UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2021

OR

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

For the transition period from _____ to _____

Commission File Number: 001-39485

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 November 5, 2021, the registrant had 87,546,430 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.
- 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, our receipt of necessary regulatory approvals could be delayed or prevented.
- Our future 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.

- 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.

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 trials and related preparatory work, the period during which the results of the trials will become available, and our research and development programs;

- our ability to discover and develop product candidates efficiently;

- 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 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 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 its industry;
- the effect of the 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 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.” 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 Website

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 Securities and Exchange Commission ("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.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

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

	September 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 204,974	$ 28,381
Marketable securities	298,831	161,939
Accounts receivable	8,000	2,000
Prepaid expenses and other current assets	4,534	1,312
Total current assets	516,339	193,632
Property and equipment, net	4,706	3,823
Operating lease right-of-use assets	6,732	7,480
Restricted cash	2,279	2,279
Other assets	81	38
Total assets	$ 530,137	$ 207,252
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,109	$ 1,841
Accrued expenses and other current liabilities	9,978	6,140
Operating lease liabilities	1,092	959
Deferred revenue	27,807	31,977
Total current liabilities	41,986	40,917
Operating lease liabilities, net of current portion	6,089	6,925
Deferred revenue, net of current portion	116,649	120,805
Other long-term liabilities	-	5
Total liabilities	164,724	168,652
Commitments and contingencies (Note 8)		
Preferred stock, $0.001 par value; 10,000,000 shares authorized; no shares issued and outstanding as of September 30, 2021 and December 31, 2020	-	-
Stockholders' equity:		
Common stock, $0.001 par value; 200,000,000 and 56,393,261 shares authorized at September 30, 2021 and December 31, 2020; 87,544,002 and 40,372,133 shares issued and outstanding as of September 30, 2021 and December 31, 2020, respectively	88	40
Additional paid-in capital	504,625	141,644
Accumulated other comprehensive (loss) income	(10)	17
Accumulated deficit	(139,290)	(103,101)
Total stockholders' equity	365,413	38,600
Total liabilities and stockholders' equity	$ 530,137	$ 207,252

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 September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Collaboration revenue	$ 6,787	$ (11,275)	$ 20,326	$ (2,169)
License revenue	-	14	11,000	683
Total revenue	6,787	(11,261)	31,326	(1,486)
Operating expenses:				
Research and development	21,923	12,977	56,002	34,928
General and administrative	4,433	2,518	11,530	6,849
Total operating expenses	26,356	15,495	67,532	41,777
Loss from operations	(19,569)	(26,756)	(36,206)	(43,263)
Other income (expense):				
Interest income (expense)	91	(50)	299	37
Other (expense) income, net	(50)	4	(167)	118
Total other income (expense), net	41	(46)	132	155
Loss before income taxes	(19,528)	(26,802)	(36,074)	(43,108)
Provision for income taxes	(62)	-	(115)	-
Net loss	$ (19,590)	$ (26,802)	$ (36,189)	$ (43,108)
Net loss per common share – basic and diluted	$ (0.28)	$ (0.76)	$ (0.68)	$ (1.48)
Weighted average number of common shares outstanding – basic and diluted	70,160,663	35,069,988	53,397,557	29,176,082
Net loss	(19,590)	(26,802)	(36,189)	(43,108)
Other comprehensive (loss) income:				
Unrealized (loss) gain on marketable securities	(12)	15	(27)	16
Comprehensive loss	$ (19,602)	$ (26,787)	$ (36,216)	$ (43,092)

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 (DEFICIT)
(in thousands, except share data)
(Unaudited)

	Redeemable Convertible Preferred Stock											
	Series A		Series B		Series B-1		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Balance at December 31, 2020	55,700,000	$ 55,700	22,686,025	$ 29,761	27,152,255	$ 51,083	4,518,833	$ 4	$ 5,136	$ 17	$ (103,101)	$ (97,944)
Retroactive application of recapitalization	(55,700,000)	(55,700)	(22,686,025)	(29,761)	(27,152,255)	(51,083)	35,853,300	36	136,508	—	—	136,544
Recasted balance as of 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 less than $0.1 million	—	—	22,686,026	29,990	—	—	—	—	—	—	—	—
Retroactive application of recapitalization	—	—	(22,686,026)	(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
Exercise of stock options	—	—	—	—	—	—	210,748	—	324	—	—	324
Vesting of restricted common stock awards	—	—	—	—	—	—	—	—	3	—	—	3
Stock based compensation expense	—	—	—	—	—	—	—	—	1,196	—	—	1,196
Other comprehensive loss	—	—	—	—	—	—	—	—	—	(30)		(30)
Net loss	—	—	—	—	—	—	—	—	—	—	(4,493)	(4,493)
Balance at June 30, 2021	—	-	-	-	-	-	48,593,822	49	174,540	2	(119,700)	54,891
Shares issued in Business Combination and PIPE Financing, net of issuance costs of $15.6 million							38,880,436	39	326,462	—	—	326,501
Exercise of stock options	—	—	—	—	—	—	69,744	—	193	—	—	193
Stock based compensation expense	—	—	—	—	—	—	—	—	3,430	—	—	3,430
Other comprehensive loss	—	—	—	—	—	—	—	—	—	(12)	—	(12)
Net loss	—	—	—	—	—	—	—	—	—	—	(19,590)	(19,590)
Balance at September 30, 2021	—	—	—	—	—	—	87,544,002	88	504,625	(10)	(139,290)	365,413

	Redeemable Convertible Preferred Stock											
	Series A		Series B		Series B-1		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Balance at December 31, 2019	55,700,000	$ 55,700	—	$ —	—	$ —	4,530,115	$ 5	$ 3,319	$ 10	$ (51,129)	$ (47,795)

Retroactive application of recapitalization	(55,700,000)	(55,700)	—	—	—	—	18,922,317	19	55,681	—	—	55,700
Recasted balance as of December 31, 2019	—	—	—	—	—	—	23,452,432	24	59,000	10	(51,129)	7,905
Repurchase of restricted common stock awards	—	—	—	—	—	—	(25,479)	—	—	—	—	—
Vesting of restricted common stock awards	—	—	—	—	—	—	—	—	3	—	—	3
Stock based compensation expense	—	—	—	—	—	—	—	—	408	—	—	408
Other comprehensive income	—	—	—	—	—	—	—	—	—	15	—	15
Net loss	—	—	—	—	—	—	—	—	—	—	(7,914)	(7,914)
Balance at March 31, 2020	—	$ —	—	$ —	—	$ —	23,426,953	$ 24	$ 59,411	$ 25	$ (59,043)	$ 417
Issuance of Series B-1 redeemable convertible preferred stock, net of issuance costs of less than $0.2 million	—	—	22,686,025	29,761	—	—	—	—	—	—	—	—
Retroactive application of recapitalization	—	—	(22,686,025)	(29,761)	—	—	7,706,861	8	29,753	—	—	29,761
Exercise of Stock Options	—	—	—	—	—	—	6,688	—	9	—	—	9
Vesting of restricted common stock awards	—	—	—	—	—	—	—	—	3	—	—	3
Stock based compensation expense	—	—	—	—	—	—	—	—	407	—	—	407
Other comprehensive loss	—	—	—	—	—	—	—	—	—	(14)	—	(14)
Net loss	—	—	—	—	—	—	—	—	—		(8,392)	(8,392)
Balance at June 30, 2020	—	$ —	—	$ —	—	$ —	31,140,502	$ 32	$ 89,583	$ 11	$ (67,435)	$ 22,191
Issuance of Series B-1 redeemable convertible preferred stock, net of issuance costs of less than $0.2 million	—	—	—	—	27,152,255	51,083	—	—	—	—	—	—
Retroactive application of recapitalization	—	—	—	—	(27,152,255)	(51,083)	9,224,122	8	51,075	—	—	51,083
Repurchase of restricted common stock awards	—	—	—	—	—	—	(12,695)	—	—	—	—	—
Exercise of Stock Options	—	—	—	—	—	—	1,142	—	1	—	—	1
Vesting of restricted common stock awards	—	—	—	—	—	—	—	—	3	—	—	3
Stock based compensation expense	—	—	—	—	—	—	—	—	418	—	—	418
Other comprehensive loss	—	—	—	—	—	—	—	—	—	15	—	15
Net loss	—	—	—	—	—	—	—	—	—		(26,802)	(26,802)
Balance at September 30, 2020	—	$ —	—	$ —	—	$ —	40,353,071	$ 40	$ 141,080	$ 26	$ (94,237)	$ 46,909

See Note 3 for discussion on the retroactive application of recapitalization

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)

	Nine Months Ended September 30,	
	2021	**2020**
Cash flows from operating activities		
Net loss	$ (36,189)	$ (43,108)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:		
Depreciation	641	527
Noncash operating lease expense	748	671
Stock-based compensation	5,576	1,233
Other, net	171	(107)
Changes in operating assets and liabilities:		
Accounts receivable	(6,000)	-
Prepaid expenses and other current assets	(3,222)	421
Other long-term assets	18	-
Accounts payable	867	914
Accrued expenses and other liabilities	3,794	1,802
Operating lease liabilities	(703)	(440)
Deferred revenue	(8,326)	126,223
Net cash (used in) provided by operating activities	$ (42,625)	$ 88,136
Cash flows from investing activities		
Purchase of property and equipment	(1,141)	(650)
Sales and maturities of marketable securities	130,890	16,337
Purchases of marketable securities	(267,976)	(101,943)
Net cash used in investing activities	$ (138,227)	$ (86,256)
Cash flows from financing activities		
Proceeds from issuance of preferred stock, net of issuance costs	29,990	80,934
Proceeds from issuance of common stock upon exercise of stock options	957	11
Business Combination and PIPE Financing, gross proceeds	342,113	-
Payment of Business Combination and PIPE Financing transaction costs	(15,615)	-
Net cash provided by financing activities	$ 357,445	$ 80,945
Net change in cash, cash equivalents and restricted cash	$ 176,593	$ 82,825
Cash, cash equivalents and restricted cash, beginning of period	30,660	25,168
Cash, cash equivalents and restricted cash, end of period	$ 207,253	$ 107,993
Supplemental cash flow information:		
Cash paid for leases	$ 1,372	$ 1,332
Supplemental disclosure of noncash investing and financing activity:		
Conversion of Preferred Shares to Common Shares	$ 166,534	$ -
Purchases of property and equipment included in accounts payable and accrued expenses	$ 417	$ 7

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 (together with its consolidated subsidiaries, “Tango” or the “Company”) formerly known as BCTG Acquisition Corp. (“BCTG”), was incorporated in Delaware on May 21, 2020. BCTG was a Special Purpose Acquisition Company (“SPAC”) formed for the purpose of effecting a merger, capital stock exchange, asset acquisition, stock purchase, reorganization or similar business combination.

The registration statement for the Company’s initial public offering (“IPO”) was declared effective on September 2, 2020. On September 8, 2020, the Company consummated its Initial Public Offering of 16,675,000 shares of common stock (the “Public Shares”), including the 2,175,000 Public Shares as a result of the underwriters’ full exercise of their over-allotment option, at an offering price of $10.00 per Public Share, generating gross proceeds of approximately $166.8 million, and incurring offering costs of approximately $9.6 million, inclusive of approximately $5.8 million in deferred underwriting commissions. Simultaneously with the closing of the Initial Public Offering, the Company consummated the private placement (“Private Placement”) of 533,500 shares of common stock (the “Private Placement shares”), at a price of $10.00 per Private Placement Share to the Sponsor, generating gross proceeds of approximately $5.3 million. Upon the closing of the Initial Public Offering and the Private Placement, approximately $166.8 million ($10.00 per share), representing the net proceeds of the Initial Public Offering and certain of the proceeds of the Private Placement was placed in a trust account (“Trust Account”) in the United States maintained by Continental Stock Transfer & Trust Company, as trustee, and will remain invested only in U.S. government treasury bills, notes and bonds with a maturity of 185 days or less or in money market funds meeting certain conditions under Rule 2a-7 under the Investment Company Act and which invest solely in U.S. Treasuries, until the earlier of: (i) the completion of a Business Combination and (ii) the distribution of the Trust Account as described below.

Merger with BCTG Acquisition Corporation

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") 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 (the “Business Combination”). The Business Combination was approved on August 9, 2021 by shareholders of BCTG, resulting in BCTG acquiring 100% of Old Tango's issued and outstanding equity securities on August 10, 2021. The Business Combination was accounted for as a “reverse recapitalization” in accordance with accounting principles generally accepted in the United States of America (“U.S. GAAP”). As a result of the Business Combination, BCTG was renamed Tango Therapeutics, Inc. The Company's common stock is trading on The Nasdaq Global Market under the ticker symbol TNGX.

Tango received gross proceeds of $167.1 million upon the closing of the Business Combination. Tango continues to operate under the current Tango management team. Simultaneous with the closing of the Business Combination, an aggregate of 18,610,000 shares of common stock (the “PIPE Financing”) were purchased, resulting in gross proceeds of an additional $186.1 million upon the closing of the PIPE Financing. Total transaction costs and redemptions approximated $26.7 million, resulting in total net proceeds of $326.5 million.

Description of Business following the Merger

The Company is now a precision oncology company committed to the discovery and development of novel new drugs in defined patient populations with high unmet medical need.

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 subsidiary 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 and nine months ended September 30, 2021 and 2020 are not necessarily indicative of the results for the year ending December 31, 2021, any other interim periods, or any future year or period. The unaudited condensed consolidated financial statements for the three and nine months ended September 30, 2021 and 2020 have been prepared on the same basis as and should be read in conjunction with the audited consolidated financial statements and notes for the year ended December 31, 2020 included in the Company's Prospectus as filed with the SEC pursuant to Rule 424(b)(3) on October 8, 2021 (the "Prospectus").

2. Summary of Significant Accounting Policies

Other than policies noted below, 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 for the year ended December 31, 2020 included in the Company's Prospectus.

Recently Adopted Accounting Pronouncements

In December 2019, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update ("ASU") 2019-12, *Simplifying the Accounting for Income Taxes*, ("ASC 740"). The ASU enhances and simplifies various aspects of the income tax accounting guidance in Accounting Standards Codification ("ASC") 740, including requirements related to hybrid tax regimes, the tax basis step-up in goodwill obtained in a transaction that is not a business combination, separate financial statements of entities not subject to tax, the intra-period tax allocation exception to the incremental approach, ownership changes in investments, changes from a subsidiary to an equity method investment, interim-period accounting for enacted changes in tax law, and the year-to-date loss limitation in interim-period tax accounting. This guidance is effective for the Company for annual and interim periods beginning after December 31, 2020; however, early adoption was permitted The Company adopted this standard as of January 1, 2021 on a prospective basis. The adoption did not have a material impact on the Company's condensed consolidated financial statements.

In August 2020, the FASB issued ASU 2020-06, *Debt — Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging — Contracts in Entity's Own Equity (Subtopic 815 — 40)*. The amendments in this update affect entities that issue convertible instruments and/or contracts indexed to and potentially settled in an entity's own equity. The new ASU eliminates the beneficial conversion and cash conversion accounting models for convertible instruments. It also amends the accounting for certain contracts in an entity's own equity that are currently accounted for as derivatives because of specific settlement provisions. In addition, the new guidance modifies how particular convertible instruments and certain contracts that may be settled in cash or shares impact the diluted earnings per share ("EPS") computation. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020, including interim periods within those fiscal years. The Company elected to early adopt this guidance on January 1, 2021. The Company issued the second tranche of its redeemable convertible Series B preferred stock in March 2021 at an original issue price of $1.32 per share, which would have resulted in the recognition of a beneficial conversion feature of $28.4 million prior to the adoption of ASU 2020-06.

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 as of September 30, 2021 (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	(15,615)
Net cash proceeds from the Business Combination and PIPE Financing	326,498
Add: non-cash net assets assumed from BCTG	3
Net contributions from Business Combination and PIPE Financing	$ 326,501

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 55,000,0000 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 Company comprises all of the ongoing operations of Old Tango, the Company comprises a majority of the governing body of Old Tango, and the 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.

Retroactive Application of Recapitalization to Unaudited Condensed Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders’ Equity (Deficit)

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 as follows:

Date	Description	Redeemable Convertible Preferred Stock	Preferred to Common Exchange Ratio	Common Stock Shares	8/10/2021 Merger Recapitalization Exchange Ratio	Recapitalization Common Stock
12/31/2019	Series A	55,700,000	1.00	55,700,000	0.34	18,922,317
4/7/2020	Series B (tranche 1)	22,686,025	1.00	22,686,025	0.34	7,706,861
8/17/2020	Series B-1	27,152,255	1.00	27,152,255	0.34	9,224,122
3/18/2021	Series B (tranche 2)	22,686,025	1.00	22,686,025	0.34	7,706,861

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 (deficit) and/or in the related notes are presented on an as-converted basis, converted at the ratio of 0.34.

Retroactive Application of Recapitalization to Unaudited Condensed Consolidated Statements of Operations and Comprehensive Loss

In accordance with the retroactive application of recapitalization to the accompanying unaudited condensed consolidated statements of redeemable convertible preferred stock and stockholders' equity (deficit), the basic and diluted weighted-average shares of common stock outstanding for the three and nine month periods ended September 30, 2021 and 2020 have been retroactively converted using the exchange ratio of 0.34.

The following table summarizes the weighted-average common shares, basic and diluted, for the three months ended September 30, 2020:

Date	Description	As previously recorded	8/10/2021 Merger Exchange Ratio	Recapitalized Common Stock	Days Outstanding in 2020	% of weighting	Weighted average common shares
9/30/2020	Weighted-average shares, basic and diluted	11,723,528	0.34	3,982,482		100%	3,982,482
12/31/2019	Series A shares	55,700,000	0.34	18,921,290	91	100%	18,921,290
4/7/2020	Series B shares	22,686,025	0.34	7,706,443	91	100%	7,706,443
8/17/2020	Series B-1 shares	27,152,255	0.34	9,223,621	44	48%	4,459,773
	Weighted average number of common shares outstanding – basic and diluted for the three months ended September 30, 2020						35,069,988

The following table summarizes the weighted-average common shares, basic and diluted, for the nine months ended September 30, 2020:

Date	Description	As previously recorded	8/10/2021 Merger Exchange Ratio	Recapitalized Common Stock	Days Outstanding in 2020	% of weighting	Weighted average common shares
9/30/2020	Weighted-average shares, basic and diluted	11,186,180	0.34	3,799,945		100%	3,799,945
12/31/2019	Series A shares	55,700,000	0.34	18,921,290	273	100%	18,921,290
4/7/2020	Series B shares	22,686,025	0.34	7,706,443	176	64%	4,968,256
8/17/2020	Series B-1 shares	27,152,255	0.34	9,223,621	44	16%	1,486,591
	Weighted average number of common shares outstanding – basic and diluted for the nine months ended September 30, 2020						29,176,082

Retroactive Application of Recapitalization to Unaudited Condensed Consolidated Balance Sheets

To conform to the retroactive application of recapitalization to the accompanying unaudited condensed consolidated statements of redeemable convertible preferred stock and stockholders' equity (deficit), 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 periods ended September 30, 2021 and 2020, respectively.

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 Old Tango's Series B-1 preferred stock offering. At the time of the original investment, as well as through the September 30, 2021 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; 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.

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 September 30, 2021. 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 and nine months ended September 30, 2021, the Company recognized $6.8 million and $20.3 million, respectively, of revenue associated with the Gilead Agreements based on performance completed during each period. During the three and nine months ended September 30, 2020, the Company recognized a reduction in revenue in the amounts of $11.3 million and $2.2 million, respectively, driven by a cumulative catch-up adjustment that was recorded during the third quarter in connection with the Amended Gilead Agreement. During the nine months ended September 30, 2021, the Company recognized revenue of $11.0 million, associated with the payment received in the second quarter of 2021 pursuant to the April 2021 program license. During the three and nine months ended September 30, 2020, the Company recognized revenue of $0 and $0.7 million, respectively, associated with the payments received in 2019 pursuant to the program license and Gilead Letter Agreement. The consideration allocated to the Gilead License was recognized upon delivery of the underlying license in 2019 as Gilead could benefit from the license on its own and the Gilead License was separately identifiable from the Gilead Letter Agreement research services.

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 September 30, 2021 and December 31, 2020, the Company had short-term deferred revenue of $27.8 million and $32.0 million, respectively, and long-term deferred revenue of $116.6 million and $120.8 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 5.9 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 sheet. As of September 30, 2021, $6.0 million of the total research extension fees of $24.0 million had been received, $8.0 million had been recorded as accounts receivable and the remaining $10.0 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 September 30, 2021			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Cash equivalents:				
Money market funds	$ 93,387	$ —	$ —	$ 93,387
U.S. Treasury bills	—	51,647	—	51,647
Marketable debt securities:				
U.S. Treasury bills	—	253,232	—	253,232
U.S. government agency bonds	—	45,599	—	45,599
Total assets	$ 93,387	$ 350,478	$ —	$ 443,865

	Fair Market Value Measurements as of December 31, 2020			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Cash equivalents				
Money market funds	$ 12,698	$ —	$ —	$ 12,698
U.S. Treasury bills	—	7,175	—	7,175
Marketable debt securities				
U.S. Treasury bills	—	131,939	—	131,939
U.S. government agency bonds	—	30,000	—	30,000
Total assets	$ 12,698	$ 169,114	$ —	$ 181,812

There were no transfers between fair value levels during the nine months ended September 30, 2021.

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 September 30, 2021			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Loss	Fair Value
	(in thousands)			
Marketable debt securities:				
U.S. Treasury bills	$ 253,232	$ 12	$ (12)	$ 253,232
U.S. government agency bonds	45,609	3	(13)	45,599
	$ 298,841	$ 15	$ (25)	$ 298,831

	Fair Value Measurements as of December 31, 2020			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Loss	Fair Value
	(in thousands)			
Marketable debt securities:				
U.S. Treasury bills	$ 131,927	$ 12	$ —	$ 131,939
U.S. government agency bonds	29,995	5	—	30,000
	$ 161,922	$ 17	$ —	$ 161,939

The Company holds investment grade marketable securities, with less than $0.1 million of U.S. government agency bonds considered to be in an unrealized loss position as of September 30, 2021 and none considered to be in an unrealized loss position as of December 31, 2020. Although the U.S. government agency bonds are held at an unrealized loss position at September 30, 2021, 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 $0.1 million in accrued interest at September 30, 2021 and December 31, 2020.

7. Supplemental Balance Sheet Information

Property and Equipment

Property and equipment, net as of September 30, 2021 and December 31, 2020 consists of the following:

	September 30, 2021	December 31, 2020
	(in thousands)	
Laboratory equipment	$ 5,567	$ 4,580
Computer equipment	172	172
Computer software	125	125
Furniture and fixtures	467	384
Leasehold improvements	246	246
Construction in progress	447	—
	7,024	5,507
Less: Accumulated depreciation	(2,318)	(1,684)
Property and equipment, net	$ 4,706	$ 3,823

Depreciation expense was $0.2 million for each of the three months ended September 30, 2021 and 2020 and $0.6 million and $0.5 million for the nine months ended September 30, 2021 and 2020, respectively.

Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities as of September 30, 2021 and December 31, 2020 include the following:

	September 30, 2021	December 31, 2020
	(in thousands)	
Payroll and employee-related costs	$ 2,556	$ 2,652
Research and development costs	6,347	2,695
Other	1,075	793
Total accrued expenses and other current liabilities	$ 9,978	$ 6,140

Restricted Cash

As of both September 30, 2021 and September 30, 2020, the Company maintained a restricted cash balance of $2.3 million, 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:

	September 30, 2021	September 30, 2020
	(in thousands)	
Cash and cash equivalents	$ 204,974	$ 105,714
Restricted cash	2,279	2,279
Cash, cash equivalents and restricted cash	$ 207,253	$ 107,993

8. Commitments and Contingencies

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 and clinical 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 September 30, 2021, 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 2017, Old Tango executed a stock purchase agreement to sell 55,000,000 shares of redeemable convertible series A preferred stock (“Series A”). This agreement was subsequently amended in July 2017 to increase the authorized capital to 55,700,000 shares of Series A. The Series A stock purchase agreement was structured to close in three tranches, each contingent upon the achievement of certain specified milestones.

Pursuant to the initial closing of the Series A stock purchase agreement, Old Tango issued an aggregate of 18,700,000 shares of Series A convertible preferred stock for $1.00 per share, resulting in net proceeds of $14.0 million after deducting $4.7 million related to the settlement of the convertible notes and accrued interest that were previously outstanding. During the year-ended December 31, 2018, Old Tango issued 26,000,000 additional shares of Series A preferred stock at a price of $1.00 per share upon the achievement of specified development milestones in connection with the second tranche of the Series A stock purchase agreement. Total proceeds from this issuance were $26.0 million. In January 2019, Old Tango issued 11,000,000 additional shares of Series A preferred stock at a price of $1.00 per share upon the achievement of specified development milestones in connection with the third tranche of the Series A stock purchase agreement. Total proceeds from this issuance were $11.0 million. The aggregate issuance costs associated with the issuance of all three tranches of Series A preferred stock was less than $0.1 million.

In April 2020, Old Tango executed a stock purchase agreement to sell shares of redeemable convertible series B preferred stock (“Series B”). The Series B stock purchase agreement allows for the issuance of up to 45,372,051 shares. In April 2020, Old Tango issued 22,686,025 shares of Series B at a price of $1.32 per share. Proceeds from this issuance totaled $29.8 million, net of $0.2 million in issuance costs. In March 2021, Old Tango sold 22,686,025 additional shares of Series B redeemable convertible preferred 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 second tranche of the Series B preferred stock was less than $0.1 million.

In August 2020, Old Tango executed a stock purchase agreement to sell shares of redeemable convertible series B-1 preferred stock (“Series B-1”). The Series B-1 stock purchase agreement allows for the issuance of up to 27,152,255 shares. All 27,152,255 shares of Series B-1 were issued at a price of $1.89 per share in August 2020. Proceeds from this issuance was $51.1 million, net of $0.1 million in issuance costs.

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 as discussed further in Note 1 and Note 3.

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 September 30, 2021, the Company had 6,908,373 shares available for future issuance.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
	(in thousands)			
Research and development	$ 2,558	$ 233	$ 3,570	$ 682
General and administrative	872	185	2,006	551
Total	$ 3,430	$ 418	$ 5,576	$ 1,233

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 1 and Note 3.

The following table summarizes the stock option activity for the nine months ended September 30, 2021:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Contractual Term	Aggregate Intrinsic Value
			(in years)	
Options outstanding as of December 31, 2020	4,094,544	$ 1.88	8.58	$ 6,625,511
Granted	5,564,341	6.92		
Exercised	(584,561)	1.64		
Cancelled	(247,427)	3.37		
Options outstanding as of September 30, 2021	8,826,897	$ 5.03	8.68	$ 69,725,604
Options exercisable as of September 30, 2021	1,843,814	$ 2.56	6.65	$ 19,120,394

As of September 30, 2021, total unrecognized compensation expense related to stock options was $26.4 million, which the Company expects to recognize over a remaining weighted-average period of 3.1 years.

Restricted Stock Awards

During the nine months ended September 30, 2021, 256,385 RSAs vested. Stock-based compensation expense attributable to RSAs during the nine months ended September 30, 2021 totaled $0.5 million.

11. Net Loss Per Share

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	(in thousands, except per share data)			
	2021	2020	2021	2020
Numerator:				
Net loss	$ (19,590)	$ (26,802)	$ (36,189)	$ (43,108)
Net loss attributable to common stockholders – basic and diluted	(19,590)	(26,802)	(36,189)	(43,108)
Denominator:				
Weighted-average common stock outstanding – basic and diluted	70,160,663	35,069,988	53,397,557	29,176,082
Net loss per share attributable to common stockholders – basic and diluted	$ (0.28)	$ (0.76)	$ (0.68)	$ (1.48)

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:

	September 30,	
	2021	2020
Stock options to purchase common stock	8,826,897	3,379,915
Unvested restricted common stock	213	599,276
Total	8,827,110	3,979,191

12. Income Taxes

The Company's effective income tax rate was 0.3% and 0.0% for the three months ended September 30, 2021 and 2020, respectively, and 0.7% and 0.0% for the nine months ended September 30, 2021 and 2020, respectively. The income tax provision was $62 thousand and $0 for the three months ended September 30, 2021 and 2020, respectively, and $115 thousand and $0 for the nine months ended September 30, 2021 and 2020, respectively. The change in the provision for income taxes for the three and nine months ended September 30, 2021, respectively, compared to the three and nine months ended September 30, 2020 was primarily due to taxable deferred revenue partially offset by the utilization of federal and state net operating losses and federal and state tax credits.

The effective income tax rate for the three and nine months ended September 30, 2021 and 2020 differed from the federal statutory rate primarily due to the valuation allowance maintained against the Company's deferred tax assets.

13. Subsequent Events

100 Binney Street Lease Modification

In November 2021, the Company entered into a lease termination agreement for the Company's 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, for which the earlier date shall be no later than October 15, 2022.

The Company estimates that the execution of the lease termination agreement will result in material reductions to the associated lease liability and right-of-use asset balances in the fourth quarter of 2021. The Company also expects to reduce the useful life assigned to leasehold improvements associated with the Binney Street lease, resulting in an increase to depreciation expense recognized over the remaining term of the modified lease. The restricted cash balance will be reduced by $0.6 million on the last day of the modified lease term, at which time the related security deposit will be returned to the Company.

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, with our audited consolidated financial statements and related notes for the year ended December 31, 2020 included in the Prospectus as filed with the SEC pursuant to Rule 424(b)(3) on October 8, 2021, or the Prospectus.

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 Old Tango (as defined below) and its subsidiary prior to the closing of the business combination with BCTG Acquisition Corp. and to Tango 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. We plan to file an Investigational New Drug, or IND, application for TNG908 in the fourth quarter of 2021 and initiate a Phase 1/2 clinical trial in the first half of 2022. We are also developing a ubiquitin-specific protease 1, or USP1, inhibitor that is synthetic lethal with BRCA1 mutations, which are present in approximately 15% of ovarian cancers, 5% of breast cancers, and 1% of prostate cancers. *In vitro* and *in vivo* preclinical data for USP1 demonstrated potent anti-tumor activity. We plan to file an IND in 2022 and expect this molecule to have both single agent activity in PARPi-naïve and PARPi-resistant BRCA1 mutant cancers and to synergize with PARP inhibitors. Our Target 3 program, an undisclosed synthetic lethal target, reverses the immune evasion effect of serine-threonine kinase 11 (STK11) loss-of-function mutations, which are present in approximately 20% of non-small cell lung cancers. In combination with a PD-1 inhibitor, Target 3 sustained strong regressions in animal models. We plan to file 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. "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, the PIPE Investors purchased an aggregate of 18,610,000 shares of our common stock at a price of $10.00 per share, which resulted in gross proceeds of an additional $186.1 million upon the closing of the PIPE Financing. Total transaction costs and redemptions approximated $26.7 million, resulting in total net proceeds of $326.5 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 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 approximately $166.9 million of gross proceeds from the sale of our preferred shares, approximately $342.1 million in gross proceeds through the closing of the Business Combination and PIPE Financing transactions (as described below) and another $210.1 million through our collaboration with Gilead.

We believe that our existing cash, cash equivalents and marketable securities on hand as of September 30, 2021 of $503.8 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 nine months ended September 30, 2021 and 2020, our net losses were $36.2 million and $43.1 million, respectively. We had an accumulated deficit of $139.3 million and $103.1 million as of September 30, 2021 and December 31, 2020, respectively. 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.

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 July 2019, Gilead licensed a program from us, and also separately contracted for additional services related to the program through a letter agreement. As of December 31, 2019, we had substantially completed our required obligations under the license and side letter agreement, and as a result, recognized $9.4 million of revenue. As of December 31, 2020, all remaining obligations under the license and side letter agreement were completed, resulting in the recognition of the remaining consideration of $0.7 million of revenue.

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 $18.0 million of fees related to the research extensions have not been received as of September 30, 2021 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 September 30, 2021, $44.6 million has been recognized as collaboration revenue related to the upfront and research extension payments from the Gilead Agreement.

During the three and nine months ended September 30, 2021, the Company recognized $6.8 million and $20.3 million, respectively, of revenue associated with the Gilead Agreement based on performance completed during each period. During the three and nine months ended September 30, 2020, the Company recognized a reduction in revenue in the amounts of $11.3 million and $2.2 million, respectively, driven by a cumulative catch-up adjustment that was recorded during the third quarter in connection with the execution of the Gilead Agreement in August 2020.

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, 2020 included in the Company's Prospectus, 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 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 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 September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
	(in thousands)		(in thousands)	
TNG908 direct program expenses	$ 2,822	$ 3,017	$ 8,349	$ 7,077
USP1 direct program expenses	2,209	1,213	5,698	3,035
Discovery direct program expenses	7,750	3,167	19,118	8,749
Unallocated research and development expenses				
Personnel related expenses	6,709	3,752	16,180	10,420
Facilities and other related expenses	2,433	1,828	6,657	5,647
Total research and development expenses	$ 21,923	$ 12,977	$ 56,002	$ 34,928

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 and efficacy 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 significantly 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 (Expense)

Interest income (expense) 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) Income, Net

Other (expense) income, net consists of miscellaneous income and 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 have recorded an insignificant provision for income taxes for the three and nine months ended September 30, 2021. There is no provision for income taxes for the three and nine months ended September 30, 2020 because we have historically incurred net operating losses and maintain a full valuation allowance against our deferred tax assets.

Results of Operations

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

The following table summarizes our results of operations for the three months ended September 30, 2021 and 2020:

	Three Months Ended September 30,		
	2021	2020	Change
	(in thousands)		
Collaboration revenue	$ 6,787	$ (11,275)	$ 18,062
License revenue	-	14	(14)
Operating expenses:			
Research and development	21,923	12,977	8,946
General and administrative	4,433	2,518	1,915
Total operating expenses	26,356	15,495	10,861
Loss from operations	(19,569)	(26,756)	7,187
Other income (expense), net:			
Interest income (expense)	91	(50)	141
Other (expense) income, net	(50)	4	(54)
Total other income (expense), net	41	(46)	87
Loss before income taxes	(19,528)	(26,802)	7,274
Provision for income taxes	(62)	-	(62)
Net loss	(19,590)	(26,802)	7,212
Net loss and comprehensive loss	$ (19,602)	$ (26,787)	$ 7,185

Collaboration Revenue

Collaboration revenue of $6.8 million and ($11.3) million for the three months ended September 30, 2021 and 2020, respectively, was derived from the Gilead collaboration. The increase of $18.1 million is primarily due the charge against revenue of $11.3 million for the three months ended September 30, 2020 driven by a cumulative catch-up adjustment to the revenue previously recognized from the Gilead collaboration due to a change to the transaction price resulting from the execution of the Gilead Agreement during the third quarter of 2020.

License Revenue

License revenue was $0 for the three months ended September 30, 2021 compared to an amount of less than $0.1 million for the three months ended September 30, 2020. License revenue was not significant for both the three months ended September 30, 2021 and 2020.

Research and Development Expenses

Research and development expense was $21.9 million for the three months ended September 30, 2021 compared to $13.0 million for the three months ended September 30, 2020. The increase of $8.9 million was primarily due to a $4.9 million increase in external CRO expenses and lab supplies primarily relating to our lead product candidate, TNG908, and the advancement of our other drug discovery programs. Additionally, personnel-related costs increased $3.1 million primarily due to an increase of share-based compensation expense and additional headcount to support our research and development activities, as well as a $0.9 million increase in IT spend, consulting and professional fees.

General and Administrative Expenses

General and administrative expense was $4.4 million for the three months ended September 30, 2021 compared to $2.5 million for the three months ended September 30, 2020. The increase of $1.9 million was primarily due to a $1.2 million increase in personnel-related costs due to an increase in share-based compensation expense and additional headcount.

Interest Income

Interest income was $0.1 million for the three months ended September 30, 2021 compared to interest expense of $0.1 million for the three months ended September 30, 2020. Interest income and expense was not significant for the three month periods primarily due to low interest rates in each period.

Other (Expense) Income, Net

Other expense, net was less than $0.1 million for the three months ended September 30, 2021 compared to other income, net of $0.1 million for the three months ended September 30, 2020. Other expense and income was not significant for both the three months ended September 30, 2021 and 2020.

Provision for Income Taxes

Provision for income taxes was $0.1 million for the three months ended September 30, 2021 compared to $0 for the three months ended September 30, 2020. The increase of $0.1 million 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.

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

The following table summarizes our results of operations for the nine months ended September 30, 2021 and 2020:

	Nine Months Ended September 30,		
	2021	2020	Change
		(in thousands)	
Collaboration revenue	$ 20,326	$ (2,169)	$ 22,495
License revenue	11,000	683	10,317
Operating expenses:			
Research and development	56,002	34,928	21,074
General and administrative	11,530	6,849	4,681
Total operating expenses	67,532	41,777	25,755
Loss from operations	(36,206)	(43,263)	7,057
Other income, net:			
Interest income	299	37	262
Other (expense) income, net	(167)	118	(285)
Total other income, net	132	155	(23)
Loss before income taxes	(36,074)	(43,108)	7,034
Provision for income taxes	(115)	-	(115)
Net loss	(36,189)	(43,108)	6,919
Net loss and comprehensive loss	$ (36,216)	$ (43,092)	$ 6,876

Collaboration Revenue

Collaboration revenue of $20.3 million and $(2.2) million for the nine months ended September 30, 2021 and 2020, respectively, was derived from the Gilead collaboration. The increase of $22.5 million is primarily due to an increase in the total transaction price allocated to the combined performance obligation related to the execution of the Gilead Agreement during the third quarter of 2020, which resulted in a cumulative catch-up adjustment to reduce a portion of the revenue previously recognized from the Gilead collaboration, as well as incremental costs incurred under the Gilead Agreement during the nine months ended September 30, 2021 as compared to the nine months ended September 30, 2020.

License Revenue

License revenue was $11.0 million for the nine months ended September 30, 2021 compared to $0.7 million for the nine months ended September 30, 2020. The increase of $10.3 million is primarily due to the incremental revenue recognized during the nine months ended September 30, 2021 from Gilead licensing a program for an $11.0 million fee as compared to residual 2019 Gilead Letter Agreement revenue of $0.7 million recognized during the nine months ended September 30, 2020.

Research and Development Expenses

Research and development expense was $56.0 million for the nine months ended September 30, 2021 compared to $34.9 million for the nine months ended September 30, 2020. The increase of $21.1 million was primarily due to a $14.0 million increase in external CRO expenses and lab supplies primarily relating to our lead product candidate, TNG908, and the advancement of our other drug discovery programs. Additionally, personnel-related costs increased $5.4 million primarily due to an increase in share-based compensation expense and additional headcount to support our research and development activities, as well as a $1.7 million increase in IT spend, consulting and professional fees.

General and Administrative Expenses

General and administrative expense was $11.5 million for the nine months ended September 30, 2021 compared to $6.8 million for the nine months ended September 30, 2020. The increase of $4.7 million was primarily due to a $2.8 million increase in personnel-related costs due to an increase in share-based compensation expense and additional headcount and a $1.2 million increase in consulting and professional fees.

Interest Income

Interest income was $0.3 million for the nine months ended September 30, 2021 compared to $0.1 million for the nine months ended September 30, 2020. Interest income was not significant for the nine month periods primarily due to low interest rates in each period.

Other (Expense) Income, Net

Other expense, net was $0.2 million for the nine months ended September 30, 2021 compared to other income, net of $0.1 million for the nine months ended September 30, 2020. Other expense and income was not significant for both the nine months ended September 30, 2021 and 2020.

Provision for Income Taxes

Provision for income taxes was $0.1 million for the nine months ended September 30, 2021 compared to $0 for the nine months ended September 30, 2020. The increase of less than $0.1 million 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 $210.1 million through the collaboration and license agreement with Gilead. As of September 30, 2021, we had cash and cash equivalents and marketable securities of $503.8 million.

Funding Requirements

We believe that our existing cash, cash equivalents and marketable securities on hand as of September 30, 2021 of $503.8 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 Nine Months Ended September 30, 2021 and 2020

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

	Nine Months Ended September 30,		
	2021	2020	Change
		(in thousands)	
Net cash (used in) provided by operating activities	$ (42,625)	$ 88,136	$ (130,761)
Net cash used in investing activities	(138,227)	(86,256)	(51,971)
Net cash provided by financing activities	357,445	80,945	276,500
Net increase in cash, cash equivalents and restricted cash	$ 176,593	$ 82,825	$ 93,768

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 $42.6 million for the nine months ended September 30, 2021 compared to net cash provided by operating activities of $88.1 million for the nine months ended September 30, 2020. The increase in net cash used in operating activities for the nine months ended September 30, 2021 was primarily driven by our net loss of $36.2 million for the period, along with a higher non-cash items, including an increase in accounts receivable of $6.0 million and a decrease in deferred revenue of $8.3 million, and a partial offset attributable to an increase in stock-based compensation expense of $5.6 million. The increase in net cash provided by operating activities for the nine months ended September 30, 2020 is primarily due to an upfront, non-refundable payment of $125.0 million from Gilead paid upon execution of the Gilead Agreement in the third quarter of 2020, partially offset by the net loss of $43.1 million during the period.

Investing Activities

Net cash used in investing activities was $138.3 million for the nine months ended September 30, 2021 compared to net cash used in investing activities of $86.3 million for the nine months ended September 30, 2020. The increase in cash used in investing activities was primarily due to increase in purchases of marketable securities partially offset by increased sales and maturities of marketable securities.

Financing Activities

Net cash provided by financing activities was $357.4 million for the nine months ended September 30, 2021 compared to net cash provided by financing activities of $80.9 million for the nine months ended September 30, 2020. The increase net cash provided by financing activities for the nine months ended September 30, 2021 was primarily due to net proceeds of $326.5 million received upon the closing of the Business Combination and PIPE Financing in August 2021, as well as $30.0 million in proceeds related to the issuance of shares of redeemable convertible Series B preferred stock in March 2021. The increase in net cash provided by financing activities for the nine months ended September 30, 2020 was primarily due to net proceeds of $30.0 million related to the issuance of shares of redeemable convertible Series B preferred stock in April 2020 and net proceeds of $51.2 million related to the issuance of shares of redeemable convertible Series-B-1 preferred stock in August 2020.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations at September 30, 2021 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	$ 9,424	$ 1,877	$ 3,926	$ 3,621	$ —
Total	$ 9,424	$ 1,877	$ 3,926	$ 3,621	$ —

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, which expires June 2026. These commitments are also recognized as operating lease liabilities in our balance sheet at September 30, 2021. In November 2021, the Company entered into a lease termination agreement for the Company's 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. See Note 13 of the unaudited condensed consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q for additional discussion of the impact resulting from the lease termination agreement that was executed as a subsequent event.

The table does not include the minimum payments due under our new operating lease for office and laboratory space at the 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 September 30, 2021. 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 once the new lease payments commence. The fixed annual rent payable under the lease is $5.1 million, increasing by 3% annually from the rent commencement date. We will also be required to pay the remaining security deposit balance of $1.7 million for the 201 Brookline Avenue lease on the delivery date notice, which is expected to occur in the first half of 2022.

Purchase Obligations

In the normal course of business, we enter into contracts with third parties for preclinical studies 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 September 30, 2021.

License Agreement Obligations

We have also entered into license agreements under which we may be obligated to make milestone and royalty payments. We have not included future milestone or royalty payments under these agreements 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 September 30, 2021 and December 31, 2020, we were unable to estimate the timing or likelihood of achieving these milestones or generating future product sales. See Note 8 to our audited consolidated financial statements and related notes for the year ended December 31, 2020 included in the Prospectus.

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, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions. 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 for the year ended December 31, 2020 included in the Company's Prospectus, 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. Our board of directors determines the fair value of each share of common stock underlying stock-based awards 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.

Off-Balance Sheet Arrangements

We did not have, during the periods presented, and we do not currently have any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Recently Adopted Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position, results of operations or cash flows is disclosed within the 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 for the year ended December 31, 2020 included in the Company's Prospectus.

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.

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 $503.8 million and $190.3 million as of September 30, 2021 and December 31, 2020, 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 September 30, 2021.

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 September 30, 2021 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. 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. 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.

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 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 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 precision oncology programs 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 our stockholders' deficit 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 nine months ended September 30, 2021, our net loss was $36.2 million. As of September 30, 2021, we had an accumulated deficit of $139.3 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 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, 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 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 products 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 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 and the acceptance of our IND for TNG908 and our other programs in order to commence our future clinical trials;
- successfully enroll subjects in, and complete, our planned clinical trials and 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;
- establish commercial manufacturing capabilities or make 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 one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which 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.

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 preclinical development. We plan to file an IND for TNG908 in the fourth quarter of 2021 and begin a Phase 1/2 clinical trial in the first half of 2022. We also plan to file an IND for our USP1 inhibitor program in 2022 and also file an IND for our undisclosed target for STK11-mutant cancers (Target 3) 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 more recently due to the 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, your ownership interest 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 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, 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. Our programs are still in preclinical development and may never advance to clinical development. We plan to file an IND for TNG908 in the fourth quarter of 2021 and expect to begin a Phase 1/2 clinical trial in the first half of 2022. We also plan to file an IND our USP1 inhibitor program in 2022 and also file an IND for our undisclosed target for STK11-mutant cancers (Target 3) in 2023. We may not be able to file such IND 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. 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. Commencing each of these clinical trials is subject to finalizing the trial design based on discussions with the FDA and other regulatory authorities. 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 a new drug application, or 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. We currently do not have any product candidates in clinical development. Our lead development candidate, TNG908, is currently in IND-enabling studies. However, we do not know whether this will advance to future clinical trials, and if so, whether it or any of our future clinical trials will 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:

- 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
- experience having 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 an emerging field, 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 for each alternation will be large enough to allow us to successfully obtain approval for each alternation type and commercialize our product candidates and achieve profitability.

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

Our preclinical studies and future clinical trials may not be successful. Currently, all our programs are in preclinical development. 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. 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 and ongoing clinical trials may not be successful.

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.

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 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 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 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. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. 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. Interim data from clinical trials 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. 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 top-line data we previously published. As a result, preliminary, interim and top-line data should be viewed with caution until the final data are 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 for the product, commercialization of any approved product and the business prospects of our company in general. 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 actual results, or if regulatory authorities or others 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, or 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 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 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 orphan indications have small populations, our ability to enroll eligible patients may be limited or may result in slower enrollment than we anticipate.

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. Furthermore, our ability to enroll patients may be significantly delayed by the evolving COVID-19 pandemic, 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 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 participation in the FDA's expedited review and development programs, including Breakthrough Therapy Designation and Fast Track Designation (to the extent these are available to us in the future), 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 have the potential to be administered in combination with existing standards of care like 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 used 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 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 combination 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 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.

Any results from our early 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 expect to file an IND for TNG908 in the fourth quarter of 2021, file an IND for our USP1 inhibitor program in 2022 and an IND for our undisclosed target for STK11-mutant cancers (Target 3) 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. 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 future 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 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. While we have not yet initiated clinical trials for our precision oncology programs, it is likely, as is the case with many oncology therapies, that there may be side effects associated with their use. Results of our trials could reveal a high and unacceptable severity and prevalence of side effects. 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.

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 any of our 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 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 we 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 may in the future choose to conduct certain clinical trials outside the United States, including in Europe, Australia or other foreign jurisdictions. The acceptance of trial data from clinical trials conducted outside the United States by the FDA 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 (iii) the data may be considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an 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.

Research programs to pursue the development of our existing and planned product candidates for 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 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;

- 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 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. Currently, all of our product candidates are in discovery or preclinical development, and 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 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.

Public health crises such as pandemics or similar outbreaks could adversely impact our business. In 2020 and continuing into 2021, a novel strain of a virus named SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2), or coronavirus, which causes COVID-19 has spread to most countries across the world, including all 50 states within the United States, including Cambridge, Massachusetts, where our primary office and laboratory space is located. The coronavirus pandemic is evolving, and has led to 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 or clinical trial operations, will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration of the outbreak, new information that will emerge concerning the severity of the coronavirus and the actions to contain the coronavirus or treat its impact, among others. The continued spread of COVID-19 globally could adversely impact our preclinical or clinical trial operations in the United States, 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 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 being affected by 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, 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 affect 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;
- business disruptions caused by potential workplace, laboratory and office closures and an increased reliance on employees working from home, 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.

We have 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. 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 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 operation and financial condition. 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. 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, and others are based on entirely different approaches. These companies include divisions of large pharmaceutical companies and biotechnology companies of various sizes. 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 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 these or other 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 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, genetic alteration which occurs in 10 to 15% of all human tumors, including many commonly occurring cancers with high unmet need such as squamous cell lung, esophageal and bladder cancer. Our second product candidate, USP1, is a strong synthetic lethal target for BRCA1-mutant which are present in approximately 15% of ovarian cancer, 5% of breast cancer, and 1% of prostate cancer. Additionally, our undisclosed Target 3 program is being developed for patients with STK11 loss-of-function mutations, a genetic alteration in approximately 20% of non-small cell lung cancer. 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 access to 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 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;
- the commercial success of the checkpoint blockade drugs with which 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 for 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 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 planned Phase 1/2 clinical trial of TNG908 and 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.

Such arrangements will likely provide us 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, resulting from the investigator-sponsored trials. 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 these parties for execution of clinical trials for our product candidates and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on CROs 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 up to and including criminal prosecution.

We, our principal investigators and our CROs are required to comply with regulations, including Good Clinical Practices, or 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 must be conducted with product candidates produced under current Good Manufacturing Practice, or cGMP, regulations. Our failure or the failure of our principal investigators 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 plan to design our Phase 1/2 clinical trial of TNG908 and intend to design the future clinical trials for our product candidates, these trials are conducted 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 revenue 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 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 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, 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. 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.

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. 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 potential global health concerns such as the COVID-19 pandemic, as well as potential supply chain disruptions, 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 their 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. 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 and 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. 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.

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 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 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. 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 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 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. 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.

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 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. 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 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 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. Recent 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. However, the Leahy-Smith Act and its implementation could make it more difficult to obtain patent protection for our inventions and increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could harm our business, results of operations and financial condition.

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 existing patents and 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 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.

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, 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 Europe. The European exclusivity period 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 can be approved for the same condition. 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. Products 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 or decide that the time period for FDA review or approval will not be shortened.

We may seek fast track designation for some of our product candidates. If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the 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.

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 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 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 government agencies, 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 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 agency 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 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. The FDA has developed a rating system to assist in determining when and where it is safest to conduct prioritized domestic inspections and resumed inspections in China and India in early 2021. In April 2021, the FDA issued guidance for industry formally announcing plans to employ remote interactive evaluations, using risk management methods, to meet user fee commitments and goal dates and in May 2021 announced plans to continue progress toward resuming standard operational levels. 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 a complete response letter or defer action on the application until an inspection can be completed.

Further, if there is inadequate information to make a determination on the acceptability of a facility, the FDA may defer action on the application until an inspection can be completed. Additionally, as of May 26, 2021, the FDA noted it is continuing to ensure timely reviews of applications for medical products during the ongoing COVID-19 pandemic in line with its user fee performance goals and conducting mission critical domestic and foreign inspections to ensure compliance of manufacturing facilities with the FDA

quality standards. However, the FDA may not be able to continue its current pace and approval timelines could be extended, including where a pre-approval inspection or an inspection of clinical sites is required and due to the ongoing COVID-19 pandemic and travel restrictions FDA is unable to complete such required inspections during the review period. 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 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; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the ACA was passed, which substantially changed the way health care is financed by both governmental and private insurers, and significantly impacted the U.S. biopharmaceutical industry. The ACA, among other things, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees and taxes on manufacturers of certain branded prescription drugs, and created a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% (increased to 70% pursuant to the Bipartisan Budget Act of 2018, effective as of 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D. There have been many legal challenges to the ACA as well as legislative and regulatory modifications. There are also other initiatives at the federal and state level intended to contain healthcare costs by requiring manufacturers to provide greater discounts or by limiting the amount of government reimbursement for pharmaceutical products. We expect these changes to continue between now and the time we may launch a commercial product with uncertain consequences.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace, which began on February 15, 2021 and remained open through August 15, 2021. 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. In December 2018, the Centers for Medicare & Medicaid Services, or CMS, published a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of the federal district court litigation regarding the method CMS uses to determine this risk adjustment. Since then, the ACA risk adjustment program payment parameters have been updated annually. We cannot predict what effect the healthcare reform measures of the Biden administration or other efforts, if any, to challenge, repeal or replace the ACA would have on our business.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year, and, due to subsequent legislative amendments, will remain in effect through 2030 unless additional Congressional action is taken. Pursuant to the Coronavirus Aid, Relief, and Economic Security Act, also known as the CARES Act, as well as subsequent legislation, these reductions have been suspended from May 1, 2020 through December 31, 2021 due to the COVID-19 pandemic. Proposed legislation, if passed, would extend this suspension until the end of the pandemic.

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 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.

At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control biopharmaceutical and biologic 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. Restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment of up to ten years, and exclusion from government healthcare programs. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers, on the one hand, and prescribers, purchasers and formulary managers, on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution;
- the federal civil and criminal false claims and civil monetary penalties laws, including the federal False Claims Act, or FCA, which imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. In addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false of fraudulent claim for purposes of the FCA;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program (e.g. public or private), or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the federal physician payment transparency requirements, sometimes referred to as the "Sunshine Act" under the ACA, which require manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report to HHS information related to transfers of value made to physicians (currently defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests of such physicians and their immediate family members. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made to certain non-physician providers such as physician assistants and nurse practitioners;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, which impose obligations on certain covered entity healthcare providers, health plans, and healthcare clearinghouses as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;

- federal price reporting laws, which require manufacturers to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and/or discounts on approved products; and
- analogous state laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers. Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures. Further, many state laws governing the privacy and security of health information in certain circumstances, differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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 anticipated activities to be conducted by our sales team, 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.

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 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.

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. 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.

In the event we decide to conduct clinical trials or continue to enroll subjects in our ongoing or future clinical trials, we may 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. Compliance with the GDPR will be a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, 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.

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 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, 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 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 may collect and use a variety of personal data, such as names, mailing addresses, email addresses, phone numbers and clinical trial information. 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. 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.

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 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 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 September 30, 2021, we had 83 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 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 August 31, 2021, 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. As of December 31, 2020, we had federal net operating loss carryforwards of approximately $41.0 million, and our ability to utilize those net operating loss carryforwards could be limited by an "ownership change" as described above, which could result in increased tax liability to us. We have not yet conducted a study to assess whether a change of control has occurred as a result of the Business Combination. A study will be conducted in the near term. If we experience a change of control, as defined by Section 382 of the Code, as a result of the Business Combination or otherwise, utilization of net operating loss carryforwards or research and development tax credit carryforwards could be subject to an annual limitation under Sections 382 and 383 of the Code, as applicable. Any limitation may result in expiration of a portion of the net operating loss carryforwards or research and development tax credit carryforwards before utilization. Moreover, our ability to utilize our net operating loss carryforwards or credits is conditioned upon our attaining profitability and generating U.S. federal and state taxable income. As a result, the amount of the net operating loss and tax credit carryforwards presented in our financial statements could be limited and may expire unutilized. 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 generated after December 31, 2017. 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 in this prospectus 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 in this prospectus 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. In addition, while the Delaware Supreme Court ruled in March 2020 that federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court are "facially valid" under Delaware law, there is uncertainty as to whether other courts will enforce our Federal Forum Provision. If the Federal Forum Provision is found to be unenforceable, we may incur additional costs associated with resolving such matters. The Federal Forum Provision may also impose additional litigation costs on stockholders who assert that the provision is not enforceable or invalid. The Court of Chancery of the State of Delaware and the 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 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 plan 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, 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, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our 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 is likely 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;
- market conditions in the pharmaceutical and biotechnology sectors;
- 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 will be 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 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. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our services. 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.

Concurrently with the execution of the Business Combination, we entered into subscription agreements, or the "Subscription Agreements", with each of the PIPE Investors, pursuant to which the PIPE Investors subscribed for and purchased an aggregate of 18,610,000 shares of Common Stock at a price of $10.00 per share for aggregate gross proceeds of $186,100,000. These shares were issued to the PIPE Investors immediately following the closing of the Business Combination on August 10, 2021.

Originally, the shares of Common Stock issued pursuant to the Subscription Agreements, or the "PIPE Financing Shares", had not been registered under the Securities Act in reliance upon the exemption provided in Section 4(a)(2) of the Securities Act. Pursuant to the Subscription Agreements, on September 9, 2021, we filed with the SEC (at our sole cost and expense) a registration statement, or the "Resale Registration Statement", registering the resale of the PIPE Financing Shares.

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
2.1+	Agreement and Plan of Merger, dated as of April 13, 2021, by and among BCTG Acquisition Corp., BCTG Merger Sub Inc. and Tango Therapeutics, Inc. (incorporated by reference to Annex A to the Proxy Statement/ Prospectus).
3.1	Second Amended and Restated Certificate of Incorporation of Tango Therapeutics, Inc. (incorporated by reference to Exhibit 3.1 to the Registrant's registration statement on Form S-1 filed with the SEC on September 10, 2021).
3.2	Amended and Restated By-laws of Tango Therapeutics, Inc. (incorporated by reference to Exhibit 4.2 to the Registrant's registration statement on Form S-8 filed with the SEC on October 14, 2021).
10.1	Form of Lock-Up Agreement (incorporated by reference to Exhibit D to Exhibit 2.1).
10.2	Amended and Restated Registration and Stockholder Rights Agreement, dated August 10, 2021, by and among Tango Therapeutics, Inc. and the stockholders party thereto (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed by the Registrant on August 13, 2021).
10.3#	Tango Therapeutics, Inc. 2021 Stock Option and Incentive Plan (incorporated by reference to Exhibit 10.4 to the Current Report on Form 8-K filed by the Registrant on August 13, 2021).
10.4#	Forms of Award Agreements under the Tango Therapeutics, Inc. 2021 Stock Option and Incentive Plan (incorporated by reference to Exhibit 10.5 to the Current Report on Form 8-K filed by the Registrant on August 13, 2021).
10.5#	Tango Therapeutics, Inc. 2021 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.6 to the Current Report on Form 8-K filed by the Registrant on August 13, 2021).
10.6#	Form of Executive Employment Agreement (incorporated by reference to Exhibit 10.7 to the Current Report on Form 8-K filed by the Registrant on August 13, 2021).
10.7	Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.8 to the Current Report on Form 8-K filed by the Registrant on August 13, 2021).
10.8	Form of Indemnification Agreement (Directors) (incorporated by reference to Exhibit 10.9 to the Current Report on Form 8-K filed by the Registrant on August 13, 2021).
10.9#	Form of Indemnification Agreement (Officers) (incorporated by reference to Exhibit 10.10 to the Current Report on Form 8-K filed by the Registrant on August 13, 2021).
10.10#	Senior Executive Cash Annual Incentive Plan (incorporated by reference to Exhibit 10.11 to the Current Report on Form 8-K filed by the Registrant on August 13, 2021).
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 (embedded within the Inline XBRL document)

* Furnished herewith.

** The certifications furnished in Exhibit 32.1 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.

\+ The schedules and exhibits to this agreement have been omitted pursuant to Item 601(b)(2) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the SEC upon request.

\# Indicates management contract or compensatory plan or arrangement.

SIGNATURES

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

Tango Therapeutics, Inc.

Dated: November 9, 2021

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)

Exhibit 31.1

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)) 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) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

(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: November 9, 2021

/s/ Barbara Weber, M.D.

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

Exhibit 31.2

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)) 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) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

(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: November 9, 2021 /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 September 30, 2021 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: November 9, 2021 /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 September 30, 2021 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: November 9, 2021 /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.