UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2022

OR

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

For the transition period from _____ to _____

Commission File Number: 001-39485

TANGO THERAPEUTICS, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**85-1195036**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
100 Binney St., Suite 700 Cambridge, MA	**02142**
(Address of principal executive offices)	**(Zip Code)**

(857) 320-4900
(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, par value $0.001 per share	TNGX	Nasdaq Global Market

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

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

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

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

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

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

As of May 2, 2022, the registrant had 87,897,475 shares of common stock, $0.001 par value per share, outstanding.

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Summary of Material Risks Associated with Our Business

Our business is subject to numerous material and other risks that you should be aware of before making an investment decision. These risks are described more fully in the section of this Quarterly Report on Form 10-Q entitled "*Risk Factors*." These risks include, among others, the following:

- We are a precision oncology company with a limited operating history. We have no products approved for commercial sale, have not generated any revenue from product sales and may never become profitable.
- We have incurred significant net losses since our inception and anticipate that we will continue to incur losses for the foreseeable future.
- We will need to raise substantial additional funding. If we are unable to raise capital when needed or on terms acceptable to us, we would be forced to delay, reduce or eliminate some of our product development programs or commercialization efforts.
- We have never successfully completed any clinical trials and we may be unable to do so for any product candidates we develop. Certain of our programs are still in preclinical development and may never advance to clinical development.
- Our programs are focused on the development of oncology therapeutics for patients with genetically defined or biomarker-driven cancers, which is a rapidly evolving area of science, and the approach we are taking to discover and develop drugs is novel and may never lead to approved or marketable products.
- If we are unable to successfully validate, develop and obtain regulatory approval for companion diagnostic tests for our product candidates that require or would commercially benefit from such tests, or experience significant delays in doing so, we may not realize the full commercial potential of these product candidates.
- Clinical product development involves a lengthy and expensive process, with an uncertain outcome. Further, our current and potential future collaborations may not realize the anticipated benefits.
- Interim, top-line, and preliminary data from our future clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to confirmation, audit and verification procedures that could result in material changes in the final data.
- Results from early preclinical studies of our programs and product candidates are not necessarily predictive of the results of later preclinical studies and clinical trials of our programs and product candidates. If we cannot replicate the results from our earlier preclinical studies of our programs and product candidates in our later preclinical studies and clinical trials, we may be unable to successfully develop, obtain regulatory approval for and commercialize our product candidates.
- If we experience delays or difficulties in the initiation or enrollment of patients in clinical trials, the announcement of clinical trial results and our receipt of necessary regulatory approvals (if any) could be delayed or prevented.
- Our clinical trials or those of our current or future collaborators may reveal significant adverse events not seen in our preclinical or nonclinical studies and may result in a safety profile that could inhibit regulatory approval or market acceptance of any of our product candidates.
- Some of our product candidates modulate pathways for which there are currently no approved or effective therapies, and utilize novel binding locations, which may result in greater research and development expenses, regulatory issues that could delay or prevent approval, or discovery of unknown or unanticipated adverse effects.
- If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for our product candidates, we will not be able to commercialize, or will be delayed in commercializing, our product candidates, and our ability to generate revenue will be materially impaired.

- The COVID-19 pandemic, or a similar pandemic, epidemic, or outbreak of an infectious disease, may materially and adversely affect our business and our financial results and could cause a disruption to the development of our product candidates and the initiation and completion of clinical trials.

- We expect to rely on third parties to conduct our future clinical trials, as well as investigator-sponsored clinical trials of our product candidates. If these third parties do not successfully carry out their contractual duties, comply with regulatory requirements or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

- We contract with third parties for the manufacture of our product candidates for preclinical development and expect to continue to do so for clinical testing and commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

- The third parties upon whom we rely for the supply of the active pharmaceutical ingredients and drug product to be used in our product candidates are our sole source of supply, and the loss of any of these suppliers could significantly harm our business.

- If we are unable to obtain and maintain patent and other intellectual property protection for our technology and product candidates or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and drugs similar or identical to ours, and our ability to successfully commercialize our technology and drugs may be impaired.

- We may be subject to damages or settlement costs resulting from claims that we or our employees have violated the intellectual property rights of third parties, or are in breach of our agreements.

Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q contains express or implied forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). Words such as "anticipates," "continue," "could," "may," "forecasts," "expects," "intends," "plans," "potentially," "believes," "seeks," "estimates," "predict," "target," and variations of such words and similar expressions are intended to identify such forward-looking statements, although not all forward-looking statements contain these identifying words. Forward-looking statements are not guarantees of future performance and are subject to certain risks, uncertainties, and assumptions that are difficult to predict; therefore, actual results may differ materially from those expressed or forecasted in any such statements. Such forward-looking statements are based on current expectations, estimates and projections about our industry and business, management's beliefs, and certain assumptions made by our management, and may include, but are not limited to, statements regarding:

- the initiation, timing, progress, results, and cost of our research and development programs and our current and future preclinical studies and clinical trials, including statements regarding the timing of initiation and completion of studies or clinical trials and related preparatory work, the period during which the results of the clinical trials will become available, and our research and development programs;

- our ability to discover and develop product candidates efficiently (including the advancement of development candidates on the timelines identified);

- our ability and the potential to manufacture our drug substances and product candidates successfully for preclinical use, for clinical trials and on a larger scale for commercial use, if approved;

- the ability and willingness of our third-party strategic collaborators to continue research and development activities relating to our development candidates and product candidates;

- our ability to obtain funding for our operations necessary to complete further development and commercialization of our product candidates (and that existing cash, cash equivalents and marketable securities will enable us to fund our operating expenses and capital expenditure requirements at least into the second half of 2024);

- our ability to obtain and, if approved, maintain regulatory approval of our product candidates;

- our ability to commercialize our products, if approved;
- the pricing and reimbursement of our product candidates, if approved;
- the implementation of our business model, and strategic plans for our business and product candidates;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates;
- estimates of our future expenses, capital requirements, and our need for additional financing;
- the potential benefits of strategic collaboration agreements, our ability to enter into strategic collaborations or arrangements, and our ability to attract collaborators with development, regulatory and commercialization expertise;
- future agreements with third parties in connection with the commercialization of product candidates (if approved) and any other approved products;
- the size and growth potential of the markets for our product candidates, and our ability to serve those markets;
- our financial performance, including the expectation that we will continue to incur operating losses and negative cash flow;
- the rate and degree of market acceptance of our product candidates;
- regulatory developments in the United States and foreign countries;
- our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately;
- our ability to produce our products or product candidates with advantages in turnaround times or manufacturing cost;
- the success of competing therapies that are or may become available;
- our ability to attract and retain key scientific or management personnel;
- the impact of laws and regulations;
- developments relating to our competitors and industry;
- the effect of the on-going COVID-19 pandemic, including mitigation efforts and economic effects, on any of the foregoing or other aspects of our business operations, including but not limited to our preclinical studies and clinical trials and any future studies or trials; and
- other risks and uncertainties, including those listed in this Quarterly Report on Form 10-Q under the section titled “Risk Factors.”

The forward-looking statements contained in this Quarterly Report on Form 10-Q are based on current expectations and beliefs concerning future developments and their potential effects on us. There can be no assurance that future developments affecting us will be those that we have anticipated. These forward-looking statements involve a number of risks, uncertainties (some of which are beyond our control) or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to, those factors described under the heading “Risk Factors” in Part II, Item 1A of this Quarterly Report on Form 10-Q. Should one or more of these risks or uncertainties materialize, or should any of our assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements. Some of these risks and uncertainties may in the future be amplified by the COVID-19 outbreak and there may be additional risks that we consider immaterial or which are unknown. It is not possible to predict or identify

all such risks. We do not undertake any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws.

Corporate Information and Corporate Website

We were formerly known as BCTG Acquisition Corp. ("BCTG") and were incorporated in Delaware May 2020 as a special purpose acquisition company, formed for the purpose of effecting a merger, capital stock exchange, asset acquisition, stock purchase, reorganization or other similar business. On August 10, 2021, we consummated the merger pursuant to the Agreement and Plan of Merger, dated as of April 13, 2021, by and among BCTG, BCTG Merger Sub Inc. and Tango Therapeutics Sub, Inc. Upon the consummation of the merger, we changed our name to "Tango Therapeutics, Inc."

Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, including exhibits, proxy and information statements and amendments to those reports filed or furnished pursuant to Sections 13(a), 14, and 15(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, are available through the "Investors" portion of our website free of charge as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission ("SEC"). We also make available, free of charge on our website, the reports filed with the SEC by our executive officers, directors and 10% stockholders pursuant to Section 16 under the Exchange Act as soon as reasonably practicable after copies of those filings are provided to us by those persons. Accordingly, investors should monitor such portions of the company's website, in addition to following the company's press releases, SEC filings and public conference calls and webcasts (if any). Information on our website is not to be deemed to be incorporated by reference in, and is not part of, this Quarterly Report on Form 10-Q or any of our other securities filings, unless specifically incorporated herein by reference, and should not be relied upon in making a decision as to whether or not to purchase our common stock. Our filings with the SEC may be accessed through the SEC's Interactive Data Electronic Applications system at http://www.sec.gov. All statements made in any of our securities filings, including all forward-looking statements or information, are made as of the date of the document in which the statement is included, and we do not assume or undertake any obligation to update any of those statements or documents unless we are required to do so by law.

Further, the company intends to use its website http://www.tangotx.com as a means of disclosing material non-public information and for complying with its disclosure obligations under the SEC Regulation FD. Such disclosures will be included on the company's website under the heading "Investors." Accordingly, investors should monitor such portions of the company's website, in addition to following the company's press releases, SEC filings and public conference calls and webcasts.. The information contained on, or that may be accessed through, the website is not part of, and is not incorporated into, this Quarterly Report on Form 10-Q.

Our principal executive office is located at 100 Binney Street, Suite 700, Cambridge, Massachusetts.

Item 1. Financial Statements.

TANGO THERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share amounts)
(Unaudited)

	March 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 99,909	$ 142,745
Marketable securities	349,976	342,510
Accounts receivable	2,000	2,000
Restricted cash	567	567
Prepaid expenses and other current assets	8,202	4,516
Total current assets	460,654	492,338
Property and equipment, net	6,538	4,832
Operating lease right-of-use assets	894	1,254
Restricted cash, net of current portion	3,423	1,712
Other assets	16	19
Total assets	$ 471,525	$ 500,155
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,367	$ 3,226
Accrued expenses and other current liabilities	9,693	9,887
Operating lease liabilities	1,075	1,503
Deferred revenue	25,024	26,022
Income tax payable	52	52
Total current liabilities	39,211	40,690
Operating lease liabilities, net of current portion	—	—
Deferred revenue, net of current portion	111,958	114,718
Other long-term liabilities	—	—
Total liabilities	151,169	155,408
Commitments and contingencies (Note 8)		
Preferred stock, $0.001 par value; 10,000,000 shares authorized; no shares issued and outstanding as of March 31, 2022 and December 31, 2021, respectively	—	—
Stockholders' equity:		
Common stock, $0.001 par value; 200,000,000 shares authorized at March 31, 2022 and December 31, 2021; 87,709,499 and 87,598,184 shares issued and outstanding as of March 31, 2022 and December 31, 2021, respectively	88	88
Additional paid-in capital	510,222	506,760
Accumulated other comprehensive loss	(3,410)	(765)
Accumulated deficit	(186,544)	(161,336)
Total stockholders’ equity	320,356	344,747
Total liabilities and stockholders’ equity	$ 471,525	$ 500,155

The accompanying notes are an integral part of the unaudited condensed consolidated financial statements.

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

	Three Months Ended March 31,	
	2022	2021
Collaboration revenue	$ 5,758	$ 6,386
Operating expenses:		
Research and development	24,330	15,000
General and administrative	6,807	3,467
Total operating expenses	31,137	18,467
Loss from operations	(25,379)	(12,081)
Other income (expense):		
Interest income	218	104
Other expense, net	(47)	(55)
Total other income, net	171	49
Loss before income taxes	(25,208)	(12,032)
Provision for income taxes	-	(74)
Net loss	$ (25,208)	$ (12,106)
Net loss per common share – basic and diluted	$ (0.29)	$ (0.29)
Weighted average number of common shares outstanding – basic and diluted	87,670,653	41,575,143
Net loss	(25,208)	(12,106)
Other comprehensive (loss) income:		
Unrealized (loss) gain on marketable securities	(2,645)	15
Comprehensive loss	$ (27,853)	$ (12,091)

The accompanying notes are an integral part of the unaudited condensed consolidated financial statements.

TANGO THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY
(in thousands, except share amounts)
(Unaudited)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2021	87,598,184	$ 88	$ 506,760	$ (765)	$ (161,336)	$ 344,747
Exercise of stock options	111,315	—	265	—	—	265
Stock based compensation expense	—	—	3,205	—	—	3,205
Business combination and PIPE financing, issuance costs	—	—	(8)	—	—	(8)
Other comprehensive loss	—	—	—	(2,645)	—	(2,645)
Net loss	—	—	—	—	(25,208)	(25,208)
Balance at March 31, 2022	87,709,499	$ 88	$ 510,222	$ (3,410)	$ (186,544)	$ 320,356

	Series B		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance at December 31, 2020	—	$ —	40,372,133	$ 40	$ 141,644	$ 17	$ (103,101)	$ 38,600
Issuance of Series B redeemable convertible preferred stock, net of issuance costs of $0.1 million	22,686,025	29,990	—	—	—	—	—	—
Retroactive application of recapitalization	(22,686,025)	(29,990)	7,706,861	8	29,982	—	—	29,990
Exercise of stock options	—	—	304,080	1	439	—	—	440
Vesting of restricted common stock awards	—	—	—	—	2	—	—	2
Stock based compensation expense	—	—	—	—	950	—	—	950
Other comprehensive income	—	—	—	—	—	15	—	15
Net loss	—	—	—	—	—	—	(12,106)	(12,106)
Balance at March 31, 2021	—	$ —	48,383,074	$ 49	$ 173,017	$ 32	$ (115,207)	$ 57,891

The accompanying notes are an integral part of the unaudited condensed consolidated financial statements.

TANGO THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)
(Unaudited)

	Three Months Ended March 31,	
	2022	**2021**
Cash flows from operating activities		
Net loss	$ (25,208)	$ (12,106)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	309	204
Noncash operating lease expense	361	242
Stock-based compensation	3,205	950
Other, net	54	58
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(3,687)	(132)
Other long-term assets	4	8
Accounts payable	(359)	2,557
Accrued expenses and other liabilities	(157)	(636)
Operating lease liabilities	(429)	(372)
Deferred revenue	(3,758)	(4,386)
Net cash used in operating activities	(29,665)	(13,613)
Cash flows from investing activities		
Purchase of property and equipment	(1,561)	(165)
Sales and maturities of marketable securities	44,415	40,645
Purchases of marketable securities	(54,571)	(19,868)
Net cash (used in) provided by investing activities	(11,717)	20,612
Cash flows from financing activities		
Proceeds from issuance of preferred stock, net of issuance costs	-	29,998
Proceeds from issuance of common stock upon exercise of stock options	265	439
Payment of Business Combination and PIPE Financing transaction costs	(8)	(26)
Net cash provided by financing activities	257	30,411
Net change in cash, cash equivalents and restricted cash	(41,125)	37,410
Cash, cash equivalents and restricted cash, beginning of period	145,024	30,660
Cash, cash equivalents and restricted cash, end of period	$ 103,899	$ 68,070
Supplemental cash flow information:		
Cash paid for leases	$ 465	$ 452
Supplemental disclosure of noncash investing and financing activity:		
Purchases of property and equipment included in accounts payable and accrued expenses	$ 500	$ 81
Preferred stock issuance costs included in accounts payable and accrued expenses	$ -	$ 8
Merger with BCTG and PIPE financing deferred offering costs included in accounts payable and accrued expenses	$ -	$ 347

The accompanying notes are an integral part of the unaudited condensed consolidated financial statements.

1. Nature of the Business and Basis of Presentation

Tango Therapeutics, Inc. (“Tango” or the “Company”) is a precision oncology company committed to the discovery and development of novel drugs in defined patient populations with high unmet medical need.

Tango Therapeutics, Inc. (together with its consolidated subsidiaries, “Tango” or the “Company”) was incorporated in Delaware on May 21, 2020. On April 13, 2021, the Company, BCTG Merger Sub Inc., a Delaware corporation, and Tango Therapeutics, Inc. (now known as Tango Therapeutics Sub, Inc. or “Old Tango”) signed a definitive merger agreement (the "Merger Agreement"). Pursuant to the Merger Agreement, the business combination ("Business Combination") was approved on August 9, 2021 by shareholders of BCTG Acquisition Corp. ("BCTG"), resulting in BCTG acquiring 100% of Old Tango's issued and outstanding equity securities on August 10, 2021. As a result of the Business Combination, BCTG was renamed Tango Therapeutics, Inc.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in conformity with U.S. GAAP. The year-end balance sheet data was derived from audited financial statements, but does not include all disclosures required by U.S. GAAP. The accompanying unaudited condensed consolidated financial statements reflect the operations of Tango and its wholly owned subsidiaries. All intercompany accounts and transactions have been eliminated. The functional and reporting currency of the Company and its subsidiaries is the U.S. dollar.

In the opinion of management, all adjustments necessary for a fair statement of the financial information, which are of a normal and recurring nature, have been made for the interim periods reported. Results of operations for the three months ended March 31, 2022 and 2021 are not necessarily indicative of the results for the year ending December 31, 2022, any other interim periods, or any future year or period. The unaudited condensed consolidated financial statements for the three months ended March 31, 2022 and 2021 have been prepared on the same basis as and should be read in conjunction with the audited consolidated financial statements and notes included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2021 as filed with the SEC on March 28, 2022.

2. Summary of Significant Accounting Policies

There have been no significant changes from the significant accounting policies disclosed in Note 2, *Summary of Significant Accounting Policies*, of the audited consolidated financial statements and notes included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2021.

Use of Estimates

The preparation of consolidated financial statements requires that the Company make estimates, judgments and assumptions that may affect the reported amounts of assets, liabilities, equity, revenues and expenses and related disclosure of contingent assets and liabilities. Significant estimates and assumptions made in the consolidated financial statements include, but are not limited to, the revenue recognized from collaboration agreements, the valuation of stock-based awards and the accrual for research and development expenses. On an ongoing basis, the Company evaluates its estimates, judgments and methodologies. The Company bases its estimates on historical experience and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets, liabilities and equity and the amount of revenues and expenses. As of the date of issuance of these consolidated financial statements, the Company is not aware of any specific event or circumstance that would require the Company to update estimates, judgments or revise the carrying value of any assets or liabilities. Actual results may differ from these estimates under different assumptions or conditions. Changes in estimates are reflected in reported results in the period in which they become known.

Recently Issued Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies and adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company believes that recently issued standards that are not yet effective will not have a material impact on the Company’s consolidated financial statements.

3. Business Combination

On August 10, 2021 (the "Closing Date"), BCTG, a Delaware corporation and now predecessor of the Company, consummated the Business Combination, pursuant to the Merger Agreement, by and among BCTG, BCTG Merger Sub Inc., a Delaware corporation ("BCTG Merger Sub"), and Old Tango. Prior to consummation of the Business Combination, Old Tango changed its name from “Tango Therapeutics, Inc.” to “Tango Therapeutics Sub, Inc.” and in connection with the Business Combination, BCTG changed its name to “Tango Therapeutics, Inc.” (the former name of Old Tango). Pursuant to the Merger Agreement, on the Closing Date, BCTG Merger Sub merged with and into Old Tango, or the Merger, with Old Tango surviving the Merger as a wholly-owned subsidiary of BCTG, and BCTG changed its name to “Tango Therapeutics, Inc.”, or New Tango.

Pursuant to the terms and conditions of the Merger Agreement, the aggregate consideration paid to Old Tango equity holders upon the closing of the Merger was 55,000,000 shares of New Tango common stock. Subsequent to the closing of the Business Combination, New Tango entered into subscription agreements with certain investors ("PIPE Investors") pursuant to which the PIPE Investors purchased 18,610,000 shares of New Tango common stock at $10.00 per share, for aggregate gross proceeds of $186.1 million, under the PIPE Financing.

The following table summarizes the elements of the net proceeds from the Business Combination and PIPE Financing transaction (in thousands):

	Recapitalization
Cash - BCTG's Trust Account and cash (net of redemptions)	$ 156,013
Cash - PIPE Financing	186,100
Less transaction costs and advisory fees paid	(15,844)
Net cash proceeds from the Business Combination and PIPE Financing	326,269
Add: non-cash net assets assumed from BCTG	3
Net contributions from Business Combination and PIPE Financing	$ 326,272

The following table summarizes the number of shares of common stock outstanding immediately following the consummation of the Business Combination and PIPE Financing transaction:

	Number of Shares
BCTG common shares outstanding prior to the Business Combination	21,377,250
Less redemption of BCTG shares	(1,106,814)
Common shares of BCTG outstanding as of the Business Combination	20,270,436
Shares issued pursuant to the PIPE Financing	18,610,000
Business Combination and PIPE Financing shares	38,880,436
Old Tango common shares (after preferred shares were converted 1-for-1 for common shares)	48,593,803
Total shares of Common Stock immediately after Business Combination consummation	87,474,239

The merger consideration of 55,000,000 shares of New Tango common stock issued to Old Tango equity holders consists of 48,593,803 shares issued in exchange for Old Tango common and preferred shares outstanding, included in the table above, as well as 6,406,197 shares issued in exchange for the Old Tango unvested restricted stock awards and unexercised stock options outstanding immediately prior to the effective time of the Business Combination.

Retroactive Application of Recapitalization

As discussed above, the Business Combination with BCTG, which was consummated on August 10, 2021, is accounted for as a reverse recapitalization of equity structure. Under the reverse recapitalization model, the Business Combination was treated as Old Tango issuing equity for the net assets of BCTG, with no goodwill or intangible assets recorded. Under this method of accounting, BCTG was treated as the “acquired” company for financial reporting purposes. This determination was primarily based on the fact that subsequent to the Business Combination, Old Tango’s stockholders possess a majority of the voting power of the combined company, the combined company comprises all of the ongoing operations of Old Tango, the combined company comprises a majority of the

governing body of Old Tango, and the combined company's senior management comprises all of the senior management of Old Tango.

These unaudited condensed consolidated financial statements contain recasted stockholders' equity balances resulting from the retroactive application of reverse recapitalization accounting in accordance with U.S. GAAP.

Pursuant to the terms of the Merger Agreement, upon the closing of the Business Combination on August 10, 2021 (the "Effective Time"), each share of Old Tango's redeemable convertible preferred stock (the "Preferred Stock") issued and outstanding immediately prior to the Effective Time was converted into a share of the Company's common stock using the exchange ratio of 0.34.

All common shares, as well as previously issued share options and restricted stock awards ("RSAs"), presented in the accompanying unaudited recasted condensed consolidated statements of redeemable convertible preferred stock and stockholders' equity and/or in the related notes are presented on an as-converted basis, converted at the ratio of 0.34. The basic and diluted weighted-average shares of common stock outstanding for the three month period ended March 31, 2021 has been retroactively converted using the exchange ratio of 0.34. The historical proceeds from the issuance of preferred stock, less the par value of the historical preferred shares that were converted into common shares using the 0.34 ratio at the Effective Time, have been reclassified to additional paid in capital for the three month period ended March 31, 2021.

Date	Description	Redeemable Convertible Preferred Stock	Preferred to Common Exchange Ratio	Common Stock Shares	8/10/2021 Merger Recapitalization Exchange Ratio	Recapitalization Common Stock
3/18/2021	Series B (tranche 2)	22,686,025	1.00	22,686,025	0.34	7,706,861

The following table summarizes the weighted-average common shares, basic and diluted, for the three months ended March 31, 2021:

Date	Description	As previously recorded	8/10/2021 Merger Exchange Ratio	Recapitalized Common Stock	Days Outstanding in 2021	% of weighting	Weighted average common shares
3/31/2021	Weighted-average shares, basic and diluted	13,731,583	0.34	4,643,802	89	100%	4,643,802
12/31/2019	Series A shares	55,700,000	0.34	18,922,317	89	100%	18,922,317
4/7/2020	Series B shares	22,686,025	0.34	7,706,443	89	100%	7,706,443
8/17/2020	Series B-1 shares	27,152,255	0.34	9,223,621	89	100%	9,223,621
3/18/2021	Series B shares (tranche 2)	22,686,025	0.34	7,706,861	13	14%	1,078,960
						Weighted average number of common shares outstanding – basic and diluted for the three months ended March 31, 2021	41,575,143

4. Collaboration Agreements

2018 Gilead Agreement

In October 2018, the Company entered into a Research Collaboration and License Agreement (the "2018 Gilead Agreement") with Gilead Sciences, Inc. ("Gilead"). Pursuant to the 2018 Gilead Agreement, the Company performed target discovery and validation activities in accordance with an agreed-upon multi-year research plan. During the initial three-year research term, Gilead had the option to obtain exclusive, worldwide licenses to develop and commercialize up to five validated programs ("Gilead Program License").

In 2018, Gilead paid the Company a $50.0 million non-refundable upfront payment upon the execution of the 2018 Gilead Agreement. The Company was eligible to receive milestone payments of up to $1.7 billion across all programs and royalties on future sales of commercialized products, if any. For up to two programs licensed by Gilead, the Company had the option to co-develop and co-promote certain programs licensed by Gilead in the U.S. and was eligible to receive royalties on ex-U.S. sales.

The Company assessed this arrangement in accordance with ASC 606, *Revenue from Contracts with Customers,* and concluded that the contract counterparty, Gilead, was a customer. The Company identified a single performance obligation under the arrangement consisting of the combination of participating on the joint steering committee and the research and development services provided during the research term. The identified promises were determined to not be individually distinct due to the specialized nature of the early-stage research services to be provided by the Company and the interdependent relationship between the promises. The Company determined that the option for Gilead to extend the term of the arrangement was not priced at a discount, and therefore did not provide Gilead with a material right. This option will be excluded from the transaction price until exercised. At the inception

of the 2018 Gilead Agreement, the Company also determined that the Gilead program license options provided to Gilead did not include a material right.

The total transaction price, subject to variable consideration constraints, was allocated to the combined single performance obligation. The Company determined that the single combined performance obligation is satisfied over time as the customer is simultaneously receiving and consuming the benefit of the Company's performance. The future milestone payments represent variable consideration that is fully constrained at inception of the arrangement as the achievement of the milestone events are highly uncertain.

Amended Gilead Agreement

In August 2020, Gilead made an equity investment of $20.0 million into the Company as a participant in the Company's Series B-1 preferred stock offering. At the time of the original investment, as well as of the March 31, 2022 balance sheet date, Gilead maintains an ownership of less than 10% of the Company's common stock and is thus not considered to be a related party to the Company.

In August 2020, the Company and Gilead also entered into an Amended Research Collaboration and License Agreement (the "Gilead Agreement"), which superseded and replaced the 2018 Gilead Agreement. The Gilead Agreement represents a continuation of the initial target discovery and validation research and development efforts begun under the 2018 Gilead Agreement. Under the Gilead Agreement:

- The Company received upfront, non-refundable consideration of $125.0 million from Gilead upon execution of the Gilead Agreement in 2020;
- The term of the 2018 Gilead Agreement ended on the date the Gilead Agreement was executed. The Gilead Agreement has a research term of seven years;
- Gilead expanded its option to license up to 15 programs for which Gilead may obtain exclusive, worldwide licenses to develop and commercialize therapies, subject to applicable license fees;
- Prior to exercising its option to license a program, Gilead may "extend" such program, in which case Gilead will pay research extension fees and the Company will continue to collaborate with Gilead to discover and develop programs, potentially through early clinical development;
- Gilead has the option to "reserve" a target during which Gilead may: (i) license the target, (ii) "extend" the target, or (iii) decline the target, during the designated reserve target period. If, during the reserve target period Tango elects to work on the reserved target, Tango will retain full rights to the target program and Gilead receives a right of first negotiation in connection with any future partnering or licensing of such target by Tango, if any; and
- For up to five programs licensed by Gilead, the Company has the option to co-develop and co-promote the lead product in the U.S., subject to certain exceptions, and is eligible to receive tiered royalties in the first decile on ex-U.S. sales.

The Company is eligible to receive up to $410.0 million per program in license, research extension, and clinical, regulatory, and commercial milestones and royalties on future sales of commercialized products, if any.

The Gilead Agreement was accounted for as a modification of the 2018 Gilead Agreement under ASC 606 as both the scope and price of the contract were changed under the Gilead Agreement. The additional goods and services to be provided under the Gilead Agreement are not distinct from the combined performance obligation identified under the 2018 Gilead Agreement which was only partially satisfied at the date of contract modification. As such, the Company identified a single combined performance obligation under the Gilead Agreement consisting of the research services and continued participation on the joint steering committee during the research term. As a result, the Company's progress towards completing its research services to Gilead over the seven-year term of the Amended Gilead Agreement was lower than its progress under the three-year term of the 2018 Gilead Agreement and a cumulative catch-up adjustment was recorded during the third quarter of 2020 resulting in a charge of $11.3 million against revenue previously recognized through the date of the Gilead Agreement.

In December 2020 and in September 2021, Gilead elected to extend two programs for a research extension fee of $12.0 million each. The Company determined that the additional goods and services relating to the continued research services were not distinct from the early-stage research services already promised to Gilead under the on-going research plan. Consideration pertaining to each of the research extensions is paid to the Company in equal quarterly installment payments over an agreed upon payment schedule. Although future research installment payments are not payable in the event of scientific failure, the Company determined that the variable consideration of $12.0 million for each of the extensions should not be constrained as the potential for a significant reversal of

cumulative revenue recognized at the contract level is remote, and therefore the research extension consideration was added to the transaction price under the Gilead Agreement.

In April 2021, Gilead licensed a program for an $11.0 million license fee. The $11.0 million license fee was received and recognized as revenue in the second quarter of 2021 since Tango has no continued involvement in the advancement of the program, Gilead can benefit from the license on its own and the license is separately identifiable from the research services.

Gilead Revenue Recognized

The total transaction price allocated to the combined performance obligation under the Gilead Agreement was $199.0 million at March 31, 2022. The total transaction price was comprised of the $50.0 million upfront payment pursuant to the 2018 Gilead Agreement, the $125.0 million upfront payment pursuant to the Gilead Agreement, the $12.0 million payment pursuant to the research extension fee in December 2020, and the $12.0 million payment pursuant to the research extension fee in September 2021. During the three months ended March 31, 2022 and 2021, the Company recognized $5.8 million and $6.4 million, respectively, of collaboration revenue associated with the Gilead Agreements based on performance completed during each period.

The Company reevaluates the transaction price and the total estimated costs expected to be incurred to satisfy the performance obligations at the end of each reporting period and as uncertain events, such as changes to the expected timing and cost of certain research and development activities that the Company is responsible for, are resolved or other changes in circumstances occur. As of March 31, 2022 and December 31, 2021, the Company had short-term deferred revenue of $25.0 million and $26.0 million, respectively, and long-term deferred revenue of $112.0 million and $114.7 million, respectively, related to the Gilead collaboration. The remaining long-term revenue is expected to be recognized proportionally to the completed obligations over an expected remaining contractual term of approximately 5.4 years.

Amounts due to the Company that have not yet been received are recorded as accounts receivable and amounts received that have not yet been recognized as revenue are recorded as deferred revenue on the Company's unaudited condensed consolidated balance sheets. As of March 31, 2022, $4.0 million of the ongoing research extension fee total of $12.0 million had been received, $2.0 million had been recorded as accounts receivable and the remaining $6.0 million was determined to be conditional upon the satisfaction of additional research obligations, and thus a contract asset. The contract asset balance is presented net of the deferred revenue contract liability.

Costs incurred pursuant to the Gilead Agreements are recorded as research and development expense.

5. Fair Value Measurements

The following tables present information about the Company's financial assets measured at fair value on a recurring basis:

	Fair Market Value Measurements as of March 31, 2022			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Cash equivalents:				
Money market funds	$ 13,861	$ —	$ —	$ 13,861
U.S. Treasury bills	—	38,797	—	38,797
Marketable debt securities:				
U.S. Treasury bills	—	290,201	—	290,201
U.S. government agency bonds	—	59,775	—	59,775
Total assets	$ 13,861	$ 388,773	$ —	$ 402,634

	Fair Market Value Measurements as of December 31, 2021			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Cash equivalents				
Money market funds	$ 62,244	$ —	$ —	$ 62,244
U.S. Treasury bills	—	38,433	—	38,433
Marketable debt securities				
U.S. Treasury bills	—	287,123	—	287,123
U.S. government agency bonds	—	55,387	—	55,387
Total assets	$ 62,244	$ 380,943	$ —	$ 443,187

There were no transfers between fair value levels during the three months ended March 31, 2022.

6. Marketable Securities

The Company values its marketable securities using independent pricing services which normally derive security prices from recently reported trades for identical or similar securities, making adjustments based on significant observable transactions. At each balance sheet date, observable market inputs may include trade information, broker or dealer quotes, bids, offers or a combination of these data sources.

The following table summarizes the Company's marketable debt securities, classified as available-for-sale:

	Fair Value Measurements as of March 31, 2022			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Loss	Fair Value
	(in thousands)			
Marketable debt securities:				
U.S. Treasury bills	$ 292,838	$ —	$ (2,637)	$ 290,201
U.S. government agency bonds	60,548	—	(773)	59,775
	$ 353,386	$ —	$ (3,410)	$ 349,976

	Fair Value Measurements as of December 31, 2021			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Loss	Fair Value
	(in thousands)			
Marketable debt securities:				
U.S. Treasury bills	$ 287,699	$ 1	$ (577)	$ 287,123
U.S. government agency bonds	55,576	—	(189)	55,387
	$ 343,275	$ 1	$ (766)	$ 342,510

The Company holds investment grade marketable securities, with $3.4 million of U.S. Treasury bills and U.S. government agency bonds considered to be in an unrealized loss position as of March 31, 2022 and $0.8 million considered to be in an unrealized loss position as of December 31, 2021. Although these marketable securities are held at an unrealized loss position at March 31, 2022, the Company does not intend to sell the marketable securities prior to the value of the securities being recovered. Further, the Company has concluded that it is more likely than not that the marketable securities cost basis values will be recovered prior to sale of the securities and that there are no conditions or events that might require the Company to sell the securities before recovery of the cost basis occurs. As a result, the Company did not record any impairments to marketable securities or reserves for credit losses related to its marketable debt securities during the periods then ended. Marketable securities include $0.2 million in accrued interest at both March 31, 2022 and December 31, 2021.

7. Supplemental Balance Sheet Information

Property and Equipment

Property and equipment, net as of March 31, 2022 and December 31, 2021 consists of the following:

	March 31, 2022	December 31, 2021
	(in thousands)	
Laboratory equipment	$ 5,703	$ 5,587
Computer equipment	198	198
Computer software	125	125
Furniture and fixtures	467	467
Leasehold improvements	246	246
Construction in progress	2,629	738
	9,368	7,361
Less: Accumulated depreciation	(2,830)	(2,529)
Property and equipment, net	$ 6,538	$ 4,832

Depreciation expense was $0.3 million and $0.2 million for the three months ended March 31, 2022 and 2021, respectively.

Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities as of March 31, 2022 and December 31, 2021 include the following:

	March 31, 2022	December 31, 2021
	(in thousands)	
Payroll and employee-related costs	$ 1,352	$ 3,688
Research and development costs	7,441	5,533
Other	900	666
Total accrued expenses and other current liabilities	$ 9,693	$ 9,887

Restricted Cash

As of March 31, 2022 and 2021, the Company maintained a restricted cash balance of $4.0 million and $2.3 million, respectively, all of which was related to security deposits associated with the Company's facility leases. The cash will remain restricted in accordance with the lease agreements absent the event of a lease termination or modification. The reconciliation of cash and cash equivalents and restricted cash to amounts presented in the condensed consolidated statements of cash flows are as follows:

	March 31, 2022	March 31, 2021
	(in thousands)	
Cash and cash equivalents	$ 99,909	$ 65,791
Restricted cash	3,990	2,279
Cash, cash equivalents and restricted cash	$ 103,899	$ 68,070

8. Commitments and Contingencies

Other Funding Commitments

As of March 31, 2022, the Company had ongoing preclinical and clinical studies. The Company enters into contracts in the normal course of business with contract research organizations in preparation for clinical trials, professional consultants for expert advice and other vendors for clinical supply manufacturing or other preclinical services. These contracts are generally cancellable, with notice, at the Company's option and do not have significant cancellation penalties.

Guarantees

The Company enters into certain agreements with other parties in the ordinary course of business that contain indemnification provisions. These typically include agreements with directors and officers, business partners, contractors, landlords, construction companies, contract research organizations and clinical trial sites. Under these provisions, the Company generally indemnifies and holds harmless the indemnified party for losses suffered or incurred by the indemnified party under the terms of the contract, including as a result of the Company's activities. These indemnification provisions generally survive termination of the underlying agreement. The maximum potential amount of future payments the Company could be required to make under these indemnification provisions is unlimited. However, to date the Company has not incurred material costs to defend lawsuits or settle claims related to these indemnification provisions. As a result, the estimated fair value of these obligations is minimal.

Litigation

The Company, from time to time, may be party to litigation arising in the ordinary course of business. The Company was not subject to any material legal proceedings as of March 31, 2022, and no material legal proceedings are currently pending or threatened. Because of uncertainties related to claims, proceedings and litigation, assessments of potential liabilities are based on the Company's best estimates based on information available at the time of the assessment. On a periodic basis, as additional information becomes available, or based on specific events such as the outcome of litigation, court decisions or settlement of claims (and offers of settlement), the Company may reassess the potential liability related to these matters and may revise these estimates, which could result in a material adverse effect on the operating results of the Company. Costs associated with involvement in legal proceedings are expensed as incurred. The outcome of any such proceedings, regardless of the merits, is inherently uncertain. If the Company were to be unable to prevail in any such proceedings, the consolidated financial position, results of operations, and future cash flows of the Company may be materially impacted.

9. Redeemable Convertible Preferred Stock

In March 2021, Old Tango sold 22,686,025 additional shares of Series B stock at a price of $1.32 per share upon the achievement of specified development milestones in connection with the second tranche of the Series B stock purchase agreement. Proceeds from this issuance totaled $30.0 million. Total issuance costs associated with the March 2021 issuance of Series B preferred stock was less than $0.1 million.

Conversion of Redeemable Convertible Preferred Stock

Pursuant to the terms of the Merger Agreement, upon the Effective Time, each share of Old Tango's Preferred Stock issued and outstanding immediately prior to the Effective Time was converted into a share of Old Tango's common stock and subsequently converted into shares of New Tango common stock using an exchange ratio of 0.34. A retroactive adjustment has been applied to all periods presented to reflect the Business Combination and reverse recapitalization, therefore, resulting in no outstanding Preferred Stock as of March 31, 2022 and 2021. Refer to Note 3 for additional discussion.

Undesignated Preferred Stock

The Company's Certificate of Incorporation, as amended and restated, authorizes the Company to issue shares of preferred stock with a par value of $0.001 per share. The number of shares of preferred stock authorized to be issued is 10,000,000 shares as of March 31, 2022. The shares of preferred stock are currently undesignated.

10. Stock-Based Compensation

Stock Incentive Plan

In March 2017, Old Tango's stockholders approved the 2017 Stock Option and Grant Plan, pursuant to which Old Tango issued stock options, restricted stock awards ("RSAs"), unrestricted stock awards, restricted stock units, or any combination of the forgoing to eligible employees, officers, directors, consultants, or other key persons who provide services to the Company.

The 2021 Stock Option and Incentive Plan (the "2021 Plan") became effective upon the closing of the Business Combination and replaced the 2017 Stock Option and Grant Plan. The 2021 Plan allows the Company to make equity and equity-based incentive

awards to officers, employees, non-employee directors and consultants. As of March 31, 2022, the Company had 7,149,519 shares available for future issuance under the 2021 Plan.

The Company recorded stock-based compensation expense in the following expense categories in its accompanying condensed consolidated statements of operations:

	Three Months Ended March 31,	
	2022	2021
	(in thousands)	
Research and development	$ 1,642	$ 460
General and administrative	1,563	490
Total	$ 3,205	$ 950

Stock Option Activity

Pursuant to the terms of the Business Combination, upon the Closing Date, each option to purchase Old Tango's common stock became an option to purchase shares of common stock of the surviving entity and was subsequently adjusted using an exchange ratio of 0.34. A retroactive adjustment has been applied to all periods presented to reflect the Business Combination and reverse recapitalization as discussed further in Note 3.

The following table summarizes the stock option activity for the three months ended March 31, 2022:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Contractual Term	Aggregate Intrinsic Value
			(in years)	
Options outstanding as of December 31, 2021	9,372,993	$ 5.59	8.55	$ 51,415,394
Granted	3,499,675	9.31		
Exercised	(111,315)	2.39		
Cancelled	(19,407)	2.84		
Options outstanding as of March 31, 2022	12,741,946	$ 6.64	8.49	$ 27,139,806
Options exercisable as of March 31, 2022	2,898,853	$ 2.84	6.68	$ 14,120,122

As of March 31, 2022, total unrecognized compensation expense related to stock options was $27.1 million, which the Company expects to recognize over a remaining weighted-average period of 3.1 years.

11. Net Loss Per Share

Basic and diluted net loss per share attributable to common stockholders was calculated as follows:

	Three Months Ended March 31, (in thousands, except per share data)	
	2022	2021
Numerator:		
Net loss	$ (25,208)	$ (12,106)
Denominator:		
Weighted-average common stock outstanding – basic and diluted	87,670,653	41,575,143
Net loss per common share – basic and diluted	$ (0.29)	$ (0.29)

The Company's potential dilutive securities, which include common stock options and unvested restricted common stock, have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted-average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. The Company excluded the following potential common shares, presented based on amounts

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

	March 31,	
	2022	2021
Stock options to purchase common stock	12,741,946	6,445,622
Unvested restricted common stock	—	87,249
Total	12,741,946	6,532,871

12. Income Taxes

The Company's effective income tax rate was 0.0% and -0.6% for the three months ended March 31, 2022 and 2021, respectively. The income tax provision was $0 and $74 thousand for the three months ended March 31, 2022 and 2021, respectively. The change in the provision for income taxes for the three months ended March 31, 2022 compared to the three months ended March 31, 2021 was primarily due to taxable deferred revenue in 2021 partially offset by the utilization of federal and state net operating losses and federal and state tax credits. For 2022, the Company assessed the new requirement to capitalize and amortize research and experimentation expenditures for US tax purposes, which became effective as of January 1, 2022. The Company is forecasting a taxable loss position in 2022 for which no tax benefit is recorded due to the valuation allowance maintained against the Company's deferred tax assets.

The effective income tax rate for the three months ended March 31, 2022 and 2021 differed from the federal statutory rate primarily due to the valuation allowance maintained against the Company's deferred tax assets.

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

The following discussion and analysis of our financial condition and results of operations should be read together with our unaudited condensed consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q and with our audited consolidated financial statements and related notes for the year ended December 31, 2021 included in our Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Quarterly Report on Form 10-Q, our actual results could differ materially from the results described in, or implied by, the forward-looking statements contained in the following discussion and analysis.

Unless otherwise indicated, references in this Management's Discussion and Analysis of Financial Condition and Results of Operations section to "Tango," "we," "us," "our" and other similar terms refer to our wholly-owned subsidiary Tango Therapeutics Sub, Inc. and its subsidiary prior to the closing of the business combination with BCTG Acquisition Corp. and to Tango Therapeutics, Inc. and its consolidated subsidiaries after giving effect to the Business Combination.

Overview

We are a precision oncology company leveraging our state-of-the-art target discovery platform to identify novel targets and develop new drugs directed at tumor suppressor gene loss in defined patient populations with high unmet medical need. Tumor suppressor gene loss remains a largely untouched target space specifically because these genetic events cannot be directly targeted. Empowered by recent advances in CRISPR technology, we are now able to employ a unique functional genomics approach and apply the principles of synthetic lethality to target the loss of specific tumor suppressor genes at scale. We believe this will result in establishing a sustainable pipeline designed to deliver meaningfully clinical benefit to patients. Our novel small molecules are designed to be selectively active in cancer cells with specific tumor suppressor gene loss, killing those cancer cells while being relatively inert in normal cells. We also are extending this target space beyond the classic, cell-autonomous effects of tumor suppressor gene loss to include the discovery of novel targets that reverse the effects of tumor suppressor gene loss that prevent the immune system from recognizing and killing cancer cells (immune evasion). We believe this approach will provide the ability to deliver the deep, sustained target inhibition necessary for prolonged tumor regression and meaningful clinical benefit as a result of the unique ability of synthetic lethal targeting to spare normal cells.

Our lead program, TNG908, a protein arginine methyl transferase 5, or PRMT5, inhibitor is synthetic lethal with MTAP deletion, is being developed as a treatment for cancers with MTAP deletions. MTAP deletions occur in 10% to 15% of all human cancers. In preclinical studies, TNG908 demonstrated 15-fold greater potency in cells with MTAP deletions than those without and showed strong regressions in multiple cancer types. In the first quarter of 2022, the U.S. Food and Drug Administration (FDA) cleared the Investigational New Drug (IND) application for the Phase 1/2 clinical trial and granted Fast Track designation to TNG908. The Phase 1/2 clinical trial is open for enrollment and will evaluate safety and efficacy in multiple indications, with specific cohorts for non-small cell lung cancer, malignant peripheral nerve sheath cancer, mesothelioma, and cholangiocarcinoma, with glioblastoma planned for the dose expansion phase. The clinical trial also includes a histology-agnostic cohort for all other MTAP-deleted solid tumors. We expect to have initial safety and efficacy data in the first half of 2023.

Given the large number of patients with MTAP-deleted cancers, we are investing in our PRMT5 franchise to develop a product candidate with increased potency, MTAP-deletion selectivity, as well as longer target coverage. TNG462, our next-generation PRMT5 inhibitor, is 45-fold more potent in cells with an MTAP deletion than those without and induces deep tumor regressions in preclinical models of multiple cancer types. We plan to file an IND for TNG462 in the first half of 2023. The clinical development path for TNG462 is expected to be similar to TNG908, evaluating safety and efficacy in multiple tumor types in a Phase 1/2 clinical trial. Glioblastoma will be excluded from the clinical trial as TNG462 does not cross the blood-brain barrier in preclinical primate models.

Our development candidate, TNG260, an inhibitor of an undisclosed synthetic lethal target (Target 3), reverses the immune evasion effect of serine-threonine kinase 11 (STK11) loss-of-function mutations. In syngeneic models with an STK11 mutation and an intact immune system, the combination of TNG260 with an anti-PD1 antibody resulted in sustained complete tumor regressions and the induction of immune memory against re-implantation of tumors. We expect to file an IND for TNG260 in 2023.

We are also developing a ubiquitin-specific protease 1, or USP1, inhibitor that is synthetic lethal with BRCA1 and BRCA2-mutant tumors. *In vitro* and *in vivo* preclinical data for USP1 demonstrated potent anti-tumor activity. We expect this molecule to have both single agent activity in PARPi-naïve and PARPi-resistant BRCA1/2 mutant cancers and to synergize with PARP inhibitors. We anticipate declaring a development candidate in the second half of 2022 and filing an IND for this program in 2023.

Business Combination

On April 13, 2021, the Company, BCTG Merger Sub Inc., a Delaware corporation, and Tango Therapeutics, Inc. (now known as Tango Therapeutics Sub, Inc., or "Old Tango") signed a definitive merger agreement, or the Merger Agreement, memorializing the terms of BCTG's acquisition of 100% of Old Tango's issued and outstanding equity securities in exchange for $550.0 million worth of consideration in the form of BCTG common stock, or the Business Combination. The Business Combination was approved on August 9, 2021 by shareholders of BCTG, resulting in BCTG acquiring 100% of our issued and outstanding equity securities on August 10, 2021. Upon the closing of the Business Combination, BCTG Merger Sub Inc. merged with and into Tango, with Tango as the surviving company in the Merger, and BCTG changed its name to "Tango Therapeutics, Inc.", or New Tango. For additional information on the Business Combination, see Note 3 to the unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

We received gross proceeds of $167.1 million upon the closing of the Business Combination. Simultaneous with the closing of the Business Combination, Tango entered into agreements with certain investors, the PIPE Investors, pursuant to which these PIPE Investors purchased 18,610,000 shares of our common stock at $10.00 per share, for aggregate gross proceeds of $186.1 million, upon the closing of the PIPE financing. Total transaction costs and redemptions totaled $26.9 million, resulting in total net proceeds of $326.3 million.

Subject to the terms of the Merger Agreement, at the effective time of the Business Combination, each share of Old Tango redeemable convertible preferred stock issued and outstanding immediately prior to the effective time of the Business Combination was converted into a share of New Tango common stock, at the conversion ratio of 0.34. At the effective time of the Business Combination, each option to purchase Old Tango common stock became an option to purchase shares of New Tango common stock, subject to adjustment in accordance with the exchange ratio.

Financial Overview

Since the Company's inception, we have focused primarily on organizing and staffing our company, business planning, raising capital, discovering product candidates, securing related intellectual property, and conducting research and development activities for our programs. Since our inception, we have funded our operations primarily through equity financings and from the proceeds received from our collaboration agreement with Gilead Sciences, Inc., or Gilead. Since inception, we have raised an aggregate of $166.9 million of gross proceeds from the sale of our preferred shares, $342.1 million in gross proceeds through the closing of the Business Combination and PIPE Financing transactions (as described above) and another $214.1 million through our collaboration with Gilead.

We believe that our existing cash, cash equivalents and marketable securities on hand as of March 31, 2022 of $449.9 million will enable us to fund our operating expenses and capital expenditure requirements at least into the second half of 2024. Since inception, we have incurred significant operating losses. For the three months ended March 31, 2022 and 2021, our net losses were $25.2 million and $12.1 million, respectively. We had an accumulated deficit of $186.5 million as of March 31, 2022. We expect to continue to incur significant and increasing expenses and operating losses for the foreseeable future, as we advance our product candidates through preclinical and clinical development and seek regulatory approvals, manufacture drug product and drug supply, maintain and expand our intellectual property portfolio, as well as hire additional personnel, pay for accounting, audit, legal, regulatory and consulting services, and pay costs associated with maintaining compliance with Nasdaq listing rules and the requirements of the U.S. Securities and Exchange Commission, or SEC, director and officer liability insurance, investor and public relations activities and other expenses associated with operating as a public company. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our preclinical studies, our clinical trials and our expenditures on other research and development activities.

We do not have any product candidates approved for sale and have not generated any revenue from product sales. We will not generate revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for our product candidates, if ever. In addition, if we obtain regulatory approval for our product candidates and do not enter into a third-party commercialization partnership, we expect to incur significant expenses related to developing our commercialization capability to support product sales, marketing, manufacturing and distribution activities. As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of public or private equity offerings and debt financings or other sources, such as potential collaboration agreements, strategic alliances and licensing arrangements. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on acceptable terms, or at all. Our failure to raise capital or enter into such agreements as, and when needed, could have a negative effect on our business, results of operations and financial condition.

Because of the numerous risks and uncertainties associated with pharmaceutical development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate revenues from the sale of our therapies, we may not become profitable. If we fail to become profitable or are unable to

sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce our operations.

Revenue

To date, we have not recognized any revenue from product sales, and we do not expect to generate any revenue from the sale of products in the next several years. If our development efforts for our product candidates are successful and result in regulatory approval, or license agreements with third parties, we may generate revenue in the future from product sales. However, there can be no assurance as to when we will generate such revenue, if at all.

Collaboration Agreements with Gilead Sciences

In October 2018, we entered into a collaboration agreement with Gilead, or the "2018 Gilead Agreement". Pursuant to the terms of the 2018 Gilead Agreement, we received an initial upfront payment of $50.0 million. The upfront payment was initially recorded as deferred revenue on our balance sheet and is recognized as revenue as or when the performance obligation under the contract is satisfied.

In August 2020, the 2018 Gilead Agreement was expanded into a broader collaboration via an amended and restated research collaboration and license agreement, or the "Gilead Agreement". Pursuant to the terms of the Gilead Agreement, we received an upfront payment of $125.0 million. Consistent with the treatment of the previously received upfront payment, this upfront payment was recorded as deferred revenue on our balance sheet and is recognized as revenue as or when the performance obligation under the contract is satisfied.

In December 2020 and September 2021, Gilead elected to extend two programs for research extension fees totaling $24.0 million, which was added to our estimate of the transaction price to total $199.0 million. A total of $8.0 million of fees related to the research extensions have not been received as of March 31, 2022 as these were determined to be conditional upon the satisfaction of additional research obligations, and thus a contract asset, however, we determined that achievement of the entire research extension fees was probable and that a significant reversal in the amount of cumulative revenue recognized would not occur.

In April 2021, Gilead licensed a program for an $11.0 million fee. The $11.0 million license fee was received and recognized as revenue in the second quarter of 2021 since we have no continued involvement in the advancement of the program, Gilead can benefit from the license on its own and the license is separately identifiable from the research services.

As of March 31, 2022, $56.0 million has been recognized as collaboration revenue related to the upfront and research extension payments from the Gilead Agreement.

During the three months ended March 31, 2022 and 2021, we recognized $5.8 million and $6.4 million, respectively, of collaboration revenue associated with the Gilead Agreement based on performance completed during each period.

Refer to Note 4 to our unaudited condensed consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q and our audited consolidated financial statements and related notes for the year ended December 31, 2021 included in our Annual Report on Form 10-K for additional information regarding our revenue recognition accounting policy and our collaboration agreement with Gilead.

Operating Expenses

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for our research activities, including our drug discovery efforts and the development of our product candidates. We expense research and development costs as incurred, which include:

- employee-related expenses, including salaries, bonuses, benefits, stock-based compensation, other related costs for those employees involved in research and development efforts;
- external research and development expenses incurred under agreements with contract research organizations, or CROs, as well as consultants that conduct our preclinical studies and development services;
- costs related to manufacturing material for our preclinical and clinical studies;
- laboratory supplies and research materials;

- costs to fulfill our obligations under the collaboration with Gilead;
- costs related to compliance with regulatory requirements; and
- facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent, utilities and insurance.

Costs for certain activities are recognized based on an evaluation of the progress to completion of specific tasks using data such as information provided to us by our vendors and analyzing the progress of our preclinical studies or other services performed. Significant judgment and estimates are made in determining the accrued expense balances at the end of any reporting period.

Our direct external research and development expenses consist primarily of fees paid to CROs and outside consultants in connection with our preclinical and clinical development and manufacturing activities. Our direct external research and development expenses also include fees incurred under license agreements. We track these external research and development costs on a program-by-program basis once we have identified a product candidate.

We do not allocate employee costs, costs associated with our target discovery efforts, laboratory supplies, and facilities, including depreciation or other indirect costs, to specific programs because these costs are deployed across multiple programs and, as such, are not separately classified. We characterize research and development costs incurred prior to the identification of a product candidate as discovery costs. We use internal resources primarily to conduct our research and discovery activities as well as for managing our preclinical, development and manufacturing activities.

The following table summarizes our research and development expenses:

	Three Months Ended March 31,	
	2022	2021
	(in thousands)	
TNG908 direct program expenses	$ 2,529	$ 2,207
USP1 direct program expenses	2,183	1,468
Discovery direct program expenses	10,485	4,927
Unallocated research and development expenses:		
Personnel related expenses	6,530	3,879
Facilities and other related expenses	2,603	2,519
Total research and development expenses	$ 24,330	$ 15,000

The successful development of our product candidates is highly uncertain. We plan to substantially increase our research and development expenses for the foreseeable future as we continue the development of our product candidates and manufacturing processes and conduct discovery and research activities for our preclinical programs. We cannot determine with certainty the timing of initiation, the duration or the completion costs of current or future preclinical studies and clinical trials of our product candidates or the timing of regulatory filings in connection with clinical trials or regulatory approval, due to the inherently unpredictable nature of preclinical and clinical development. Clinical and preclinical development timelines, the probability of success and development costs can differ materially from expectations. We anticipate that we will make determinations as to which product candidates to pursue and how much funding to direct to each product candidate on an ongoing basis in response to the results of ongoing and future preclinical studies and clinical trials, regulatory developments and our ongoing assessments as to each product candidate's commercial potential. Our clinical development costs are expected to increase significantly as we commence clinical trials. We anticipate that our expenses will increase substantially, particularly due to the numerous risks and uncertainties associated with developing product candidates, including the uncertainty of:

- the scope, rate of progress, and expenses of our ongoing research activities as well as any preclinical studies, clinical trials and other research and development activities;
- establishing an appropriate safety profile with IND enabling studies;
- successful enrollment in and completion of clinical trials;
- whether our product candidates show safety and efficacy in our clinical trials;
- receipt of marketing approvals from applicable regulatory authorities;
- the progress of our collaboration with Gilead;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;

- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- commercializing product candidates, if and when approved, whether alone or in collaboration with others; and
- continued acceptable safety profile of products following any regulatory approval.

Any changes in the outcome of any of these variables with respect to the development of our product candidates in preclinical and clinical development could mean a significant change in the costs and timing associated with the development of these product candidates. We may never succeed in achieving regulatory approval for any of our product candidates. We may obtain unexpected results from our clinical trials. We may elect to discontinue, delay or modify clinical trials of some product candidates or focus on other product candidates. For example, if the U.S. Food and Drug Administration, or FDA, European Medicines Agency, or EMA, or another regulatory authority were to delay our planned start of clinical trials or require us to conduct clinical trials or other testing beyond those that we currently expect or if we experience significant delays in enrollment in any of our planned clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development of that product candidate.

General and Administrative Expenses

General and administrative expense consists primarily of employee related costs, including salaries, bonuses, benefits, stock-based compensation and other related costs. General and administrative expense also includes professional services, including legal, accounting and audit services and other consulting fees as well as facility costs not otherwise included in research and development expenses, insurance and other general administrative expenses.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our continued research activities and development of our product candidates. We also anticipate that we will incur increased accounting, audit, legal, regulatory, compliance and director and officer insurance costs as well as investor and public relations expenses associated with operating as a public company.

Other Income (Expense), Net

Interest Income

Interest income consists of income earned and losses incurred in connection with our investments in money market funds, U.S. Treasury bills and U.S. government agency bonds.

Other Expense, Net

Other expense, net consists of miscellaneous expense unrelated to our core operations.

Provision for Income Taxes

Our provision for income tax consists of an estimate for U.S. federal and state income taxes based on enacted rates, as adjusted for allowable credits, deductions, uncertain tax positions, changes in deferred tax assets and liabilities and changes in tax law. We recorded no provision for income taxes for the three months ended March 31, 2022 and an insignificant provision for income taxes for the three months ended March 31, 2021.

Results of Operations

Comparison of the three months ended March 31, 2022 and 2021

The following table summarizes our results of operations for the three months ended March 31, 2022 and 2021:

	Three Months Ended March 31,		
	2022	2021	Change
	(in thousands)		
Collaboration revenue	$ 5,758	$ 6,386	$ (628)
Operating expenses:			
Research and development	24,330	15,000	9,330
General and administrative	6,807	3,467	3,340
Total operating expenses	31,137	18,467	12,670
Loss from operations	(25,379)	(12,081)	(13,298)
Other income (expense):			
Interest income	218	104	114
Other expense, net	(47)	(55)	8
Total other income, net	171	49	122
Loss before income taxes	(25,208)	(12,032)	(13,176)
Provision for income taxes	—	(74)	74
Net loss	(25,208)	(12,106)	(13,102)
Net loss and comprehensive loss	$ (27,853)	$ (12,091)	$ (15,762)

Collaboration Revenue

Collaboration revenue of $5.8 million and $6.4 million for the three months ended March 31, 2022 and 2021, respectively, was derived from the Gilead collaboration. The decrease of $0.6 million was due to lower research costs incurred under the collaboration during the three months ended March 31, 2022 resulting in lower collaboration revenue recognition.

Research and Development Expenses

Research and development expense was $24.3 million for the three months ended March 31, 2022 compared to $15.0 million for the three months ended March 31, 2021. The increase of $9.3 million was primarily due to a $6.2 million increase in external CRO expenses and lab supplies primarily relating to the advancement of our programs. Additionally, personnel-related costs increased $2.2 million primarily due to an increase of share-based compensation expense and additional headcount to support our research and development activities.

General and Administrative Expenses

General and administrative expense was $6.8 million for the three months ended March 31, 2022 compared to $3.5 million for the three months ended March 31, 2021. The increase of $3.3 million was primarily due to a $2.0 million increase in personnel-related costs due to an increase in share-based compensation expense and additional headcount.

Interest Income

Interest income was $0.2 million for the three months ended March 31, 2022 compared to interest income of $0.1 million for the three months ended March 31, 2021. Interest income and expense was not significant for the three month periods primarily due to low interest rates in each period.

Other Expense, Net

Other expense, net was less than $0.1 million for both the three months ended March 31, 2022 and 2021. Other expense was not significant for both the three months ended March 31, 2022 and 2021.

Provision for Income Taxes

Provision for income taxes was $0 for the three months ended March 31, 2022 compared to $0.1 million for the three months ended March 31, 2021. The tax provision in the period ended March 31, 2021 is primarily attributable to taxable deferred revenue partially offset by the utilization of federal and state net operating losses and federal and state tax credits.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have generated recurring net losses. We have not yet commercialized any product and we do not expect to generate revenue from sales of any products for several years, if at all. Since our inception, we have funded our operations primarily through proceeds from the issuance of equity in the form of stock and from the proceeds received from our collaboration with Gilead. To date, we have raised an aggregate of approximately $166.9 million of gross proceeds from the private placement of preferred shares, $342.1 million of gross proceeds from the Business Combination and PIPE Financing transactions, and $214.1 million through the collaboration with Gilead. As of March 31, 2022, we had cash and cash equivalents and marketable securities of $449.9 million.

Funding Requirements

We believe that our existing cash, cash equivalents and marketable securities on hand as of March 31, 2022 of $449.9 million will enable us to fund our operating expenses and capital expenditure requirements at least into the second half of 2024. We have based this estimate on assumptions that may prove to be wrong, and we could expend our capital resources sooner than we expect.

Cash Flows

Comparison of the three months ended March 31, 2022 and 2021

The following table summarizes our cash flows for each of the nine month periods presented:

	Three Months Ended March 31,		
	2022	2021	Change
	(in thousands)		
Net cash used in operating activities	$ (29,665)	$ (13,613)	$ (16,052)
Net cash (used in) provided by investing activities	(11,717)	20,612	(32,329)
Net cash provided by financing activities	257	30,411	(30,154)
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (41,125)	$ 37,410	$ (78,535)

Operating Activities

Cash flows from operating activities represent the cash receipts and disbursements related to all of our activities other than investing and financing activities. Operating cash flow is derived by adjusting our net loss for non-cash operating items such as depreciation, and stock-based compensation as well as changes in operating assets and liabilities, which reflect timing differences between the receipt and payment of cash associated with transactions and when they are recognized in our results of operations.

Net cash used in operating activities was $29.7 million for the three months ended March 31, 2022 compared to net cash used in operating activities of $13.6 million for the three months ended March 31, 2021. The increase in net cash used in operating activities for the three months ended March 31, 2022 was primarily due to an increase to the net loss as a direct result of higher operating expenses related to the advancement of our programs and personnel-related costs. The increase was partially offset by higher non-cash expenses, including stock compensation.

Investing Activities

Net cash used in investing activities was $11.7 million for the three months ended March 31, 2022 compared to net cash provided by investing activities of $20.6 million for the three months ended March 31, 2021. The increase in net cash used in investing activities was primarily due to an increase in purchases of marketable securities partially offset by increased sales and maturities of marketable securities as compared to the three month period ended March 31, 2021.

Financing Activities

Net cash provided by financing activities was $0.3 million for the three months ended March 31, 2022 compared to net cash provided by financing activities of $30.4 million for the three months ended March 31, 2021. The decrease in net cash provided by financing activities was a result of $30.0 million in net proceeds related to the issuance of shares of redeemable convertible Series B preferred stock in March 2021. The cash provided by financing activities for the three months ended March 31, 2022 was the result of cash provided from the exercises of stock options.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations at March 31, 2022 and the effects that such obligations are expected to have on our liquidity and cash flows in future periods:

	Payments Due by Period				
	Total	Less than 1 Year	1 – 3 Years	3 – 5 Years	More than 5 Years
			(in thousands)		
Operating lease commitments	$ 1,108	$ 1,108	$ —	$ —	$ —
Total	$ 1,108	$ 1,108	$ —	$ —	$ —

The commitment amounts in the table above reflect the minimum payments due under our operating lease for office and laboratory space at our 100 Binney Street, Cambridge, Massachusetts location. These commitments are also recognized as operating lease liabilities in our balance sheet at March 31, 2022. In November 2021, we entered into a lease termination agreement for the leased office and laboratory space at 100 Binney Street in Cambridge, Massachusetts. The lease termination agreement is a modification of the lease agreement for these premises that provides, among other things, the acceleration of the expiration of the original term of the lease from June 30, 2026 to an earlier lease termination date, which earlier date shall be no later than October 15, 2022.

The table does not include the minimum payments due under our new operating lease for office and laboratory space at 201 Brookline Avenue, Boston, Massachusetts as we have not occupied the premises and the lease payments in connection with this lease are yet to commence as of March 31, 2022. Commitments pertaining to the 201 Brookline Avenue lease will be added to the table above, and also recognized as operating lease liabilities on our balance sheet upon achievement of the new lease commencement date. The fixed annual rent payable under the lease is $5.1 million, increasing by 3% annually from the rent commencement date.

Purchase Obligations

In the normal course of business, we enter into contracts with third parties for preclinical studies, clinical operations, manufacturing and research and development supplies. These contracts generally do not contain minimum purchase commitments and provide for termination on notice, and therefore are cancellable contracts. These payments are not included in the table above as the amount and timing of such payments are not known as of March 31, 2022.

License Agreement Obligations

We have also entered into a license agreement under which we may be obligated to make milestone and royalty payments. We have not included future milestone or royalty payments under the agreement in the table above since the payment obligations are contingent upon future events, such as achieving certain development, regulatory, and commercial milestones or generating product sales. As of March 31, 2022 and December 31, 2021, we were unable to estimate the timing or likelihood of achieving these milestones or generating future product sales. Refer to Note 8 of our unaudited condensed consolidated financial statements and related notes in this Quarterly Report on Form 10-Q for a description of our license agreement.

Critical Accounting Policies and Significant Judgments and Estimates

Our consolidated financial statements have been prepared in accordance with U.S. GAAP. The preparation of these consolidated financial statements requires us to make judgments and estimates that affect the reported amounts of assets, liabilities, revenues and expenses, and the disclosure of contingent assets and liabilities in our financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances and at the time these estimates are made, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Some of the judgments and estimates we make can be subjective and complex. Our actual results may differ from these estimates under different

assumptions or conditions. On an ongoing basis, we evaluate our judgments and estimates in light of changes in circumstances, facts, and experience. The effects of material revisions in estimates, if any, will be reflected in the consolidated financial statements prospectively from the date of change in estimates.

While our significant accounting policies are described in more detail in Note 2 to our audited consolidated financial statements and related notes included in our Annual Report on Form 10-K for the year ended December 31, 2021, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our financial statements.

Revenue Recognition

The terms of our collaboration agreements may include consideration such as non-refundable up-front payments, license fees, research extension fees, and clinical, regulatory and sales-based milestones and royalties on product sales.

We recognize revenue under ASC Topic 606, *Revenue from Contracts with Customers*, or ASC 606, which applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. ASC 606 provides a five-step framework whereby revenue is recognized when control of promised goods or services is transferred to a customer at an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. To determine revenue recognition for arrangements that we determine are within the scope of the revenue standard, we perform the following five steps: (i) identify the promised goods or services in the contract; (ii) determine whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measure the transaction price, including the constraint on variable consideration; (iv) allocate the transaction price to the performance obligations; and (v) recognize revenue when (or as) we satisfy each performance obligation. We only apply the five-step model to contracts when collectability of the consideration to which we are entitled in exchange for the goods or services we transfer to the customer is determined to be probable. At contract inception, once the contract is determined to be within the scope of ASC 606, we assess whether the goods or services promised within each contract are distinct and, therefore, represent a separate performance obligation. Goods and services that are determined not to be distinct are combined with other promised goods and services until a distinct bundle is identified. We then allocate the transaction price (the amount of consideration we expect to be entitled to from a customer in exchange for the promised goods or services) to each performance obligation and recognize the associated revenue when (or as) each performance obligation is satisfied. Our estimate of the transaction price for each contract includes all variable consideration to which we expect to be entitled.

We recognize the transaction price allocated to license payments as revenue upon delivery of the license to the customer and resulting ability of the customer to use and benefit from the license, if the license is determined to be distinct from the other performance obligations identified in the contract. If the license is considered to not be distinct from other performance obligations, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied (i) at a point in time, but only for licenses determined to be distinct from other performance obligations in the contract, or (ii) over time; and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from license payments. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

We evaluate whether it is probable that the consideration associated with each milestone payment will not be subject to a significant reversal in the cumulative amount of revenue recognized. Amounts that meet this threshold are included in the transaction price using the most likely amount method, whereas amounts that do not meet this threshold are considered constrained and excluded from the transaction price until they meet this threshold. Milestones tied to regulatory approval, and therefore not within our control, are considered constrained until such approval is received. Upfront and ongoing development milestones under our collaboration agreements are not subject to refund if the development activities are not successful. At the end of each subsequent reporting period, we re-evaluate the probability of a significant reversal of the cumulative revenue recognized for the milestones, and, if necessary, adjust the estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues from collaborators in the period of adjustment. We exclude sales-based milestone payments and royalties from the transaction price until the sale occurs (or, if later, until the underlying performance obligation to which some or all of the royalty has been allocated has been satisfied or partially satisfied), because the license to our intellectual property is deemed to be the predominant item to which the royalties relate as it is the primary driver of value.

ASC 606 requires us to allocate the arrangement consideration on a relative standalone selling price basis for each performance obligation after determining the transaction price of the contract and identifying the performance obligations to which that amount should be allocated. The relative standalone selling price is defined in ASC 606 as the price at which an entity would sell a promised good or service separately to a customer. If other observable transactions in which we have sold the same performance obligation separately are not available, we are required to estimate the standalone selling price of each performance obligation. Key assumptions

to determine the standalone selling price may include forecasted revenues, development timelines, reimbursement rates for personnel costs, discount rates and probabilities of technical and regulatory success.

Whenever we determine that multiple promises to a customer are not distinct and comprise a combined performance obligation that includes services, we recognize revenue over time using the cost-to-cost input method, based on the total estimated cost to fulfill the obligation. Significant management judgment is required in determining the level of effort required under an arrangement and the period over which we are expected to complete our performance obligations under an arrangement.

Consideration that does not meet the requirements to satisfy the above revenue recognition criteria is a contract liability and is recorded as deferred revenue in the consolidated balance sheets. We have recorded short-term and long-term deferred revenue on our consolidated balance sheets based on our best estimate of when such revenue will be recognized. Short-term deferred revenue consists of amounts that are expected to be recognized as revenue in the next 12 months. Amounts that we expect will not be recognized within the next 12 months are classified as long-term deferred revenue.

In certain instances, the timing of and total costs of satisfying these obligations under our collaboration agreement can be difficult to estimate. Accordingly, our estimates may change in the future. Such changes to estimates would result in a change in revenue recognition amounts. If these estimates and judgments change over the course of these agreements, it may affect the timing and amount of revenue that we will recognize and record in future periods.

Under ASC 606, we will recognize revenue when we fulfill our performance obligations under the agreement with Gilead. As the required performance obligation is satisfied, we will recognize revenue for the portion satisfied and record a receivable for any fees that have not been received. Amounts are recorded as short-term collaboration receivables when our right to consideration is unconditional. A contract liability is recognized when a customer prepays consideration or owes payment to an entity in advance of our performance according to a contract. We do not assess whether a contract has a significant financing component if the expectation at contract inception is that the period between payment by the customer and the transfer of the promised goods or services to the customer will be one year or less. We expense incremental costs of obtaining a contract as and when incurred if the expected amortization period of the asset that we would have recognized is one year or less or the amount is immaterial.

Accrued Research and Development Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued research and development expenses. This process involves estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual costs. The majority of our service providers invoice us in arrears for services performed, on a pre-determined schedule or when contractual milestones are met; however, some require advance payments, which would be recorded as a prepaid expense in other assets, or if there is the right of offset, offset against our liability balance with the counterparty. We make estimates of our accrued expenses as of each balance sheet date in the consolidated financial statements based on facts and circumstances known to us at that time. At each period end, we corroborate the accuracy of these estimates with the service providers and make adjustments, if necessary.

We record the expense and accrual related to research and development activities performed by our vendors based on our estimates of the services received and efforts expended considering a number of factors, including our knowledge of the progress towards completion of the research and development activities; invoicing to date under the contracts; communication from the vendors of any actual costs incurred during the period that have not yet been invoiced; and the costs included in the contracts and purchase orders. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we adjust the accrual or prepaid expense accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period. To date, there have not been any material adjustments to our prior estimates of accrued research and development expenses.

Stock-Based Compensation

We estimate the fair value of our stock option awards using the Black Scholes method utilizing the “simplified method,” for determining the expected life of the award, which is based on the mid-point between the vesting date and the end of the contractual term as all options granted after becoming a public entity will be granted “at-the-money.” We determine the volatility for options granted based on an analysis of reported data for a peer group of companies. The expected volatility of granted options has been determined using a weighted-average of the historical volatility measures of this peer group of companies. We will continue to apply

this method until a sufficient amount of historical information regarding the volatility of our own stock price becomes available. The fair value of each share of common stock underlying stock-based awards is based on the closing price of our common stock as reported by Nasdaq on the date of grant. The risk-free interest rate utilized in our calculations is based on a treasury instrument whose term is consistent with the expected life of the stock options. The expected dividend yield is assumed to be zero as we have never paid dividends and do not have current plans to pay any dividends on our common stock.

We measured stock-based awards granted to employees, non-employees and directors based on their fair value on the date of the grant using the Black-Scholes option-pricing model for options or the difference between the purchase price per share of the award, if any, and the fair value of our common stock for restricted common stock awards.

Prior to the consummation of the Business Combination, as there was not a public market for our common stock prior to becoming publicly traded in August 2021, the estimated fair value of our common stock was determined by our board of directors as of the date of grant of each option or restricted stock award, considering our most recently available third-party valuations of common stock and our board of directors' assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent valuation through the date of the grant. These third-party valuations were performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. Our common stock valuations were prepared using either an option pricing method, or OPM, or a hybrid method, both of which used market approaches to estimate our enterprise value. The OPM treats common stock and preferred stock as call options on the total equity value of a company, with exercise prices based on the value thresholds at which the allocation among the various holders of a company's securities changes. Under this method, the common stock had value only if the funds available for distribution to stockholders exceed the value of the preferred stock liquidation preferences at the time of the liquidity event, such as a strategic sale or a merger. The hybrid method was a probability-weighted expected return method, or PWERM, where the equity value in one or more scenarios is calculated using an OPM. The PWERM is a scenario-based methodology that estimated the fair value of common stock based upon an analysis of future values for the company, assuming various outcomes. The common stock value was based on the probability-weighted present value of expected future investment returns considering each of the possible outcomes available as well as the rights of each class of stock. The future value of the common stock under each outcome was discounted back to the valuation date at an appropriate risk-adjusted discount rate and probability weighted to arrive at an indication of value for the common stock. A discount for lack of marketability of the common stock is then applied to arrive at an indication of value for the common stock. The Black-Scholes option-pricing model also uses as inputs the fair value of our common stock and assumptions we make for the volatility of our common stock, the expected term of our common stock options, the risk-free interest rate for a period that approximates the expected term of our common stock options, and our expected dividend yield.

Compensation expense for awards is recognized over the requisite service period, which is generally the vesting period of the respective award for employees and directors and the period during which services are performed for non-employees. We use the straight-line method to record the expense of awards with service-based vesting conditions.

We believe our methodologies are reasonable based upon our internal peer company analyses. If different assumptions had been made, equity-based compensation expense, consolidated net loss and consolidated net loss per share could have been significantly different.

Recently Adopted Accounting Pronouncements

A description of recently issued and adopted accounting pronouncements that may potentially impact our financial position, results of operations or cash flows is disclosed within Note 2 of our unaudited condensed consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q and also in Note 2 to our audited consolidated financial statements and related notes in our Annual Report on Form 10-K for the year ended December 31, 2021.

Emerging Growth Company Status

We are an "emerging growth company," under the JOBS Act. Section 107 of the JOBS Act provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of delayed adoption of new or revised accounting standards and, therefore, we will be subject to the same requirements to adopt new or revised accounting standards as

private entities. As an emerging growth company, we may take advantage of certain exemptions and reduced reporting requirements under the JOBS Act. Subject to certain conditions, as an emerging growth company:

- we may present only two years of audited financial statements and only two years of related Management's Discussion and Analysis of Financial Condition and Results of Operations in our periodic reports and registration statements;
- we may avail ourselves of the exemption from providing an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act;
- we may provide reduced disclosure about our executive compensation arrangements; and
- we may not require nonbinding advisory votes on executive compensation or stockholder approval of any golden parachute payments.

We will remain an emerging growth company until the earliest of (i) December 31, 2025, (ii) the last day of the fiscal year in which we have total annual gross revenues of $1.07 billion or more, (iii) the last day of the fiscal year in which we are deemed to be a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our common stock held by non-affiliates exceeded $700.0 million as of the last business day of the second fiscal quarter of such year, provided we have been subject to the Exchange Act for at least 12 calendar months and have filed at least one annual report pursuant to the Exchange Act or (iv) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period. We may choose to take advantage of some but not all of these exemptions.

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to certain market risks in the ordinary course of our business. Market risk represents the risk of loss that may impact our financial position due to adverse changes in financial market prices and rates.

Interest Rate Risk

We had cash, cash equivalents and marketable securities of $449.9 million and $485.3 million as of March 31, 2022 and December 31, 2021, respectively, which consisted of cash, money market funds, U.S. Treasury bills and U.S. government agency bonds. Interest income is sensitive to changes in the general level of interest rates; however, due to the nature of these investments, an immediate 1% change in interest rates would not have a material effect on the fair market value of our investment portfolio.

Foreign Currency Exchange Risk

Our reporting and functional currency is the U.S. dollar. We currently do not have significant exposure to foreign currencies as we hold no foreign exchange contracts, option contracts, or other foreign hedging arrangements. Our operations may be subject to fluctuations in foreign currency exchange rates in the future.

Effects of Inflation

We do not believe that inflation has had a material effect on our business, financial condition or results of operations. Our operations may be subject to inflation in the future.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

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 defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this Quarterly Report on Form 10-Q. Management recognizes that any disclosure controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives. Our disclosure controls and procedures have been designed to provide reasonable assurance of achieving their objectives. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of March 31, 2022.

Changes in Internal Controls Over Financial Reporting

There were no changes in the Company's internal control over financial reporting identified in connection with the evaluation required by paragraph (d) of Exchange Act Rules 13a-15 or 15d-15 that occurred during the quarter ended March 31, 2022 that materially affected, or were reasonably likely to materially affect, the Company's internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we may become involved in litigation or other legal proceedings. Regardless of outcome, litigation can have an adverse impact on our business, financial condition, results of operations and prospects because of defense and settlement costs, diversion of management resources and other factors.

We are not currently a party to any litigation or legal proceedings that, in the opinion of our management, are probable to have a material adverse effect on our business.

Item 1A. Risk Factors.

Investing in our securities involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with all other information in this Quarterly Report on Form 10-Q, including our financial statements and the related notes and the "Management's Discussion and Analysis of Financial Condition and Results of Operations." The occurrence of one or more of the events or circumstances described in these risk factors, alone or in combination with other events or circumstances, may have a material adverse effect on our business, reputation, revenue, financial condition, results of operations and future prospects, in which event the market price of our common stock could decline, and you could lose part or all of your investment. Unless otherwise indicated, reference in this section and elsewhere in this Quarterly Report on Form 10-Q to our business being adversely affected, negatively impacted or harmed will include an adverse effect on, or a negative impact or harm to, our business, reputation, financial condition, results of operations, revenue and our future prospects. The material and other risks and uncertainties summarized above and described below are not intended to be exhaustive and are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations. This Quarterly Report on Form 10-Q also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of a number of factors, including the risks described below. See also the section titled "Note Regarding Forward-Looking Statements" above.

Risks Related to Our Limited Operating History, Financial Position, and Capital Requirements

We are a precision oncology company with a limited operating history.

We are a precision oncology company with a limited operating history. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. Since the Company's inception, we have devoted substantially all of our efforts to organizing and staffing our company, acquiring and developing intellectual property, business planning, raising capital, conducting discovery, research and development activities, and providing general and administrative support for these operations. We have no products approved for commercial sale and therefore have never generated any revenue from product sales, and we do not expect to in the foreseeable future. We have not obtained regulatory approvals for any of our product candidates, and there is no assurance that we will obtain approvals in the future. Our first investigational new drug, or IND, application, for TNG908, was cleared by the FDA in the first quarter of 2022. Other than TNG908, all of our product candidates are still in preclinical development. We expect to continue to incur significant expenses and operating losses over the next several years and for the foreseeable future. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on cash and cash equivalent holdings, our stockholders' equity and working capital.

We have incurred significant net losses since our inception and anticipate that we will continue to incur losses for the foreseeable future.

We have incurred significant net losses since our inception. For the three months ended March 31, 2022, our net loss was $25.2 million. As of March 31, 2022, we had an accumulated deficit of $186.5 million. Substantially all of our net losses have resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations. We expect our research and development expenses to increase significantly in connection with the commencement and continuation of clinical trials of our product candidates. In addition, if we obtain regulatory approval for our product candidates, we will incur significant sales, marketing and manufacturing expenses. As a result, we expect to continue to incur significant and increasing operating losses for the foreseeable future. Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the extent of any future losses or when we will become profitable, if at all. Even if we do become profitable, we may not be able to sustain or increase our profitability on a quarterly or annual basis.

The amount of our future losses is uncertain and our quarterly and annual 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. Our quarterly and annual operating results may fluctuate significantly in the future due to a variety of factors, many of which are outside of our control and may be difficult to predict, including the following:

the timing and success or failure of future clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners;

our ability to obtain INDs for our pipeline product candidates, successfully open clinical trial sites and recruit and retain subjects for clinical trials, and any delays caused by difficulties in such efforts;

our ability to obtain regulatory approval for our product candidates, and the timing and scope of any such approvals we may receive;

the timing and cost of, and level of investment in, research and development activities relating to our product candidates and any future product candidates and research-stage programs, which may change from time to time;

the cost of manufacturing our product candidates and products, should they receive regulatory approval, which may vary depending on FDA and other comparable foreign regulatory requirements, the quantity of production and the terms of our agreements with manufacturers;

our ability to attract, hire and retain qualified personnel;

expenditures that we will or may incur to develop additional product candidates;

the level of demand for our product candidates should they receive regulatory approval, which may vary significantly;

the risk/benefit profile, cost and reimbursement policies with respect to our product candidates, if approved, and existing and potential future therapeutics that compete with our product candidates;

the changing and volatile U.S. and global economic environments, including as a result of the COVID-19 pandemic; and

future accounting pronouncements or changes in our accounting policies.

The individual or cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated guidance we may provide.

We have no products approved for commercial sale and have not generated any revenue from product sales.

Our ability to become profitable depends upon our ability to generate revenue. To date, we have not generated any revenue from product sales, and we do not expect to generate any revenue from the sale of products in the near future. We do not expect to generate significant product revenue unless and until we obtain regulatory approval of, and begin to sell, one or more of our product candidates. Our ability to generate revenue depends on a number of factors, including, but not limited to, our ability to:

successfully complete our planned preclinical studies for our novel precision oncology development programs;

timely file INDs for our other programs, and clearance of these INDs to allow for commencement of such future clinical trials;

timely patient enrollment and patient dosing in our TNG908 clinical trial;

successfully complete our TNG908 clinical trial and any future clinical trials;

initiate and successfully complete all safety and efficacy studies required to obtain U.S. and foreign regulatory approval for our product candidates;

make and maintain arrangements with third-party manufacturers for clinical supply and commercial manufacturing;

obtain and maintain patent and trade secret protection or regulatory exclusivity for our product candidates;

launch commercial sales of our products, if and when approved, whether alone or in collaboration with others;

obtain and maintain acceptance of our products, if and when approved, by patients, the medical community and third-party payors;

position our products to effectively compete with other therapies;

obtain and maintain healthcare coverage and adequate reimbursement;

enforce and defend intellectual property rights and claims;

implement measures to help minimize the risk of COVID-19 to our employees as well as patients and subjects to be enrolled in our clinical trials; and

maintain a continued acceptable safety profile of our products following approval.

If we do not achieve these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which would materially harm our business. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations or we may be required to sell or license assets to third parties on terms that are not favorable to us, if at all.

Further, our most advanced program is a PRMT5 inhibitor, TNG908. Given the large number of patients with MTAP-deleted cancers, we are investing in our PRMT5 franchise to develop a product candidate with increased potency, MTAP-deletion selectivity, as well as longer target coverage. TNG462, our next-generation PRMT5 inhibitor, is 45-fold more potent in cells with an MTAP deletion than those without and induces deep tumor regressions in preclinical models of multiple cancer types. The clinical development path for TNG462 is expected to be similar to TNG908, evaluating safety and efficacy in multiple tumor types in a Phase 1/2 clinical trial. Glioblastoma will be excluded from the clinical trial as TNG462 does not cross the blood-brain barrier in preclinical primate models. If additional preclinical or clinical evaluation of our next-generation compounds supports this hypothesis, we may elect to promote TNG462 as our lead PRMT5 inhibitor, which may result in a delay to our development timeline for the lead PRMT5 program of approximately 12 to 18 months. If we elect to promote this next-generation compound, it may result in the delay in receiving potential revenue from product sales, if approved by regulatory authorities.

We will need to raise substantial additional funding. If we are unable to raise capital when needed or on terms acceptable to us, we would be forced to delay, reduce or eliminate some of our product development programs or commercialization efforts.

The development of pharmaceutical products is capital-intensive. We are currently advancing our precision oncology programs through clinical and preclinical development. We received FDA clearance of our IND application for TNG908 in the first quarter of 2022 and our Phase 1/2 clinical trial is open for enrollment. We also plan to file an IND for TNG462, our next generation PRMT5 inhibitor, in the first half of 2023. Additionally, we plan to file INDs for TNG260, our inhibitor of an undisclosed target for STK11-mutant cancers (Target 3) and for our USP1 inhibitor program in 2023. Consequently, we expect our expenses to significantly increase in connection with our ongoing activities, particularly as we continue the research and development of, initiate and complete clinical trials of, and seek regulatory approval for, our product candidates.

In addition, depending on the status of regulatory approval or, if we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. We may also need to raise additional funds sooner if we choose to pursue additional indications and/or geographies for our current or future product candidates or otherwise expand more rapidly than we presently anticipate. Furthermore, we have, and will continue to, incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate certain of our research and development programs or future commercialization efforts.

We expect that our existing cash, cash equivalents and marketable securities will fund our projected operating requirements at least into the second half of 2024. However, our future capital requirements will depend on and could increase significantly as a result of many factors (which may result in exhausting such cash resources prior to the second half of 2024), including:

- the scope, progress, results and costs of product discovery, preclinical and clinical development, and clinical trials for our product candidates;
- the potential additional expenses attributable to adjusting our development plans (including any supply related matters) to the COVID-19 pandemic;
- the scope, prioritization and number of our research and development programs;
- the costs, timing and outcome of regulatory review of our product candidates;
- our ability to establish and maintain additional collaborations on favorable terms, if at all;
- the achievement of milestones or occurrence of other developments that trigger payments under our existing collaboration agreements or any additional collaboration agreements we may establish;
- the extent to which we are obligated to reimburse, or entitled to reimbursement of, clinical trial costs under future collaboration agreements, if any;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- the extent to which we acquire or in-license other product candidates and technologies;
- the costs of securing manufacturing arrangements for clinical and commercial production;
- our ability to hire and retain skilled scientific and operational personnel to meet our development, clinical and commercial objectives;
- costs related to the development of any companion diagnostics we may use in the future; and
- the costs of establishing or contracting for sales and marketing capabilities if we obtain regulatory approvals to market our product candidates.

Identifying potential product candidates and conducting preclinical development testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenue, if any, will be derived from sales of products that we do not expect to be commercially available for many years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. Disruptions in the financial markets in general and due to the ongoing COVID-19 pandemic may make equity and debt financing more difficult to obtain and may have a material adverse effect on our ability to meet our fundraising needs. We cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all.

If we are unable to obtain funding on a timely basis or on acceptable terms, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs or the commercialization of any product that has received regulatory approval or be unable to expand our operations or otherwise capitalize on our business opportunities as desired, which could materially affect our business, financial condition and results of operations.

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

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of private and public equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. We do not have any committed external source of funds. The terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our shares to decline. To the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, the ownership interest of our existing common stockholders will be diluted, and the terms of those securities may include liquidation or other preferences that may materially adversely affect your rights as a common stockholder. Debt financing, if available, would increase our fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, acquiring, selling or licensing intellectual property rights, and making capital expenditures, declaring dividends, repurchase shares of our common stock, or other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to meet certain milestones in connection with debt financing and the failure to achieve such milestones by certain dates may force us to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us which could have a material adverse effect on our business, operating results and prospects.

We also could be required to seek funds through arrangements with additional collaborators or otherwise at an earlier stage than otherwise would be desirable. If we raise funds through additional collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our intellectual property, future revenue streams, research programs or product candidates, grant licenses on terms that may not be favorable to us or grant rights to develop and market our product candidates that we would otherwise prefer to develop and market ourselves, any of which may have a material adverse effect on our business, operating results and prospects.

Risks Related to the Development of our Precision Oncology and Other Programs and Product Candidates

We have never successfully completed any clinical trials and we may be unable to do so for any product candidates we develop. Certain of our programs are still in preclinical development and may never advance to clinical development.

We have not yet demonstrated our ability to successfully register, initiate, enroll and complete clinical trials, including large-scale, pivotal clinical trials, obtain regulatory approvals, manufacture a commercial scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization. We received FDA clearance of our IND application for TNG908 in the first quarter of 2022. Other than TNG908, our programs are still in preclinical development and may never advance to clinical development. We plan to file an IND for TNG462, our next generation PRMT5 inhibitor, in the first half of 2023. Additionally, we plan to file INDs for TNG260, our inhibitor of an undisclosed target for STK11-mutant cancers (Target 3) and for our USP1 inhibitor program in 2023. We may not be able to file such INDs or INDs for any of our other product candidates on the timelines we expect, if at all. Further, timelines for developing and filing INDs are subject to significant uncertainties and projected timelines can be improved upon or delayed.

For example, we extended the timeline for filing an IND for our USP1 inhibitor program as we continue to work on a development candidate that has improved pharmaceutical properties. Moreover, we cannot be sure that submission of an IND will result in the U.S. Food and Drug Administration, or FDA, allowing clinical trials to begin, or that, once begun, issues will not arise that require us to suspend or terminate clinical trials. Any guidance we receive from the FDA or other regulatory authorities is subject to change. These regulatory authorities could change their position, including on the acceptability of our trial designs or the clinical endpoints selected, which may require us to complete additional clinical trials or result in the imposition of stricter approval conditions than we currently expect. Successful completion of our clinical trials is a prerequisite to submitting an NDA to the FDA, a Marketing Authorization Application, or MAA, to the European Medicines Agency, or EMA, or other marketing applications to regulatory authorities in other jurisdictions, for each product candidate and, consequently, the regulatory approval of each product candidate. While the IND for our lead program, TNG908, was cleared by the FDA, it is possible that patients may not be enrolled and the study may not be completed (and preliminary, initial or final trial results may not be available) on time. Similarly, future clinical trials may not begin on time or be completed on schedule, if at all.

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

- be delayed in obtaining regulatory approval for our product candidates;
- not obtain regulatory approval at all;
- obtain regulatory approval for indications or patient populations that are not as broad as intended or desired;
- continue to be subject to post-marketing testing requirements; or
- have the product removed from the market after obtaining regulatory approval.

Our programs are focused on the development of oncology therapeutics for patients with genetically defined or biomarker-driven cancers, which is a rapidly evolving area of science, and the approach we are taking to discover and develop drugs is novel and may never lead to approved or marketable products.

The discovery and development of oncology therapeutics for patients with genetically defined or biomarker-driven cancers is a rapidly evolving area, and the scientific discoveries that form the basis for our efforts to discover and develop product candidates are relatively new. Our unique functional genomics discovery approach is based on the genetic concept of synthetic lethality. The scientific evidence to support the feasibility of developing product candidates based on these discoveries is both preliminary and limited. Although we believe, based on our preclinical work, that the genetic markers targeted by our programs drive the formation and spread of certain cancers, clinical results may not confirm this hypothesis or may only confirm it for certain alterations or certain tumor types. The patient populations for our product candidates are limited to those with specific target alterations and may not be completely defined but are substantially smaller than the general treated cancer population, and we will need to screen and identify these patients with targeted alterations. Successful identification of patients is dependent on several factors, including achieving certainty as to how specific alterations respond to our product candidates and the ability to identify such alterations. Furthermore, even if we are successful in identifying patients with specific targets, we cannot be certain that the resulting patient populations with each mutation will be large enough to allow us to successfully obtain approval for each such mutation and commercialize our product candidates and achieve profitability.

Clinical product development involves a lengthy and expensive process, with an uncertain outcome.

Our preclinical studies, our TNG908 clinical trial and future clinical trials may not be successful. It is impossible to predict when or if any of our product candidates will prove effective and safe in humans or will receive regulatory approval. Before obtaining regulatory approval from regulatory authorities for the sale of any product candidate, we must complete preclinical studies and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and outcomes are uncertain. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical development testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results (or be indicative of safety and efficacy if commercialized and used in a broader population). Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain regulatory approval of their product candidates. Our preclinical studies and future clinical trials may not be successful.

If we are unable to successfully validate, develop and obtain regulatory approval for diagnostic tests for our product candidates that require or would commercially benefit from such tests, or experience significant delays in doing so, we may not realize the full commercial potential of these product candidates.

In connection with the clinical development of our product candidates for certain indications, we may engage third parties to develop or otherwise obtain access to in vitro companion diagnostic tests to identify patient subsets within a disease category who may derive selective and meaningful benefit from our product candidates. Such companion diagnostics may be used during our clinical trials as well as in connection with the commercialization of our products that receive regulatory approval. To be successful, we or our collaborators will need to address a number of scientific, technical, regulatory and logistical challenges. The FDA and comparable foreign regulatory authorities regulate *in vitro* companion diagnostics as medical devices and, under that regulatory framework, will likely require the conduct of clinical trials to demonstrate the safety and effectiveness of any diagnostics we or third parties may develop, which we expect will require separate regulatory clearance or approval prior to commercialization.

We intend to rely on third parties for the design, development and manufacture of companion diagnostic tests for our therapeutic product candidates that may require such tests. If we enter into such collaborative agreements, we will be dependent on the sustained cooperation and effort of our future collaborators in developing and obtaining approval for these companion diagnostics. It may be necessary to resolve issues such as selectivity/specificity, analytical validation, reproducibility, or clinical validation of companion diagnostics during the development and regulatory approval processes. Moreover, even if data from preclinical studies and early clinical trials appear to support development of a companion diagnostic for a product candidate, data generated in later clinical trials may fail to support the analytical and clinical validation of the companion diagnostic. We and our future collaborators may encounter difficulties in developing, obtaining regulatory clearance or approval for, manufacturing and commercializing companion diagnostics similar to those we face with respect to our therapeutic product candidates themselves, including issues with achieving regulatory clearance or approval, production of sufficient quantities at commercial scale and with appropriate quality standards, and in gaining market acceptance. If we are unable to successfully develop companion diagnostics for these therapeutic product candidates, or experience delays in doing so, the development and commercialization of these therapeutic product candidates may be adversely affected, these therapeutic product candidates may not obtain regulatory approval, and we may not realize the full commercial potential of any of these therapeutic products that obtain regulatory approval. As a result, our business, results of operations and financial condition could be materially harmed. In addition, a diagnostic company with whom we contract may decide to discontinue selling or manufacturing the companion diagnostic test that we anticipate using in connection with development and commercialization of our product candidates or our relationship with such diagnostic company may otherwise terminate. We may not be able to enter into arrangements with another diagnostic company to obtain supplies of an alternative diagnostic test for use in connection with the development and commercialization of our product candidates or do so on commercially reasonable terms, which could adversely affect and/or delay the development or commercialization of our therapeutic product candidates.

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

From time to time, we may publicly disclose interim, top-line or preliminary data from our current and future 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. For example, we may report responses in certain patients that are unconfirmed at the time and which do not ultimately result in confirmed responses to treatment after follow-up evaluations. We may 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. As a result, the interim, top-line or preliminary results that we report may differ from future results of the same trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Preliminary, interim or top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, preliminary, interim and top-line data should be viewed with caution until the final data are available. In addition, we may report interim analyses of only certain endpoints rather than all endpoints. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects and may cause the price of our common stock to fluctuate or decline.

Further, regulatory agencies and others 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 adversely impact the

potential of the particular program, the likelihood of obtaining regulatory approval of the particular product candidate, the scope of product label, and commercialization of any approved product. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is derived from information that is typically extensive, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure.

If the preliminary, interim or top-line data that we report differ from final or actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be significantly impaired, which could materially harm our business, operating results, prospects or financial condition.

We may incur additional costs or experience delays in initiating or completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

We may experience delays in initiating or completing our preclinical studies or clinical trials, including as a result of delays in obtaining, or failure to obtain, the FDA's clearance to initiate clinical trials under future INDs. Additionally, we cannot be certain that preclinical studies or clinical trials for our product candidates will not require redesign, will enroll an adequate number of subjects on time, or will be completed on schedule, if at all. We may experience numerous unforeseen events during, or as a result of, preclinical studies and clinical trials that could delay or prevent our ability to receive regulatory approval or commercialize our product candidates, including the following:

- we may receive feedback from regulatory authorities that require us to modify the design or implementation of our preclinical studies or clinical trials or to delay or terminate a clinical trial;
- regulators or institutional review boards, or IRBs, or ethics committees may delay or may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective clinical research organizations, or CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- preclinical studies or clinical trials of our product candidates may fail to show safety or efficacy or otherwise produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials, or we may decide to abandon product research or development programs;
- preclinical studies or clinical trials of our product candidates may not produce differentiated or clinically significant results across tumor types or indications;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements, fail to maintain adequate quality controls, be unable to provide us with sufficient product supply to conduct or complete preclinical studies or clinical trials, fail to meet their contractual obligations to us in a timely manner, or at all;
- our clinical trial sites or investigators may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators;
- we may elect to, or regulators or IRBs or ethics committees may require us or our investigators to, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants in our clinical trials are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- clinical trials of our product candidates may be delayed due to complications associated with the evolving COVID-19 pandemic;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or IRBs or ethics committees to suspend or terminate the trials, or reports may arise from preclinical or clinical testing of other cancer therapies that raise safety or efficacy concerns about our product candidates;
- regulators may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate; and
- regulatory developments with respect to our competitors' products, including any developments, litigation or public concern about the safety of such products.

We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions at which such trials are being conducted, by the Data Safety Monitoring Board, or DSMB, for such trial or by the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination or clinical hold due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, adverse findings upon an inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. 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. Further, the FDA may disagree with our clinical trial design or our interpretation of data from clinical trials or may change the requirements for approval even after it has reviewed and commented on the design for our clinical trials.

Moreover, principal investigators for our current or future clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected the interpretation of the study. The FDA or comparable foreign regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site, and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of regulatory approval of one or more of our product candidates.

Our product development costs will also increase if we experience delays in testing or regulatory approvals. We do not know whether any of our current or future clinical trials will begin as planned, or whether any of our current or future clinical trials will need to be restructured or will be completed on schedule, if at all. Significant preclinical study or clinical trial delays, including those caused by the COVID-19 pandemic, also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do, which would impair our ability to successfully commercialize our product candidates and may significantly harm our business, operating results, financial condition and prospects.

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 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 comparable foreign regulatory authorities, or as needed to provide appropriate statistical power for a given trial. In particular, because we are focused on patients with specific genetic mutations for the development of our precision oncology programs and because some of the indications we are pursuing are orphan indications that have small populations, our ability to enroll eligible patients may be limited or may result in slower enrollment than we anticipate. For example, following the FDA's clearance of our IND application for the Phase 1/2 clinical trial of TNG908, we and our third-party CRO have initiated multiple clinical trial sites and engaged with the clinical trial sites to enroll patients. While patients have not been dosed in the TNG908 trial to date, we continue to expect that the trial will enroll patients in the second quarter of 2022. If we were to experience slower than expected enrollment, due to limited site resources resulting from COVID-19, limited trial populations due to competitive trials or other factors beyond our control, the results from the TNG908 Phase 1/2 trials (as well as the timing for dose escalation and dose expansion) and the regulatory approval (if any) for TNG908 may extend beyond the period we have targeted or beyond the timeline expected by investors.

We may experience difficulties with identifying specific patient populations for any biomarker-defined trial cohorts. The patient eligibility criteria defined in our trial protocols, including biomarker-driven identification, may limit the patient populations eligible for our clinical trials to a greater extent than competing clinical trials for the same indication that do not have biomarker-driven patient eligibility criteria. We will also rely on the willingness and ability of clinicians to screen their patients for biomarkers to indicate which patients may be eligible for enrollment in our clinical trials.

In addition, some of our competitors have ongoing clinical trials for product candidates that treat the same indications as do our product candidates, and patients who would otherwise be eligible for our clinical trials may choose instead to enroll in clinical trials of our competitors' product candidates (for example, three INDs have been cleared by the FDA for clinical trials of MTA-cooperative PRMT5 inhibitors for the treatment of cancer patients). Furthermore, our ability to enroll patients

may be significantly delayed by the ongoing COVID-19 pandemic (including due to lack of resources and personnel at trial sites), and we cannot accurately predict the extent and scope of such delays at this point.

In addition to the competitive trial environment, the eligibility criteria of our future clinical trials will further limit the pool of available study participants as we will require that patients have specific characteristics that we can measure to assure their cancer is either severe enough or not too advanced to include them in a study. Additionally, the process of finding patients may prove costly. We also may not be able to identify, recruit or enroll a sufficient number of patients to complete our clinical studies because of the perceived risks and benefits of the product candidates under study, the availability and efficacy of competing therapies and clinical trials, the proximity and availability of clinical trial sites for prospective patients, and the patient referral practices of physicians. If patients are unwilling to participate in our studies for any reason, the timeline for recruiting patients, conducting studies, reporting preliminary and final trial results and obtaining regulatory approval of potential products may be delayed.

We may also engage third parties to develop companion diagnostics for use in our clinical trials, but such third parties may not be successful in developing such companion diagnostics, limiting our ability to identify patients with the targeted genetic mutations for our clinical trials. Further, if we are required to develop companion diagnostics and are unable to include patients with the targeted genetic mutations, this could compromise our ability to seek designations under applicable FDA expedited review and development programs, including Breakthrough Therapy Designation and Fast Track Designation (to the extent these are available to us), or otherwise seek to accelerate clinical development and regulatory timelines. Patient enrollment may be affected by other factors, including:

the severity of the disease under investigation;
the efforts to obtain and maintain patient consents and facilitate timely enrollment in clinical trials;
the ability to monitor patients adequately during and after treatment;
the risk that patients enrolled in clinical trials will drop out of the clinical trials before clinical trial completion;
the ability to recruit clinical trial investigators with the appropriate competencies and experience;
reporting of the preliminary results of any of our clinical trials; and
factors we may not be able to control, including the impacts of the COVID-19 pandemic, that may limit patients, principal investigators or staff or clinical site availability.

We anticipate that certain of our current product candidates and future product candidates could be used in combination with third-party drugs or biologics, some of which are still in development, and we have limited or no control over the supply, regulatory status, or regulatory approval of such drugs or biologics.

Certain of our current product candidates and any future product candidates may have the potential to be administered in combination with existing standards of care such as checkpoint inhibitor immunotherapies, chemotherapies, targeted therapies or radiotherapy. Our ability to develop and ultimately commercialize our current programs and product candidates and any future programs or product candidates for use in combination with other therapies will depend on our ability to access such drugs or biologics on commercially reasonable terms for the clinical trials and their availability for use with our commercialized product, if approved. We cannot be certain that current or potential future commercial relationships will provide us with a steady supply of such drugs or biologics on commercially reasonable terms or at all.

Any failure to maintain or enter into new successful commercial relationships, or the expense of purchasing checkpoint inhibitor immunotherapies or other potential combination or comparator therapies in the market, may delay our development timelines, increase our costs and jeopardize our ability to develop our current product candidates and any future product candidates as commercially viable therapies. If any of these occur, our business, financial condition, operating results, stock price and prospects may be materially harmed.

Moreover, the development of product candidates for use in combination with another product or product candidate may present challenges that are not faced for single agent product candidates. The FDA or comparable foreign regulatory authorities may require us to use more complex clinical trial designs in order to evaluate the contribution of each product and product candidate to any observed effects. It is possible that the results of such trials could show that any positive previous trial results are attributable to the other therapy and not our current product candidates and any future product candidates. Moreover, following product approval, the FDA or comparable foreign regulatory authorities may require that products used in conjunction with each other be cross labeled for combined use. To the extent that we do not have rights to the other product, this may require us to work with a third party to satisfy such a requirement. Moreover, developments related to the other product may impact our clinical trials for the combination as well as our commercial prospects should we receive regulatory approval. Such developments may include changes to the other product's safety or efficacy profile, changes to the

availability of the other product, quality, manufacturing and supply issues with respect to the other product, and changes to the standard of care.

In the event that any future collaborator or supplier cannot continue to supply their products on commercially reasonable terms, we would need to identify alternatives for accessing potential combination or targeted therapies. Additionally, should the supply of products from any current or future collaborator or supplier be interrupted, delayed or otherwise be unavailable to us, our clinical trials may be delayed. In the event we are unable to source an alternative supply, or are unable to do so on commercially reasonable terms, our business, financial condition, operating results, stock price and prospects may be materially harmed.

Results from earlier preclinical studies of our programs and product candidates are not necessarily predictive of the results of later preclinical studies and clinical trials of our programs and product candidates. If we cannot replicate the results from our earlier preclinical studies of our programs and product candidates in our later preclinical studies and clinical trials, we may be unable to successfully develop, obtain regulatory approval for and commercialize our product candidates.

Any results from our earlier preclinical studies of our programs or our product candidates may not necessarily be predictive of the results from later preclinical studies and clinical trials. Similarly, even if we are able to complete our planned preclinical studies and clinical trials of our product candidates according to our current development timeline, the results from such preclinical studies and clinical trials of our product candidates may not be replicated in subsequent preclinical studies or clinical trial results.

Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in early-stage development, and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, preclinical and other nonclinical findings made while clinical trials were underway, or safety, pharmacokinetic or efficacy observations made in preclinical studies and clinical trials, including previously unreported adverse events. Moreover, preclinical, nonclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain regulatory approval.

We may not be able to file INDs for our precision oncology and other programs to commence clinical trials on the timelines we expect, and even if we are able to, the FDA may not permit us to proceed.

We received clearance of our IND application for TNG908 in the first quarter of 2022 and our Phase 1/2 clinical trial is now open for enrollment. We also plan to file an IND for TNG462, our next generation PRMT5 inhibitor, in the first half of 2023. Additionally, we plan to file INDs for TNG260, our inhibitor of an undisclosed target for STK11-mutant cancers (Target 3), and for our USP1 inhibitor program in 2023. However, we may not be able to file such INDs or INDs for future product candidates for our precision oncology or other programs on the timelines we expect. We have in the past, for example, extended the timeline for filing an IND for our USP1 inhibitor program as we continue to work on a development candidate that has improved pharmacologic properties.

Further, we may experience manufacturing delays or other delays with IND-enabling studies. Moreover, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate clinical trials. Additionally, even if the FDA agrees with the design and implementation of the clinical trials set forth in an IND, we cannot guarantee that it will not change its requirements in the future. These considerations also apply to new clinical trials we may submit as amendments to existing INDs or to a new IND. Any failure to file INDs on the timelines we expect or to obtain regulatory approvals for our planned clinical trials may prevent us from initiating or completing our clinical trials or commercializing our product candidates on a timely basis, if at all.

Our clinical trials or those of our current or future collaborators may reveal significant adverse events not seen in our preclinical or nonclinical studies and may result in a safety profile that could inhibit regulatory approval or market acceptance of any of our product candidates.

Before obtaining regulatory approvals for the commercial sale of any products, we must demonstrate through lengthy, complex and expensive preclinical studies and clinical trials that our product candidates are both safe and effective for use in each target indication. Clinical testing is expensive and can take many years to complete, and outcomes are inherently uncertain. Failure can occur at any time during the clinical trial process. Because our precision oncology programs and our product candidates are in an early stage of development, there is a high risk of failure, and we may never succeed in developing marketable products. There is typically an extremely high rate of attrition from the failure of product candidates

proceeding through clinical trials. Product candidates in later stages of clinical trials also may fail to show the desired safety and efficacy profile despite having progressed through nonclinical studies and initial clinical trials. If the results of our current and future preclinical studies and clinical trials are inconclusive with respect to the safety, pharmacokinetics or efficacy of our product candidates, if we do not meet the clinical endpoints with statistical and clinically meaningful significance, or if there are safety concerns associated with our product candidates, we may be prevented from, or delayed in, obtaining regulatory approval for such product candidates. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants. There may be side effects experienced during clinical trials in connection with the use of oncology therapies. Results of our trials could reveal a high and unacceptable severity and prevalence of side effects as a result of the use of our therapy (or due to other factors). In such an event, our trials could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims (the latter can be expensive to defend and result in significant damages and harm to our reputation). While we do have insurance to cover certain product liability claims, including in connection with injury during clinical trials, the coverage may not be sufficient to cover all expenses related to any injury and we may be required to pay damages from our own resources.

Further, our product candidates could cause undesirable side effects in clinical trials related to on-target toxicity. If on-target toxicity is observed, or if our product candidates have characteristics that are unexpected, we may need to abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. In addition, our product candidates could cause undesirable side effects that we have not yet observed. Many compounds that initially showed promise in early-stage testing for treating cancer have later been found to cause side effects that prevented further development of the compound. Most product candidates that commence clinical trials are never approved as products, and there can be no assurance that any of our current or future clinical trials will ultimately be successful or support further clinical development or regulatory approval of any of our product candidates.

We may develop future product candidates in combination with one or more cancer therapies. The uncertainty resulting from the use of our product candidates in combination with other cancer therapies may make it difficult to accurately predict side effects in future clinical trials. As is the case with many treatments for cancer and rare diseases, it is likely that there may be side effects associated with the use of our product candidates. If significant adverse events or other side effects are observed in our clinical trial for TNG908 or in any of our other future clinical trials, we may have difficulty recruiting patients to our clinical trials, patients may drop out of our trials, or we may be required to abandon the trials or our development efforts of one or more product candidates altogether. We, the FDA or other applicable regulatory authorities, or an IRB may suspend or terminate clinical trials of a product candidate at any time for various reasons, including a belief that subjects in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential therapeutics developed in the biotechnology industry that initially showed therapeutic promise in early-stage trials have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the product from obtaining or maintaining regulatory approval, undesirable side effects may inhibit market acceptance of the approved product due to its tolerability versus other therapies. Any of these developments could materially harm our business, operating results, financial condition and prospects.

Some of our product candidates modulate pathways for which there are currently no approved or effective therapies, and utilize novel binding locations, which may result in greater research and development expenses, regulatory issues that could delay or prevent approval, or discovery of unknown or unanticipated adverse effects.

Some of our product candidates modulate pathways for which there are currently no approved or effective therapies, which may result in uncertainty regarding our current and future development efforts and ability to obtain regulatory approval for such candidates. We select programs for cancer driver targets based on what we believe is compelling biological rationale. We explore new programs based on extensive preclinical data analysis which sometimes cannot predict efficacy or safety in humans.

Some of our product candidates utilize novel binding locations, which may result in greater research and development expenses, regulatory issues that could delay or prevent drug candidate development and approval, or discovery of unknown or unanticipated adverse effects. We utilize structural biology in tight integration with our medicinal chemistry and biology capabilities to predict and design the compounds that we believe will achieve the most desirable characteristics, including potency, selectivity, bioavailability, and drug-like properties. A disruption in any of these capabilities may have significant adverse effects in our ability to expand our pipeline of product candidates, and we cannot predict whether we will continue to

have access to these capabilities in the future to support our pipeline development. In addition, there can be no assurance that we will be able to rapidly identify, design and synthesize the necessary compounds or that these or other problems related to the development of product candidates will not arise in the future, which may cause significant delays or raise problems we may not be able to resolve.

Regulatory approval of novel product candidates such as ours can be more expensive, riskier and take longer than for other, more well-known or extensively studied pharmaceutical or biopharmaceutical product candidates due to our and regulatory agencies' lack of experience with them. The novelty of the mechanism of action of any of our product candidates may lengthen the regulatory review process, require us to conduct additional studies or clinical trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions. The novel mechanism of action also means that fewer people are trained in or experienced with product candidates of this type, which may make it more difficult to find, hire and retain personnel for research, development and manufacturing positions. If our inhibitors utilize a novel mechanism of action that has not been the subject of extensive study compared to more well-known product candidates, there is also an increased risk that we may discover previously unknown or unanticipated adverse effects during our preclinical studies and clinical trials. Any such events could adversely impact our business prospects, operating results and financial condition.

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

We plan to conduct certain clinical trials outside the United States, and these jurisdictions may include countries in Europe, Australia or other foreign jurisdictions. The acceptance of trial data from clinical trials conducted outside the United States by the FDA, or comparable foreign regulatory authorities, may be subject to certain conditions. In cases where data from clinical trials conducted outside the United States are intended to serve as the sole basis for regulatory approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the United States population and United States medical practices, (ii) the trials were performed by clinical investigators of recognized competence and pursuant to Good Clinical Practices, or 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 on-site inspection or other appropriate means. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory bodies 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 United States or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in our product candidates not receiving regulatory approval or clearance for commercialization in the applicable jurisdiction.

Although we intend to explore other therapeutic opportunities in addition to the programs and product candidates that we are currently developing, we may fail to identify viable new product candidates for clinical development for a number of reasons. If we fail to identify additional product candidates, our business could be materially harmed.

The ongoing success of businesses in the biopharmaceutical industry depend, to a large extent, on the ability to continue to introduce new products, especially as exclusivity rights to given therapies or indications expire. Research programs to pursue the development of our existing and planned product candidates for new or additional indications and to identify new product candidates and disease targets require substantial technical, financial and human resources whether or not they are ultimately successful. Our screening technology and research programs may initially show promise in identifying potential indications and/or product candidates, yet fail to yield results for clinical development for a number of reasons, including:

- the research methodology used may not be successful in identifying potential indications and/or product candidates (or the development of a chemical compound or formulation that has the desired effect cannot be developed);
- potential product candidates may, after further study, be shown to have harmful adverse effects or other characteristics that indicate they are unlikely to be effective products; or
- it may take greater human and financial resources than we will possess to identify additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through internal research programs, thereby limiting our ability to develop, diversify and expand our potential product portfolio.

Because we have limited financial and human resources, we intend to initially focus on research programs and product candidates for a limited set of indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential or a greater likelihood of success. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities.

Accordingly, there can be no assurance that we will ever be able to identify additional therapeutic opportunities for our product candidates or to develop suitable product candidates through internal research programs, which could materially adversely affect our future growth and prospects. We may focus our efforts and resources on potential product candidates or other potential programs that ultimately prove to be unsuccessful.

If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for our product candidates, we will not be able to commercialize, or will be delayed in commercializing, our product candidates, and our ability to generate revenue will be materially impaired.

Our product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, distribution, import and export are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable foreign regulatory authorities. Before we can commercialize any of our product candidates, we must obtain regulatory approval. We received clearance of our IND application for TNG908 in the first quarter of 2022 and our Phase 1/2 clinical trial is now open for enrollment, otherwise, all of our product candidates are in discovery or preclinical development. We have not received approval to market any of our product candidates from regulatory authorities in any jurisdiction. It is possible that our product candidates, including any product candidates we may seek to develop in the future, will never obtain regulatory approval. We have limited experience in filing and supporting the applications necessary to gain regulatory approvals and expect to rely on third-party CROs and/or regulatory consultants to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended pharmacokinetics, side effects, toxicities or other characteristics that may preclude our obtaining regulatory approval or prevent or limit commercial use. In addition, regulatory authorities may find fault with our manufacturing process or facilities or that of third-party contract manufacturers. We and our third-party manufacturers that we expect to rely on for commercial production of our therapies, if approved, may also face greater than expected difficulty in manufacturing our product candidates.

The process of obtaining regulatory approvals, both in the United States and abroad, is expensive and often takes many years. If the FDA or a comparable foreign regulatory authority requires that we perform additional preclinical studies or clinical trials, approval may be delayed, if obtained at all. The length of such a delay varies substantially based upon a variety of factors, including the type, complexity and novelty of the product candidate involved. Changes in regulatory approval policies during the development period, changes in or enactment of additional statutes or regulations, or changes in regulatory review policies for each submitted NDA, premarket approval application, or PMA, or equivalent application types, may cause delays in the approval or rejection of an application. The FDA and comparable foreign regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. Our product candidates could be delayed in receiving, or fail to receive, regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may not be able to enroll a sufficient number of patients in our clinical studies;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication or a related companion diagnostic is suitable to identify appropriate patient populations;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA, or other submission or to obtain regulatory approval in the United States or elsewhere;

the FDA or comparable foreign regulatory authorities may find deficiencies with or fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and

the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change such that our clinical data are insufficient for approval.

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

If we experience delays in obtaining, or if we fail to obtain, approval of our product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenue will be materially impaired.

The COVID-19 pandemic, or a similar pandemic, epidemic, or outbreak of an infectious disease, may materially and adversely affect our business and our financial results and could cause a disruption to the development of our product candidates and the initiation and completion of clinical trials.

Public health crises such as pandemics or similar outbreaks could adversely impact our business. Beginning in 2020 and continuing through the date of this filing, a novel strain of a virus named SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2), or coronavirus, which causes COVID-19 has spread across the world. Despite progress with distribution and administration of vaccines, COVID-19 and its effects continue to evolve, and countries continue to respond the implementation of various responses, including government-imposed quarantines, travel restrictions and other public health safety measures. The extent to which the coronavirus impacts our operations or those of our third-party partners, including our preclinical studies and clinical trial operations, will depend on future developments, which are highly uncertain and cannot be predicted with confidence and could adversely impact our preclinical or clinical trial operations in the United States and our future clinical trial sites in foreign jurisdictions, including our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 if an outbreak occurs in their geography. For example, similar to other biopharmaceutical companies, we may experience delays in initiating IND-enabling studies, protocol deviations, enrolling our clinical trials, or dosing of patients in our clinical trials as well as in activating new trial sites. COVID-19 may also affect employees of third-party CROs located in affected geographies that we expect that we will rely upon to carry out our clinical trials. Any negative impact COVID-19 has to patient enrollment or treatment or the execution of our product candidates could cause costly delays to clinical trial activities, which could adversely affect our ability to obtain regulatory approval for and to commercialize our product candidates, increase our operating expenses, and have a material adverse effect on our financial results.

Additionally, timely enrollment in planned clinical trials and the reporting of clinical trial results is dependent upon clinical trial sites which could be adversely affected by global health matters, such as pandemics. We plan to conduct clinical trials for our product candidates in geographies which are currently affected by the COVID-19 pandemic, including our clinical trial for TNG908, a Phase 1/2 clinical trial that is now open for enrollment in the United States (the timing of which may be impacted by, among other things, the COVID-19 pandemic). Some factors from the COVID-19 pandemic that may delay or otherwise adversely affect enrollment in the clinical trials of our product candidates, including TNG908, as well as our business generally, include:

the potential diversion of healthcare resources away from the conduct of clinical trials to focus on pandemic concerns, including the attention of physicians serving as our clinical trial investigators, hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our prospective clinical trials;

limitations on travel that could interrupt key trial and business activities, such as clinical trial site initiations and monitoring, domestic and international travel by employees, contractors or patients to clinical trial sites, including any government-imposed travel restrictions or quarantines that will impact the ability or willingness of patients, employees or contractors to travel to our clinical trial sites or secure visas or entry permissions, a loss of face-to-face meetings and other interactions with potential partners, any of which could delay or adversely impact the conduct or progress of our prospective clinical trials;

the potential negative effect on the operations of our third-party manufacturers;

interruption in global shipping affecting the transport of clinical trial materials, such as patient samples, investigational drug product and conditioning drugs and other supplies used in our prospective clinical trials;

staffing shortages at clinical trial sites, both healthcare professionals (e.g. physicians, nurses) and support staff, caused by the COVID-19 pandemic and the challenges of finding replacements may adversely impact the timing and on-going performance of a clinical trial;

business disruptions caused by potential workplace, laboratory and office closures and an increased reliance on employees working from home, and disruptions to or delays in ongoing laboratory experiments;

operations, staffing shortages, travel limitations, global supply chain delays or mass transit disruptions, any of which could adversely impact our business operations or delay necessary interactions with local regulators, ethics committees and other important agencies and contractors;

changes in local regulations as part of a response to the COVID-19 pandemic, which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue such clinical trials altogether; and

interruption or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines.

Our employees, including our lab personnel, are currently working at our office headquarters. We have, in the past, taken temporary precautionary measures intended to help minimize the risk of the virus to our employees, including temporarily requiring certain of our employees to work remotely, suspending all non-essential travel worldwide for our employees, implementing COVID-19 testing policies for employees in certain instances and discouraging employee attendance at industry events and in-person work-related meetings, which could negatively affect our business (and certain of these measures remain in place). We cannot presently predict the scope and severity of the planned and potential shutdowns or disruptions of businesses and government agencies, such as the SEC or FDA.

These and other factors arising from COVID-19 (and any future variant of the COVID-19 virus) could worsen in countries that are already afflicted with COVID-19 or could continue to spread to additional countries. Any of these factors, and other factors related to any such disruptions that are unforeseen, could have a material adverse effect on our business and our results of operations and financial condition and our clinical trials. Further, uncertainty around these and related issues could lead to adverse effects on the economy of the United States and other economies, which could impact our ability to raise the necessary capital needed to develop and commercialize our programs and product candidates.

Risks Related to Commercialization

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

The development and commercialization of new products in the biopharmaceutical and related industries is highly competitive. We compete in the segments of the pharmaceutical, biotechnology, and other related markets that address structural biology-guided chemistry-based drug design to develop therapies in the fields of cancer and genetic diseases. There are other companies focusing on precision oncology to develop therapies in the fields of cancer and other diseases. Specifically, with respect to TNG908 (for which we recently received FDA clearance of our IND application), we are aware that Mirati Therapeutics, Inc. and Amgen each have a clinical MTA-cooperative PRMT5 inhibitor program, using the same mechanism of action as TNG908 (and there are other indirect competitors in the PRMT5 inhibition space as well).

We also compete more broadly across the market for cost-effective and reimbursable cancer treatments. Some of these competitive products and therapies are based on scientific approaches that are the same as or similar to our approach (as noted above), and others are based on entirely different approaches. These companies include divisions of large pharmaceutical companies and biotechnology companies of various sizes, such as Amgen. We face competition with respect to our current product candidates, and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

Any product candidates that we successfully develop and commercialize will compete with currently approved therapies and new therapies that may become available in the future from segments of the pharmaceutical, biotechnology and other related markets. Key product features that would affect our ability to effectively compete with other therapeutics include the efficacy, safety and convenience of our products. We believe principal competitive factors to our business include, among other things, our ability to identify biomarkers, ability to successfully transition research programs into clinical development, ability to raise capital, and the scalability of the platform, pipeline, and business.

Many of the companies that we compete against or which we may compete against in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and marketing, promoting and selling approved products than we do. Mergers and acquisitions in the pharmaceutical, biotechnology and diagnostic industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. If barriers to entry do not remain in place, other companies may be able to more directly or effectively compete with us.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we or our collaborators may develop. Our competitors also may obtain FDA or other regulatory approval for their products sooner than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we or our collaborators are able to enter the market. The key competitive factors affecting the success of all of our product candidates, if approved, are likely to be their efficacy, safety, convenience, price, level of generic competition and novel competition that utilize the same mechanism of action and availability of reimbursement from government and other third-party payors.

If the market opportunities for our programs and product candidates are smaller than we estimate or if any regulatory approval that we obtain is based on a narrower definition of the patient population, our revenue and ability to achieve profitability will be adversely affected, possibly materially.

The incidence and prevalence for target patient populations of our programs and product candidates have not been established with precision. Our lead product candidate, TNG908, is an oral small molecule inhibitor of PRMT5. We are developing TNG908 for the treatment of patients with solid tumors with MTAP deletion, a genetic alteration which occurs in 10% to 15% of all human tumors, including NSCLC, mesothelioma, cholangiocarcinoma, and GBM, as well as indications where there are limited treatment options with no standard of care, including MPNST. Our next-generation PRMT5 product candidate, TNG462, is being developed for the same patient population as TNG908 with the exception of GMB as TNG462 does not cross the blood-brain barrier in preclinical primate models. Additionally, our undisclosed Target 3 program is being developed for certain patients with STK11 loss-of-function mutations. STK11 loss-of-function mutations are a genetic alteration in approximately 15% of NSCLC, 15% of cervical cancers, 10% carcinoma of unknown primary, 5% of breast cancers and 3% of pancreatic cancers. USP1 is a strong synthetic lethal target for BRCA1/2-mutant, which are present in approximately 15% of ovarian cancers, 10% of breast cancers, 10% of prostate cancers, 5% of endometrial cancers and 5% of pancreatic cancers. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our programs and product candidates, are based on our estimates.

The total addressable market opportunity will ultimately depend upon, among other things, the diagnosis criteria included in the final label, the indications for which our product candidates are approved for sale, acceptance by the medical community and patient access, product pricing and reimbursement. The number of patients with the cancers and solid tumors for which our product candidates may be approved as treatment may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our products, or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business. We may not be successful in our efforts to identify additional product candidates. Due to our limited resources and capital, we must prioritize development of certain product candidates, which may prove to be the wrong choice and may adversely affect our business.

If our current product candidates or any future product candidates do not achieve broad market acceptance, the revenue that we generate from their sales may be limited, and we may never become profitable.

We have never commercialized a product candidate for any indication. Even if our current product candidates and any future product candidates are approved by the appropriate regulatory authorities for marketing and sale, they may not gain acceptance among physicians, patients, third-party payors, and others in the medical community. If any product candidates for which we obtain regulatory approval do not gain an adequate level of market acceptance, we may not generate significant revenue and may not become profitable or may be significantly delayed in achieving profitability. Market acceptance of our current product candidates and any future product candidates by the medical community, patients and third-party payors will depend on a number of factors, some of which are beyond our control. For example, physicians are often reluctant to switch their patients, and patients may be reluctant to switch, from existing therapies even when new and potentially more effective

or safer treatments enter the market. If public perception is influenced by claims that the use of certain precision oncology product candidates or immunotherapies and targeted therapies is unsafe, whether related to our or our competitors' products, our potential future products may not be accepted by the general public or the medical community. Future adverse events in precision oncology, immuno-oncology or the biopharmaceutical industry could also result in greater governmental regulation, stricter labeling requirements and potential regulatory delays in the testing or approvals of our product candidates.

Efforts to educate the medical community and third-party payors on the benefits of our current product candidates and any future product candidates may require significant resources and may not be successful. If our current product candidates or any future product candidates are approved but do not achieve an adequate level of market acceptance, we could be prevented from or significantly delayed in achieving profitability. The degree of market acceptance of any of our current product candidates and any future product candidates will depend on a number of factors, including:

the efficacy of our current product candidates and any future product candidates as single agents and in combination with marketed combination therapies or other therapies that are also pending regulatory approval;

the commercial success of the checkpoint blockade drugs with which certain of our products may be co-administered;

the prevalence and severity of adverse events associated with our current product candidates and any future product candidates or those products with which they may be co-administered;

the clinical indications for which our product candidates are approved and the approved claims that we may make for the products;

limitations or warnings contained in the product's FDA-approved labeling or those of comparable foreign regulatory authorities, including potential limitations or warnings for our current product candidates and any future product candidates that may be more restrictive than other competitive products;

changes in the standard of care for the targeted indications of our current product candidates and any future product candidates, which could reduce the marketing impact of any claims that we could make following FDA approval or approval by comparable foreign regulatory authorities, if obtained;

the relative convenience and ease of administration of our current product candidates and any future product candidates (including the number of doses required in a given period) and any products with which they are co-administered;

the cost of treatment compared with the economic and clinical benefit of alternative treatments or therapies;

the availability of adequate coverage or reimbursement by third-party payors, including government healthcare programs such as Medicare and Medicaid and other healthcare payors;

the price concessions required by third-party payors to obtain coverage;

the willingness of patients to pay out-of-pocket in the absence of adequate coverage and reimbursement;

the extent and strength of our marketing and distribution of our current product candidates and any future product candidates;

the safety, efficacy, and other potential advantages over, and availability of, alternative treatments already used or that may later be approved;

distribution and use restrictions imposed by the FDA or comparable foreign regulatory authorities with respect to our current product candidates and any future product candidates or to which we agree as part of a risk evaluation and mitigation strategy, or REMS, or voluntary risk management plan;

the timing of market introduction of our current product candidates and any future product candidates, as well as competitive products;

our ability to offer our current product candidates and any future product candidates for sale at competitive prices;

the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;

the extent and strength of our third-party manufacturer and supplier support;

the actions of companies that market any products with which our current product candidates and any future product candidates may be co-administered;

the approval of other new products;

adverse publicity about our current product candidates and any future product candidates or any products with which they are co-administered, or favorable publicity about competitive products; and

potential product liability claims.

Risks Related to Our Reliance on Third Parties

We expect to rely on third parties to conduct our future clinical trials, as well as investigator-sponsored clinical trials of our product candidates. If these third parties do not successfully carry out their contractual duties, comply with regulatory requirements or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We do not have the ability to independently conduct clinical trials. We expect to rely on medical institutions, clinical investigators, contract laboratories and other third parties, such as CROs, to conduct or otherwise support clinical trials for our product candidates, including our Phase 1/2 clinical trial of TNG908, and for any other product candidates that emerge from our precision oncology programs. We may also rely on academic and private non-academic institutions to conduct and sponsor clinical trials relating to our product candidates. We will not control the design or conduct of the investigator-sponsored trials, and it is possible that the FDA or non-U.S. regulatory authorities will not view these investigator-sponsored trials as providing adequate support for future clinical trials, whether controlled by us or third parties, for any number of reasons, including elements of the design or execution of the trials or safety concerns or other trial results.

We are likely to have certain information rights with respect to the investigator-sponsored trials, including access to and the ability to use and reference the data, including for our own regulatory filings. However, we would not have control over the timing and reporting of the data from investigator-sponsored trials, nor would we own the data from the investigator-sponsored trials. If we are unable to confirm or replicate the results from the investigator-sponsored trials or if negative results are obtained, we would likely be further delayed or prevented from advancing further clinical development of our product candidates. Further, if investigators or institutions breach their obligations with respect to the clinical development of our product candidates, or if the data proves to be inadequate compared to the first-hand knowledge we might have gained had the investigator-sponsored trials been sponsored and conducted by us, then our ability to design and conduct any future clinical trials ourselves may be adversely affected.

We rely and expect to continue to rely heavily on third parties for execution of clinical trials for our product candidates and control only certain aspects of their activities (and such control may be based on contractual provisions that may be breached by the third-party). For example, for the Phase 1/2 clinical trial of TNG908, we expect to rely on one CRO for the conduct of the trial and one manufacturer to manufacture the study drug to be used during the course of the trial. We are responsible for ensuring that each of our clinical trials and the study drug is conducted and manufactured in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on a CRO or CDMO will not relieve us of our regulatory responsibilities. For any violations of laws and regulations during the conduct of our clinical trials, we could be subject to warning letters or enforcement action that may include civil penalties, suspension/hold or termination of trials and other penalties up to and including criminal prosecution.

We, our principal investigators and our CROs are required to comply with regulations, including GCPs for conducting, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate, and that the trial patients are adequately informed of the potential risks of participating in clinical trials and their rights are protected. These regulations are enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities for any products in clinical development. The FDA enforces GCP regulations through periodic inspections of clinical trial sponsors, principal investigators and trial sites. If we, our principal investigators or our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA will determine that any of our future clinical trials will comply with GCPs. In addition, our clinical trials generally must be conducted with product candidates produced under current Good Manufacturing Practice, or cGMP, regulations. Our failure or the failure of our principal investigators, third party manufacturers or CROs to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process, significantly increase our expenditures and could also subject us to enforcement action. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Although we have designed our Phase 1/2 clinical trial of TNG908 and intend to design the future clinical trials for our product candidates, the operational details of these trials will be executed by CROs and we expect CROs will conduct all of our future clinical trials. As a result, many important aspects of our development programs, including their conduct and timing, are outside of our direct control. Our reliance on third parties to conduct future clinical trials also results in less direct control over the management of data developed through clinical trials than would be the case if we were relying entirely upon our own staff. Communicating with outside parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Outside parties may have staffing difficulties, fail to comply with contractual obligations, experience regulatory compliance issues, undergo changes in priorities or become financially distressed or form relationships with other entities, some of which may be our competitors.

These factors may materially adversely affect the willingness or ability of third parties to conduct our clinical trials and may subject us to unexpected cost increases that are beyond our control. If the principal investigators or CROs do not perform clinical trials in a satisfactory manner, breach their obligations to us or fail to comply with regulatory requirements, the development, regulatory approval and commercialization of our product candidates may be delayed, we may not be able

to obtain regulatory approval and commercialize our product candidates or our development program may be materially and irreversibly harmed. If we are unable to rely on clinical data collected by our principal investigators or CROs, we could be required to repeat, extend the duration of, or increase the size of any clinical trials we conduct and this could significantly delay commercialization and require significantly greater expenditures.

If any of our relationships with these third-party principal investigators or CROs terminate, we may not be able to enter into arrangements with alternative CROs. If principal investigators or CROs do not successfully carry out their contractual obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, any clinical trials such principal investigators or CROs are associated with may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize, our product candidates. As a result, we believe that our financial results and the commercial prospects for our product candidates in the subject indication would be harmed, our costs could increase and our ability to generate future revenue, if any, could be delayed.

We have entered into collaborations and may enter into additional collaborations in the future, and we might not realize the anticipated benefits of such collaborations.

Research, development, commercialization and/or strategic collaborations, including the existing collaboration that we have with Gilead, are subject to numerous risks, which include the following:

collaborators may have significant control or discretion in determining the efforts and resources that they will apply to a collaboration, and might not commit sufficient efforts and resources or might misapply those efforts and resources;

we may have limited influence or control over the approaches to research, development and/or commercialization of product candidates in the territories in which our collaboration partners lead research, development and/or commercialization;

collaborators might not pursue research, development and/or commercialization of collaboration product candidates or might elect not to continue or renew research, development and/or commercialization programs based on nonclinical and/or clinical trial results, changes in their strategic focus, availability of funding or other factors, such as a business combination that diverts resources or creates competing priorities;

collaborators might delay, provide insufficient resources to, or modify or stop research or clinical development for collaboration product candidates or require a new formulation of a product candidate for clinical testing;

collaborators with sales, marketing and distribution rights to one or more product candidates might not commit sufficient resources to sales, marketing and distribution or might otherwise fail to successfully commercialize those product candidates;

collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates;

collaborators might not properly maintain or defend our intellectual property rights or might use our intellectual property improperly or in a way that jeopardizes our intellectual property or the potential commercial benefit of our product candidates or exposes us to potential liability;

collaboration activities might result in the collaborator having intellectual property covering our activities or product candidates, which could limit our rights or ability to research, develop and/or commercialize our product candidates;

collaborators might not be in compliance with laws applicable to their activities under the collaboration, which could impact the collaboration and us;

disputes might arise between a collaborator and us that could cause a delay or termination of the collaboration or result in costly litigation that diverts management attention and resources; and

collaborations might be terminated, which could result in a need for additional capital to pursue further research, development and/or commercialization of our product candidates.

In addition, funding provided by a collaborator might not be sufficient to advance product candidates under the collaboration. For example, although Gilead provided us with $175.0 million upfront payments and a $20.0 million equity investment in connection with certain collaboration agreements with Gilead, we might need additional funding to advance product candidates prior to the completion of the clinical milestones of the collaboration agreement with Gilead.

If a collaborator terminates a collaboration or a program under a collaboration, including by failing to exercise a license or other option under the collaboration, whether because we fail to meet a milestone or otherwise, any potential revenue from the collaboration would be significantly reduced or eliminated. In addition, we will likely need to either secure other funding to advance research, development and/or commercialization of the relevant product candidate or abandon that program (or abandon a different program to allocate resources to the program rejected by the collaborator), the development of the relevant product candidate could be significantly delayed, and our cash expenditures could increase significantly if we are to continue research, development and/or commercialization of the relevant product candidates.

Any one or more of these risks, if realized, could reduce or eliminate future revenue from product candidates under our collaborations, and could have a material adverse effect on our business, financial condition, results of operations and/or growth prospects.

We contract with third parties for the manufacture of our product candidates for preclinical development and expect to continue to do so for clinical testing and commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not currently own or operate, nor do we have any plans to establish in the future, any manufacturing facilities. We rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for preclinical development and clinical testing, as well as for the commercial manufacture of our products if any of our product candidates receive regulatory approval. In some cases, we rely on one party to manufacture our preclinical and clinical products and we exercise limited direct control over this manufacturer (and it would be time consuming and expensive to move production to a new manufacturer, if we were able to do so at all). This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts. For example, we rely on a limited number of CROs to perform certain chemistry-related work on our preclinical product candidates. One such CRO is located in Ukraine, which was invaded by Russia in February 2022 and, as a result, their work on our behalf of was interrupted. Another CRO, with operations in Shanghai, was impacted when lock-down procedures were recently implemented due to COVID-19 and was unable to operate at full capacity. Events such as those in Ukraine and China may delay development of our future product candidates, and such delay may materially impact the timing for moving products into development candidate stage and IND-enabling studies, as well as initiating trials.

The facilities used by our contract manufacturers to manufacture our product candidates must be inspected by the FDA pursuant to pre-approval inspections that will be conducted after we submit our marketing applications to the FDA. We do not control the manufacturing process of, and will be completely dependent on, our contract manufacturers for compliance with cGMPs in connection with the manufacture of our product candidates. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to pass regulatory inspections and/or maintain regulatory compliance for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority finds deficiencies with or does not approve these facilities for the manufacture of our product candidates or if it finds deficiencies or withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

If any contract manufacturing organization, or CMO, with whom we contract fails to perform its obligations, we may be forced to enter into an agreement with a different CMO, which we may not be able to do on reasonable terms, if at all. In such scenario, our clinical trials supply could be delayed significantly as we establish alternative supply sources. In some cases, the technical skills required to manufacture our products or product candidates may be unique or proprietary to the original CMO and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change CMOs for any reason, we will be required to verify that the new CMO maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidate according to the specifications previously submitted to the FDA or another regulatory authority. The delays associated with the verification of a new CMO could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. Furthermore, a CMO may possess technology related to the manufacture of our product candidate that such CMO owns independently. This would increase our reliance on such CMO or require us to obtain a license from such CMO in order to have another CMO manufacture our product candidates. In addition, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials.

Further, our failure, or the failure of our third-party manufacturers to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, if approved, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business and supplies of our product candidates.

We may be unable to establish any additional agreements with third-party manufacturers or do so on acceptable terms. Reliance on third-party manufacturers entails additional risks, including:

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

Our product candidates and any products that we may develop may compete with other product candidates and approved products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us.

Any performance failure on the part of our existing or future manufacturers could delay clinical development or regulatory approval. If our current contract manufacturers cannot perform as agreed, we may be required to replace such manufacturers. We may incur added costs and delays in identifying and qualifying any such replacement.

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

The third parties upon whom we rely for the supply of the active pharmaceutical ingredients and drug product to be used in our product candidates are our sole source of supply, and the loss of any of these suppliers could significantly harm our business.

The active pharmaceutical ingredients, or API, and drug product we expect to use in all of our product candidates are supplied to us from single-source suppliers. In some cases, both the API and drug product are manufactured and supplied by the same single-source (as is the case with respect to the supply of TNG908 for use in our Phase 1/2 clinical trial). Our ability to successfully develop our product candidates, and to ultimately supply our commercial products in quantities sufficient to meet the market demand (and to meet requirements in connection with our planned clinical trials), depends in part on our ability to obtain the API and drug product for these products in accordance with regulatory requirements and in sufficient quantities for clinical testing and commercialization. We are also unable to predict how changing global economic conditions or global health concerns such as the ongoing COVID-19 pandemic, as well as potential supply chain disruptions or cost increases related thereto, will affect our third-party suppliers and manufacturers. Any negative impact of such matters on our third-party suppliers and manufacturers may also have an adverse impact on our results of operations or financial condition.

For all of our product candidates, we intend to identify and qualify additional manufacturers to provide such API and drug product prior to submission of an NDA to the FDA and/or an MAA to the EMA. We are not certain, however, that our single-source suppliers will be able to meet our demand for products, either because of the nature of our agreements with those suppliers, our limited experience with those suppliers or our relative importance as a customer to those suppliers. It may be difficult for us to assess their ability to timely meet our demand in the future based on past performance. While our suppliers have generally met our demand for their products on a timely basis in the past, they may subordinate our needs in the future to their other customers.

Establishing additional or replacement suppliers for the API and drug product used in our product candidates, if required, may not be accomplished quickly (or at all). If we are able to find a replacement supplier, such replacement supplier would need to be qualified and may require additional regulatory inspection or approval, which could result in further delay. While we seek to maintain adequate inventory of the API and drug product used in our product candidates, any interruption or delay in the supply of components or materials, or our inability to obtain such API and drug product from alternate sources at acceptable prices in a timely manner could impede, delay, limit or prevent our development efforts, which could harm our business, results of operations, financial condition and prospects.

We may seek to establish additional collaborations, and, if we are not able to establish them on commercially reasonable terms, or at all, we may have to alter our development and commercialization plans.

Our product development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. For some of our product candidates, we may decide to collaborate with additional pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's own evaluation of a potential collaboration. Factors a potential collaborator will use to evaluate a collaboration may include the design or results of clinical trials, the likelihood of approval by the FDA or comparable foreign regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, as well as industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. The terms of any additional collaborations or other arrangements that we may establish may not be favorable to us.

We may also be restricted under collaboration agreements from entering into future agreements on certain terms with potential collaborators. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate additional collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all and it may be difficult to recruit and retain the expertise needed to launch and commercialize a new drug therapy. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

In addition, any future collaborations that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations. Disagreements between parties to a collaboration arrangement regarding clinical development and commercialization matters can lead to delays in the development process or commercializing the applicable product candidate and, in some cases, termination of the collaboration arrangement. These disagreements can be difficult to resolve if neither of the parties has final decision-making authority. Collaborations with pharmaceutical or biotechnology companies and other third parties often are terminated or allowed to expire by the other party. Any such termination or expiration would adversely affect us financially and could harm our business reputation.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent and other intellectual property protection for our technology and product candidates or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and drugs similar or identical to ours, and our ability to successfully commercialize our technology and drugs may be impaired.

Our commercial success depends in part on our ability to obtain and maintain proprietary or intellectual property protection in the United States and other countries for our current or future product candidates, including our current lead product candidate, TNG908, and our other future product candidates, as well as for their respective compositions, formulations, methods used to manufacture them, and methods of treatment, in addition to successfully defending these patents against third-party challenges. We seek to protect our proprietary and intellectual property position by, among other methods, filing patent applications in the United States and abroad related to our proprietary technology, inventions, and improvements that are important to the development and implementation of our business. Our ability to stop unauthorized third parties from making, using, selling, offering to sell, or importing our product candidates is dependent upon the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. We also rely on trade secrets, know-how and continuing technological innovation to develop and maintain our proprietary and intellectual property position. As of the date of the filing of this Quarterly Report on Form 10-Q, we have filed patent applications, but have no issued patents in the United States or elsewhere for our product candidates.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. The degree of patent protection we require to successfully commercialize our current or future product candidates may be unavailable or severely limited in some cases and the intellectual property protections we may obtain may not adequately protect our rights or permit us to gain or keep any competitive advantage. We cannot provide any assurances that any of our pending patent applications that mature into issued patents will include claims with a scope sufficient to protect TNG908 or our other current or future product candidates. In addition, if the breadth or strength of protection provided by our patent applications or any patents we may own or in-license is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, in jurisdictions outside the United States, a license may not be enforceable unless all the owners of the intellectual property agree or consent to the license. Accordingly, any actual or purported co-owner of our patent rights could seek monetary or equitable relief requiring us to pay it compensation for, or refrain from, exploiting these patents due to such co-ownership. Furthermore, patents have a limited lifespan. In the United States and most other jurisdictions in which we have undertaken patent filings, the natural expiration of a patent is generally twenty years after it is filed, assuming all maintenance fees are paid. Various extensions may be available, on a jurisdiction-by-jurisdiction basis; however, the life of a patent, and thus the protection it affords, is limited. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, patents we may own or in-license may not provide us with adequate and continuing patent protection sufficient to exclude others from commercializing drugs similar or identical to our current or future product candidates, including generic versions of such drugs.

Other parties have developed technologies that may be related or competitive to our own, and such parties may have filed or may file patent applications, or may have received or may receive patents, claiming inventions that may overlap or conflict with those claimed in our own patent applications or issued patents, with respect to either the same compounds, methods, formulations or other subject matter, in either case that we may rely upon to dominate our patent position in the market. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until at least 18 months after the earliest priority date of patent filing, or, in some cases, not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in patents we may own or in-license patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights cannot be predicted with any certainty.

In addition, the patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. Further, with respect to certain pending patent applications covering our current or future product candidates, prosecution has yet to commence. Patent prosecution is a lengthy process, during which the scope of the claims initially submitted for examination by the relevant patent office(s) may be significantly narrowed by the time they issue, if they ever do. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from or to third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

Even if we acquire patent protection that we expect should enable us to establish and/or maintain a competitive advantage, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. We may become involved in post-grant proceedings such as opposition, derivation, reexamination, *inter partes* review, post-grant review, or interference proceedings challenging our patent rights or the patent rights of others from whom we license or we may in the future obtain licenses to such rights, in the U.S. Patent and Trademark Office, or USPTO, the European Patent Office, or EPO, or in other countries. In addition, we may be subject to a third-party submission to the USPTO, the EPO, or elsewhere, that may reduce the scope or preclude the granting of claims from our pending patent applications. Competitors may allege that they invented the inventions claimed in our issued patents or patent applications prior to us, or may file patent applications before we do. Competitors may also claim that we are infringing their patents and that we therefore cannot practice our technology as claimed under our patents or patent applications. Competitors may also contest our patents by claiming to an administrative patent authority or judge that the invention was not patent-eligible, was not original, was not novel, was obvious, and/or lacked inventive step, and/or that the patent application filing failed to meet relevant requirements

relating to description, basis, enablement, and/or support. In litigation, a competitor could claim that our patents, if issued, are not valid or are unenforceable for a number of reasons. If a court or administrative patent authority agrees, we would lose our protection of those challenged patents.

In addition, we may in the future be subject to claims by our former employees or consultants asserting an ownership right in our patents or patent applications, as a result of the work they performed on our behalf. Although we generally require all of our employees, consultants and advisors and any other third parties who have access to our proprietary know-how, information or technology to assign or grant similar rights to the inventions they make in the course of their work to us, we cannot be certain that we have executed such agreements with all parties who may have contributed to our intellectual property, nor can we be certain that our agreements with such parties will be upheld in the face of a potential challenge, or that they will not be breached, for which we may not have an adequate remedy.

An adverse determination in any such submission or proceeding may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and drugs, without payment to us, or could limit the duration of the patent protection covering our technology and current or future product candidates. Such challenges may also result in our inability to manufacture or commercialize our current or future product candidates without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Even if they are unchallenged, our issued patents and our pending patent applications, if issued, may not provide us with any meaningful protection or prevent competitors from designing around our patent claims to circumvent patents we may own or in-license by developing similar or alternative technologies or drugs in a non-infringing manner. For example, a third party may develop a competitive drug that provides benefits similar to one or more of our current or future product candidates but that has a different composition that falls outside the scope of our patent protection. If the patent protection provided by the patents and patent applications we hold or pursue with respect to our current or future product candidates is not sufficiently broad to impede such competition, our ability to successfully commercialize our current or future product candidates could be negatively affected, which would harm our business.

Furthermore, even if we are able to issue patents with claims of valuable scope in one or more jurisdictions, we may not be able to secure such claims in all relevant jurisdictions, or in a sufficient number to meaningfully reduce competition. Our competitors may be able to develop and commercialize their products, including products identical to ours, in any jurisdiction in which we are unable to obtain, maintain, or enforce such patent claims.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, deadlines, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated if we fail to comply with these requirements. We may miss a filing deadline for patent protection on these inventions.

The USPTO and foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process and after issuance of any patent. In addition, periodic maintenance fees, renewal fees, annuity fees and/or various other government fees are required to be paid periodically. While an inadvertent lapse can, in some cases, be cured by payment of a late fee, or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market with similar or identical products or platforms, which could have a material adverse effect on our business prospects and financial condition.

If we do not obtain patent term extension for our product candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of FDA marketing approval of our product candidates, one or more of our U.S. patents or those of our future licensors may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments). The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. A maximum of one patent may be extended per FDA approved product as compensation for the patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of

a patent beyond a total of 14 years from the date of product approval and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. Patent term extension may also be available in certain foreign countries upon regulatory approval of our product candidates. However, we may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or restoration or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced, possibly materially. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

If our trademarks and trade names for our products or company name are not adequately protected in one or more countries where we intend to market our products, we may delay the launch of product brand names, use different trademarks or tradenames in different countries, or face other potentially adverse consequences to building our product brand recognition.

Our trademarks or trade names may be challenged, infringed, diluted, circumvented or declared generic or determined to be infringing on other marks. We intend to rely on both registration and common law protection for our trademarks. 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. Further we have not, and may not, register for trademark protection in every potential jurisdiction where we may conduct business or sell products (if approved). During the trademark registration process, we have in the past received and may in the future receive Office Actions from the USPTO or from comparable agencies in foreign jurisdictions objecting to the registration of our trademark. Although we may be given an opportunity to respond to those objections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and/or to seek the cancellation of registered trademarks. Opposition or cancellation proceedings may be filed against our trademark applications or registrations, and our trademark applications or registrations may not survive such proceedings. If we are unable to obtain a registered trademark, or do not seek registered trademarks, or 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.

If we are unable to adequately protect and enforce our trade secrets, our business and competitive position would be harmed.

In addition to the protection afforded by patents we may own or in-license, we seek to rely on trade secret protection, confidentiality agreements, and license agreements to protect proprietary know-how that may not be patentable, processes for which patents are difficult to enforce and any other elements of our product discovery and development processes that involve proprietary know-how, information, or technology that may not be covered by patents. Although we seek to require all of our employees, consultants, advisors, and any third parties who have access to our proprietary know-how, information, or technology to enter into confidentiality agreements, trade secrets can be difficult to protect and we have limited control over the protection of trade secrets used by our collaborators and suppliers. We cannot be certain that we have or will obtain these agreements in all circumstances and we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary information.

Moreover, any of these parties might breach the agreements and intentionally or inadvertently disclose our trade secret information and we may not be able to obtain adequate remedies for such breaches. In addition, competitors may otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Furthermore, the laws of some foreign countries do not protect proprietary rights and trade secrets to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property or proprietary information to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, financial condition, results of operations and future prospects.

Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. If we choose to go to court to stop a third party from using any of our trade secrets, we may incur substantial costs. These lawsuits may consume our time and other resources even if we are successful. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and

techniques or otherwise gain access to our trade secrets or disclose our technology. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us.

Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual or entity during the course of the party's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In addition, we take other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of our proprietary technology by third parties. In the case of employees, the agreements provide that all inventions conceived by the individual, and which are related to our current or planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information, are our exclusive property. Although we require all of our employees to assign their inventions 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. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We may initiate, become a defendant in, or otherwise become party to lawsuits to protect or enforce our intellectual property rights, which could be expensive, time-consuming, and unsuccessful.

Competitors may infringe any patents we may own or in-license. In addition, any patents we may own or in-license also may become involved in inventorship, priority, validity or unenforceability disputes. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful (and we may not be able to prevent the commercialization of the competitor product). In addition, in an infringement proceeding, a court may decide that one or more of any patents we may own or in-license is not valid or is unenforceable or that the other party's use of our technology that may be patented falls under the safe harbor to patent infringement under 35 U.S.C. § 271(e)(1). There is also the risk that, even if the validity of these patents is upheld, the court may refuse to stop the other party from using the technology at issue on the grounds that any patents we may own or in-license do not cover the technology in question or that such third party's activities do not infringe our patent applications or any patents we may own or in-license. An adverse result in any litigation or defense proceedings could put one or more of any patents we may own or in-license at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, patient support or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace and may negatively impact our stock price.

Post-grant proceedings provoked by third parties or brought by the USPTO may be necessary to determine the validity or priority of inventions with respect to our patent applications or any patents we may own or in-license. These proceedings are expensive and an unfavorable outcome could result in a loss of our current patent rights (or technology covered under current patent applications) and could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. In addition to potential USPTO post-grant proceedings, we may become a party to patent opposition proceedings in the EPO, or similar proceedings in other foreign patent offices or courts where our patents may be challenged. The costs of these proceedings could be substantial, and may result in a loss of scope of some claims or a loss of the entire patent. An unfavorable result in a post-grant challenge proceeding may result in the loss of our right to exclude others from practicing one or more of our inventions in the relevant country or jurisdiction, which could have a material adverse effect on our business. Litigation or post-grant proceedings within patent offices may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States.

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. 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.

We may not be able to detect infringement against any patents we may own or in-license. Even if we detect infringement by a third party of any patents we may own or in-license, we may choose not to pursue litigation against or settlement with the third party. If we later sue such third party for patent infringement, the third party may have certain legal defenses available to it, which otherwise would not be available except for the delay between when the infringement was first detected and when the suit was brought. Such legal defenses may make it impossible for us to enforce any patents we may own or in-license against such third party.

Intellectual property litigation and administrative patent office patent validity challenges in one or more countries could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, patient support or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. As noted above, 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. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace, including compromising our ability to raise the funds necessary to initiate and continue our clinical trials, continue our research programs, license necessary technology from third parties, or enter into development collaborations that would help us commercialize our current or future product candidates, if approved. Any of the foregoing events would harm our business, financial condition, results of operations and prospects.

We may be subject to damages or settlement costs resulting from claims that we or our employees have violated the intellectual property rights of third parties, or are in breach of our agreements. We may be accused of, allege or otherwise become party to lawsuits or disputes alleging wrongful disclosure of third-party confidential information by us or by another party, including current or former employees, contractors or consultants. In addition to diverting attention and resources to such disputes, such disputes could adversely impact our business reputation and/or protection of our proprietary technology.

The intellectual property landscape relevant to our product candidates and programs is crowded, and third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business. Our commercial success depends upon our ability to develop, manufacture, market and sell our current and future product candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including derivation, interference, reexamination, *inter partes* review and post grant review proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. We or any of our current or future licensors or strategic partners may be party to, exposed to, or threatened with, future adversarial proceedings or litigation by third parties having patent or other intellectual property rights alleging that our current or future product candidates and/or proprietary technologies infringe, misappropriate or otherwise violate their intellectual property rights. We cannot assure you that our current or future product candidates and other technologies that we have developed, are developing or may develop in the future do not or will not infringe, misappropriate or otherwise violate existing or future patents or other intellectual property rights owned by third parties. For example, many of our employees were previously employed at other biotechnology or pharmaceutical companies. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's former employer. We may also be subject to claims that patents and applications we have filed to protect inventions of our employees, consultants and advisors, even those related to one or more of our current or future product candidates, are rightfully owned by their former or concurrent employer. Litigation may be necessary to defend against these claims.

While certain activities related to development and clinical testing of our current or future product candidates may be subject to safe harbor of patent infringement under 35 U.S.C. §271(e)(1), upon receiving FDA approval for such candidates we or any of our future licensors or strategic partners may immediately become party to, exposed to, or threatened with, future adversarial proceedings or litigation by third parties having patent or other intellectual property rights alleging that such product candidates infringe, misappropriate or otherwise violate their intellectual property rights. If such actions are successful, the third party may be able to, among other things, prevent launch of a product (which may happen only after the significant expense of development and clinical trials). Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our current or future product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our current or future product candidates may give rise to claims of infringement of the patent rights of others. Moreover, it is not always clear to industry participants, including us, which patents cover various types of drugs, products or their methods of use or manufacture. Thus, because of the large number of patents issued and patent applications filed in our fields, there may be a risk that third parties may allege they have patent rights encompassing our current or future product candidates, technologies or methods.

If a third party claims that we infringe, misappropriate or otherwise violate its intellectual property rights, we may face a number of issues, including, but not limited to:

infringement, misappropriation and other intellectual property claims which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management's attention from our core business and may impact our reputation;

substantial damages for infringement, misappropriation or other violations, which we may have to pay if a court decides that the product candidate or technology at issue infringes, misappropriates or violates the third party's rights, and, if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees;

a court prohibiting us from developing, manufacturing, marketing or selling our current product candidate, including TNG908, or future product candidates, or from using our proprietary technologies, unless the third party licenses its product rights to us, which it is not required to do, on commercially reasonable terms or at all;

if a license is available from a third party, we may have to pay substantial royalties, upfront fees and other amounts, and/or grant cross-licenses to intellectual property rights for our products, or the license to us may be non-exclusive, which would permit third parties to use the same intellectual property to compete with us;

redesigning our current or future product candidates or processes so they do not infringe, misappropriate or violate third-party intellectual property rights, which may not be possible or may require substantial monetary expenditures and time; and

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. 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. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, results of operations, financial condition and prospects. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition, results of operations or prospects.

We may choose to challenge the patentability of claims in a third party's U.S. patent by requesting that the USPTO review the patent claims in an ex-parte re-exam, *inter partes* review or post-grant review proceedings. These proceedings are expensive and may consume our time or other resources. We may choose to challenge a third party's patent in patent opposition proceedings in the EPO or other foreign patent office. The costs of these opposition proceedings could be substantial, and may consume our time or other resources. If we fail to obtain a favorable result at the USPTO, EPO or other patent office then we may be exposed to litigation by a third party alleging that the patent may be infringed by our current or future product candidates or proprietary technologies.

Third parties may assert that we are employing their proprietary technology without authorization. Patents issued in the United States by law enjoy a presumption of validity that can be rebutted in U.S. courts only with evidence that is "clear and convincing," a heightened standard of proof. There may be issued third-party patents of which we are currently unaware with claims to compositions, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our current or future product candidates. Patent applications can take many years to issue. In addition, because some patent applications in the United States may be maintained in secrecy until the patents are issued, patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after their earliest priority filing date, and publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications covering our current or future product candidates or technology. If any such patent

applications issue as patents, and if such patents have priority over our patent applications or patents we may own or in-license, we may be required to obtain rights to such patents owned by third parties which may not be available on commercially reasonable terms or at all, or may only be available on a non-exclusive basis. There may be currently pending third-party patent applications which may later result in issued patents that our current or future product candidates may infringe. It is also possible that patents owned by third parties of which we are aware, but which we do not believe are relevant to our current or future product candidates or other technologies, could be found to be infringed by our current or future product candidates or other technologies. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Moreover, we may fail to identify relevant patents or incorrectly conclude that a patent is invalid, not enforceable, exhausted, or not infringed by our activities. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of our current or future product candidates, molecules used in or formed during the manufacturing process, or any final product itself, the holders of any such patents may be able to block our ability to commercialize the product candidate unless we obtained a license under the applicable patents, or until such patents expire or they are finally determined to be held invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy or patient selection methods, the holders of any such patent may be able to block our ability to develop and commercialize the product candidate unless we obtained a license or until such patent expires or is finally determined to be held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, our ability to commercialize our current or future product candidates may be impaired or delayed, which could in turn significantly harm our business. Even if we obtain a license, it may be nonexclusive, thereby giving our competitors access to the same technologies licensed to us.

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

We may be unable to obtain patent or other intellectual property protection for our current or future product candidates or our future products, if any, in all jurisdictions throughout the world, and we may not be able to adequately enforce our intellectual property rights even in the jurisdictions where we seek protection.

We may not be able to pursue patent coverage of our current or future product candidates in all countries. Filing, prosecuting and defending patents on current or future product candidates in all countries throughout the world would be prohibitively expensive, and intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but where intellectual property rights enforcement is not as strong as that in the United States. These products may compete with our current or future product candidates and in jurisdictions where we do not have any issued patents our patent applications or other intellectual property rights may not be effective or sufficient to prevent them from competing. Much of our patent portfolio is at the very early stage. We will need to decide whether and in which jurisdictions to pursue protection for the various inventions in our portfolio prior to applicable deadlines.

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

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

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 are forced to grant a license to third parties with respect to any patents we may own or license that are relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations, and prospects may be adversely affected.

We may not obtain or grant licenses or sublicenses to intellectual property rights in all markets on equally or sufficiently favorable terms with third parties.

It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our products, in which case we would be required to obtain a license from these third parties. The licensing of third-party intellectual property rights is a competitive area, and more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. More established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to license such technology, or if we are forced to license such technology on unfavorable terms, our business could be materially harmed. If we are unable to obtain a necessary license, we may be unable to develop or commercialize the affected current or future product candidates, which could materially harm our business, and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties or other forms of compensation. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. Any of the foregoing could harm our competitive position, business, financial condition, results of operations and prospects.

If we fail to comply with our obligations in any agreements under which we may license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

We may from time to time be party to license and collaboration agreements with third parties to advance our research or allow commercialization of current or future product candidates. Such agreements may impose numerous obligations, such as development, diligence, payment, commercialization, funding, milestone, royalty, sublicensing, insurance, patent prosecution, enforcement and other obligations on us and may require us to meet development timelines, or to exercise commercially reasonable efforts to develop and commercialize licensed products, in order to maintain the licenses. In spite of our best efforts, our licensors might conclude that we have materially breached our license agreements and might therefore terminate the license agreements, thereby removing or limiting our ability to develop and commercialize products and technologies covered by these license agreements.

Any termination of these licenses, or if the underlying patents fail to provide the intended exclusivity, could result in the loss of significant rights and could harm our ability to commercialize our current or future product candidates, and competitors or other third parties would have the freedom to seek regulatory approval of, and to market, products identical to ours and we may be required to cease our development and commercialization of certain of our current or future product candidates. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Disputes may also arise between us and our licensors regarding intellectual property subject to a license agreement, including:

the scope of rights granted under the license agreement and other interpretation-related issues;
whether and the extent to which our technology and processes infringe, misappropriate or otherwise violate intellectual property rights of the licensor that is not subject to the licensing agreement;
our right to sublicense patent and other rights to third parties under collaborative development relationships;

our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our current or future product candidates, and what activities satisfy those diligence obligations;

the priority of invention of any patented technology; and

the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our future licensors and us and our partners.

In addition, the agreements under which we may license intellectual property or technology from third parties are likely to be complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we may license prevent or impair our ability to maintain future licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected current or future product candidates, which could have a material adverse effect on our business, financial conditions, results of operations and prospects.

Any granted patents we may own or in-license covering our current or future product candidates or other valuable technology could be narrowed or found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad, including the USPTO and the EPO. A patent asserted in a judicial court could be found invalid or unenforceable during the enforcement proceeding. Administrative or judicial proceedings challenging the validity of our patents or individual patent claims could take months or years to resolve.

If we or our licensors or strategic partners initiate legal proceedings against a third party to enforce a patent covering one of our current or future product candidates, the defendant could counterclaim that the patent covering our product candidate, as applicable, is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of patentable subject matter, lack of written description, 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, in the process of obtaining the patent during patent prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, *inter partes* review, post grant review and equivalent proceedings in foreign jurisdictions (such as opposition proceedings). Such proceedings could result in revocation or amendment to our patent applications or any patents we may own or in-license in such a way that they no longer cover our current or future product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, any rights we may have from our patent applications or any patents we may own or in-license, allow third parties to commercialize our current or future product candidates or other technologies and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Moreover, we may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge our or our future licensors' priority of invention or other features of patentability with respect to our patent applications and any patents we may own or in-license. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated, or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our current or future product candidates and other technologies. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we or our future licensing partners and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, or if we are otherwise unable to adequately protect our rights, we would lose at least part, and perhaps all, of the patent protection on our current or future product candidates. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize or license our technology and current or future product candidates.

Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. If we are unsuccessful in any such proceeding or other priority or inventorship dispute, we may be required to obtain and maintain licenses from third parties, including parties involved in any such interference proceedings or other priority or inventorship disputes. Such licenses may not be available on commercially reasonable terms or at all, or may be non-exclusive. If we are unable to obtain and maintain such licenses, we may need to cease the development, manufacture, and commercialization of one or more of the current or future product candidates we

may develop. The loss of exclusivity or the narrowing of our patent application claims could limit our ability to stop others from using or commercializing similar or identical technology and products. Any of the foregoing could have a material adverse effect on our business, results of operations, financial condition and prospects.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our current or future product candidates.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act, or Leahy-Smith Act, signed into law on September 16, 2011, could increase those uncertainties and costs. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. An adverse determination in any such submission or proceeding could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action.

In addition, the Leahy-Smith Act has transformed the U.S. patent system into a "first inventor to file" system. The first-inventor-to-file provisions, however, only became effective on March 16, 2013. Accordingly, it is not yet clear what, if any, impact the Leahy-Smith Act will have on the operation of our business.

The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Additionally, there have been recent proposals for additional changes to the patent laws of the United States and other countries that, if adopted, could impact our ability to obtain patent protection for our proprietary technology or our ability to enforce our proprietary technology. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our rights under patents that we might obtain in the future.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might subject us to infringement claims or adversely affect our ability to develop and market our current or future product candidates.

We cannot guarantee that any of our or our licensors' patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending patent application in the United States and abroad that is relevant to or necessary for the commercialization of our current or future product candidates in any jurisdiction. For example, U.S. patent applications filed before November 29, 2000 and certain U.S. patent applications filed after that date that will not be filed outside the United States remain confidential until patents issue. As mentioned above, patent applications in the United States 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 current or future product candidates could have been filed by third parties without our knowledge. Additionally, identification of third-party patent rights that may be relevant to our operations is difficult because patent searching is imperfect due to, for example, differences in terminology among patents or incomplete databases. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our current or future product candidates or the use of our current or future product candidates. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our current or future product candidates. We may incorrectly determine that our current or future product candidates are not covered by a third-party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and

market our current or future product candidates. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our current or future product candidates.

If we fail to identify and correctly interpret relevant patents, we may be subject to infringement claims. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being forced to pay damages, which may be significant, we may be temporarily or permanently prohibited from commercializing any of our current or future product candidates that are held to be infringing. We might, if possible, also be forced to redesign current or future 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 and could adversely affect our business, financial condition, results of operations and prospects.

Intellectual property rights do not guarantee commercial success of current or future product candidates or other business activities. Numerous factors may limit any potential competitive advantage provided by our intellectual property rights.

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

patent applications that we own or may in-license may not lead to issued patents;

patents, should they issue, that we may own or in-license, may not provide us with any competitive advantages, may be narrowed in scope, or may be challenged and held invalid or unenforceable;

others may be able to develop and/or practice technology, including compounds that are similar to the chemical compositions of our current or future product candidates, that is similar to our technology or aspects of our technology but that is not covered by the claims of any patents we may own or in-license, should any patents issue;

third parties may compete with us in jurisdictions where we do not pursue and obtain patent protection;

we, or our future licensors or collaborators, might not have been the first to make the inventions covered by a patent application that we own or may in-license;

we, or our future licensors or collaborators, might not have been the first to file patent applications covering a particular invention;

others may independently develop similar or alternative technologies without infringing, misappropriating or otherwise violating our intellectual property rights;

our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights, and may then use the information learned from such activities to develop competitive products for sale in our major commercial markets;

we may not be able to obtain and/or maintain necessary licenses on reasonable terms or at all;

third parties may assert an ownership interest in our intellectual property and, if successful, such disputes may preclude us from exercising exclusive rights, or any rights at all, over that intellectual property;

we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such trade secrets or know-how;

we may not be able to maintain the confidentiality of our trade secrets or other proprietary information;

we may not develop or in-license additional proprietary technologies that are patentable; and

the patents of others may have an adverse effect on our business.

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

Risks Related to Government Regulation

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.

Assuming that our product candidates prove to be safe and effective in clinical trials, we expect that we will file for marketing approval for such product candidates in the United States and we may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product

candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or fail to receive applicable regulatory approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed and future potential revenue may be less than expected by investors and analysts.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants regulatory approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional nonclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In short, the foreign regulatory approval process involves all of the risks associated with FDA approval. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we may intend to charge for our products will also be subject to approval.

We may seek priority review designation for one or more of our product candidates, but we might not receive such designation, and even if we do, such designation may not lead to a faster regulatory review or approval process.

If the FDA determines that a product candidate offers a treatment for a serious condition and, if approved, the product would provide a significant improvement in safety or effectiveness, the FDA may designate the product candidate for priority review. A priority review designation means that the goal for the FDA to review an application is six months from the date of filing, rather than the standard review period of ten months. We may request priority review for our product candidates. The FDA has broad discretion with respect to whether or not to grant priority review status to a product candidate, so even if we believe a particular product candidate is eligible for such designation or status, the FDA may decide not to grant it. Moreover, a priority review designation does not necessarily result in an expedited regulatory review or approval process or necessarily confer any advantage with respect to approval compared to conventional FDA procedures. Receiving priority review from the FDA does not guarantee approval within the six-month review cycle or at all.

We may seek orphan drug designation for certain 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 certain of our product candidates, and we may be unsuccessful. Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is a product intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States, or a patient population of 200,000 or more in the United States where there is no reasonable expectation that the cost of developing the product 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 towards clinical trial costs, tax advantages and user-fee waivers.

Similarly, in Europe, the European Commission, upon the recommendation of the EMA's Committee for Orphan Medicinal Products, grants orphan drug designation to promote the development of drugs that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting not more than five in 10,000 persons in Europe and for which no satisfactory method of diagnosis, prevention, or treatment has been authorized (or the product would be a significant benefit to those affected). Additionally, designation is granted for drugs intended for the diagnosis, prevention, or treatment of a life-threatening, seriously debilitating or serious and chronic condition and when, without incentives, it is unlikely that sales of the drug in Europe would be sufficient to justify the necessary investment in developing the drug. In Europe, orphan drug designation entitles a party to financial incentives such as reduction of fees or fee waivers.

Generally, if a product with an orphan drug designation subsequently receives the first regulatory approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or the EMA from approving another marketing application for the same product and indication for that time period, except in limited circumstances. The applicable period is seven years in the United States and ten years in the European

Union. The exclusivity period in the European Union can be reduced to six years if a product no longer meets the criteria for orphan drug designation or if the product is sufficiently profitable so that market exclusivity is no longer justified.

Even if we obtain orphan drug exclusivity for one of our product candidates, that exclusivity may not effectively protect our product candidate from competition because different products having different chemical compositions can be approved for the same condition and the same therapies can be approved for different conditions but used off-label. Even after an orphan drug is approved, the FDA can subsequently approve the same product for the same condition if the FDA concludes that the later product is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In addition, a designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. Moreover, orphan drug exclusive marketing rights in the United States 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 quantity of the product to meet the needs of patients with the rare disease or condition or if another product with the same active moiety is determined to be safer, more effective, or represents a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time of a product nor gives the product any advantage in the regulatory review or approval process. While we may seek orphan drug designation for our product candidates, we may never receive such designations. Even if we do receive such designations, there is no guarantee that we will enjoy the benefits of those designations.

A breakthrough therapy designation and fast track designation by the FDA, even if granted for any of our product candidates, may not lead to a faster development, regulatory review or approval process, and each designation does not increase the likelihood that any of our product candidates will receive regulatory approval in the United States.

We may seek a breakthrough therapy designation for some of our product candidates. A breakthrough therapy is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug or biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For product candidates that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Product candidates designated as breakthrough therapies by the FDA may also be eligible for priority review and accelerated approval. Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a breakthrough therapy designation for a product candidate may not result in a faster development process, review or approval compared to therapies considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that such product candidates no longer meet the conditions for qualification and rescind the designation or decide that the time period for FDA review or approval will not be shortened.

We may also seek fast track designation for some of our product candidates and, in the case of TNG908, we were granted fast track designation by the FDA in the first quarter of 2022. If a drug is intended for the treatment of a serious or life-threatening condition and preclinical or clinical data demonstrates the potential to address unmet medical needs for this condition, the sponsor may apply for fast track designation. 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 withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program. Fast track designation alone does not guarantee qualification for the FDA's priority review procedures.

We may seek accelerated approval of our current or future product candidates using the FDA's accelerated approval pathway. Accelerated approval by the FDA, even if granted for our current or any other future product candidates, may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our product candidates will receive regulatory approval.

We may seek accelerated approval of our current or future product candidates, where applicable, using the FDA's accelerated approval pathway. A product may be eligible for accelerated approval if it treats a serious or life-threatening condition and generally provides a meaningful advantage over available therapies. In addition, it must demonstrate an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, or IMM, that is reasonably likely to predict an effect on IMM or other clinical

benefit. As a condition of approval, the FDA requires that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. These confirmatory trials must be completed with due diligence. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. Even if we do receive accelerated approval, we may not experience a faster development or regulatory review or approval process, and receiving accelerated approval does not provide assurance of ultimate FDA approval.

The FDA, the EMA and other regulatory authorities may implement additional regulations or restrictions on the development and commercialization of our product candidates, and such changes can be difficult to predict.

The FDA, the EMA and regulatory authorities in other countries have each expressed interest in further regulating biotechnology products. Agencies at both the federal and state level in the United States, as well as the U.S. Congressional committees and other governments or governing agencies, have also expressed interest in further regulating the biotechnology industry. Such action may delay or prevent commercialization of some or all of our product candidates. Adverse developments in clinical trials of products conducted by others may cause the FDA or other oversight bodies to change the requirements for conducting clinical trials or for approval of any of our product candidates. These regulatory review agencies and committees and the new requirements or guidelines they promulgate may lengthen the regulatory review process, require us to perform additional studies or trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions. As we advance our product candidates, we will be required to consult with these regulatory agencies and comply with applicable requirements and guidelines. If we fail to do so, we may be required to delay or discontinue development of such product candidates. These additional processes may result in a review and approval process that is longer than we otherwise would have expected. Delays as a result of an increased or lengthier regulatory approval process or further restrictions on the development of our product candidates can be costly and could negatively impact our ability to complete clinical trials and commercialize our current and future product candidates in a timely manner, if at all.

Inadequate funding for the FDA, the SEC and other U.S. government agencies or the EMA or comparable foreign regulatory authorities, including from government shut downs, or other disruptions to these agencies' operations, could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA, the EMA or comparable foreign regulatory authorities to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and enact statutory, regulatory and policy changes. Average review times at the FDA or other regulatory authorities have fluctuated in recent years as a result. Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business.

In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA, the EMA and other agencies may also slow the time necessary for new product candidates 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 and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Separately, since March 2020 when foreign and domestic inspections were largely placed on hold due to the COVID-19 pandemic, the FDA has been working to resume routine surveillance, bioresearch monitoring and pre-approval inspections on a prioritized basis. Since April 2021, the FDA has conducted limited inspections and employed remote interactive evaluations, using risk management methods, to meet user fee commitments and goal dates. Ongoing travel restrictions and other uncertainties continue to impact oversight operations abroad and it is unclear when standard operational levels will resume. The FDA is continuing to complete mission-critical work, prioritize other higher-tiered inspectional needs (e.g., for-cause inspections), and carry out surveillance inspections using risk-based approaches for evaluating public health. Should

the FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel, and the FDA does not determine a remote interactive evaluation to be adequate, the agency has stated that it generally intends to issue, depending on the circumstances, a complete response letter or defer action on the application until an inspection can be completed.

In 2020 and in 2021, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications.

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 to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

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

Changes in regulations, statutes or the interpretation of existing regulations and statutes could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products (if any products are approved by applicable regulatory authorities); or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business. For additional information, see section entitled "*Business – Current and future healthcare reform legislation*" as set forth in the Annual Report on Form 10-K for the fiscal year ended December 31, 2021.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or 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 to initiate 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, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how other healthcare reform measures of the Biden administration or other efforts, if any, to challenge repeal or replace the ACA, will impact our business.

Separately, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or may not provide adequate payment for our product candidates. There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs.

In addition, there have been several changes to the 340B drug pricing program, which imposes ceilings on prices that drug manufacturers can charge for medications sold to certain health care facilities. On December 27, 2018, the District Court for the District of Columbia invalidated a reimbursement formula change under the 340B drug pricing program, and CMS subsequently altered the Fiscal Years 2019 and 2018 reimbursement formula on specified covered outpatient drugs, or SCODs. The court ruled this change was not an "adjustment" which was within the Secretary's discretion to make but was instead a fundamental change in the reimbursement calculation. However, most recently, on July 31, 2020, the U.S. Court of Appeals for the District of Columbia Circuit overturned the district court's decision and found that the changes were within the Secretary's authority. On September 14, 2020, the plaintiffs-appellees filed a Petition for Rehearing En Banc (i.e., before the full court), but was denied on October 16, 2020. It is unclear how these developments could affect covered hospitals who might purchase our future products and affect the rates we may charge such facilities for our approved products in the future, if any.

At the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, former President Trump announced several executive orders related to prescription drug pricing that seek to implement several of the administration's proposals. In response, the FDA released a final rule on September 24, 2020, which went into effect on November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020 CMS issued an Interim Final Rule implementing the Most Favored Nation, or MFN, Model under which Medicare Part B reimbursement rates will be calculated for certain drugs and biologicals based on the lowest price drug manufacturers receive in Organization for Economic Cooperation and Development countries with a similar gross domestic product per capita. The MFN Model regulations mandate participation by identified Part B providers and will apply in all U.S. states and territories for a seven-year period beginning January 1, 2021 and ending December 31, 2027. The Interim Final Rule has not been finalized and is subject to revision and challenge. Additionally, on November 20, 2020, DHHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. Implementation of the amendments to the discount safe harbor have been delayed until at least January 1, 2023. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the Biden administration may reverse or otherwise change these measures, Congress has indicated that it will continue to seek new legislative measures to control drug costs.

Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payers. In addition, individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

These laws, and future state and federal healthcare reform measures may be adopted in the future, any of which may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used. Additionally, we expect to experience pricing pressures in connection with the sale of any future approved product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, cost containment initiatives and additional legislative changes.

Our relationships with customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, exclusion from government healthcare programs, contractual damages, reputational harm and diminished profits and future earnings.

Although we do not currently have any products on the market, once 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 regulatory 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 regulatory approval. See section entitled "*Business – Other healthcare laws"* as set forth in the Annual Report on Form 10-K for the fiscal year ended December 31, 2021.

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 or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations, including future sales of our product candidates (following regulatory approval of such therapy) by us or third-parties that we engage, were to be found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment. Further, defending against any such actions can be costly and time consuming, and may require significant financial and personnel

resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the above occur, our ability to operate our business and our results of operations could be adversely affected.

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

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot, however, eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, 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, hazardous or radioactive materials.

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 post-market study requirements, marketing and labeling restrictions, and even recall or market withdrawal if unanticipated safety issues are discovered following approval. In addition, we may be subject to penalties or other enforcement action if we fail to comply with regulatory requirements.

Any regulatory approvals that we receive for our product candidates will require surveillance to monitor the safety and efficacy of the product candidate. If the FDA or a comparable foreign regulatory authority approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, import, export, adverse event reporting, storage, advertising, promotion, monitoring, 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, establishment registration and listing, as well as continued compliance with cGMPs and GCPs for any clinical trials that we conduct post-approval and pharmacovigilance reporting obligations. Any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing studies, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product. The FDA may also require a REMS in order to approve our product candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. 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;
- manufacturing delays and supply disruptions where regulatory inspections identify observations of noncompliance requiring remediation;
- revisions to the labeling, including limitation on approved uses or the addition of additional warnings, contraindications or other safety information, including boxed warnings;
- imposition of a REMS which may include distribution or use restrictions;
- requirements to conduct additional post-market clinical trials to assess the safety of the product;
- clinical trial holds;
- fines, warning letters or other regulatory enforcement action;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of 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 and other regulatory authorities' 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 regulatory approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

European data collection is governed by restrictive regulations governing the use, processing and cross-border transfer of personal information.

We plan to conduct clinical trials and enroll subjects in our planned or future clinical trials, and therefore we will be subject to additional privacy restrictions. The collection, use, storage, disclosure, transfer, or other processing of personal data regarding individuals in the European Union, including personal health data, is subject to the EU General Data Protection Regulation, or GDPR. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. While we have commenced the process of implementing procedures to comply with the GDPR, compliance with these regulations will be a rigorous and time-intensive process that we expect will increase our cost of doing business and require us to change certain of our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European activities. Further, many countries interpret the application of the provisions of the GDPR in different manner, making compliance in certain countries and across the European Union challenging.

Laws and regulations governing any international operations we may have in the future may preclude us from developing, manufacturing and selling certain products outside of the United States and require us to develop and implement costly compliance programs.

If we expand our operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the United States, it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our development costs.

The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

Risks Relating to Employee Matters and Managing Anticipated Growth

Our future success depends on our ability to retain key executives and experienced scientists and to attract, retain and motivate qualified personnel.

We are highly dependent on many of our key employees and members of our executive management team as well as the other principal members of our management, scientific and clinical team. Although we have entered into employment letter agreements with certain of our executive officers, each of them may terminate their employment with us at any time. We do not maintain "key person" insurance for any of our executives or other employees. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

Recruiting and retaining qualified scientific, clinical, medical, manufacturing and sales and marketing personnel will also be critical to our success. The loss of the services of our executive officers or other key employees, including temporary loss due to illness, could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific, medical and clinical personnel from universities and research institutions. Failure to succeed in clinical trials may make it more challenging to recruit and retain qualified scientific personnel.

In particular, we have experienced a very competitive hiring environment in Cambridge, Massachusetts, where we are headquartered. Many of the other pharmaceutical companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate and success with which we can discover and develop product candidates and our business will be limited.

We may be unable to adequately protect our information systems from cyberattacks, which could result in the disclosure of confidential or proprietary information, including personal data, damage our reputation, and subject us to significant financial and legal exposure.

We rely on information technology systems that we or our third-party providers operate to process, transmit and store electronic information in our day-to-day operations. In connection with our product discovery efforts, we collect and use a variety of personal data, such as names, mailing addresses, email addresses, phone numbers. In addition, in connection with our Phase 1/2 clinical trial, we will have access to, and may store, clinical and health information of the patients participating in the trial.

A successful cyberattack could result in the theft or destruction of intellectual property, data, or other misappropriation of assets, or otherwise compromise our confidential or proprietary information and disrupt our operations. Cyberattacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. Cyberattacks could include wrongful conduct by hostile foreign governments, industrial espionage, wire fraud and other forms of cyber fraud, the deployment of harmful malware, denial-of-service, social engineering fraud or other means to threaten data security, confidentiality, integrity and availability. A successful cyberattack could cause serious negative consequences for us, including, without limitation, the disruption of operations, the misappropriation of confidential business information, including financial information, trade secrets, financial loss and the disclosure of corporate strategic plans. Although we devote resources to protect our information systems, we realize that cyberattacks are a threat, and there can be no assurance that our efforts will prevent information security breaches that would result in business, legal, financial or reputational harm to us, or would have a material adverse effect on our results of operations and financial condition. Any failure to prevent or mitigate security breaches or improper access to, use of, or disclosure of our clinical data or patients' personal data could result in significant liability under state (e.g., state breach notification laws), federal (e.g., HIPAA, as amended by HITECH), and international law (e.g., the GDPR) and may cause a material adverse impact to our reputation, affect our ability to conduct new studies and potentially disrupt our business.

We rely on our third-party providers to implement effective security measures and identify and correct for any such failures, deficiencies or breaches. If we or our third-party providers fail to maintain or protect our information technology systems and data integrity effectively or fail to anticipate, plan for or manage significant disruptions to our information technology systems, we or our third-party providers could have difficulty preventing, detecting and controlling such cyber-attacks and any such attacks could result in the losses described above as well as disputes with physicians, patients and our

partners, regulatory sanctions or penalties, increases in operating expenses, expenses or lost revenue or other adverse consequences, any of which could have a material adverse effect on our business, results of operations, financial condition, prospects and cash flows. Any failure by such third parties to prevent or mitigate security breaches or improper access to or disclosure of such information could have similarly adverse consequences for us. If we are unable to prevent or mitigate the impact of such security or data privacy breaches, we could be exposed to litigation and governmental investigations, which could lead to a potential disruption to our business. By way of example, the California Consumer Privacy Act, or CCPA, which went into effect on January 1, 2020, creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal data. 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. The CCPA may increase our compliance costs and potential liability, and many similar laws have been proposed at the federal level and in other states.

Further, a new California privacy law, the California Privacy Rights Act, or CPRA, was passed by California voters on November 3, 2020. The CPRA will create additional obligations with respect to processing and storing personal information that are scheduled to take effect on January 1, 2023 (with certain provisions having retroactive effect to January 1, 2022). Additionally, some observers have noted that the CCPA and CPRA could mark the beginning of a trend toward more stringent privacy legislation in the U.S., which could increase our potential liability and adversely affect our business. Already, in the United States, we have witnessed significant developments at the state level. For example, on March 2, 2021, Virginia enacted the Consumer Data Protection Act (the "CDPA") and, on July 8, 2021, Colorado's governor signed the Colorado Privacy Act ("CPA"), into law. The CDPA and the CPA will both become effective January 1, 2023. While the CDPA and CPA incorporate many similar concepts of the CCPA and CPRA, there are also several key differences in the scope, application, and enforcement of the law that will change the operational practices of regulated businesses. The new laws will, among other things, impact how regulated businesses collect and process personal sensitive data, conduct data protection assessments, transfer personal data to affiliates, and respond to consumer rights requests.

A number of other states have proposed new privacy laws, some of which are similar to the above discussed recently passed laws. Such proposed legislation, if enacted, may add additional complexity, variation in requirements, restrictions and potential legal risk, require additional investment of resources in compliance programs, impact strategies and the availability of previously useful data and could result in increased compliance costs and/or changes in business practices and policies. The existence of comprehensive privacy laws in different states in the country would make our compliance obligations more complex and costly and may increase the likelihood that we may be subject to enforcement actions or otherwise incur liability for noncompliance.

By way of example regarding foreign laws and regulations with respect to data privacy and security, the GDPR went into effect in the European Union in May 2018 and introduces strict requirements for processing the personal data of EU data subjects. 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 €20 million or 4% of the annual global revenue of the noncompliant company, whichever is greater. In addition, further to the U.K.'s exit from the EU on January 31, 2020, the GDPR ceased to apply in the U.K. at the end of the transition period on December 31, 2020. However, as of January 1, 2021, the U.K.'s European Union (Withdrawal) Act 2018 incorporated the U.K. GDPR into U.K. law. The U.K. GDPR and the U.K. Data Protection Act 2018 set out the U.K.'s data protection regime, which is independent from but aligned to the EU's data protection regime. Non-compliance with the U.K. GDPR may result in monetary penalties of up to £17.5 million or 4% of worldwide revenue, whichever is higher. Although the UK is regarded as a third country under the EU's GDPR, the European Commission has now issued a decision recognizing the UK as providing adequate protection under the EU GDPR and, therefore, transfers of personal data originating in the EU to the UK remain unrestricted. Like the EU GDPR, the UK GDPR restricts personal data transfers outside the UK to countries not regarded by the UK as providing adequate protection. The UK government has confirmed that personal data transfers from the UK to the EEA remain free flowing.

To enable the transfer of personal data outside of the EEA or the UK, adequate safeguards must be implemented in compliance with European and UK data protection laws. On June 4, 2021, the EC issued new forms of standard contractual clauses for data transfers from controllers or processors in the EU/EEA (or otherwise subject to the GDPR) to controllers or processors established outside the EU/EEA (and not subject to the GDPR). The new standard contractual clauses replace the standard contractual clauses that were adopted previously under the EU Data Protection Directive. The Information Commissioner's Office, or ICO, has recently introduced new mechanisms for international transfers of personal data originating from the U.K. (an International Data Transfer Agreement, or IDTA, along with a separate addendum to the EU SCCs), which are in force as of March 21, 2022, to replace the old form EU SCCs for U.K. transfers. The new IDTA or the U.K. addendum must be used for any new contract entered into as of September 21, 2022 and implemented in existing contracts that incorporate the prior version of the SCCs by March 21, 2024. Implementing these new safeguards will require

significant effort and cost. These and other future developments regarding the flow of data across borders could increase the cost and complexity of delivering our services in some markets and may lead to governmental enforcement actions, litigation, fines, and penalties or adverse publicity, which could adversely affect our business and financial position.

Compliance with these and any other applicable privacy and data security laws and regulations is a rigorous and time-intensive process, and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. If we fail to comply with any such laws or regulations, we may face significant fines and penalties that could adversely affect our business, financial condition and results of operations.

If we or third-party CMOs, CROs or other contractors or consultants fail to comply with U.S. and international data protection laws and regulations, it could result in government enforcement actions (which could include civil or criminal penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects about whom we, our CRO operating our trials, or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we or such third-party have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

We expect to expand our development and regulatory capabilities and potentially implement sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

As of March 31, 2022, we had 98 full-time employees. We expect to experience significant growth in the number of our employees and the scope of our operations, particularly as we function as a public company and in the areas of product development, regulatory affairs and, if any of our product candidates receives regulatory approval, sales, medical affairs, marketing and distribution. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources, we may not be able to effectively manage the planned expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

We may acquire additional businesses or products, form strategic alliances or create joint ventures with third parties that we believe will complement or augment our existing business. If we acquire businesses with promising markets or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to successfully integrate them with our existing operations and company culture. We may encounter numerous difficulties in developing, manufacturing and marketing any new products resulting from a strategic alliance or acquisition that delay or prevent us from realizing their expected benefits or enhancing our business. We cannot assure you that, following any such acquisition, we will achieve the expected synergies to justify the transaction.

Risks Related to Our Common Stock

Our executive officers, directors, principal stockholders and their affiliates own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

Based on our common stock outstanding as of March 31, 2022, our executive officers, directors and their affiliates and our principal stockholders beneficially held, in the aggregate, approximately 40% of our outstanding voting stock. These stockholders, acting together, would be able to significantly influence all matters requiring stockholder approval. For example, these stockholders would be able to significantly influence elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. These stockholders may have interests, with respect to their common stock, that are different from those of other investors and the concentration of voting power among these stockholders may have an adverse effect on the price of our common stock. In addition, this concentration of ownership might adversely affect the market price of our common stock by delaying, deferring or preventing a change of control of us, impeding a merger, consolidation, takeover or other business combination involving us or discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

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, as amended, or the Code, if a corporation undergoes an "ownership change" (generally defined as a greater than 50 percentage point change (by value) in the ownership of its equity over a 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 may be limited. We have experienced such ownership changes in the past, and we may experience ownership changes in the future as a result of shifts in our stock ownership, some of which are outside our control. The Company has performed an analysis of ownership changes through December 31, 2021, and determined that on February 6, 2017 and August 17, 2020, ownership changes had occurred. Based on this analysis, the Company's ability to use its pre-change tax attributes to offset federal and state taxable income are subject to annual limitations and a portion of the attributes generated prior to February 6, 2017, will expire unutilized, which could potentially result in an increased future tax liability. The Company has adjusted its deferred tax assets and valuation allowance balance for the affected tax attribute carryforwards to reflect the expiration of the attributes.

Federal net operating loss carryforwards generated in taxable years beginning after December 31, 2017 will not be subject to expiration. However, any such net operating loss carryforwards may only offset 80% of our annual taxable income in taxable years beginning after December 31, 2020. There is also a risk that due to regulatory changes, such as suspensions on the use of net operating loss carryforwards or other unforeseen reasons, our existing net operating loss carryforwards could expire or otherwise be unavailable to offset future income tax liabilities, including for state tax purposes. In future years, if and when a net deferred tax asset is recognized related to our net operating loss carryforwards, the changes in the carryforward/carryback periods as well as the new limitation on use of net operating loss carryforwards may significantly impact our valuation allowance assessments for net operating loss carryforwards. For these reasons, we may not be able to utilize some portion of our net operating loss carryforwards, none of which are currently reflected on our balance sheet, even if we attain profitability.

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.

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

a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;
a requirement that special meetings of the stockholders may be called only by the board of directors acting pursuant to a resolution approved by the affirmative vote of a majority of the directors then in office, and special meetings of stockholders may not be called by any other person or persons;
advance notice requirements for stockholder proposals and nominations for election to our board of directors;
a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and then, in addition to any other vote required by law, only upon the approval of not less than 66 2/3% of all outstanding shares of our capital stock then entitled to vote in the election of directors;
supermajority voting requirements to amend our bylaws by stockholder action (unless our board recommends that our stockholders approve such amendment(s)) and to amend specific provisions of our certificate of incorporation; and
the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval, which preferred stock may include rights superior to the rights of the holders of common stock.

These anti-takeover provisions and other provisions in our certificate of incorporation and bylaws could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors and could also delay or impede a merger, tender offer or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

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

Pursuant to our bylaws, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for any state law claims for (i) any derivative action or

proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, or other employees to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the General Corporation Law of the State of Delaware, or the DGCL, or our certificate of incorporation or bylaws (including the interpretation, validity or enforceability thereof), or (iv) any action asserting a claim governed by the internal affairs doctrine. We refer to the foregoing provision as the Delaware Forum Provision. The Delaware Forum Provision will not apply to any causes of action arising under the Securities Act or the Exchange Act. Our bylaws further provide that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States shall be the sole and exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. We refer to such provision as the Federal Forum Provision. Our bylaws provide that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock is deemed to have notice of and consented to the Delaware Forum Provision and the Federal Forum Provision; provided, however, that stockholders cannot and will not be deemed to have waived our compliance with the U.S. federal securities laws and the rules and regulations thereunder.

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

We are subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations. We can face serious consequences for violations.

Among other matters, U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations, which are collectively referred to as Trade Laws, prohibit companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors, and other partners and representatives from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We also expect our non-U.S. activities to increase in time. We have, and we expect we will continue to, engage third parties for clinical trials and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals and we can be held liable for the corrupt or other illegal activities of our personnel, agents, representatives or partners, even if we do not explicitly authorize or have prior knowledge of such activities.

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

We are exposed to the risk that our employees, principal investigators, CROs and consultants may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violate the regulations of the FDA and other regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities; healthcare fraud and abuse laws and regulations in the United States and abroad; or laws that require the reporting of financial information or data accurately. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations 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 also involve the improper use of information obtained in the course of clinical trials or creating fraudulent data in our preclinical studies or clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of conduct applicable to all of our employees, but it is not always possible to identify and deter misconduct by employees and other third

parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, imposition of a monitor, possible exclusion from participation in federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

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

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

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

Our stock price has been and is likely to continue to be volatile. The stock market in general, and the market for biopharmaceutical companies in particular, have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your common stock. The market price for our common stock may be influenced by many factors, including:

- the success of competitive products or technologies;
- advancement of our preclinical programs, such as our targeted oncology programs, into clinical testing;
- results of clinical trials of our product candidates or those of our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our programs and product candidates or preclinical and clinical development programs;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates or products;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems and third-party reimbursement decisions;
- market conditions in the pharmaceutical and biotechnology sectors;
- limited trading volume;
- future sales of common stock by our officers, directors and significant stockholders;
- general economic, industry and market conditions; and
- the other factors described in this "*Risk Factors*" section.

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

As a public company, and particularly after we are no longer an "emerging growth company," we will incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act and rules subsequently implemented by the SEC and The Nasdaq Global Market, or Nasdaq, have imposed various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, these rules and regulations have made it more expensive for us to obtain director and officer liability insurance.

Pursuant to Section 404 of the Sarbanes-Oxley Act, we are required to furnish a report by our management on our internal control over financial reporting, including an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that neither we nor our independent registered public accounting firm will be able to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements. In addition, if we are not able to continue to meet these requirements, we may not be able to remain listed on Nasdaq.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our stock, the price of our stock could decline.

The trading market for our common stock relies in part on the research and reports that industry or financial analysts publish about us or our business. We do not control these analysts. If one or more of the analysts covering our business downgrade their evaluations of our stock, the price target for our stock or publish inaccurate or unfavorable evaluations of our company or our stock, the price of our stock could decline. If one or more of these analysts cease to cover our stock or fail to publish reports covering our company regularly, we could lose visibility in the market for our stock, which in turn could cause our stock price to decline. In addition, if we are the subject of negative publicity, whether from an analyst, academic, industry group or the general or financial press, our stock price may decline.

We may be subject to securities litigation, which is expensive and could divert management attention.

The market price of our common stock may be volatile. The stock market in general, and Nasdaq and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. In the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

General Risk Factors

Comprehensive tax reform legislation could adversely affect our business and financial condition.

The tax regimes we are subject to or operate under are unsettled and may be subject to significant change. Changes in tax laws (including in response to the COVID-19 pandemic) or tax rulings, or changes in interpretations of existing laws, could cause us to be subject to additional income-based taxes and non- income taxes (such as payroll, sales, use, value-added, digital tax, net worth, property, and goods and services taxes), which in turn could materially affect our financial position and results of operations. Additionally, new, changed, modified, or newly interpreted or applied tax laws could increase our customers' and our compliance, operating and other costs, as well as the costs of our products, if approved. As we expand the scale of our business activities, any changes in the U.S. taxation of such activities may increase our effective tax rate and

harm our business, financial condition, and results of operations. For example, the change in administration and control of Congress in the United States following the 2020 elections may result in additional U.S. tax law changes that could have a material impact on our future effective tax rate, which could have a negative impact on our results of operations in the future. Complying with these tax laws is complex and the statutes and regulations can be subject to varying interpretation which can make compliance challenging.

Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. For example, in 2008, the global financial crisis caused extreme volatility and disruptions in the capital and credit markets and the current COVID-19 pandemic has caused significant volatility and uncertainty in U.S. and international markets. A severe or prolonged economic downturn could result in a variety of risks to our business, including, weakened demand for our product candidates and our ability to raise additional capital when needed on acceptable terms, if at all. In addition, our business may be generally exposed to the impact of political or civil unrest or military action, including the current conflict between Russia and Ukraine (where a vendor that performs chemistry related work on our pre-clinical product candidates is located) and, while we do not otherwise have direct exposure to Ukraine, our business and results of operations may be impacted based upon the events taking place there. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

An active trading market for our common stock may not be sustained, and you may not be able to resell your shares at the price you paid.

Although our common stock is listed on The Nasdaq Global Market, an active trading market for our shares may not be sustained. In the absence of an active trading market for our common stock, investors may be unable to sell their shares.

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

The information required by Item 701 of Regulation S-K was previously included in our Quarterly Report on Form 10-Q filed on November 9, 2021.

Use of Proceeds from our Initial Public Offering

Of the gross proceeds received from the Initial Public Offering, including an additional 2,175,000 shares of common stock to cover the over-allotments, $166.8 million was placed in a trust account. The net proceeds of the Initial Public Offering were applied to fund the Business Combination and related expenses.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit Number	Description
10.1*	Non-Employee Director Compensation Policy
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104*	Cover Page Interactive Data File (formatted in as Inline XBRL with applicable taxonomy extension information contained in Exhibits 101)

* Filed herewith.

** The certifications furnished in Exhibit 32.1 and Exhibit 32.2 hereto are deemed to be furnished with this Quarterly Report on Form 10-Q and will not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, except to the extent that the Registrant specifically incorporates it by reference.

SIGNATURES

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

Tango Therapeutics, Inc.

Dated: May 11, 2022

By: /s/ Barbara Weber

Barbara Weber, MD
President and Chief Executive Officer
(Principal Executive Officer)

Tango Therapeutics, Inc.

By: /s/ Daniella Beckman

Daniella Beckman
Chief Financial Officer
(Principal Financial Officer)

TANGO THERAPEUTICS, INC.
NON-EMPLOYEE DIRECTOR COMPENSATION POLICY

The purpose of this Non-Employee Director Compensation Policy (the "Policy") of Tango Therapeutics, Inc. (the "Company") is to provide a total compensation package that enables the Company to attract and retain, on a long-term basis, high-caliber directors who are not employees or officers of the Company or its subsidiaries ("Outside Directors"). This Policy will become effective upon the Closing (as defined in the Agreement and Plan of Merger, dated as of April 13, 2021, by and among the Company (formerly known as BCTG Acquisition Corp.), BCTG Merger Sub Inc., and Tango Therapeutics, Inc.) (the "Effective Date"). In furtherance of the purpose stated above, all Outside Directors shall be paid compensation for services provided to the Company as set forth below:

Cash Retainers

Annual Retainer for Board Membership: $40,000 for general availability and participation in meetings and conference calls of our Board of Directors, to be paid quarterly in arrears, pro-rated based on the number of actual days served by the director during such calendar quarter. No additional compensation will be paid for attending individual meetings of the Board of Directors.

Additional Annual Retainer for Non-Executive Chair:	$30,000
Additional Annual Retainer for Lead Independent Director:	$15,000
Additional Annual Retainers for Committee Membership:	
Audit Committee Chair:	$15,000
Audit Committee member:	$7,500
Compensation Committee Chair:	$10,000
Compensation Committee member:	$5,000
Nominating and Corporate Governance Committee Chair:	$8,000
Nominating and Corporate Governance Committee member:	$4,000

Chair and committee member retainers are in addition to retainers for members of the Board of Directors. No additional compensation will be paid for attending individual committee meetings of the Board of Directors.

Equity Retainers

Initial Award: An initial, one-time stock option award (the "Initial Award") to purchase 80,000 shares will be granted to each new Outside Director upon his or her election to the Board of Directors, which shall vest in 36 substantially equal monthly installments over three years from

the date of grant, provided, however, that all vesting shall cease if the director ceases to serve on the Board of Directors, unless the Board of Directors determines that the circumstances warrant continuation of vesting. The Initial Award shall expire not later than ten years from the date of grant, and shall have a per share exercise price equal to the Fair Market Value (as defined in the Company's 2021 Stock Option and Incentive Plan) of the Company's common stock on the date of grant. This Initial Award applies only to Outside Directors who are first elected to the Board of Directors subsequent to the Effective Date.

Annual Award: On each date of each Annual Meeting of Stockholders of the Company following the Effective Date (the "Annual Meeting"), each continuing Outside Director, other than a director receiving an Initial Award, will receive an annual stock option award (the "Annual Award") to purchase 40,000 shares; provided, however, that Annual Awards made to Outside Directors who were elected in the 12 months preceding the date of grant of such Annual Awards will be pro-rated on a monthly basis for time in service. The Annual Award shall vest in 12 substantially equal monthly installments over one year from the date of grant provided, however, that all vesting shall cease if the director ceases to serve on the Board of Directors, unless the Board of Directors determines that the circumstances warrant continuation of vesting. Such Annual Award shall expire no later than ten years from the date of grant, and shall have a per share exercise price equal to the Fair Market Value of the Company's common stock on the date of grant.

Sale Event Acceleration: All outstanding Initial Awards and Annual Awards held by an Outside Director shall become fully vested and exercisable upon a Sale Event (as defined in the Company's 2021 Stock Option and Incentive Plan).

Expenses

The Company will reimburse all reasonable out-of-pocket expenses incurred by non-employee directors in attending meetings of the Board of Directors or any committee thereof.

Maximum Annual Compensation

The aggregate amount of compensation, including both equity compensation and cash compensation, paid by the Company to any Outside Director in a calendar year for services as an Outside Director period shall not exceed $750,000; provided, however, that such amount shall be $1,000,000 for the calendar year in which the applicable Outside Director is initially elected or appointed to the Board of Directors; (or such other limits as may be set forth in Section 3(b) of the Company's 2021 Stock Option and Incentive Plan or any similar provision of a successor plan). For this purpose, the "amount" of equity compensation paid in a calendar year shall be determined based on the grant date fair value thereof, as determined in accordance with FASB ASC Topic 718 or its successor provision, but excluding the impact of estimated forfeitures related to service-based vesting conditions.

Adopted June 9, 2021.

Amended: May 10, 2022

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO RULE 13a-14(a) / RULE 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

I, Barbara Weber, M.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Tango 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, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

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

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

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

5. The registrant's other certifying officer 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.

Dated: May 11, 2022 /s/ Barbara Weber, M.D.

Barbara Weber, M.D.
Chief Executive Officer
(Principal Executive Officer)

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO RULE 13a-14(a) / RULE 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

I, Daniella Beckman, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Tango 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, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

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

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

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

5. The registrant's other certifying officer 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.

Dated: May 11, 2022 /s/ Daniella Beckman

Daniella Beckman
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q of Tango Therapeutics, Inc. (the "Company") for the fiscal quarter ended March 31, 2022 as filed with the Securities and Exchange Commission (the "Report"), I, Barbara Weber, M.D., Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, to my knowledge, 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.

Dated: May 11, 2022 /s/ Barbara Weber, M.D.

Barbara Weber, M.D.
Chief Executive Officer
(Principal Executive Officer)

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Exhibit 32.2

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

In connection with the Quarterly Report on Form 10-Q of Tango Therapeutics, Inc. (the "Company") for the fiscal quarter ended March 31, 2022 as filed with the Securities and Exchange Commission (the "Report"), I, Daniella Beckman, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, to my knowledge, 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.

Dated: May 11, 2022 /s/ Daniella Beckman

Daniella Beckman
Chief Financial Officer
(Principal Financial Officer)

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.