may also impair our ability to raise capital by selling shares and may impair our ability to acquire other businesses, applications or technologies using our shares as consideration.

***Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.***

As of June 30, 2022, our executive officers, directors, holders of 5% or more of our capital stock based on publicly available filings made with the SEC and their respective affiliates beneficially owned approximately 37% of our outstanding common stock. Therefore, these stockholders have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that our stockholders may feel are in their best interest.

***Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.***

Provisions in our amended and restated certificate of incorporation and our amended and restated bylaws may delay or prevent an acquisition of us or a change in our management. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or

remove our current management by making it more difficult for stockholders to replace members of our board of directors. Because our board of directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt by our stockholders to replace current members of our management team. These provisions include:

- a prohibition on actions by our stockholders by written consent;
- a requirement that special meetings of stockholders, which our company is not obligated to call more than once per calendar year, be called only by the chairman of our board of directors, our chief executive officer, our board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors, or, subject to certain conditions, by our secretary at the request of the stockholders holding of record, in the aggregate, shares entitled to cast not less than ten percent of the votes at a meeting of the stockholders (assuming all shares entitled to vote at such meeting were present and voted);
- advance notice requirements for election to our board of directors and for proposing matters that can be acted upon at stockholder meetings;
- division of our board of directors into three classes, serving staggered terms of three years each; and
- the authority of the board of directors to issue preferred stock with such terms as the board of directors may determine.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, as amended, which prohibits a person who owns in excess of 15 percent of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15 percent of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. These provisions would apply even if the proposed merger or acquisition could be considered beneficial by some stockholders.

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

As a public company, we incur significant legal, accounting and other expenses. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The Nasdaq Global Select Market 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 need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, which in turn could make it more difficult for us to attract and retain qualified members of our board of directors. However, these rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

***If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act of 2002 in a timely manner or with adequate compliance, we may be subject to sanctions by regulatory authorities.***

Section 404 of the Sarbanes-Oxley Act of 2002 requires that we evaluate and determine the effectiveness of our internal controls over financial reporting and provide a management report on the internal control over financial reporting. If we have a material weakness in our internal controls over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. We evaluate our internal controls systems to allow management to report on the effectiveness of the operation of our internal controls.

However, if we are not able to comply with the requirements of Section 404, or if we or our independent registered public accounting firm identify deficiencies in our internal controls that are deemed to be material weaknesses, we could be subject to sanctions or investigations by The Nasdaq Global Select Market, the SEC or other regulatory authorities, which would entail expenditure of additional financial and management resources and could materially adversely affect our stock price. Deficient internal controls could also cause us to fail to meet our reporting obligations or cause investors to lose confidence in our reported financial information, which could have a negative effect on our stock price.

***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.



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

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an “ownership change,” generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period, the corporation’s ability to use its pre-change NOL and other pre-change tax attributes, such as research and development tax credits, to offset its post-change income or taxes may be limited. We may have experienced ownership changes in the past and may experience ownership changes as a result of subsequent shifts in our stock ownership, some of which are outside our control. As a result, our ability to use our pre-change NOLs and tax credits to offset post-change taxable income, if any, could be subject to limitations. Similar provisions of state tax law may also apply. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. For example, California recently imposed limits on the usability of California state NOLs and tax credits to offset California taxable income in tax years beginning after 2019 and before 2023. As a result, even if we attain profitability, we may be unable to use a material portion of our NOLs and tax credits.

***We may incur significant costs from class action litigation due to our expected stock volatility.***

Our stock price may fluctuate for many reasons, including as a result of public announcements regarding the progress of our development efforts or the development efforts of future collaborators or competitors, the addition or departure of our key personnel, variations in our quarterly operating results and changes in market valuations of biopharmaceutical and biotechnology companies.

This risk is especially relevant to us because biopharmaceutical and biotechnology companies have experienced significant stock price volatility in recent years. When the market price of a stock has been volatile as our stock price may be, holders of that stock have occasionally brought securities class action litigation against the company that issued the stock. For example, in May 2020, a putative securities class action lawsuit was brought against us (“Class Action Lawsuit”). While the Class Action Lawsuit was voluntarily dismissed without prejudice by the plaintiff and his attorneys in January 2021, a similar lawsuit or another lawsuit could be filed in the future. Stockholder lawsuits of this type against us, even if it is without merit, could cause us to incur substantial costs defending the lawsuit. The lawsuit could also divert the time and attention of our management.

***Our amended and restated bylaws designate the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders’ ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.***

Our amended and restated bylaws provide that, subject to limited exceptions, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for any derivative action or proceeding brought on our behalf, 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, any action asserting a claim against us arising pursuant to any provision of the Delaware General Corporation Law, as amended, our amended and restated certificate of incorporation or our amended and restated bylaws, any action to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or our amended and restated bylaws or any other action asserting a claim against us that is governed by the internal affairs doctrine. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our amended and restated certificate of incorporation described above. This choice of forum provision may limit a stockholder’s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and employees. Alternatively, if a court were to find these provisions of our amended and restated certificate of incorporation inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business and financial condition.

**General Risk Factors**

***We may acquire assets or form strategic alliances in the future, and we may not realize the benefits of such acquisitions.***

As we continue to mature our Probody platform and our clinical stage pipeline, we may seek to acquire and/or in-license other oncology products, product candidates, programs or companies that we consider complimentary to our efforts. Such efforts may never result in a transaction and any future growth through acquisition or in-licensing will depend upon the availability of suitable products, product candidates, programs or companies for acquisition or in-licensing on acceptable prices, terms and conditions. Even if appropriate opportunities are available, we may not be able to acquire rights to them on acceptable terms, or at all. The competition to acquire or in-license rights to promising products, product candidates, programs and companies is fierce, and many of our competitors are large, multinational pharmaceutical and biotechnology companies with considerably more financial, development and commercialization resources, personnel, and experience than we have. In order to compete successfully in the current business climate, we may have to pay higher prices for assets than may have been paid historically, which may make it more difficult for us to realize an adequate return on any acquisition. In

addition, even if we succeed in identifying promising products, product candidates, programs or companies, we may not have the ability to develop, obtain regulatory approval for and commercialize such opportunities, or the financial resources necessary to pursue them.

Even if we are able to successfully identify and acquire or in-license new products, product candidates, programs or companies, we may not be able to successfully manage the risks associated with integrating any products, product candidates, programs or companies into our business or the risks arising from anticipated and unanticipated problems in connection with an acquisition or in-licensing. Further, while we seek to mitigate risks and liabilities of potential acquisitions through, among other things, due diligence, there may be risks and liabilities that such due diligence efforts fail to discover, that are not disclosed to us, or that we inadequately assess. Any failure in identifying and managing these risks and uncertainties effectively would have a material adverse effect on our business. In any event, we may not be able to realize the anticipated benefits of any acquisition or in-licensing for a variety of reasons, including the possibility that a product candidate fails to advance to clinical development, proves not to be safe or effective in clinical trials, or fails to reach its forecasted commercial potential or that the integration of a product, product candidate, program or company gives rise to unforeseen difficulties and expenditures. Any failure in identifying and managing these risks and uncertainties would have a material adverse effect on our business.

In addition, acquisitions create other uncertainties and risks, particularly when the acquisition takes the form of a merger or other business consolidation. We may encounter unexpected difficulties, or incur unexpected costs, in connection with transition activities and integration efforts, which include:

- high acquisition costs;
- the need to incur substantial debt or engage in dilutive issuances of equity securities to pay for acquisitions;
- the potential disruption of our historical business and our activities under our collaboration agreements;
- the strain on, and need to expand, our existing operational, technical, financial and administrative infrastructure;
- our lack of experience in late-stage product development and commercialization;
- the difficulties in assimilating employees and corporate cultures;
- the difficulties in hiring qualified personnel and establishing necessary development and/or commercialization capabilities;
- the failure to retain key management and other personnel;
- the challenges in controlling additional costs and expenses in connection with and as a result of the acquisition;
- the need to write down assets or recognize impairment charges;
- the diversion of our management's attention to integration of operations and corporate and administrative infrastructures; and
- any unanticipated liabilities for activities of or related to the acquired business or its operations, products or product candidates.

If we fail to integrate or otherwise manage an acquired business successfully and in a timely manner, resulting operating inefficiencies could increase our costs more than we planned, could negatively impact the market price of our common stock and could otherwise distract us from execution of our strategy. Failure to maintain effective financial controls and reporting systems and procedures could also impact our ability to produce timely and accurate financial statements.

***Our future growth may depend, in part, on our ability to operate in foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.***

Our future growth may depend, in part, on our ability to develop and commercialize our product candidates in foreign markets for which we may rely on collaboration with third parties. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the applicable regulatory authority in that foreign market, and we may never receive such regulatory approval for any of our product candidates. To obtain separate regulatory approval in many other countries we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of our product candidates, and we cannot predict success in these jurisdictions. If we obtain approval of our product candidates and ultimately commercialize our product candidates in foreign markets, we would be subject to the risks and uncertainties, including the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements and the reduced protection of intellectual property rights in some foreign countries. We may need to rely on third parties to market, distribute and sell our products in foreign markets.

***Our information technology systems, or those of our CROs or other contractors or consultants we may utilize, may fail, suffer disruptions or suffer security breaches, which could result in a material disruption of our product development programs.***

We are increasingly dependent on information technology systems and infrastructure, including mobile technologies, to operate our business. In the ordinary course of our business, we collect and store confidential and sensitive electronic information on our networks and in our data centers. This information includes, among other things, our intellectual property and proprietary information, the confidential information of our collaborators and licensees, and the personally identifiable information of our employees. It is important to our operations and business strategy that this electronic information remains secure and is perceived to be secure. Our information technology and other internal infrastructure systems and those of our CROs and contractors and consultants are vulnerable to damage and interruption from computer viruses, unauthorized access, natural disasters, terrorism, war, telecommunication and electrical failures, hacking, cyberattacks, phishing attacks and other social engineering schemes, malicious code, employee theft or misuse, human error, fraud, denial or degradation of service attacks, sophisticated nation-state and nation-state-supported actors or unauthorized access or use by persons inside our organization, or persons with access to systems inside our organization. A system interruption or security breach that leads to disclosure or modification of or prevents access to personally identifiable information or other protected information could harm our reputation, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, require us to verify the correctness of database contents and otherwise subject us to liability under laws and regulations that protect personal data, resulting in increased costs or loss of revenue. Similarly, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

Attacks upon information technology systems are also increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. As a result of the COVID-19 pandemic and resulting shelter-in-place and stay-at-home restrictions, we may also face increased cybersecurity risks due to our dependency on remote working technology and electronic monitoring of clinical trial sites, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data, or inappropriate disclosure of confidential or proprietary information, we could incur liability, recovery of our data could take a prolonged period of time, and the development of our research or product candidates could be delayed.

As cyber threats continue to evolve, we may be required to expend significant additional resources to continue to modify or enhance our protective measures or to investigate and remediate any information security vulnerabilities. While we have implemented security measures to protect our data security and information technology systems, such measures may not prevent such events. Significant disruptions of our information technology systems or breaches of data security could have a material adverse effect on our business, financial condition and results of operations.

***The ongoing armed conflict between Russia and Ukraine could adversely affect our business, financial condition, and results of operations.***

On February 24, 2022, Russian military forces launched a military action in Ukraine, and sustained conflict and disruption in the region is likely. The length, impact, and outcome of this ongoing military conflict is highly unpredictable, and could lead to significant market and other disruptions, including significant volatility in commodity prices and supply of energy resources, instability in financial markets, supply chain interruptions, political and social instability, trade disputes or trade barriers, changes in consumer or purchaser preferences, as well as an increase in cyberattacks and espionage.

Russia's recognition of two separatist republics in the Donetsk and Luhansk regions of Ukraine and subsequent military action against Ukraine have led to substantial expansion of sanction programs imposed by the United States, the European Union, the United Kingdom, Canada, Switzerland, Japan, and other countries against Russia, Belarus, the Crimea Region of Ukraine, the so-called Donetsk People's Republic, and the so-called Luhansk People's Republic, including, among others:

- blocking sanctions against some of the largest state-owned and private Russian financial institutions (and their subsequent removal from the Society for Worldwide Interbank Financial Telecommunication (SWIFT) payment system) and certain Russian businesses, some of which have significant financial and trade ties to the European Union;
- blocking sanctions against Russian and Belarusian individuals, including the Russian President, other politicians, and those with government connections or involved in Russian military activities; and
- blocking of Russia's foreign currency reserves as well as expansion of sectoral sanctions and export and trade restrictions, limitations on investments and access to capital markets, and bans on various Russian imports.

In retaliation against new international sanctions and as part of measures to stabilize and support the volatile Russian financial and currency markets, the Russian authorities also imposed significant currency control measures aimed at restricting the outflow of foreign currency and capital from Russia, imposed various restrictions on transacting with non-Russian parties, banned exports of various products, and imposed other economic and financial restrictions. The situation is rapidly evolving, additional sanctions by Russia on the one hand, and by the other countries on the other hand, could adversely affect the global economy, financial markets, energy supply and prices, certain critical materials and metals, supply chains, and global logistics and could adversely affect our business, financial condition, and results of operations.

We are actively monitoring the situation in Ukraine and Russia and assessing its impact on our business, including our business partners and customers. To date we have not experienced any material interruptions in our infrastructure, supplies, technology systems, or networks needed to support our operations. We have no way to predict the progress or outcome of the military conflict in Ukraine or its impacts in Ukraine, Russia, Belarus, Europe, or the U.S. The extent and duration of the military action, sanctions, and resulting market disruptions could be significant and could potentially have substantial impact on the global economy and our business for an unknown period of time.

***If we do not comply with laws regulating the protection of the environment and health and human safety, our business could be adversely affected.***

Our research and development activities involve the use of hazardous materials and various chemicals. We maintain quantities of various flammable and toxic chemicals in our facilities in South San Francisco, California that are required for our research and development activities. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. We believe our procedures for storing, handling and disposing these materials in our South San Francisco facilities comply with the relevant guidelines of South San Francisco, the state of California and the Occupational Safety and Health Administration of the U.S. Department of Labor. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards mandated by applicable regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. If an accident occurs, we could be held liable for resulting damages, which could be substantial. We are also subject to numerous environmental, health and workplace safety laws and regulations, including those governing laboratory procedures, exposure to blood-borne pathogens and the handling of animals and biohazardous materials. 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 these materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological or hazardous materials. Additional federal, state and local laws and regulations affecting our operations may be adopted in the future. We may incur substantial costs to comply with, and substantial fines or penalties if we violate, any of these laws or regulations.

***Changes in U.S. or foreign tax laws or regulations that are applied adversely to us may have a material adverse effect on our business, cash flow, financial condition or results of operations.***

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business and financial condition. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act (the "Tax Act"), enacted many significant changes to the U.S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to the Tax Act may affect us, and certain aspects of the Tax Act could be repealed or modified in future legislation. Changes in applicable tax rules, including changes to corporate tax rates, the realization of net deferred tax assets relating to our operations, the taxation of foreign earnings, and the deductibility of expenses under future reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future tax expense.

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

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. If any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our target studies and operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

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

### ***Recent Sales of Unregistered Equity Securities***

None

***Use of Proceeds***

None

***Repurchases of Shares or of Company Equity Securities***

None

**Item 3. Defaults Upon Senior Securities.**

None

**Item 4. Mine Safety Disclosures.**

Not applicable

**Item 5. Other Information.**

None

**Item 6. Exhibits**

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
3.1	<a href="#">Amended and Restated Certificate of Incorporation.</a>	8-K	10/19/2015	3.1	
3.2	<a href="#">Certificate of Amendment to Amended and Restated Certificate of Incorporation of CytomX Therapeutics, Inc.</a>	8-K	6/23/2020	3.1	
3.3	<a href="#">Amended and Restated Bylaws.</a>	8-K	10/19/2015	3.2	
4.1	Reference is made to Exhibits 3.1 through 3.2.				
4.2	<a href="#">Specimen Common Stock Certificate</a>	S-1/A	9/28/2015	4.1	
31.1	<a href="#">Certification of Chief Executive Officer required by Rule 13a-14(a) or Rule 15d-14(a).</a>				X
31.2	<a href="#">Certification of Chief Financial Officer required by Rule 13a-14(a) or Rule 15d-14(a).</a>				X
32.1*	<a href="#">Certification of Chief Executive Officer required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350).</a>				X
32.2*	<a href="#">Certification of Chief Financial Officer required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350).</a>				X
101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document				X
101.SCH	Inline XBRL Taxonomy Extension Schema Document.				X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document				X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.				X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.				X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.				X
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)				X

\* The certifications attached as Exhibit 32.1 and 32.2 that accompany this Quarterly Report on Form 10-Q are not deemed filed with the SEC and are not to be incorporated by reference into any filing of CytomX Therapeutics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Form 10-Q, irrespective of any general incorporation language contained 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 hereunto duly authorized.

**CytomX Therapeutics, Inc.**

Date: August 4, 2022

By: \_\_\_\_\_  
*/s/ Sean A. McCarthy*  
**Sean A. McCarthy, D. Phil.**  
**Chief Executive Officer and Chairman**  
*(Principal Executive Officer)*

Date: August 4, 2022

By: \_\_\_\_\_  
*/s/ Carlos Campoy*  
**Carlos Campoy**  
**Chief Financial Officer**  
*(Principal Financial Officer and Principal Accounting Officer)*

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

I, Sean A. McCarthy, Chief Executive Officer of CytomX Therapeutics, Inc., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of CytomX 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 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 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 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: August 4, 2022

By: /s/ Sean A. McCarthy  
Name: Sean A. McCarthy, D. Phil.  
Title: Chief Executive Officer

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

I, Carlos Campoy, Chief Financial Officer of CytomX Therapeutics, Inc., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of CytomX 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 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 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 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: August 4, 2022

By: /s/ Carlos Campoy  
Name: Carlos Campoy  
Title: Chief Financial Officer

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**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 CytomX Therapeutics, Inc. (the "Company") on Form 10-Q for the quarter ended June 30, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Sean A. McCarthy, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (the "Act"), 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: August 4, 2022

By: /s/ Sean A. McCarthy  
Name: Sean A. McCarthy, D. Phil.  
Title: Chief Executive Officer

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of CytomX Therapeutics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.

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**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 CytomX Therapeutics, Inc. (the "Company") on Form 10-Q for the quarter ended June 30, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Carlos Campoy, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (the "Act"), 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: August 4, 2022

By: /s/ Carlos Campoy

Name: Carlos Campoy

Title: Chief Financial Officer

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of CytomX Therapeutics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.

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