

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

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**FORM 10-Q**

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

For the quarterly period ended **March 31, 2015**

**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 **000-30929**

**TG THERAPEUTICS, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of incorporation or organization)

**36-3898269**

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

**3 Columbus Circle, 15<sup>th</sup> Floor  
New York, New York 10019**

(Address including zip code of principal executive offices)

**(212) 554-4484**

(Registrant's telephone number, including area code)

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files).

Yes  No

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

Large accelerated filer

Accelerated filer

Non-accelerated filer  (Do not check if smaller reporting company)

Smaller reporting company

Indicate by checkmark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes  No

There were 50,634,158 shares of the registrant's common stock, \$0.001 par value, outstanding as of May 8, 2015.

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TG THERAPEUTICS, INC.  
FORM 10-Q  
FOR THE QUARTER ENDED MARCH 31, 2015

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## SPECIAL CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS

Certain matters discussed in this report, including matters discussed under the caption “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” may constitute forward-looking statements for purposes of the Securities Act of 1933, as amended, or the Securities Act, and the Securities Exchange Act of 1934, as amended, or the Exchange Act, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from the future results, performance or achievements expressed or implied by such forward-looking statements. The words “anticipate,” “believe,” “estimate,” “may,” “expect” and similar expressions are generally intended to identify forward-looking statements. Our actual results may differ materially from the results anticipated in these forward-looking statements due to a variety of factors, including, without limitation, those discussed under the captions “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this report, as well as other factors which may be identified from time to time in our other filings with the Securities and Exchange Commission, or the SEC, or in the documents where such forward-looking statements appear. All written or oral forward-looking statements attributable to us are expressly qualified in their entirety by these cautionary statements. Such forward-looking statements include, but are not limited to, statements about our:

- expectations for increases or decreases in expenses;
- expectations for the clinical and pre-clinical development, manufacturing, regulatory approval, and commercialization of our pharmaceutical product candidates or any other products we may acquire or in-license;
- use of clinical research centers and other contractors;
- expectations for incurring capital expenditures to expand our research and development and manufacturing capabilities;
- expectations for generating revenue or becoming profitable on a sustained basis;
- expectations or ability to enter into marketing and other partnership agreements;
- expectations or ability to enter into product acquisition and in-licensing transactions;
- expectations or ability to build our own commercial infrastructure to manufacture, market and sell our drug candidates;
- expectations for the acceptance of our products by doctors, patients or payors;
- ability to compete against other companies and research institutions;
- ability to secure adequate protection for our intellectual property;
- ability to attract and retain key personnel;
- approval of reimbursement for our products;
- estimates of the sufficiency of our existing cash and cash equivalents and investments to finance our operating requirements, including expectations regarding the value and liquidity of our investments;
- stock price volatility;
- expected losses; and
- expectations for future capital requirements.

The forward-looking statements contained in this report reflect our views and assumptions only as of the date this report is signed. Except as required by law, we assume no responsibility for updating any forward-looking statements.

We qualify all of our forward-looking statements by these cautionary statements. In addition, with respect to all of our forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

**PART I. FINANCIAL INFORMATION**

**ITEM 1. FINANCIAL STATEMENTS**

**TG Therapeutics, Inc.**  
Condensed Consolidated Balance Sheets

	<u>March 31, 2015</u> <u>(Unaudited)</u>	<u>December 31, 2014</u>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 86,004,445	\$ 55,713,784
Short-term investment securities	19,131,437	23,062,034
Interest receivable	89,710	85,516
Prepaid research and development	9,810,887	6,179,743
Other current assets	701,862	173,952
Total current assets	115,738,341	85,215,029
Restricted cash	576,072	575,012
Equipment, net	24,821	20,357
Goodwill	799,391	799,391
Other assets	130,626	137,101
Total assets	<u>\$ 117,269,251</u>	<u>\$ 86,746,890</u>
<b>Liabilities and equity</b>		
Current liabilities:		
Notes payable, current portion	\$ 272,206	\$ 275,190
Accounts payable and accrued expenses	8,880,438	3,991,625
Accrued compensation	248,000	702,000
Current portion of deferred revenue	152,381	152,381
Total current liabilities	9,553,025	5,121,196
Deferred revenue, net of current portion	1,485,714	1,523,810
Total liabilities	<u>11,038,739</u>	<u>6,645,006</u>
Commitments and contingencies		
Equity:		
Preferred stock, \$0.001 par value per share (10,000,000 shares authorized, none issued and outstanding as of March 31, 2015 and December 31, 2014)	--	--
Common stock, \$0.001 par value per share (150,000,000 shares authorized, 47,471,904 and 44,974,248 shares issued, 47,430,595 and 44,932,939 shares outstanding at March 31, 2015 and December 31, 2014, respectively)	47,472	44,974
Contingently issuable shares	6	6
Additional paid-in capital	216,180,386	175,476,521
Treasury stock, at cost, 41,309 shares at March 31, 2015 and December 31, 2014	(234,337)	(234,337)
Accumulated deficit	(109,763,015)	(95,185,280)
Total equity	106,230,512	80,101,884
Total liabilities and equity	<u>\$ 117,269,251</u>	<u>\$ 86,746,890</u>

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

**TG Therapeutics, Inc.**  
Condensed Consolidated Statements of Operations  
(Unaudited)

	<b>Three months ended March 31,</b>	
	<b>2015</b>	<b>2014</b>
License revenue	\$ 38,095	\$ 38,095
Costs and expenses:		
Research and development:		
Noncash compensation	1,337,908	1,901,610
Other research and development	8,279,431	2,508,258
Total research and development	<u>9,617,339</u>	<u>4,409,868</u>
General and administrative:		
Noncash compensation	4,019,120	2,329,828
Other general and administrative	1,004,487	903,524
Total general and administrative	<u>5,023,607</u>	<u>3,233,352</u>
Total costs and expenses	<u>14,640,946</u>	<u>7,643,220</u>
Operating loss	<u>(14,602,851)</u>	<u>(7,605,125)</u>
Other (income) expense:		
Interest income	(22,132)	(13,474)
Other income	--	(95,427)
Interest expense	237,657	226,340
Change in fair value of notes payable	(240,641)	(175,315)
Total other income	<u>(25,116)</u>	<u>(57,876)</u>
Net loss	<u>\$ (14,577,735)</u>	<u>\$ (7,547,249)</u>
Basic and diluted net loss per common share	<u>\$ (0.35)</u>	<u>\$ (0.25)</u>
Weighted average shares used in computing basic and diluted net loss per common share	<u>41,088,752</u>	<u>30,091,000</u>

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

**TG Therapeutics, Inc.**  
Condensed Consolidated Statement of Equity  
for the three months ended March 31, 2015 (Unaudited)

	Preferred stock		Common stock		Contingently issuable shares	Additional paid-in capital	Treasury Stock		Accumulated Deficit	Total
	Shares	Amount	Shares	Amount			Shares	Amount		
Balance at January 1, 2015	--	\$ --	44,974,248	\$ 44,974	\$ 6	\$ 175,476,521	41,309	\$ (234,337)	\$ (95,185,280)	\$ 80,101,884
Issuance of common stock in connection with exercise of warrants			174,036	174		408,112				408,286
Issuance of common stock in connection with cashless exercise of warrants			2,915	3		(3)				--
Issuance of restricted stock			12,000	12		(12)				--
Forfeiture of restricted stock			(1,166)	(1)		1				--
Issuance of common stock to affiliate for cash (See Note 8)			114,855	115		749,890				750,005
Issuance of common stock in At the Market offering (net of offering costs of \$611,663)			2,195,016	2,195		34,188,849				34,191,044
Compensation in respect of restricted stock granted to employees, directors and consultants						5,357,028				5,357,028
Net loss									(14,577,735)	(14,577,735)
Balance at March 31, 2015	--	\$ --	47,471,904	\$ 47,472	\$ 6	\$ 216,180,386	41,309	\$ (234,337)	\$ (109,763,015)	\$ 106,230,512

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

**TG Therapeutics, Inc.**  
Condensed Consolidated Statements of Cash Flows  
(Unaudited)

	<b>Three months ended March 31,</b>	
	<b>2015</b>	<b>2014</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Consolidated net loss	\$ (14,577,735)	\$ (7,547,249)
Adjustments to reconcile consolidated net loss to net cash used in operating activities:		
Gain on settlement of notes payable	--	(95,427)
Noncash stock compensation expense	5,357,028	4,231,438
Depreciation	2,419	706
Amortization of premium on investment securities	80,597	15,255
Change in fair value of notes payable	(2,984)	51,025
Changes in assets and liabilities, net of effects of acquisition:		
Increase in restricted cash	(1,060)	--
Increase in other current assets	(4,159,055)	(988,252)
(Increase) decrease in accrued interest receivable	(4,194)	16,045
Decrease in other assets	25,913	8,706
Increase (decrease) in accounts payable and accrued expenses	4,434,813	(3,888,453)
Decrease in interest payable	--	(94,590)
Decrease in deferred revenue	(38,095)	(38,095)
Net cash used in operating activities	<u>(8,882,353)</u>	<u>(8,328,891)</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchases of equipment	(6,883)	(3,165)
Proceeds from maturity of short-term securities	3,850,000	--
Net cash provided by (used in) investing activities	<u>3,843,117</u>	<u>(3,165)</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from the exercise of warrants	408,286	901,472
Payment of notes payable	--	(677,778)
Proceeds from sale of common stock, net	34,941,049	17,219,223
Deferred financing costs paid	(19,438)	--
Net cash provided by financing activities	<u>35,329,897</u>	<u>17,442,917</u>
<b>NET INCREASE IN CASH AND CASH EQUIVALENTS</b>	<b>30,290,661</b>	<b>9,110,861</b>
Cash and cash equivalents at beginning of period	<u>55,713,784</u>	<u>40,485,466</u>
<b>CASH AND CASH EQUIVALENTS AT END OF PERIOD</b>	<b>\$ <u>86,004,445</u></b>	<b>\$ <u>49,596,327</u></b>
<b>NONCASH TRANSACTIONS</b>		
Accrued financing costs	\$ --	\$ 427,815

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

Unless the context requires otherwise, references in this report to “TG” “Company,” “we,” “us” and “our” refer to TG Therapeutics, Inc. (formerly known as Manhattan Pharmaceuticals, Inc., or Manhattan) and our subsidiaries.

## **NOTE 1 – ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

### ***Description of Business***

We are a biopharmaceutical company focused on the acquisition, development and commercialization of novel treatments for B-cell malignancies and autoimmune diseases. Currently, the company is developing two therapies targeting hematological malignancies. TG-1101 (ublituximab) is a novel, glycoengineered monoclonal antibody that targets a specific and unique epitope on the CD20 antigen found on mature B-lymphocytes. TG Therapeutics is also developing TGR-1202, an orally available PI3K delta inhibitor. The delta isoform of PI3K is strongly expressed in cells of hematopoietic origin and is believed to be important in the proliferation and survival of B-lymphocytes. Both TG-1101 and TGR-1202 are in clinical development for patients with hematologic malignancies. The Company also has pre-clinical programs seeking to develop IRAK4 (interleukin-1 receptor-associated kinase 4) inhibitors and anti-PD-L1 and anti-GITR antibodies.

We also actively evaluate complementary products, technologies and companies for in-licensing, partnership, acquisition and/or investment opportunities. To date, we have not received approval for the sale of any of our drug candidates in any market and, therefore, have not generated any product sales from our drug candidates.

The accompanying unaudited condensed consolidated financial statements were prepared in accordance with U.S. generally accepted accounting principles, or GAAP, for interim financial information and with the instructions to Quarterly Report on Form 10-Q and Article 10 of Regulation S-X of the Exchange Act. Accordingly, they may not include all of the information and footnotes required by GAAP for complete financial statements. All adjustments that are, in the opinion of management, of a normal recurring nature and are necessary for a fair presentation of the condensed consolidated financial statements have been included. Nevertheless, these condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements contained in our Annual Report on Form 10-K for the year ended December 31, 2014. The accompanying December 31, 2014 balance sheet has been derived from these statements. The results of operations for the three months ended March 31, 2015 are not necessarily indicative of the results that may be expected for the entire fiscal year or any other interim period.

### ***Liquidity and Capital Resources***

We have incurred operating losses since our inception and expect to continue to incur operating losses for the foreseeable future and may never become profitable. As of March 31, 2015, we have an accumulated deficit of \$109,763,015.

Our major sources of cash have been proceeds from the private placement and public offering of equity securities, warrant and option exercises, and the upfront payment from our Sublicense Agreement with Ildong Pharmaceutical Co. Ltd. (“Ildong”). We have not yet commercialized any of our drug candidates and cannot be sure if we will ever be able to do so. Even if we commercialize one or more of our drug candidates, we may not become profitable. Our ability to achieve profitability depends on many factors, including our ability to obtain regulatory approval for our drug candidates, successfully complete any post-approval regulatory obligations and successfully commercialize our drug candidates alone or in partnership. We may continue to incur substantial operating losses even if we begin to generate revenues from our drug candidates.

As of March 31, 2015, we had \$105,225,592 in cash, cash equivalents, investment securities, and interest receivable. We currently anticipate that our cash and cash equivalents and investments will be sufficient to fund our anticipated operating cash requirements for more than 24 months from March 31, 2015. The actual amount of cash that we will need to operate is subject to many factors, including, but not limited to, the timing, design and conduct of clinical trials for our drug candidates. We are dependent upon significant future financing to provide the cash necessary to execute our current strategic plan, including the commercialization of any of our drug candidates.

Our common stock is listed on the Nasdaq Capital Market and trades under the symbol “TGTX.”

### ***Recently Issued Accounting Standards***

In August 2014, the FASB issued Accounting Standards Update 2014-15, Presentation of Financial Statements—Going Concern, which requires that management of an entity should evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the entity’s ability to continue as a going concern within one year after the date that the financial statements are issued or available to be issued. This update will become effective beginning January 1, 2017, with early adoption permitted. The provisions of this standard are not expected to significantly impact the Company.

Other pronouncements issued by the FASB or other authoritative accounting standards group with future effective dates are either not applicable or not significant to our consolidated financial statements.

### ***Use of Estimates***

The preparation of financial statements in conformity with GAAP requires management to make estimates and judgments that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the applicable reporting period. Actual results could differ from those estimates. Such differences could be material to the consolidated financial statements.

### ***Cash and Cash Equivalents***

We treat liquid investments with original maturities of three months or less when purchased as cash and cash equivalents.

### ***Restricted Cash***

We record cash pledged or held in trust as restricted cash. As of March 31, 2015, we have approximately \$0.6 million of restricted cash pledged to secure a line of credit as a security deposit for a Desk Agreement (see Note 8).

### ***Investment Securities***

Investment securities at March 31, 2015 and December 31, 2014 consist of short-term and long-term government securities. We classify these securities as held-to-maturity. Held-to-maturity securities are those securities in which we have the ability and intent to hold the security until maturity. Held-to-maturity securities are recorded at amortized cost, adjusted for the amortization or accretion of premiums or discounts. Premiums and discounts are amortized or accreted over the life of the related held-to-maturity security as an adjustment to yield using the effective interest method.

A decline in the market value of any investment security below cost, that is deemed to be other than temporary, results in a reduction in the carrying amount to fair value. The impairment is charged to operations and a new cost basis for the security is established. Other-than-temporary impairment charges are included in interest and other (income) expense, net. Dividend and interest income are recognized when earned.

### ***Credit Risk***

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents, and short-term investments. The Company maintains its cash and cash equivalents with high-credit quality financial institutions. At times, such amounts may exceed federally-insured limits.

### ***Revenue Recognition***

We recognize license revenue in accordance with the revenue recognition guidance of the FASB Accounting Standards Codification, or Codification. We analyze each element of our licensing agreement to determine the appropriate revenue recognition. The terms of the license agreement may include payments to us of non-refundable up-front license fees, milestone payments if specified objectives are achieved, and/or royalties on product sales. We recognize revenue from upfront payments over the period of significant involvement under the related agreements unless the fee is in exchange for products delivered or services rendered that represent the culmination of a separate earnings process and no further performance obligation exists under the contract. We recognize milestone payments as revenue upon the achievement of specified milestones only if (1) the milestone payment is non-refundable, (2) substantive effort is involved in achieving the milestone, (3) the amount of the milestone is reasonable in relation to the effort expended or the risk associated with achievement of the milestone, and (4) the milestone is at risk for both parties. If any of these conditions are not met, we defer the milestone payment and recognize it as revenue over the estimated period of performance under the contract.

## ***Research and Development Costs***

Generally, research and development costs are expensed as incurred. Nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities are deferred and amortized over the period that the goods are delivered or the related services are performed, subject to an assessment of recoverability. We make estimates of costs incurred in relation to external clinical research organizations, or CROs, and clinical site costs. We analyze the progress of clinical trials, including levels of patient enrollment, invoices received and contracted costs when evaluating the adequacy of the amount expensed and the related prepaid asset and accrued liability. Significant judgments and estimates must be made and used in determining the accrued liability balance and expense in any accounting period. We review and accrue CRO expenses and clinical trial study expenses based on work performed and rely upon estimates of those costs applicable to the stage of completion of a study. Accrued CRO costs are subject to revisions as such trials progress to completion. Revisions are charged to expense in the period in which the facts that give rise to the revision become known. With respect to clinical site costs, the financial terms of these agreements are subject to negotiation and vary from contract to contract. Payments under these contracts may be uneven, and depend on factors such as the achievement of certain events, the successful recruitment of patients, the completion of portions of the clinical trial or similar conditions. The objective of our policy is to match the recording of expenses in our financial statements to the actual services received and efforts expended. As such, expense accruals related to clinical site costs are recognized based on our estimate of the degree of completion of the event or events specified in the specific clinical study or trial contract.

## ***Income Taxes***

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to temporary differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases, operating losses and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in operations in the period that includes the enactment date. If the likelihood of realizing the deferred tax assets or liability is less than "more likely than not," a valuation allowance is then created.

We, and our subsidiaries, file income tax returns in the U.S. Federal jurisdiction and in various states. We have tax net operating loss carryforwards that are subject to examination for a number of years beyond the year in which they were generated for tax purposes. Since a portion of these net operating loss carryforwards may be utilized in the future, many of these net operating loss carryforwards will remain subject to examination.

We recognize interest and penalties related to uncertain income tax positions in income tax expense.

## ***Stock-Based Compensation***

We recognize all share-based payments to employees and non-employee directors (as compensation for service) as noncash compensation expense in the consolidated financial statements based on the fair values of such payments. Stock-based compensation expense recognized each period is based on the value of the portion of share-based payment awards that is ultimately expected to vest during the period. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

For share-based payments to consultants and other third-parties (including related parties), noncash compensation expense is determined at the “measurement date.” The expense is recognized over the vesting period of the award. Until the measurement date is reached, the total amount of compensation expense remains uncertain. We record compensation expense based on the fair value of the award at the reporting date. The awards to consultants and other third-parties (including related parties) are then revalued, or the total compensation is recalculated based on the then current fair value, at each subsequent reporting date.

#### **Basic and Diluted Net Loss Per Common Share**

Basic net loss per share of our common stock is calculated by dividing net loss applicable to the common stock by the weighted-average number of our common stock outstanding for the period. Diluted net loss per share of common stock is the same as basic net loss per share of common stock since potentially dilutive securities from stock options, stock warrants and convertible preferred stock would have an antidilutive effect either because we incurred a net loss during the period presented or because such potentially dilutive securities were out of the money and the Company realized net income during the period presented. The amounts of potentially dilutive securities excluded from the calculation were 8,382,986 and 10,103,105 at March 31, 2015 and 2014, respectively. During the three months ended March 31, 2015 and 2014, we incurred a net loss; therefore, all of the dilutive securities are excluded from the computation of diluted earnings per share.

#### **Long-Lived Assets and Goodwill**

Long-lived assets are reviewed for an impairment loss when circumstances indicate that the carrying value of long-lived tangible and intangible assets with finite lives may not be recoverable. Management’s policy in determining whether an impairment indicator exists, a triggering event, comprises measurable operating performance criteria as well as qualitative measures. If an analysis is necessitated by the occurrence of a triggering event, we make certain assumptions in determining the impairment amount. If the carrying amount of an asset exceeds its estimated future cash flows, an impairment charge is recognized.

Goodwill is reviewed for impairment annually, or when events arise that could indicate that an impairment exists. We test for goodwill impairment using a two-step process. The first step compares the fair value of the reporting unit with the unit’s carrying value, including goodwill. When the carrying value of the reporting unit is greater than fair value, the unit’s goodwill may be impaired, and the second step must be completed to measure the amount of the goodwill impairment charge, if any. In the second step, the implied fair value of the reporting unit’s goodwill is compared with the carrying amount of the unit’s goodwill. If the carrying amount is greater than the implied fair value, the carrying value of the goodwill must be written down to its implied fair value. We will continue to perform impairment tests annually, at December 31, and whenever events or changes in circumstances suggest that the carrying value of an asset may not be recoverable.

#### **NOTE 2 – CASH AND CASH EQUIVALENTS**

The following tables summarize our cash and cash equivalents at March 31, 2015 and December 31, 2014:

	<u>March 31, 2015</u>	<u>December 31, 2014</u>
Money market funds	\$ 16,297,431	\$ 12,364,537
Checking and bank deposits	69,707,014	43,349,247
Totals	<u>\$ 86,004,445</u>	<u>\$ 55,713,784</u>

#### **NOTE 3 – INVESTMENT SECURITIES**

We record our investments as either held-to-maturity or available-for-sale. Held-to-maturity investments are recorded at amortized cost.

The following tables summarize our investment securities at March 31, 2015 and December 31, 2014:

	<u>March 31, 2015</u>			
	<u>Amortized cost, as adjusted</u>	<u>Gross unrealized holding gains</u>	<u>Gross unrealized holding losses</u>	<u>Estimated fair value</u>
Short-term investments:				
Obligations of domestic governmental agencies (maturing between April 2015 and December 2015) (held-to-maturity)	\$ 19,131,437	\$ 2,910	\$ 217	\$ 19,134,130
Total short-term investment securities	<u>\$ 19,131,437</u>	<u>\$ 2,910</u>	<u>\$ 217</u>	<u>\$ 19,134,130</u>

	December 31, 2014			
	Amortized cost, as adjusted	Gross unrealized holding gains	Gross unrealized holding losses	Estimated fair value
Short-term investments:				
Obligations of domestic governmental agencies (maturing between January 2015 and December 2015) (held-to-maturity)	\$ 23,062,034	\$ 922	\$ 5,806	\$ 23,057,150
Total short-term investment securities	<u>\$ 23,062,034</u>	<u>\$ 922</u>	<u>\$ 5,806</u>	<u>\$ 23,057,150</u>

#### NOTE 4 – FAIR VALUE MEASUREMENTS

We measure certain financial assets and liabilities at fair value on a recurring basis in the financial statements. The fair value hierarchy ranks the quality and reliability of inputs, or assumptions, used in the determination of fair value and requires financial assets and liabilities carried at fair value to be classified and disclosed in one of the following three categories:

- Level 1 – quoted prices in active markets for identical assets and liabilities;
- Level 2 – inputs other than Level 1 quoted prices that are directly or indirectly observable; and
- Level 3 – unobservable inputs that are not corroborated by market data.

As of March 31, 2015 and December 31, 2014, the fair values of cash and cash equivalents, restricted cash, and notes and interest payable, current portion approximate their carrying value.

At the time of our merger (we were then known as Manhattan Pharmaceuticals, Inc. (“Manhattan”)) with Ariston Pharmaceuticals, Inc. (“Ariston”) in March 2010, Ariston issued \$15,452,793 of five-year 5% notes payable (the “5% Notes”) in satisfaction of several note payable issuances. The 5% Notes and accrued and unpaid interest thereon are convertible at the option of the holder into common stock at the conversion price of \$1,125 per share. Ariston agreed to make quarterly payments on the 5% Notes equal to 50% of the net product cash flow received from the exploitation or commercialization of Ariston’s product candidates, AST-726 and AST-915. We have no obligations under the 5% Notes aside from a) 50% of the net product cash flows from Ariston’s product candidates, if any, payable to noteholders; and b) the conversion feature, discussed above.

In connection with the exchange transaction with TG Biologics, Inc. (“TGBio”) in December 2011, we performed a valuation of the assets and liabilities of Manhattan immediately prior to the transaction. The cumulative liability including accrued and unpaid interest of the 5% Notes was approximately \$16,876,000 immediately prior to the transaction, and \$19,544,720 at December 31, 2014 and \$19,782,377 at March 31, 2015. As the 5% Notes are tied directly to net product cash flows derived from the preexisting products of Ariston, the 5% Notes and accrued interest were recorded at fair value of \$3,287,700 as of the date of the transaction. No payments have been made on the 5% Notes as of March 31, 2015.

We elected the fair value option for valuing the 5% Notes upon the transaction with TGBio. The fair value option was elected in order to reflect in our financial statements the assumptions that market participants use in evaluating these financial instruments.

As of December 31, 2013, as a result of expiring intellectual property rights and other factors, it was determined that net product cash flows from AST-726 were unlikely. As we have no other obligations under the 5% Notes aside from the net product cash flows and the conversion feature, the conversion feature was used to estimate the 5% Notes’ fair value as of March 31, 2015 and December 31, 2014. The assumptions, assessments and projections of future revenues are subject to uncertainties, difficult to predict, and require significant judgment. The use of different assumptions, applying different judgment to inherently subjective matters and changes in future market conditions could result in significantly different estimates of fair value and the differences could be material to our consolidated financial statements.

The following table provides the fair value measurements of applicable financial liabilities as of March 31, 2015 and December 31, 2014:

	Financial liabilities at fair value as of March 31, 2015			
	Level 1	Level 2	Level 3	Total
5% Notes	\$ --	\$ --	\$ 272,206	\$ 272,206
Totals	\$ --	\$ --	\$ 272,206	\$ 272,206

  

	Financial liabilities at fair value as of December 31, 2014			
	Level 1	Level 2	Level 3	Total
5% Notes	\$ --	\$ --	\$ 275,190	\$ 275,190
Totals	\$ --	\$ --	\$ 275,190	\$ 275,190

The Level 3 amounts above represent the fair value of the 5% Notes and related accrued interest.

The following table summarizes the changes in Level 3 instruments during the three months ended March 31, 2015:

Fair value at December 31, 2014	\$ 275,190
Interest accrued on face value of 5% Notes	237,657
Change in fair value of Level 3 liabilities	(240,641)
Fair value at March 31, 2015	\$ 272,206

The change in the fair value of the Level 3 liabilities is reported in other (income) expense in the accompanying condensed consolidated statements of operations.

## NOTE 5 - STOCKHOLDERS' EQUITY

### Preferred Stock

Our amended and restated certificate of incorporation authorizes the issuance of up to 10,000,000 shares of preferred stock, \$0.001 par value, with rights senior to those of our common stock, issuable in one or more series. Upon issuance, we can determine the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting any series or the designation of such series, any or all of which may be greater than the rights of common stock.

### Common Stock

Our amended and restated certificate of incorporation authorizes the issuance of up to 150,000,000 shares of \$0.001 par value common stock.

In December 2014, we filed a shelf registration statement on Form S-3 (the "2015 S-3"), which was declared effective in January 2015. Under the 2015 S-3, the Company may sell up to a total of \$250 million of its securities. In connection with the 2015 S-3, we amended our 2013 At-the-Market Issuance Sales Agreement with MLV & Co. LLC (the "2015 ATM") such that we may issue and sell additional shares of our common stock, having an aggregate offering price of up to \$75.0 million, from time to time through MLV & Co. LLC ("MLV"), acting as the sales agent. Under the 2015 ATM, we would pay MLV a commission rate of up to 3.0% of the gross proceeds from the sale of any shares of common stock sold through MLV.

During the first quarter ended March 31, 2015, we sold a total of 2,195,016 shares of common stock under the 2015 ATM for aggregate total gross proceeds of approximately \$34.8 million at an average selling price of \$15.87 per share, resulting in net proceeds of approximately \$34.2 million after deducting commissions and other transactions costs.

From April 1, 2015 through May 8, 2015, we sold an aggregate of 518,076 shares of common stock pursuant to the 2015 ATM for total gross proceeds of approximately \$8.5 million at an average selling price of \$16.38 per share, resulting in net proceeds of approximately \$8.0 million after deducting commissions and other transactions costs.

We currently have two shelf registration statements on Form S-3 filed and declared effective by the SEC (File No. 333-189015 and File No. 333-201339). After deducting shares already sold, approximately \$273 million of common stock remains available for sale under these shelf registration statements. We may offer the securities under our shelf registration statements from time to time in response to market conditions or other circumstances if we believe such a plan of financing is in the best interests of our stockholders. We believe that these shelf registration statements provide us with the flexibility to raise additional capital to finance our operations as needed.

### **Equity Incentive Plans**

Shares available for the issuance of stock options or other stock-based awards under our stock option and incentive plans were 115,166 shares at March 31, 2015.

### Stock Options

The following table summarizes stock option activity for the three months ended March 31, 2015:

	<u>Number of shares</u>	<u>Weighted- average exercise price</u>	<u>Weighted- average Contractual Term (in years)</u>	<u>Aggregate Intrinsic Value</u>
Outstanding at December 31, 2014	194	\$ 971.70	3.50	\$ --
Granted	--	--		
Exercised	--	--		
Forfeited	--	--		
Expired	(42)	2,811.53		
Outstanding at March 31, 2015	<u>152</u>	<u>\$ 463.32</u>	<u>4.22</u>	<u>\$ --</u>
Exercisable at March 31, 2015	<u>152</u>	<u>\$ 463.32</u>	<u>4.22</u>	<u>\$ --</u>

As of March 31, 2015, there are no unvested option awards and no unrecognized compensation cost related to option awards.

### Restricted Stock

Certain employees, directors and consultants have been awarded restricted stock. The restricted stock vesting consists of milestone and time-based vesting. The following table summarizes restricted share activity for the three months ended March 31, 2015:

	<u>Number of Shares</u>	<u>Weighted Average Grant Date Fair Value</u>
Outstanding at December 31, 2014	6,400,001	\$ 5.86
Granted	12,000	14.59
Vested	(380,001)	4.23
Forfeited	(1,166)	10.53
Outstanding at March 31, 2015	<u>6,030,834</u>	<u>\$ 5.98</u>

Total expense associated with restricted stock grants was \$5,357,028 during the three months ended March 31, 2015. As of March 31, 2015, there was approximately \$13.6 million of total unrecognized compensation cost related to unvested time-based restricted stock, which is expected to be recognized over a weighted-average period of 2 years. This amount does not include, as of March 31, 2015, 134,302 shares of restricted stock outstanding which are milestone-based and vest upon certain corporate milestones; and 1,965,250 shares of restricted stock outstanding issued to non-employees. Milestone-based non-cash compensation expense will be measured and recorded if and when a milestone occurs. The expense for non-employee shares is determined at the "measurement date." The expense is recognized over the vesting period of the award. Until the measurement date is reached, the total amount of compensation expense remains uncertain. We record compensation expense based on the fair value of the award at the reporting date.

#### Warrants

The following table summarizes warrant activity for the three months ended March 31, 2015:

	Warrants	Weighted- average exercise price	Aggregate Intrinsic Value
Outstanding at December 31, 2014	4,148,228	\$ 0.94	\$ 61,792,184
Issued	--	--	
Exercised	(177,448)	2.34	
Expired	(11,364)	2.25	
Outstanding at March 31, 2015	<u>3,959,416</u>	<u>\$ 0.88</u>	<u>\$ 57,817,178</u>

#### *Stock-Based Compensation*

The fair value of stock options granted is estimated at the date of grant using the Black-Scholes pricing model. The expected term of options granted is derived from historical data and the expected vesting period. Expected volatility is based on the historical volatility of our common stock. The risk-free interest rate is based on the U.S. Treasury yield for a period consistent with the expected term of the option in effect at the time of the grant. We have assumed no expected dividend yield, as dividends have never been paid to stock or option holders and will not be paid for the foreseeable future. We did not grant any stock options during the three months ended March 31, 2015 and 2014.

The following table summarizes stock-based compensation expense information about stock options and restricted stock for the three months ended March 31, 2015:

	Three months ended March 31, 2015	Three months ended March 31, 2014
Stock-based compensation expense associated with restricted stock	\$ 5,357,028	\$ 4,231,438
Stock-based compensation expense associated with option grants	--	--
	<u>\$ 5,357,028</u>	<u>\$ 4,231,438</u>

#### **NOTE 6 – NOTES PAYABLE**

The following is a summary of notes payable:

	March 31, 2015			December 31, 2014		
	Current portion, net	Non- current portion, net	Total	Current portion, net	Non- current portion, net	Total
Convertible 5% Notes Payable	\$ 272,206	\$ -	\$ 272,206	\$ 275,190	\$ -	\$ 275,190
Total	<u>\$ 272,206</u>	<u>\$ -</u>	<u>\$ 272,206</u>	<u>\$ 275,190</u>	<u>\$ -</u>	<u>\$ 275,190</u>

We assumed the preceding notes payable as the result of the Exchange Transaction between the Company and TGBio. Accordingly, a valuation using the guidance in the accounting literature for business combinations (ASC 805) was performed and these notes were initially recorded at their fair value on the date of the transaction.

### ***Convertible 5% Notes Payable***

On March 8, 2010, Manhattan entered into an Agreement and Plan of Merger (the “Merger Agreement”) by and among Manhattan, Ariston and Ariston Merger Corp., a Delaware corporation and wholly-owned subsidiary of Manhattan (the “Merger Sub”). Pursuant to the terms and conditions of the Merger Agreement, on March 8, 2010, the Merger Sub merged with and into Ariston (the “Merger”), with Ariston being the surviving corporation of the Merger. As a result of the Merger, Ariston became a wholly-owned subsidiary of Manhattan.

The 5% Notes and accrued and unpaid interest thereon are convertible at the option of the holder into common stock at the conversion price of \$1,125 per share. Ariston agreed to make quarterly payments on the 5% Notes equal to 50% of the net product cash flow received from the exploitation or commercialization of Ariston’s product candidates, AST-726 and AST-915. We have no obligation under the 5% Notes aside from a) 50% of the net product cash flows from Ariston’s product candidates, if any, payable to noteholders; and b) the conversion feature, discussed above. Interest accrues monthly, is added to principal on an annual basis, every March 8, and is payable at maturity, which is March 8, 2015.

In connection with the exchange transaction with TGBio in December 2011, we performed a valuation of the assets and liabilities of Manhattan immediately prior to the transaction. The cumulative liability including accrued and unpaid interest of these notes was approximately \$16,876,000 immediately prior to the Exchange Transaction, and \$19,782,377 at March 31, 2015 and \$19,544,720 at December 31, 2014. As the 5% Notes are tied directly to net product cash flows derived from the preexisting products of Ariston, the 5% Notes and accrued interest were recorded at fair value of \$3,287,700 as of the date of the Exchange Transaction (See Note 4 for further details). No payments have been made on the 5% Notes as of March 31, 2015.

### **NOTE 7 – LICENSE AGREEMENTS**

#### ***Anti-PD-L1 and anti-GITR***

On March 3, 2015, we entered into a Global Collaboration Agreement (the “Collaboration”) with Checkpoint Therapeutics, Inc. (“Checkpoint”), a subsidiary of Fortress Biotech, Inc. (“Fortress”) for the development and commercialization of Checkpoint’s anti-PD-L1 and anti-GITR antibody research programs in the field of hematological malignancies. Checkpoint will develop and commercialize these antibodies in solid tumors.

Under the terms of the Collaboration, we made an up-front payment of \$500,000, will make development and sales-based milestone payments up to an aggregate of \$164 million, and will pay a tiered single digit royalty on net sales. The royalty term will terminate on a country by country basis upon the later of (i) ten years after the first commercial sale of any applicable licensed product in such country, or (ii) the expiration of the last-to-expire patent held by the Dana Farber Cancer Institute containing a valid claim to any licensed product in such country.

Mr. Weiss, our Executive Chairman, Interim CEO and President is also the Executive Vice Chairman of Fortress and the Executive Chairman of Checkpoint (See Note 8).

#### ***TG-1101***

In November 2012, we entered into an exclusive (within the territory) sublicense agreement with Ildong relating to the development and commercialization of TG-1101 in South Korea and Southeast Asia. Under the terms of the sublicense agreement, Ildong has been granted a royalty bearing, exclusive right, including the right to grant sublicenses, to develop and commercialize TG-1101 in South Korea, Taiwan, Singapore, Indonesia, Malaysia, Thailand, Philippines, Vietnam, and Myanmar.

An upfront payment of \$2,000,000, which was received in December 2012, net of \$330,000 of income tax withholdings, is being recognized as license revenue on a straight-line basis over the life of the agreement, which is through the expiration of the last licensed patent right or 15 years after the first commercial sale of a product in such country, unless the agreement is earlier terminated, and represents the estimated period over which we will have certain ongoing responsibilities under the sublicense agreement. We recorded license revenue of approximately \$38,000 for each of the three months ended March 31, 2015 and 2014, and, at March 31, 2015 and December 31, 2014, have deferred revenue of approximately \$1,638,000 and \$1,676,000, respectively, associated with this \$2,000,000 payment (approximately \$152,000 of which has been classified in current liabilities at March 31, 2015 and December 31, 2014).

We may receive up to an additional \$5.0 million in payments upon the achievement of pre-specified milestones. In addition, upon commercialization, Ildong will make royalty payments to us on net sales of TG-1101 in the sublicense territory.

#### **NOTE 8 – RELATED PARTY TRANSACTIONS**

On January 30, 2012, we entered into an exclusive license agreement with LFB Biotechnologies, GTC Biotherapeutics and LFB/GTC LLC, all wholly-owned subsidiaries of LFB Group, relating to the development of ublituximab (the “LFB License Agreement”). In connection with the LFB License Agreement, LFB Group was issued 5,000,000 shares of common stock, and a warrant to purchase 2,500,000 shares of common stock at a purchase price of \$0.001 per share. In addition, on November 9, 2012, we nominated Dr. Yann Echelard to our Board of Directors as LFB Group’s nominee. LFB Group maintains the right to nominate a board member until such time as LFB Group owns less than 10% of the outstanding common stock.

In connection with the LFB License Agreement, LFB maintained the right to purchase at least \$750,000 in additional shares of common stock at a purchase price per share as defined in a November 2012 securities exchange agreement. Accordingly, in February 2015, LFB purchased 114,855 shares of our common stock at a price of \$6.53 per share for net proceeds of \$750,000. In May 2015, LFB exercised their warrant to purchase 2,500,000 shares of common stock at a purchase price of \$0.001 per share.

Under the terms of the LFB License Agreement, we utilize LFB Group for certain development and manufacturing services. We incurred approximately \$161,000 and \$183,000 in expenses for such services during the three months ended March 31, 2015 and 2014, respectively, which have been included in other research and development expenses in the accompanying consolidated statements of operations. As of March 31, 2015 and December 31, 2014, we had approximately \$3,134,000 and \$52,000, respectively, recorded in accounts payable related to the LFB License Agreement. In conjunction with the development and manufacturing services discussed above, certain agreements between us and LFB Group require payments in advance of services performed or goods delivered. Accordingly, as of March 31, 2015 and December 31, 2014, we recorded \$6,090,548 and \$1,886,518, respectively, in prepaid research and development for such advance payments.

In March 2014, we entered into a shared services agreement with Opus Point Partners Management, LLC (“Opus”) in which the parties agreed to share the costs of a rented facility and certain other services. Michael S. Weiss, our Executive Chairman and Interim Chief Executive Officer, is a Managing Member of Opus. During the three months ended March 31, 2015, we incurred expenses of approximately \$59,000, principally for rent, related to this agreement. As of March 31, 2015, we had approximately \$20,000 recorded in accounts payable related to this shared services agreement.

As discussed in Note 7 above, with regard to the Collaboration with Checkpoint, Mr. Weiss is also the Executive Vice Chairman of Fortress and the Executive Chairman of Checkpoint. In addition, Mr. Weiss holds equity interests in TG, Fortress and Checkpoint. Therefore, Mr. Weiss will derive an indirect benefit from the Collaboration through Fortress and our share of the collaboration.

On October 3, 2014, we entered into a Desk Space Agreement (the “Desk Agreement”) with Fortress, to occupy approximately 40% of the New York, NY office space recently leased by Fortress. This Desk Agreement requires us to pay our respective share of the average annual rent and other costs of the 15 year lease. We approximate an average annual rental obligation of \$1.1 million under the Desk Agreement. Fortress does not expect to take possession of the space until late 2015 or early 2016. Michael S. Weiss, our Executive Chairman and Interim Chief Executive Officer, is on the board of directors and is Executive Vice Chairman, Strategic Development of Fortress.

In connection with the Desk Agreement, we paid \$80,000 in advance rent payments, which is recorded in other current assets in the accompanying Consolidated Balance Sheet as of March 31, 2015 and December 31, 2014. Also in connection with this lease, in October 2014 we pledged \$0.6 million to secure a line of credit as a security deposit for the Desk Agreement, which has been recorded as Restricted Cash in the accompanying consolidated balance sheet.

## **NOTE 9 – SUBSEQUENT EVENTS**

From April 1, 2015 through May 8, 2015, we sold an aggregate of 518,076 shares of common stock pursuant to the 2015 ATM for total gross proceeds of approximately \$8.5 million at an average selling price of \$16.38 per share, resulting in net proceeds of approximately \$8.0 million after deducting commissions and other transactions costs.

## **ITEM 2. MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

The following discussion and analysis contains forward-looking statements about our plans and expectations of what may happen in the future. Forward-looking statements are based on a number of assumptions and estimates that are inherently subject to significant risks and uncertainties, and our results could differ materially from the results anticipated by our forward-looking statements as a result of many known or unknown factors, including, but not limited to, those factors discussed in “Risk Factors.” See also the “Special Cautionary Notice Regarding Forward-Looking Statements” set forth at the beginning of this report.

You should read the following discussion and analysis in conjunction with the unaudited condensed consolidated financial statements, and the related footnotes thereto, appearing elsewhere in this report, and in conjunction with management’s discussion and analysis and the audited consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2014.

## **OVERVIEW**

We are a biopharmaceutical company focused on the acquisition, development and commercialization of novel treatments for B-cell malignancies and autoimmune diseases. Currently, the company is developing two therapies targeting hematological malignancies. TG-1101 (ublituximab) is a novel, glycoengineered monoclonal antibody that targets a specific and unique epitope on the CD20 antigen found on mature B-lymphocytes. TG Therapeutics is also developing TGR-1202, an orally available PI3K delta inhibitor. The delta isoform of PI3K is strongly expressed in cells of hematopoietic origin and is believed to be important in the proliferation and survival of B-lymphocytes. Both TG-1101 and TGR-1202 are in clinical development for patients with hematologic malignancies. The Company also has pre-clinical programs seeking to develop IRAK4 (interleukin-1 receptor-associated kinase 4) inhibitors and anti-PD-L1 and anti-GITR antibodies.

We also actively evaluate complementary products, technologies and companies for in-licensing, partnership, acquisition and/or investment opportunities. To date, we have not received approval for the sale of any of our drug candidates in any market and, therefore, have not generated any product sales from our drug candidates.

### ***TG-1101 (ublituximab)***

#### *Overview*

TG-1101 (ublituximab) is a chimeric, glycoengineered monoclonal antibody that targets a unique epitope on the CD20 antigen found on the surface of B-lymphocytes developed to aid in the depletion of circulating B-cells. We hold exclusive worldwide rights to develop and commercialize TG-1101 for all indications, except for the territories of France and Belgium which have been retained by LFB Biotechnologies, and South Korea and Southeast Asia which were licensed to Ildong in November 2012.

Generally, anti-CD20 antibodies are believed to exert their B-cell depleting effects through three primary mechanisms: antibody dependent cell-mediated cytotoxicity (“ADCC”), complement dependent cytotoxicity (“CDC”), and direct or programmed cell death (“DCD” or “PCD”). TG-1101 has been specifically glycoengineered to enhance ADCC activity, which should enhance its ability to deplete B-cells and may improve its anti-cancer effects when compared to Rituxan<sup>®</sup>, the leading anti-CD20 monoclonal antibody, which had worldwide sales in 2013 of approximately \$8 billion.

#### *Clinical Trials Overview and Recent Developments*

Two single-agent, dose-escalation, Phase I studies were undertaken with TG-1101 to establish an optimal dose in patients with Non-Hodgkin’s Lymphoma (“NHL”) and Chronic Lymphocytic Leukemia (“CLL”). In both studies, single agent therapy with TG-1101 was deemed well tolerated by treating investigators and displayed promising clinical activity in relapsed and refractory patients. In oncology settings, anti-CD20 therapy is generally used in combination with other anti-cancer agents where it demonstrates maximum activity as opposed to single agent usage. As a result, subsequent clinical development for TG-1101 has focused on combination therapy. Currently, our priority combination trials for TG-1101 are:

- TG-1101 in combination with ibrutinib (trade name IMBRUVICA<sup>®</sup>), a BTK inhibitor, for patients with CLL; and
- TG-1101 in combination with TGR-1202, our development stage PI3K $\delta$  inhibitor, for patients with CLL and NHL.

Further details on our priority ongoing combination trials for TG-1101 are as follows:

#### *TG-1101 in Combination with TGR-1202 for Relapsed/Refractory NHL & CLL*

In November 2013, we initiated a multi-center, Phase I study to evaluate the safety and efficacy of the combination of TG-1101 and TGR-1202, our novel, once per day, PI3K $\delta$  inhibitor, for patients with relapsed and/or refractory CLL and NHL. This is the first clinical trial evaluating the combination of TG-1101 and TGR-1202. In this study, dosing of TGR-1202 was commenced at 800mg once per day (QD) with dose escalation proceeding in a 3+3 design. Dose-escalation up to 1200mg micronized formulation is planned. Additional cohorts were added to this study to explore the triple therapy combination of TG-1101, TGR-1202, and ibrutinib.

The MD Anderson Cancer Center is the lead center for the trial with Nathan Fowler, MD, Assistant Professor and Co-Director of Clinical Research in the Department of Lymphoma, as the Study Chair for the NHL patient group and Susan O’Brien, MD, formerly of MD Anderson and now Professor and Medical Director for Cancer Clinical Trials and Research at UC Irvine as the Study Chair for the CLL patient group.

Preliminary data from this study was presented at the 56th Annual American Society of Hematology (ASH) meeting held in San Francisco, CA in December 2014.

#### *TG-1101 in Combination with Ibrutinib for Relapsed/Refractory MCL & CLL*

In December 2013, we initiated a multi-center Phase 2 clinical trial to evaluate the safety and efficacy of the combination of TG-1101 and ibrutinib for patients with CLL and Mantle Cell Lymphoma (MCL). This is the first clinical trial evaluating the combination of TG-1101 and ibrutinib, an oral Bruton’s Tyrosine Kinase (BTK) inhibitor.

TG Therapeutics partnered with the US Oncology Network and other select centers throughout the United States on the study, with Jeff Sharman, MD, Medical Director for Hematology Research, US Oncology Network, as the Study Chair. This trial has completed enrollment.

Preliminary data from this study was presented at the 56th Annual American Society of Hematology (ASH) meeting held in San Francisco, CA in December 2014.

We reached an agreement with the U.S. Food and Drug Administration (the “FDA”) regarding a Special Protocol Assessment (“SPA”) on the design, endpoints and statistical analysis approach of a Phase 3 clinical trial for TG-1101 ibrutinib for the treatment of previously treated CLL patients with high risk cytogenetics. The SPA provides agreement that the Phase 3 trial design adequately addresses objectives that would support the regulatory submission for drug approval.

The Phase 3 trial, named the GENUINE trial, is a randomized controlled clinical trial, with patients receiving either TG-1101 plus ibrutinib or ibrutinib alone. The trial will enroll approximately 330 patients, with the first 200 patients evaluated for overall response rate (“ORR”), and all patients followed for progression-free survival (“PFS”). As per the SPA, if the data is positive, we plan to use the ORR data from the trial as the basis for submission of a Biologics License Application (BLA) for accelerated approval for TG-1101, with the PFS assessment intended to support a filing for full approval.

## **TGR-1202**

### *Overview*

The phosphoinositide-3-kinases (“PI3Ks”) are a family of enzymes involved in various cellular functions, including cell proliferation and survival, cell differentiation, intracellular trafficking, and immunity. There are four isoforms of PI3K (alpha, beta, delta, and gamma), of which the delta isoform is strongly expressed in cells of hematopoietic origin, and often implicated in B-cell related lymphomas.

TGR-1202 is an orally available PI3K delta inhibitor with nanomolar potency to the delta isoform and high selectivity over the alpha, beta, and gamma isoforms. TGR-1202 has demonstrated activity in several pre-clinical models and primary cells from patients with hematologic malignancies.

We hold exclusive worldwide rights to develop and commercialize TGR-1202 for all indications worldwide, except for India which has been retained by Rhizen Pharmaceuticals S A.

### *Clinical Trials Overview and Recent Developments*

Initial clinical development of TGR-1202 was focused on establishing preliminary safety and efficacy in a wide variety of hematologic malignancies. Upon identification of safe and active doses of TGR-1202, a combination clinical trial program was opened, exploring TGR-1202 in combination with a variety of agents. Our current combination clinical trials for TGR-1202 are:

- TGR-1202 in combination with TG-1101 (ublituximab) in patients with relapsed or refractory NHL and CLL;
- TGR-1202 in combination with the anti-CD20 antibody, obinutuzumab (GAZYVA<sup>®</sup>) and chlorambucil in patients with previously untreated CLL;
- TGR-1202 in combination with the anti-CD30 antibody drug conjugate, brentuximab vedotin (ADCETRIS<sup>®</sup>), in patients with relapsed or refractory Hodgkin’s lymphoma; and
- TGR-1202 in combination with the BTK inhibitor, ibrutinib, in patients with previously treated CLL and MCL.

### *Single Agent TGR-1202 in Patients with Relapsed/Refractory Hematologic Malignancies*

In January 2013, we initiated a Phase I, open label, multi-center, first-in-human clinical trial of TGR-1202 in patients with hematologic malignancies. The study entitled TGR-1202-101, “A Phase I Dose Escalation Study Evaluating the Safety and Efficacy of TGR-1202 in Patients with Relapsed or Refractory Hematologic Malignancies,” is being run in collaboration with the Sarah Cannon Research Institute in Nashville, TN with Howard “Skip” Burris, MD, Executive Director, Drug Development as the acting Study Chair. Enrollment is open to patients with relapsed or refractory NHL, CLL, and other select hematologic malignancies. As of April 2015, TGR-1202-101 is ongoing and enrolling patients in select expansion cohorts.

Data from this ongoing Phase I study was presented at the ASH meeting held in San Francisco, CA.

## *TGR-1202 Combination Trials*

TGR-1202 is being evaluated in combination with the anti-CD20 antibody, obinutuzumab and chlorambucil in patients with previously untreated CLL, in combination with the anti-CD30 antibody drug conjugate, brentuximab vedotin, in patients with relapsed or refractory Hodgkin's lymphoma, and in combination with the BTK inhibitor, ibrutinib, in patients with previously treated CLL and MCL. It is anticipated that preliminary results from these studies will be presented at future medical conferences.

## **IRAK4**

Interleukin-1 Receptor Associated Kinase 4, referred to as IRAK4, is a key signaling kinase that becomes inappropriately activated in tumors that carry certain oncogenic mutations of MYD88, which can be found in most patients with Waldenström's Macroglobulinemia, a rare B-cell cancer, as well as in a sub-set of patients with Non-Hodgkin's Lymphoma and Chronic Lymphocytic Leukemia. Additionally, IRAK4 is a key component of signaling pathways which regulate immune and inflammatory processes suggesting that inhibition of IRAK4 may also be useful in the treatment of autoimmune related disorders. We hold global rights to develop and commercialize the IRAK4 program, which was licensed from Ligand Pharmaceuticals. Our IRAK4 program is currently in pre-clinical development. In April 2015 we presented pre-clinical data on the IRAK4 compounds at the 2015 American Association for Cancer Research (AACR) Annual Meeting.

## **PD-L1 and GITR**

In March 2015, we entered into a global collaboration agreement for the development and commercialization of anti-PD-L1 and anti-GITR antibody research programs in the field of hematological malignancies. Our anti-PD-L1 and anti-GITR programs are currently in pre-clinical development.

## **GENERAL CORPORATE**

Our license revenues currently consist of license fees arising from our agreement with Ildong. We recognize upfront license fee revenues ratably over the estimated period in which we will have certain significant ongoing responsibilities under the sublicense agreement, with unamortized amounts recorded as deferred revenue.

We have not earned any revenues from the commercial sale of any of our drug candidates.

Our research and development expenses consist primarily of expenses related to in-licensing of new product candidates, fees paid to consultants and outside service providers for clinical and laboratory development, facilities-related and other expenses relating to the design, development, manufacture, testing and enhancement of our drug candidates and technologies. We expense our research and development costs as they are incurred.

Our general and administrative expenses consist primarily of salaries and related expenses for executive, finance and other administrative personnel, recruitment expenses, professional fees and other corporate expenses, including investor relations, legal activities and facilities-related expenses.

Our results of operations include non-cash compensation expenses as a result of the grants of stock options and restricted stock. Compensation expense for awards of options and restricted stock granted to employees and directors represents the fair value of the award recorded over the respective vesting periods of the individual awards. The expense is included in the respective categories of expense in the consolidated statements of operations. We expect to continue to incur significant non-cash compensation expenses.

For awards of options and restricted stock to consultants and other third-parties, compensation expense is determined at the "measurement date." The expense is recognized over the vesting period of the award. Until the measurement date is reached, the total amount of compensation expense remains uncertain. We record compensation expense based on the fair value of the award at the reporting date. The awards to consultants and other third-parties are then revalued, or the total compensation is recalculated based on the then current fair value, at each subsequent reporting date. This results in a change to the amount previously recorded in respect of the equity award grant, and additional expense or a reversal of expense may be recorded in subsequent periods based on changes in the assumptions used to calculate fair value, such as changes in market price, until the measurement date is reached and the compensation expense is finalized.

In addition, certain restricted stock issued to employees vest upon the achievement of certain milestones; therefore, the total expense is uncertain until the milestone is probable.

Our clinical trials will be lengthy and expensive. Even if these trials show that our drug candidates are effective in treating certain indications, there is no guarantee that we will be able to record commercial sales of any of our drug candidates in the near future. In addition, we expect losses to continue as we continue to fund in-licensing and development of new drug candidates. As we continue our development efforts, we may enter into additional third-party collaborative agreements and may incur additional expenses, such as licensing fees and milestone payments. In addition, we may need to establish the commercial infrastructure required to manufacture, market and sell our drug candidates following approval, if any, by the FDA, which would result in us incurring additional expenses. As a result, our quarterly results may fluctuate and a quarter-by-quarter comparison of our operating results may not be a meaningful indication of our future performance.

## RESULTS OF OPERATIONS

### Three months ended March 31, 2015 and March 31, 2014

*License Revenue.* License revenue was \$38,095 for the three months ended March 31, 2015 and 2014. License revenue for the three months ended March 31, 2015 and 2014 was related to the amortization of an upfront payment of \$2.0 million received in 2012 associated with our license agreement with Ildong. The upfront payment from Ildong will be recognized as license revenue on a straight-line basis through December 2025, which represents the estimated period over which we will have certain ongoing responsibilities under the sublicense agreement.

*Noncash Compensation Expense (Research and Development).* Noncash compensation expense (research and development) related to equity incentive grants equaled \$1,337,908 for the three months ended March 31, 2015, as compared to \$1,901,610 during the comparable period in 2014. The decrease in noncash compensation expense was primarily related to milestone-based vesting of restricted stock grants to personnel that occurred during the period ended March 31, 2014.

*Other Research and Development Expenses.* Other research and development expenses increased by \$5,771,173 to \$8,279,431 for the three months ended March 31, 2015, as compared to \$2,508,258 for the three months ended March 31, 2014. Due to increased clinical trials, increased number of patients on study, and increased manufacturing and clinical trial expenses in preparation for the launch of Phase 3 registration programs research and development expenses related to TG-1101 and TGR-1202 increased by approximately \$4,100,000 and \$1,100,000, respectively. We also incurred an upfront cash payment of \$500,000 as part of a global collaboration agreement for the development and commercialization of anti-PD-L1 and anti-GITR antibody research programs. We expect our other research and development costs to increase modestly for the remainder of 2015 due primarily to the enrollment of additional patients in our clinical trials.

*Noncash Compensation Expense (General and Administrative).* Noncash compensation expense (general and administrative) related to equity incentive grants increased by \$1,689,292 to \$4,019,120 for the three months ended March 31, 2015, as compared to \$2,329,828 for the three months ended March 31, 2014. The increase in noncash compensation expense was primarily related to the achievement of milestone-based vesting of restricted stock grants to consultants and personnel during the period ended March 31, 2015.

*Other General and Administrative Expenses.* Other general and administrative expenses increased by \$100,963 to \$1,004,487 for the three months ended March 31, 2015, as compared to \$903,524 for the three months ended March 31, 2014. We expect our other general and administrative expenses to remain at a comparable level for the remainder of 2015.

*Other (Income) Expense.* Other income decreased by \$32,760 to \$25,116 for the three months ended March 31, 2015, as compared to \$57,876 for the three months ended March 31, 2014. The decrease is mainly due to the increase in the change in the fair value of notes payable offset by the gain on settlement of notes payable that was only present during the three months ended March 31, 2014.

## **LIQUIDITY AND CAPITAL RESOURCES**

Our primary sources of cash have been from the sale of equity securities, warrant and option exercises, and the upfront payment from our Sublicense Agreement with Ildong. We have not yet commercialized any of our drug candidates and cannot be sure if we will ever be able to do so. Even if we commercialize one or more of our drug candidates, we may not become profitable. Our ability to achieve profitability depends on a number of factors, including our ability to obtain regulatory approval for our drug candidates, successfully complete any post-approval regulatory obligations and successfully commercialize our drug candidates alone or in partnership. We may continue to incur substantial operating losses even if we begin to generate revenues from our drug candidates.

As of March 31, 2015, we had \$105,225,592 in cash and cash equivalents, investment securities, and interest receivable. Subsequent to the quarter ended March 31, 2015, we sold a total of 518,076 shares of common stock under the 2015 ATM for aggregate net proceeds of approximately \$8.0 million.

We currently anticipate that our cash and cash equivalents as of March 31, 2015 plus the amounts raised subsequent to the end of the quarter are sufficient to fund our anticipated operating cash requirements for more than 24 months from March 31, 2015. The actual amount of cash that we will need to operate is subject to many factors, including, but not limited to, the timing, design and conduct of clinical trials for our drug candidates. We are dependent upon significant financing to provide the cash necessary to execute our current operations, including the commercialization of any of our drug candidates.

Cash used in operating activities for the three months ended March 31, 2015 was \$8,882,353 as compared to \$8,328,891 for the three months ended March 31, 2014. The increase in cash used in operating activities was due primarily to increased expenditures associated with our clinical development programs for TG-1101 and TGR-1202.

For the three months ended March 31, 2015, net cash provided by investing activities was \$3,843,117 as compared to \$3,165 net cash used in investing activities for the three months ended March 31, 2014. The increase in net cash provided by investing activities was primarily due to maturities of our investment in held-to-maturity treasury securities.

For the three months ended March 31, 2015, net cash provided by financing activities of \$35,329,897 related to our ATM program, as well as proceeds from the exercise of warrants. For the three months ended March 31, 2014, net cash provided by financing activities of \$17,442,917 related to net proceeds from the issuance of common stock as part of our underwritten public offering in March 2014, as well as proceeds from the exercise of warrants.

## **OFF-BALANCE SHEET ARRANGEMENTS**

We have not entered into any transactions with unconsolidated entities whereby we have financial guarantees, subordinated retained interests, derivative instruments or other contingent arrangements that expose us to material continuing risks, contingent liabilities, or any other obligations under a variable interest in an unconsolidated entity that provides us with financing, liquidity, market risk or credit risk support.

## **CRITICAL ACCOUNTING POLICIES**

The discussion and analysis of our financial condition and results of operations is based upon our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amount of assets and liabilities and related disclosure of contingent assets and liabilities at the date of our financial statements and the reported amounts of revenues and expenses during the applicable period. Actual results may differ from these estimates under different assumptions or conditions.

We define critical accounting policies as those that are reflective of significant judgments and uncertainties and which may potentially result in materially different results under different assumptions and conditions. In applying these critical accounting policies, our management uses its judgment to determine the appropriate assumptions to be used in making certain estimates. These estimates are subject to an inherent degree of uncertainty. Our critical accounting policies include the following:

*Revenue Recognition.* We recognize license revenue in accordance with the revenue recognition guidance of the Financial Accounting Standards Board (“FASB”) Accounting Standards Codification, or Codification. We analyze each element of our licensing agreement to determine the appropriate revenue recognition. The terms of the license agreement may include payments to us of non-refundable up-front license fees, milestone payments if specified objectives are achieved, and/or royalties on product sales. We recognize revenue from upfront payments over the period of significant involvement under the related agreements unless the fee is in exchange for products delivered or services rendered that represent the culmination of a separate earnings process and no further performance obligation exists under the contract. We recognize milestone payments as revenue upon the achievement of specified milestones only if (1) the milestone payment is non-refundable, (2) substantive effort is involved in achieving the milestone, (3) the amount of the milestone is reasonable in relation to the effort expended or the risk associated with achievement of the milestone, and (4) the milestone is at risk for both parties. If any of these conditions are not met, we defer the milestone payment and recognize it as revenue over the estimated period of performance under the contract.

*Stock-Based Compensation.* We have granted stock options and restricted stock to employees, directors and consultants, as well as warrants to other third parties. For employee and director grants, the value of each option award is estimated on the date of grant using the Black-Scholes option-pricing model. The Black-Scholes model takes into account volatility in the price of our stock, the risk-free interest rate, the estimated life of the option, the closing market price of our stock and the exercise price. We base our estimates of our stock price volatility on the historical volatility of our common stock and our assessment of future volatility; however, these estimates are neither predictive nor indicative of the future performance of our stock. For purposes of the calculation, we assumed that no dividends would be paid during the life of the options and warrants. The estimates utilized in the Black-Scholes calculation involve inherent uncertainties and the application of management judgment. In addition, we are required to estimate the expected forfeiture rate and only recognize expense for those equity awards expected to vest. As a result, if other assumptions had been used, our recorded stock-based compensation expense could have been materially different from that reported. In addition, because some of the options and warrants issued to employees, consultants and other third-parties vest upon the achievement of certain milestones, the total expense is uncertain.

Total compensation expense for options and restricted stock issued to consultants is determined at the “measurement date.” The expense is recognized over the vesting period for the options and restricted stock. Until the measurement date is reached, the total amount of compensation expense remains uncertain. We record stock-based compensation expense based on the fair value of the equity awards at the reporting date. These equity awards are then revalued, or the total compensation is recalculated based on the then current fair value, at each subsequent reporting date. This results in a change to the amount previously recorded in respect of the equity award grant, and additional expense or a reversal of expense may be recorded in subsequent periods based on changes in the assumptions used to calculate fair value, such as changes in market price, until the measurement date is reached and the compensation expense is finalized.

*Accruals for Clinical Research Organization and Clinical Site Costs.* We make estimates of costs incurred in relation to external clinical research organizations, or CROs, and clinical site costs. We analyze the progress of clinical trials, including levels of patient enrollment, invoices received and contracted costs when evaluating the adequacy of the amount expensed and the related prepaid asset and accrued liability. Significant judgments and estimates must be made and used in determining the accrued balance and expense in any accounting period. We review and accrue CRO expenses and clinical trial study expenses based on work performed and rely upon estimates of those costs applicable to the stage of completion of a study. Accrued CRO costs are subject to revisions as such trials progress to completion. Revisions are charged to expense in the period in which the facts that give rise to the revision become known. With respect to clinical site costs, the financial terms of these agreements are subject to negotiation and vary from contract to contract. Payments under these contracts may be uneven, and depend on factors such as the achievement of certain events, the successful recruitment of patients, the completion of portions of the clinical trial or similar conditions. The objective of our policy is to match the recording of expenses in our financial statements to the actual services received and efforts expended. As such, expense accruals related to clinical site costs are recognized based on our estimate of the degree of completion of the event or events specified in the specific clinical study or trial contract.

*Accounting Related to Goodwill.* As of March 31, 2015 and December 31, 2014, there was \$799,391 of goodwill on our consolidated balance sheets. Goodwill is reviewed for impairment annually, or when events arise that could indicate that an impairment exists. We test for goodwill impairment using a two-step process. The first step compares the fair value of the reporting unit with the unit's carrying value, including goodwill. When the carrying value of the reporting unit is greater than fair value, the unit's goodwill may be impaired, and the second step must be completed to measure the amount of the goodwill impairment charge, if any. In the second step, the implied fair value of the reporting unit's goodwill is compared with the carrying amount of the unit's goodwill. If the carrying amount is greater than the implied fair value, the carrying value of the goodwill must be written down to its implied fair value.

We are required to perform impairment tests annually, at December 31, and whenever events or changes in circumstances suggest that the carrying value of an asset may not be recoverable. For all of our acquisitions, various analyses, assumptions and estimates were made at the time of each acquisition that were used to determine the valuation of goodwill and intangibles. In future years, the possibility exists that changes in forecasts and estimates from those used at the acquisition date could result in impairment indicators.

*Accounting For Income Taxes.* In preparing our consolidated financial statements, we are required to estimate our income taxes in each of the jurisdictions in which we operate. This process involves management estimation of our actual current tax exposure and assessment of temporary differences resulting from differing treatment of items for tax and accounting purposes. These differences result in deferred tax assets and liabilities. We must then assess the likelihood that our deferred tax assets will be recovered from future taxable income and, to the extent we believe that recovery is not likely, we must establish a valuation allowance. To the extent we establish a valuation allowance or increase this allowance in a period, we must include an expense within the tax provision in the consolidated statement of operations. Significant management judgment is required in determining our provision for income taxes, our deferred tax assets and liabilities and any valuation allowance recorded against our net deferred tax assets. We have fully offset our deferred tax assets with a valuation allowance. Our lack of earnings history and the uncertainty surrounding our ability to generate taxable income prior to the reversal or expiration of such deferred tax assets were the primary factors considered by management in maintaining the valuation allowance.

*Fair Value of 5% Notes Payable.* We measure certain financial assets and liabilities at fair value on a recurring basis in the financial statements. The hierarchy ranks the quality and reliability of inputs, or assumptions, used in the determination of fair value and requires financial assets and liabilities carried at fair value to be classified and disclosed in one of three categories.

We elected the fair value option for valuing the 5% Notes. We elected the fair value option in order to reflect in our financial statements the assumptions that market participants use in evaluating these financial instruments.

## **RECENTLY ISSUED ACCOUNTING STANDARDS**

In August 2014, the FASB issued Accounting Standards Update 2014-15, Presentation of Financial Statements—Going Concern, which requires that management of an entity should evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued or available to be issued. This update will become effective beginning January 1, 2017, with early adoption permitted. The provisions of this standard are not expected to significantly impact the Company.

Other pronouncements issued by the FASB or other authoritative accounting standards group with future effective dates are either not applicable or not significant to our consolidated financial statements.

## **ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

The primary objective of our investment activities is to preserve principal while maximizing our income from investments and minimizing our market risk. We invest in government and investment-grade corporate debt in accordance with our investment policy. Some of the securities in which we invest have market risk. This means that a change in prevailing interest rates, and/or credit risk, may cause the fair value of the investment to fluctuate. For example, if we hold a security that was issued with a fixed interest rate at the then-prevailing rate and the prevailing interest rate later rises, the fair value of our investment will probably decline. As of March 31, 2015, our portfolio of financial instruments consists of cash equivalents, including bank deposits, and investments. Due to the short-term nature of our investments, we believe there is no material exposure to interest rate risk, and/or credit risk, arising from our investments.

## ITEM 4. CONTROLS AND PROCEDURES

### Evaluation of Disclosure Controls and Procedures

As of March 31, 2015, management carried out, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Our disclosure controls and procedures are designed to provide reasonable assurance that information we are required to disclose in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in applicable rules and forms. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of March 31, 2015, our disclosure controls and procedures were effective.

### Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended March 31, 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## PART II. OTHER INFORMATION

### ITEM 1. LEGAL PROCEEDINGS

We, and our subsidiaries, are not a party to, and our property is not the subject of, any material pending legal proceedings.

### ITEM 1A. RISK FACTORS

You should carefully consider the following risks and uncertainties. If any of the following occurs, our business, financial condition or operating results could be materially harmed. These factors could cause the trading price of our common stock to decline, and you could lose all or part of your investment.

#### Risks Related to Our Business and Industry

***Because we have in-licensed our product candidates from third parties, any dispute with or non-performance by our licensors will adversely affect our ability to develop and commercialize the applicable product candidates.***

Our product candidates have been in-licensed from third parties. Under the terms of our license agreements, the licensors generally will have the right to terminate such agreement in the event of a material breach by us. The licensors will also have the right to terminate the agreement in the event we fail to use diligent and reasonable efforts to develop and commercialize the product candidate worldwide.

If there is any conflict, dispute, disagreement or issue of non-performance between us and our licensing partners regarding our rights or obligations under the license agreements, including any such conflict, dispute or disagreement arising from our failure to satisfy payment obligations under such agreement, our ability to develop and commercialize the affected product candidate and our ability to enter into collaboration or marketing agreements for the affected product candidate may be adversely affected. Any loss of our rights under these license agreements would delay or completely terminate its product development efforts for the affected product candidate.

***We do not have full internal development capabilities, and are thus reliant upon our partners and third parties to generate clinical, preclinical and quality data necessary to support the regulatory applications needed to conduct clinical trials and file for marketing approval.***

In order to submit and maintain an IND, BLA, or New Drug Application (“NDA”) to the FDA, it is necessary to submit all information on the clinical, non-clinical, chemistry, manufacturing, controls and quality aspects of the product candidate. We rely on our third party contractors and our licensing partners to provide a significant portion of this data. If we are unable to obtain this data, or the data is not sufficient to meet the regulatory requirements, we may experience significant delays in our development programs. Additionally, an IND must be active in each division in which we intend to conduct clinical trials. Currently we do not have an active IND for any of the IRAK4 inhibitors nor for our anti-PD-L1 and anti-GITR antibodies. Additionally, there can be no assurance given that any of the molecules under development in our IRAK4 inhibitor program or in our anti-PD-L1 and anti-GITR antibody research program will demonstrate sufficient pharmacologic properties during pre-clinical evaluation to advance to IND enabling studies, or that such IND enabling studies, if any are conducted, will provide data sufficient to support the filing of an IND, or that such IND, if filed, would be accepted by any FDA division under which we would seek to develop any product candidate. While we maintain an active IND for TG-1101 and TGR-1202 enabling the conduct of studies in the FDA’s Division of Hematology and Oncology, there can be no assurance that we will be successful in obtaining an active IND for TG-1101 or TGR-1202 in any other division under whose supervision we may seek to develop our product candidates, or that the FDA will allow us to continue the development of our product candidates in those divisions where we maintain an active IND.

***We are highly dependent on the success of our product candidates and cannot give any assurance that these or any future product candidates will be successfully commercialized.***

We are a development-stage biopharmaceutical company, and do not currently have any commercial products that generate revenues or any other sources of revenue. We may never be able to successfully develop marketable products. Our pharmaceutical development methods are unproven and may not lead to commercially viable products for any of several reasons.

If we are unable to develop, or receive regulatory approval for or successfully commercialize any of our product candidates, we will not be able to generate product revenues.

***Because the results of preclinical studies and early clinical trials are not necessarily predictive of future results, any product candidate we advance into clinical trials may not have favorable results in later clinical trials, if any, or receive regulatory approval.***

Pharmaceutical development has inherent risk. We will be required to demonstrate through adequate and well-controlled clinical trials that our product candidates are effective with a favorable benefit-risk profile for use in diverse populations for their target indications before we can seek regulatory approvals for their commercial sale. Success in early clinical trials does not mean that later clinical trials will be successful because product candidates in later-stage clinical trials may fail to demonstrate sufficient safety or efficacy despite having progressed through initial clinical testing. Companies frequently suffer significant setbacks in advanced clinical trials, even after earlier clinical trials have shown promising results. In addition, there is typically an extremely high rate of failure of pharmaceutical candidates proceeding through clinical trials.

We plan on conducting additional Phase I, II and III clinical trials for TG-1101 and TGR-1202. Early clinical results seen with TG-1101 and TGR-1202 in a small number of patients may not be reproduced in expanded or larger clinical trials. Additionally, individually reported outcomes of patients treated in clinical trials may not be representative of the entire population of treated patients in such studies. If the results from expansion cohorts or later trials are different from those found in the earlier studies of TG-1101 and TGR-1202, we may need to terminate or revise our clinical development plan, which could extend the time for conducting our development program and could have a material adverse effect on our business.

***If we are unable to successfully complete our clinical trial programs, or if such clinical trials take longer to complete than we project, our ability to execute our current business strategy will be adversely affected.***

Whether or not and how quickly we complete clinical trials is dependent in part upon the rate at which we are able to engage clinical trial sites and, thereafter, the rate of enrollment of patients, and the rate we collect, clean, lock and analyze the clinical trial database. Patient enrollment is a function of many factors, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the study, the existence of competitive clinical trials, and whether existing or new drugs are approved for the indication we are studying. We are aware that other companies are currently conducting or planning clinical trials that seek to enroll patients with the same diseases that we are studying. Certain clinical trials are designed to continue until a pre-determined number of events have occurred in the patients enrolled. Trials such as this are subject to delays stemming from patient withdrawal and from lower than expected event rates. They may also incur additional costs if enrollment is increased in order to achieve the desired number of events. If we experience delays in identifying and contracting with sites and/or in patient enrollment in our clinical trial programs, we may incur additional costs and delays in our development programs, and may not be able to complete our clinical trials in a cost-effective or timely manner. In addition, conducting multi-national studies adds another level of complexity and risk. We are subject to events affecting countries outside the U.S. Negative or inconclusive results from the clinical trials we conduct or unanticipated adverse medical events could cause us to have to repeat or terminate the clinical trials.

In September 2014, we announced a Phase 3 clinical trial for TG-1101 in previously treated patients with high-risk CLL which is to be conducted pursuant to an SPA with the FDA. Many companies which have been granted SPAs and/or the right to utilize the FDA's Fast Track or accelerated approval process have ultimately failed to obtain final approval to market their drugs. Since we are seeking approvals under SPAs, based on protocol designs negotiated with the FDA, we may be subject to enhanced scrutiny. Further, any changes or amendments to a protocol that is being conducted under SPA will have to be reviewed and approved by the FDA to verify that the SPA agreement is still valid. Additionally, even if the primary endpoint in a Phase 3 clinical trial is achieved, a SPA does not guarantee approval. The FDA may raise issues of safety, study conduct, bias, deviation from the protocol, statistical power, patient completion rates, changes in scientific or medical parameters or internal inconsistencies in the data prior to making its final decision. The FDA may also seek the guidance of an outside advisory committee prior to making its final decision. Even with "fast track" or "priority review" status which we intend to seek for our product candidates, such designations do not necessarily mean a faster development process or regulatory review process or necessarily confer any advantage with respect to approval compared to conventional FDA procedures.

***Any product candidates we may advance into clinical development are subject to extensive regulation, which can be costly and time consuming, cause unanticipated delays or prevent the receipt of the required approvals to commercialize our product candidates.***

The clinical development, manufacturing, labeling, storage, record-keeping, advertising, promotion, import, export, marketing and distribution of our product candidates or any future product candidates are subject to extensive regulation by the FDA in the United States and by comparable health authorities worldwide or in foreign markets. In the United States, we are not permitted to market our product candidates until we receive approval of a BLA or NDA from the FDA. The process of obtaining BLA and NDA approval is expensive, often takes many years and can vary substantially based upon the type, complexity and novelty of the products involved. Approval policies or regulations may change and the FDA has substantial discretion in the pharmaceutical approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. In addition, the FDA may require post-approval clinical trials or studies which also may be costly. The FDA approval for a limited indication or approval with required warning language, such as a boxed warning, could significantly impact our ability to successfully market our product candidates. Finally, the FDA may require adoption of a Risk Evaluation and Mitigation Strategy (REMS) requiring prescriber training, post-market registries, or otherwise restricting the marketing and dissemination of these products. Despite the time and expense invested in clinical development of product candidates, regulatory approval is never guaranteed. Assuming successful clinical development, we intend to seek product approvals in countries outside the United States. As a result, we would be subject to regulation by the European Medicines Agency ("EMA"), as well as the other regulatory agencies in many of these countries, and other regulatory agencies around the world.

Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others. As in the United States, the regulatory approval process in Europe and in other countries is a lengthy and challenging process. The FDA, and any other regulatory body around the world can delay, limit or deny approval of a product candidate for many reasons, including:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- 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 any indication;
- the FDA may not accept clinical data from trials which are conducted by individual investigators or in countries where the standard of care is potentially different from the United States;
- 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 a BLA, NDA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we or our collaborators contract for clinical and commercial supplies; or
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

In addition, recent events raising questions about the safety of certain marketed pharmaceuticals may result in increased cautiousness by the FDA and other regulatory authorities in reviewing new pharmaceuticals based on safety, efficacy or other regulatory considerations and may result in significant delays in obtaining regulatory approvals. Regulatory approvals for our product candidates may not be obtained without lengthy delays, if at all. Any delay in obtaining, or inability to obtain, applicable regulatory approvals would prevent us from commercializing our product candidates.

***Any product candidate we advance into clinical trials may cause unacceptable adverse events or have other properties that may delay or prevent their regulatory approval or commercialization or limit their commercial potential.***

Unacceptable adverse events caused by any of our product candidates that we take into clinical trials could cause either us or regulatory authorities to interrupt, delay, modify or halt clinical trials and could result in the denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications. This, in turn, could prevent us from commercializing the affected product candidate and generating revenues from its sale.

We have not completed testing of any of our product candidates for the treatment of the indications for which we intend to seek product approval in humans, and we currently do not know the extent that adverse events, if any, will be observed in patients who receive any of our product candidates. To date, clinical trials using TG-1101 and TGR-1202 have demonstrated a toxicity profile that was deemed acceptable by the investigators performing such studies. Such interpretation may not be shared by future investigators or by the FDA and in the case of TG-1101 and TGR-1202, even if deemed acceptable for oncology applications, it may not be acceptable for diseases outside the oncology setting, and likewise for any other product candidates we may develop. Additionally, the severity, duration and incidence of adverse events may increase in larger study populations. With respect to TG-1101, the toxicity when manufactured under different conditions is not known, and it is possible that additional and/or different adverse events may appear upon the human use of those formulations and those adverse events may arise with greater frequency, intensity and duration than in the current formulation. Such risk also exists for new manufacturing processes and/or formulations, if any, of TGR-1202, the clinical impact of which is not known, including the micronized formulation of TGR-1202 which has only been studied in a limited number of subjects to date. Further, with respect to TGR-1202, although more than 50 patients have been dosed in the ongoing first-in-human dose-escalation Phase I single agent study, the full adverse effect profile of TGR-1202 is not known. It is unknown as the dose escalation continues and patients are exposed for longer durations to TGR-1202, whether greater frequency and/or severity of adverse events are likely to occur as a maximum tolerated dose is reached. If any of our product candidates cause unacceptable adverse events in clinical trials, we may not be able to obtain marketing approval and generate revenues from its sale, which could have a material adverse impact on our business and operations.

Additionally, in combination clinical development, there is an inherent risk of drug-drug interactions between combination agents which may affect each component's individual pharmacologic properties and the overall efficacy and safety of the combination regimen. Both TG-1101 and TGR-1202 are being evaluated in combination together, as well as with a variety of other active anti-cancer agents, which may cause unforeseen toxicity, or impact the severity, duration, and incidence of adverse events observed compared to those seen in the single agent studies of these agents. Further, with multi-drug combinations, it is often difficult to interpret or properly assign attribution of an adverse event to any one particular agent, introducing the risk that toxicity caused by a component of a combination regimen could have a material adverse impact on the development of our product candidates. There can be no assurances given that the combination regimens being studied will display tolerability or efficacy suitable to warrant further testing or produce data that is sufficient to obtain marketing approval.

If any of our product candidates receives marketing approval and we, or others, later identify unacceptable adverse events caused by the product, a number of significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of the affected product;
- regulatory authorities may require a more significant clinical benefit for approval to offset the risk;
- regulatory authorities may require the addition of labeling statements that could diminish the usage of the product or otherwise limit the commercial success of the affected product;
- we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product;
- we may choose to discontinue sale of the product;
- we could be sued and held liable for harm caused to patients;
- we may not be able to enter into collaboration agreements on acceptable terms and execute on our business model; and
- our reputation may suffer.

Any one or a combination of these events could prevent us from obtaining or maintaining regulatory approval and achieving or maintaining market acceptance of the affected product or could substantially increase the costs and expenses of commercializing the affected product, which in turn could delay or prevent us from generating any revenues from the sale of the affected product.

***We may experience delays in the commencement of our clinical trials or in the receipt of data from preclinical and clinical trials conducted by third parties, which could result in increased costs and delay our ability to pursue regulatory approval.***

Delays in the commencement of clinical trials and delays in the receipt of data from preclinical or clinical trials conducted by third parties could significantly impact our product development costs. Before we can initiate clinical trials in the United States for our product candidates, we need to submit the results of preclinical testing, usually in animals, to the FDA as part of an IND, along with other information including information about product chemistry, manufacturing and controls and its proposed clinical trial protocol for our product candidates.

We plan to rely on preclinical and clinical trial data from third parties, if any, for the IND submissions for our product candidates. If receipt of that data is delayed for any reason, including reasons outside of our control, it will delay our plans for IND filings, and clinical trial plans. This, in turn, will delay our ability to make subsequent regulatory filings and ultimately, to commercialize our products if regulatory approval is obtained. If those third parties do not make this data available to us, we will likely, on our own, have to develop all the necessary preclinical and clinical data which will lead to additional delays and increase the costs of our development of our product candidates.

Before we can test any product candidate in human clinical trials the product candidate enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as in-vitro and animal studies to assess the potential safety and activity of the pharmaceutical product candidate. The conduct of the preclinical tests must comply with federal regulations and requirements including good laboratory practices (“GLP”).

We must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA places the IND on a clinical hold within that 30-day time period. In such a case, we must work with the FDA to resolve any outstanding concerns before the clinical trials can begin. The FDA may also impose clinical holds on a product candidate at any time before or during clinical trials due to safety concerns or non-compliance. Accordingly, 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 such clinical trial.

The FDA may require that we conduct additional preclinical testing for any product candidate before it allows us to initiate the clinical testing under any IND, which may lead to additional delays and increase the costs of our preclinical development.

Even assuming an active IND for a product candidate, we do not know whether our planned clinical trials for any such product candidate will begin on time, or at all. The commencement of clinical trials can be delayed for a variety of reasons, including delays in:

- obtaining regulatory clearance to commence a clinical trial;
- identifying, recruiting and training suitable clinical investigators;
- reaching agreement on acceptable terms with prospective contract research organizations (“CROs”) and trial sites, the terms of which can be subject to extensive negotiation, may be subject to modification from time to time and may vary significantly among different CROs and trial sites;
- obtaining sufficient quantities of a product candidate for use in clinical trials;
- obtaining institutional review board (“IRB”) or ethics committee approval to conduct a clinical trial at a prospective site;
- identifying, recruiting and enrolling patients to participate in a clinical trial;
- retaining patients who have initiated a clinical trial but may withdraw due to adverse events from the therapy, insufficient efficacy, fatigue with the clinical trial process or personal issues; and
- unexpected safety findings.

Any delays in the commencement of our clinical trials will delay our ability to pursue regulatory approval for our product candidates. In addition, many of the factors that cause, or lead to, a delay in the commencement of clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate.

***Delays in the completion of clinical testing could result in increased costs and delay our ability to generate product revenues.***

Once a clinical trial has begun, patient recruitment and enrollment may be slower than we anticipate. Clinical trials may also be delayed as a result of ambiguous or negative interim results. Further, a clinical trial may be suspended or terminated by us, an IRB, an ethics committee or a Data Safety and Monitoring Committee overseeing the clinical trial, any of our clinical trial sites with respect to that site or the FDA or other regulatory authorities due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- inspection of the clinical trial operations or clinical trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- unforeseen safety issues or any determination that the clinical trial presents unacceptable health risks; and
- lack of adequate funding to continue the clinical trial.

Changes in regulatory requirements and guidance also may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for re-examination, which may impact the costs, timing and successful completion of a clinical trial. If we experience delays in the completion of, or if we must terminate, any clinical trial of any product candidate that we advance into clinical trials, our ability to obtain regulatory approval for that product candidate will be delayed and the commercial prospects, if any, for the product candidate may be harmed. In addition, many of these factors may also ultimately lead to the denial of regulatory approval of a product candidate. Even if we ultimately commercialize any of our product candidates, other therapies for the same indications may have been introduced to the market during the period we have been delayed and such therapies may have established a competitive advantage over our product candidates.

***We intend to rely on third parties to help conduct our planned clinical trials. If these third parties do not meet their deadlines or otherwise conduct the trials as required, we may not be able to obtain regulatory approval for or commercialize our product candidates when expected or at all.***

We intend to use CROs to assist in the conduct of our planned clinical trials and will rely upon medical institutions, clinical investigators and contract laboratories to conduct our trials in accordance with our clinical protocols. Our future CROs, investigators and other third parties may play a significant role in the conduct of these trials and the subsequent collection and analysis of data from the clinical trials.

There is no guarantee that any CROs, investigators and other third parties will devote adequate time and resources to our clinical trials or perform as contractually required. If any third parties upon whom we rely for administration and conduct of our clinical trials fail to meet expected deadlines, fail to adhere to its clinical protocols or otherwise perform in a substandard manner, our clinical trials may be extended, delayed or terminated, and we may not be able to commercialize our product candidates.

If any of our clinical trial sites terminate for any reason, we may experience the loss of follow-up information on patients enrolled in our ongoing clinical trials unless we are able to transfer the care of those patients to another qualified clinical trial site. In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, the integrity of the data generated at the applicable clinical trial site may be jeopardized.

***As all of our product candidates are still under development, manufacturing and process improvements implemented in the production of those product candidates may affect their ultimate activity or function.***

Our product candidates are in the initial stages of development and are currently manufactured in small batches for use in pre-clinical and clinical studies. Process improvements implemented to date have changed, and process improvements in the future may change, the activity profile of the product candidates, which may affect the safety and efficacy of the products. No assurance can be given that the material manufactured from any of the optimized processes will perform comparably to the product candidates as manufactured to date and used in currently available pre-clinical data and or in early clinical trials reported in this or any previous filing. Additionally, future clinical trial results will be subject to the same level of uncertainty if, following such trials, additional process improvements are made. In addition, we are currently in the process of engaging a secondary manufacturer for TG-1101 to meet our current clinical and future commercial needs. No assurance can be given that the secondary manufacturing will be successful or that material manufactured by the secondary manufacturer will perform comparably to TG-1101 as manufactured to date and used in currently available pre-clinical data and or in early clinical trials reported in this or any previous filing. If the secondary manufacturer is not successful in replicating the product or experiences delays, we may experience delays in its clinical development.

***If we fail to adequately understand and comply with the local laws and customs as we expand into new international markets, these operations may incur losses or otherwise adversely affect our business and results of operations.***

We expect to operate a portion of our business in certain countries through subsidiaries or through supply and marketing arrangements. In those countries, where we have limited experience in operating subsidiaries and in reviewing equity investees, we will be subject to additional risks related to complying with a wide variety of national and local laws, including restrictions on the import and export of certain intermediates, drugs, technologies and multiple and possibly overlapping tax structures. In addition, we may face competition in certain countries from companies that may have more experience with operations in such countries or with international operations generally. We may also face difficulties integrating new facilities in different countries into our existing operations, as well as integrating employees hired in different countries into our existing corporate culture. If we do not effectively manage our operations in these subsidiaries and review equity investees effectively, or if we fail to manage our alliances, we may lose money in these countries and it may adversely affect our business and results of our operations.

***If our competitors develop treatments for the target indications for which any of our product candidates may be approved, and they are approved more quickly, marketed more effectively or demonstrated to be more effective than our product candidates, our commercial opportunity will be reduced or eliminated.***

We operate in a highly competitive segment of the biotechnology and biopharmaceutical market. We face competition from numerous sources, including commercial pharmaceutical and biotechnology enterprises, academic institutions, government agencies, and private and public research institutions. Many of our competitors have significantly greater financial, product development, manufacturing and marketing resources. Large pharmaceutical companies have extensive experience in clinical testing and obtaining regulatory approval for drugs. Additionally, many universities and private and public research institutes are active in cancer research, some in direct competition with us. We may also compete with these organizations to recruit scientists and clinical development personnel. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

The cancer indications for which we are developing our products have a number of established therapies with which we will compete. Most major pharmaceutical companies and many biotechnology companies are aggressively pursuing new cancer development programs for the treatment of NHL, CLL, and other B-cell proliferative malignancies, including both therapies with traditional, as well as novel, mechanisms of action.

If approved, we expect TG-1101 to compete directly with Roche Group's Rituxan<sup>®</sup> (rituximab) and Gazyva<sup>®</sup> (obinutuzumab or GA-101), Spectrum Pharmaceutical's Zevalin<sup>®</sup> (Y<sup>90</sup>-Ibritumomab Tiuxetan), and Genmab and GlaxoSmithKline's Arzerra<sup>®</sup> (ofatumumab) among others, each of which is currently approved for the treatment of various diseases including NHL and CLL. In addition, a number of pharmaceutical companies are developing antibodies targeting CD20, CD19, and other B-cell associated targets, chimeric antigen receptor T-cell (CAR-T) immunotherapy, and other B-cell ablative therapy which, if approved, would potentially compete with TG-1101. New developments, including the development of other pharmaceutical technologies and methods of treating disease, occur in the pharmaceutical and life sciences industries at a rapid pace.

With respect to TGR-1202, there are several PI3K delta targeted compounds both approved, such as Gilead's Zydelig<sup>™</sup> (idelalisib), and in development, including, but not limited to, Infinity Pharmaceuticals' duvelisib (IPI-145), which if approved we would expect to compete directly with TGR-1202. In addition, there are numerous other novel therapies targeting similar pathways to TGR-1202 in development, which if approved would also compete with TGR-1202 in similar indications, such as the BTK inhibitor, ibrutinib (FDA approved for MCL, CLL, and WM and marketed by Pharmacyclics and Janssen), or the bcl-2 inhibitor ABT-199 (under clinical development by AbbVie and Roche).

These developments may render our product candidates obsolete or noncompetitive. Compared to us, many of our potential competitors have substantially greater:

- research and development resources, including personnel and technology;
- regulatory experience;
- pharmaceutical development, clinical trial and pharmaceutical commercialization experience;
- experience and expertise in exploitation of intellectual property rights; and
- capital resources.

As a result of these factors, our competitors may obtain regulatory approval of their products more rapidly than us or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates. Our competitors may also develop products for the treatment of lymphoma or CLL that are more effective, better tolerated, more useful and less costly than ours and may also be more successful in manufacturing and marketing their products. Our competitors may succeed in obtaining approvals from the FDA and foreign regulatory authorities for their product candidates sooner than we do for our products.

We will also face competition from these third parties in recruiting and retaining qualified personnel, establishing clinical trial sites and enrolling patients for clinical trials and in identifying and in-licensing new product candidates.

***We rely completely on third parties to manufacture our preclinical and clinical pharmaceutical supplies and we intend to rely on third parties to produce commercial supplies of any approved product candidate, and our commercialization of any of our product candidates could be stopped, delayed or made less profitable if those third parties fail to obtain approval of the FDA, fail to provide us with sufficient quantities of pharmaceutical product or fail to do so at acceptable quality levels or prices.***

The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted only after we submit a BLA or NDA to the FDA, if at all. We do not control the manufacturing process of our product candidates and are completely dependent on our contract manufacturing partners for compliance with the FDA's requirements for manufacture of finished pharmaceutical products (good manufacturing practices, GMP). If our contract manufacturers cannot successfully manufacture material that conforms to our target product specifications, patent specifications, and/or the FDA's strict regulatory requirements of safety, purity and potency, we will not be able to secure and/or maintain FDA approval for our product candidates. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If our contract manufacturers cannot meet FDA standards, 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. No assurance can be given that a long-term, scalable manufacturer can be identified or that they can make clinical and commercial supplies of our product candidates that meet the product specifications of previously manufactured batches, or is of a sufficient quality, or at an appropriate scale and cost to make it commercially feasible. If they are unable to do so, it could have a material adverse impact on our business.

In addition, we do not have the capability to package finished products for distribution to hospitals and other customers. Prior to commercial launch, we intend to enter into agreements with one or more alternate fill/finish pharmaceutical product suppliers so that we can ensure proper supply chain management once we are authorized to make commercial sales of our product candidates. If we receive marketing approval from the FDA, we intend to sell pharmaceutical product finished and packaged by such suppliers. We have not entered into long-term agreements with our current contract manufacturers or with any fill/finish suppliers, and though we intend to do so prior to commercial launch of our product candidates in order to ensure that we maintain adequate supplies of finished product, we may be unable to enter into such an agreement or do so on commercially reasonable terms, which could have a material adverse impact upon our business.

In most cases, our manufacturing partners are single source suppliers. It is expected that our manufacturing partners will be sole source suppliers from single site locations for the foreseeable future. Given this, any disruption of supply from these partners could have a material, long-term impact on our ability to supply products for clinical trials or commercial sale. If our suppliers do not deliver sufficient quantities of our product candidates on a timely basis, or at all, and in accordance with applicable specifications, there could be a significant interruption of our supply, which would adversely affect clinical development and commercialization of our products. In addition, if our current or future supply of any of our product candidates should fail to meet specifications during its stability program there could be a significant interruption of our supply of drug, which would adversely affect the clinical development and commercialization of the product.

***We currently have no marketing and sales organization and no experience in marketing pharmaceutical products. If we are unable to establish sales and marketing capabilities or fail to enter into agreements with third parties to market and sell any products we may develop, we may not be able to effectively market and sell our products and generate product revenue.***

We do not currently have the infrastructure for the sales, marketing and distribution of our biotechnology products, and we must build this infrastructure or make arrangements with third parties to perform these functions in order to commercialize our products. We plan to either develop internally or enter into collaborations or other commercial arrangements to develop further, promote and sell all or a portion of our product candidates.

The establishment and development of a sales force, either by us or jointly with a development partner, or the establishment of a contract sales force to market any products we may develop will be expensive and time-consuming and could delay any product launch, and we cannot be certain that we or our development partners would be able to successfully develop this capability. If we or our development partners are unable to establish sales and marketing capability or any other non-technical capabilities necessary to commercialize any products we may develop, we will need to contract with third parties to market and sell such products. We currently possess limited resources and may not be successful in establishing our own internal sales force or in establishing arrangements with third parties on acceptable terms, if at all.

***If any product candidate that we successfully develop does not achieve broad market acceptance among physicians, patients, healthcare payors, and the medical community, the revenues that we generate from its sales will be limited.***

Even if our product candidates receive regulatory approval, they may not gain market acceptance among physicians, patients, healthcare payors, and the medical community. Coverage and reimbursement of our product candidates by third-party payors, including government payors, generally is also necessary for commercial success. The degree of market acceptance of any of our approved products will depend on a number of factors, including:

- the efficacy and safety as demonstrated in clinical trials;
- the clinical indications for which the product is approved;
- acceptance by physicians, major operators of cancer clinics and patients of the product as a safe and effective treatment;

- the potential and perceived advantages of product candidates over alternative treatments;
- the safety of product candidates seen in a broader patient group, including its use outside the approved indications;
- the cost of treatment in relation to alternative treatments;
- the availability of adequate reimbursement and pricing by third parties and government authorities;
- relative convenience and ease of administration;
- the prevalence and severity of adverse events; and
- the effectiveness of our sales and marketing efforts.

If any product candidate is approved but does not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors and patients, we may not generate sufficient revenue from these products and we may not become or remain profitable.

***If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.***

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials, and will face an even greater risk if we sell our product candidates commercially. Although we are not aware of any historical or anticipated product liability claims against us, if we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to cease clinical trials of our drug candidates or limit commercialization of any approved products. An individual may bring a liability claim against us if one of our product candidates causes, or merely appears to have caused, an injury. If we cannot successfully defend our self against product liability claims, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for our product candidates;
- impairment to our business reputation;
- withdrawal of clinical trial participants;
- costs of related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- the inability to commercialize our product candidates; and
- loss of revenues.

We believe that we have obtained sufficient product liability insurance coverage for our clinical trials. We intend to expand our insurance coverage to include the sale of commercial products if marketing approval is obtained for any of our product candidates. However, we may be unable to obtain this product liability insurance on commercially reasonable terms and with insurance coverage that will be adequate to satisfy any liability that may arise. On occasion, large judgments have been awarded in class action or individual lawsuits relating to marketed pharmaceuticals. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

***Reimbursement may be limited or unavailable in certain market segments for our product candidates, which could make it difficult for us to sell our products profitably.***

We intend to seek approval to market our future products in both the United States and in countries and territories outside the United States. If we obtain approval in one or more foreign countries, we will be subject to rules and regulations in those countries relating to our product. In some foreign countries, particularly in the European Union, the pricing of prescription pharmaceuticals and biologics is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product candidate. In addition, market acceptance and sales of our product candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for any of our product candidates and may be affected by existing and future healthcare reform measures.

Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which pharmaceuticals they will pay for and establish reimbursement levels. Reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

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

Obtaining coverage and reimbursement approval for a product from a government or other third-party payor is a time consuming and costly process that could require that we provide supporting scientific, clinical and cost-effectiveness data for the use of our products to the payor. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. If reimbursement of our future products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability.

In both the United States and certain foreign countries, there have been a number of legislative and regulatory changes to the healthcare system that could impact our ability to sell our products profitably. In particular, the Medicare Modernization Act of 2003 revised the payment methodology for many products reimbursed by Medicare, resulting in lower rates of reimbursement for many types of drugs, and added a prescription drug benefit to the Medicare program that involves commercial plans negotiating drug prices for their members. Since 2003, there have been a number of other legislative and regulatory changes to the coverage and reimbursement landscape for pharmaceuticals. Most recently, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, collectively, the "Affordable Care Act," was enacted. The Affordable Care Act contains a number of provisions, including those governing enrollment in federal healthcare programs, the increased use of comparative effectiveness research on healthcare products, reimbursement and fraud and abuse changes, and a new regulatory pathway for the approval of biosimilar biological products, all of which will impact existing government healthcare programs and will result in the development of new programs. An expansion in the government's role in the U.S. healthcare industry may further lower rates of reimbursement for pharmaceutical and biotechnology products.

There have been, and likely will continue to be, legislative and regulatory proposals at the federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare products and services. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may adversely affect:

- the demand for any products for which we may obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to generate revenues and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

In addition, governments may impose price controls, which may adversely affect our future profitability.

***We will need to increase the size of our organization and the scope of our outside vendor relationships, and we may experience difficulties in managing this growth.***

As of March 31, 2015, we had twenty-four full and part time employees. Over time, we will need to expand our managerial, operational, financial and other resources in order to manage and fund our operations and clinical trials, continue research and development activities, and commercialize our product candidates. Our management and scientific personnel, systems and facilities currently in place may not be adequate to support our future growth. Our need to effectively manage our operations, growth, and various projects requires that we:

- manage our clinical trials effectively;
- manage our internal development efforts effectively while carrying out our contractual obligations to licensors, contractors and other third parties;
- continue to improve our operational, financial and management controls and reporting systems and procedures; and
- attract and retain sufficient numbers of talented employees.

We may utilize the services of outside vendors or consultants to perform tasks including clinical trial management, statistics and analysis, regulatory affairs, formulation development, chemistry, manufacturing, controls, and other pharmaceutical development functions. Our growth strategy may also entail expanding our group of contractors or consultants to implement these tasks going forward. Because we rely on a substantial number of consultants, effectively outsourcing many key functions of our business, we will need to be able to effectively manage these consultants to ensure that they successfully carry out their contractual obligations and meet expected deadlines. However, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for our product candidates or otherwise advance its business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all. If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may be unable to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals.

***If we fail to attract and keep key management and clinical development personnel, we may be unable to successfully develop or commercialize our product candidates.***

We will need to expand and effectively manage our managerial, operational, financial and other resources in order to successfully pursue our clinical development and commercialization efforts for our product candidates and future product candidates. We are highly dependent on the development, regulatory, commercial and financial expertise of the members of our senior management. The loss of the services of any of our senior management could delay or prevent the further development and potential commercialization of our product candidates and, if we are not successful in finding suitable replacements, could harm our business. We do not maintain “key man” insurance policies on the lives of these individuals. We will need to hire additional personnel as we continue to expand our manufacturing, research and development activities.

Our success depends on our continued ability to attract, retain and motivate highly qualified management and scientific personnel and we may not be able to do so in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses. Our industry has experienced a high rate of turnover of management personnel in recent years. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that will impede significantly the achievement of our development objectives, our ability to raise additional capital, and our ability to implement our business strategy.

***If we fail to comply with healthcare regulations, we could face substantial penalties and our business, operations and financial condition could be adversely affected.***

In addition to FDA restrictions on the marketing of pharmaceutical and biotechnology products, several other types of state and federal laws have been applied to restrict certain marketing practices in the pharmaceutical and medical device industries in recent years, as well as consulting or other service agreements with physicians or other potential referral sources. These laws include anti-kickback statutes and false claims statutes that prohibit, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or, in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally-financed healthcare programs, and knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and any practices we adopt may not, in all cases, meet all of the criteria for safe harbor protection from anti-kickback liability. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer’s products from reimbursement under government programs, criminal fines and imprisonment. Any challenge to its business practices under these laws could have a material adverse effect on our business, financial condition, and results of operations.

***We use biological and hazardous materials, and any claims relating to improper handling, storage or disposal of these materials could be time consuming or costly.***

We use hazardous materials, including chemicals and biological agents and compounds, which could be dangerous to human health and safety or the environment. Our operations also produce hazardous waste products. Federal, state and local laws and regulations govern the use, generation, manufacture, storage, handling and disposal of these materials and wastes. Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our pharmaceutical development efforts.

In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. If one of our employees was accidentally injured from the use, storage, handling or disposal of these materials or wastes, the medical costs related to his or her treatment would be covered by our workers' compensation insurance policy. However, we do not carry specific biological or hazardous waste insurance coverage and our property and casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended, or operations otherwise affected.

***All product candidate development timelines and projections in this report are based on the assumption of further financing.***

The timelines and projections in this report are predicated upon the assumption that we will raise additional financing in the future to continue the development of our product candidates. In the event we do not successfully raise subsequent financing, our product development activities will necessarily be curtailed commensurate with the magnitude of the shortfall. If our product development activities are slowed or stopped, we would be unable to meet the timelines and projections outlined in this filing. Failure to progress our product candidates as anticipated will have a negative effect on our business, future prospects, and ability to obtain further financing on acceptable terms (if at all), and the value of the enterprise.

### **Risks Relating to Acquisitions**

***Acquisitions, investments and strategic alliances that we may make in the future may use significant resources, result in disruptions to our business or distractions of our management, may not proceed as planned, and could expose us to unforeseen liabilities.***

We may seek to expand our business through the acquisition of, investments in and strategic alliances with companies, technologies, products, and services. Acquisitions, investments and strategic alliances involve a number of special problems and risks, including, but not limited to:

- difficulty integrating acquired technologies, products, services, operations and personnel with the existing businesses;
- diversion of management's attention in connection with both negotiating the acquisitions and integrating the businesses;
- strain on managerial and operational resources as management tries to oversee larger operations;
- difficulty implementing and maintaining effective internal control over financial reporting at businesses that we acquire, particularly if they are not located near our existing operations;
- exposure to unforeseen liabilities of acquired companies;
- potential costly and time-consuming litigation, including stockholder lawsuits;
- potential issuance of securities to equity holders of the company being acquired with rights that are superior to the rights of holders of our common stock or which may have a dilutive effect on our stockholders;
- risk of loss of invested capital;
- the need to incur additional debt or use cash; and
- the requirement to record potentially significant additional future operating costs for the amortization of intangible assets.

As a result of these or other problems and risks, businesses we acquire may not produce the revenues, earnings, or business synergies that we anticipated, and acquired products, services, or technologies might not perform as we expected. As a result, we may incur higher costs and realize lower revenues than we had anticipated. We may not be able to successfully address these problems and we cannot assure you that the acquisitions will be successfully identified and completed or that, if acquisitions are completed, the acquired businesses, products, services, or technologies will generate sufficient revenue to offset the associated costs or other negative effects on our business.

Any of these risks can be greater if an acquisition is large relative to our size. Failure to effectively manage our growth through acquisitions could adversely affect our growth prospects, business, results of operations, financial condition and cash flows.

### **Risks Relating to Our Intellectual Property**

*Our success depends upon our ability to protect our intellectual property and proprietary technologies, and the intellectual property protection for our product candidates depends significantly on third parties.*

Our commercial success depends on obtaining and maintaining patent protection and trade secret protection for our product candidates and their formulations and uses, as well as successfully defending these patents against third-party challenges. If any of our licensors or partners fails to appropriately prosecute and maintain patent protection for these product candidates, our ability to develop and commercialize these product candidates may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products. This failure to properly protect the intellectual property rights relating to these product candidates could have a material adverse effect on our financial condition and results of operations.

Currently, the composition of matter patent and several method of use patents for TG-1101 in various indications and settings have been applied for but have not yet been issued, or have not yet been issued in all jurisdictions in which such applications have been filed. Composition of matter and/or method of use patents for TGR-1202 and for our IRAK4 inhibitor program and anti-PD-L1 and anti-GITR programs have also been applied for but have not yet been issued to date. There can be no guarantee that any of these patents for which an application has already been filed, nor any patents filed in the future for our product candidates will be granted in any or all jurisdictions in which there were filed, or that all claims initially included in such patent applications will be allowed in the final patent that is issued. The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or our partners will be successful in protecting our product candidates by obtaining and defending patents.

These risks and uncertainties include the following:

- the patent applications that we or our partners file may not result in any patents being issued;
- patents that may be issued or in-licensed may be challenged, invalidated, modified, revoked or circumvented, or otherwise may not provide any competitive advantage;
- as of March 16, 2013, the U.S. converted from a “first to invent” to a “first to file” system. If we do not win the filing race, we will not be entitled to inventive priority;
- our competitors, many of which have substantially greater resources than we do, and many of which have made significant investments in competing technologies, may seek, or may already have obtained, patents that will limit, interfere with, or eliminate its ability to make, use, and sell our potential products either in the United States or in international markets;
- there may be significant pressure on the U.S. government and other international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful as a matter of public policy regarding worldwide health concerns; and
- countries other than the United States may have less restrictive patent laws than those upheld by United States courts, allowing foreign competitors the ability to exploit these laws to create, develop, and market competing products.

If patents are not issued that protect our product candidates, it could have a material adverse effect on our financial condition and results of operations.

In addition to patents, we and our partners also rely on trade secrets and proprietary know-how. Although we have taken steps to protect our trade secrets and unpatented know-how, including entering into confidentiality agreements with third parties, and confidential information and inventions agreements with employees, consultants and advisors, third parties may still obtain this information or we may be unable to protect its rights. If any of these events occurs, or we otherwise lose protection for our trade secrets or proprietary know-how, the value of this information may be greatly reduced.

Patent protection and other intellectual property protection are crucial to the success of our business and prospects, and there is a substantial risk that such protections will prove inadequate.

***If we or our partners are sued for infringing intellectual property rights of third parties, it will be costly and time consuming, and an unfavorable outcome in that litigation would have a material adverse effect on our business.***

Our commercial success also depends upon our ability and the ability of any of our future collaborators to develop, manufacture, market and sell our product candidates without infringing the proprietary rights of third parties. Numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing products, some of which may be directed at claims that overlap with the subject matter of our intellectual property. For example, Roche has the Cabilly patents in the U.S. that block the commercialization of antibody products derived from a single cell line, like TG-1101. Also, Roche, Biogen Idec, and Genentech hold patents for the use of anti-CD20 antibodies utilized in the treatment of CLL in the U.S. While these patents have been challenged, to the best of our knowledge, those matters were settled in a way that permitted additional anti-CD20 antibodies to be marketed for CLL. If those patents are still enforced at the time we are intending to launch TG-1101, then we will need to either prevail in a litigation to challenge those patents or negotiate a settlement agreement with the patent holders. If we are unable to do so we may be forced to delay the launch of TG-1101 or launch at the risk of litigation for patent infringement, which may have a material adverse effect on our business and results of operations.

In addition, because patent applications can take many years to issue, there may be currently pending applications, unknown to us, which may later result in issued patents that our product candidates or proprietary technologies may infringe. Similarly, there may be issued patents relevant to our product candidates of which we are not aware.

There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and biopharmaceutical industries generally. If a third party claims that we or any collaborators of ours infringe their intellectual property rights, we may have to:

- obtain licenses, which may not be available on commercially reasonable terms, if at all;
- abandon an infringing product candidate or redesign its products or processes to avoid infringement;
- pay substantial damages, including treble damages and attorneys' fees, which we may have to pay if a court decides that the product or proprietary technology at issue infringes on or violates the third party's rights;
- pay substantial royalties, fees and/or grant cross licenses to our technology; and/or
- defend litigation or administrative proceedings which may be costly whether we win or lose, and which could result in a substantial diversion of our financial and management resources.

No assurance can be given that patents issued to third parties do not exist, have not been filed, or could not be filed or issued, which contain claims covering its products, technology or methods that may encompass all or a portion of our products and methods. Given the number of patents issued and patent applications filed in our technical areas or fields, we believe there is a risk that third parties may allege they have patent rights encompassing our products or methods.

Other product candidates that we may in-license or acquire could be subject to similar risks and uncertainties.

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

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which typically are very expensive, time-consuming and disruptive of day-to-day business operations. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly. The adverse result could also put related patent applications at risk of not issuing.

Interference proceedings provoked by third parties or brought by the U.S. Patent and Trademark Office ("PTO") may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our collaborators or licensors. An unfavorable outcome 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. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, 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 be subject to claims that our consultants or independent contractors have wrongfully used or disclosed alleged trade secrets of their other clients or former employers to it.***

As is common in the biotechnology and pharmaceutical industry, we engage the services of consultants to assist us in the development of our product candidates. Many of these consultants were previously employed at, may have previously been, or are currently providing consulting services to, other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these consultants or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers or their former or current customers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management and day-to-day business operations.

### **Risks Relating to Our Finances and Capital Requirements**

***We will need to raise additional capital to continue to operate our business.***

As of March 31, 2015, we had net cash, cash equivalents, investment securities and interest receivable of approximately \$105,226,000. We believe that our cash and cash equivalents and investments, inclusive of the amounts raised subsequent to the end of the year, will sustain our operations for more than 24 months from March 31, 2015. As a result, we will need additional capital to continue our operations beyond that time. Required additional sources of financing to continue our operations in the future might not be available on favorable terms, if at all. If we do not succeed in raising additional funds on acceptable terms, we might be unable to complete planned preclinical and clinical trials or obtain approval of any of our product candidates from the FDA or any foreign regulatory authorities. In addition, we could be forced to discontinue product development, reduce or forego sales and marketing efforts and forego attractive business opportunities. Any additional sources of financing will likely involve the issuance of our equity securities, which would have a dilutive effect to stockholders.

Currently, none of our product candidates have been approved by the FDA or any foreign regulatory authority for sale. Therefore, for the foreseeable future, we will have to fund all of our operations and capital expenditures from cash on hand and amounts raised in future offerings or financings.

***We have a history of operating losses, expect to continue to incur losses, and are unable to predict the extent of future losses or when we will become profitable, if ever.***

We have not yet demonstrated an ability to obtain regulatory approval for or commercialize a product candidate. Our short operating history makes it difficult to evaluate our business prospects and consequently, any predictions about our future performance may not be as accurate as they could be if we had a history of successfully developing and commercializing pharmaceutical or biotechnology products. Our prospects must be considered in light of the uncertainties, risks, expenses and difficulties frequently encountered by companies in the early stages of operations and the competitive environment in which we operate.

We have never been profitable and, as of March 31, 2015, we had an accumulated deficit of \$109,763,015. We have generated operating losses in all periods since we were incorporated. We expect to make substantial expenditures resulting in increasing operating costs in the future and our accumulated deficit will increase significantly as we expand development and clinical trial efforts for our product candidates. Our losses have had, and are expected to continue to have, an adverse impact on our working capital, total assets and stockholders' equity. Because of the risks and uncertainties associated with product development, we are unable to predict the extent of any future losses or when we will become profitable, if ever. Even if we achieve profitability, we may not be able to sustain or increase profitability on an ongoing basis.

***We have not generated any revenue from our product candidates and may never become profitable.***

Our ability to become profitable depends upon our ability to generate significant continuing revenues. To obtain significant continuing revenues, we must succeed, either alone or with others, in developing, obtaining regulatory approval for and manufacturing and marketing our product candidates (or utilize early access programs to generate such revenue). To date, our product candidates have not generated any revenues, and we do not know when, or if, we will generate any revenue. Our ability to generate revenue depends on a number of factors, including, but not limited to:

- successful completion of preclinical studies of our product candidates;
- successful commencement and completion of clinical trials of our product candidates and any future product candidates we advance into clinical trials;
- achievement of regulatory approval for our product candidates and any future product candidates we advance into clinical trials (unless we successfully utilize early access programs which allow for revenue generation prior to approval);
- manufacturing commercial quantities of our products at acceptable cost levels if regulatory approvals are obtained;
- successful sales, distribution and marketing of our future products, if any; and
- our entry into collaborative arrangements or co-promotion agreements to market and sell our products.

If we are unable to generate significant continuing revenues, we will not become profitable and we may be unable to continue our operations without continued funding.

***We will need substantial additional funding and may be unable to raise capital when needed, which would force us to delay, reduce or eliminate our development programs or commercialization efforts.***

We expect to spend substantial amounts on development, including significant amounts on conducting clinical trials for our product candidates, manufacturing clinical supplies and expanding our pharmaceutical development programs. We expect that our monthly cash used by operations will continue to increase for the next several years. We anticipate that we will continue to incur operating losses for the foreseeable future.

We will require substantial additional funds to support our continued research and development activities, as well as the anticipated costs of preclinical studies and clinical trials, regulatory approvals, and eventual commercialization. We anticipate that we will incur operating losses for the foreseeable future. We have based these estimates, however, on assumptions that may prove to be wrong, and we could expend our available financial resources much faster than we currently expect. Further, we will need to raise additional capital to fund our operations and continue to conduct clinical trials to support potential regulatory approval of marketing applications. Future capital requirements will also depend on the extent to which we acquire or in-license additional product candidates. We currently have no commitments or agreements relating to any of these types of transactions.

The amount and timing of our future funding requirements will depend on many factors, including, but not limited to, the following:

- the progress of our clinical trials, including expenses to support the trials and milestone payments that may become payable under our license agreements;
- the costs and timing of regulatory approvals;
- the costs and timing of clinical and commercial manufacturing supply arrangements for each product candidate;
- the costs of establishing sales or distribution capabilities;
- the success of the commercialization of our products;
- our ability to establish and maintain strategic collaborations, including licensing and other arrangements;
- the costs involved in enforcing or defending patent claims or other intellectual property rights; and
- the extent to which we in-license or invest in other indications or product candidates.

Until we can generate a sufficient amount of product revenue and achieve profitability, we expect to finance future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements, as well as through interest income earned on cash balances. If we were to be unable to raise additional capital, we would have to significantly delay, scale back or discontinue one or more of our pharmaceutical development programs. We also may be required to relinquish, license or otherwise dispose of rights to product candidates or products that it would otherwise seek to develop or commercialize itself on terms that are less favorable than might otherwise be available.

***Raising additional funds by issuing securities or through licensing or lending arrangements may cause dilution to our existing stockholders, restrict our operations or require us to relinquish proprietary rights.***

We may raise additional funds through public or private equity offerings, debt financings or licensing arrangements. To the extent that we raise additional capital by issuing equity securities, the share ownership of existing stockholders will be diluted. Any future debt financing we enter into may involve covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, redeem our stock, make certain investments and engage in certain merger, consolidation or asset sale transactions, among other restrictions.

In addition, if we raise additional funds through licensing arrangements, it may be necessary to relinquish potentially valuable rights to our product candidates, or grant licenses on terms that are not favorable to us. If adequate funds are not available, our ability to achieve profitability or to respond to competitive pressures would be significantly limited and we may be required to delay, significantly curtail or eliminate the development of one or more of our product candidates.

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

***We are controlled by current officers, directors and principal stockholders.***

Our directors, executive officers, their affiliates, and our principal stockholders beneficially own approximately 40% of our outstanding voting stock, including shares underlying outstanding options and warrants. Our directors, officers and principal stockholders, taken as a whole, have the ability to exert substantial influence over the election of our Board of Directors and the outcome of issues submitted to our stockholders.

***Our stock price is, and we expect it to remain, volatile, which could limit investors' ability to sell stock at a profit.***

The trading price of our common stock is likely to be highly volatile and subject to wide fluctuations in price in response to various factors, many of which are beyond our control. These factors include:

- publicity regarding actual or potential clinical results relating to products under development by our competitors or us;
- delay or failure in initiating, completing or analyzing nonclinical or clinical trials or the unsatisfactory design or results of these trials;
- achievement or rejection of regulatory approvals by our competitors or us;
- announcements of technological innovations or new commercial products by our competitors or us;
- developments concerning proprietary rights, including patents;
- developments concerning our collaborations;
- regulatory developments in the United States and foreign countries;
- economic or other crises and other external factors;
- period-to-period fluctuations in our revenues and other results of operations;
- changes in financial estimates by securities analysts; and
- sales of our common stock.

We will not be able to control many of these factors, and we believe that period-to-period comparisons of our financial results will not necessarily be indicative of our future performance.

In addition, the stock market in general, and the market for biotechnology companies in particular, has experienced extreme price and volume fluctuations that may have been unrelated or disproportionate to the operating performance of individual companies. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance.

***We have not paid dividends in the past and do not expect to pay dividends in the future, and any return on investment may be limited to the value of your stock.***

We have never paid dividends on our common stock and do not anticipate paying any dividends for the foreseeable future. You should not rely on an investment in our stock if you require dividend income. Further, you will only realize income on an investment in our stock in the event you sell or otherwise dispose of your shares at a price higher than the price you paid for your shares. Such a gain would result only from an increase in the market price of our common stock, which is uncertain and unpredictable.

***Certain anti-takeover provisions in our charter documents and Delaware law could make a third-party acquisition of us difficult. This could limit the price investors might be willing to pay in the future for our common stock.***

Provisions in our amended and restated certificate of incorporation and restated bylaws could have the effect of making it more difficult for a third party to acquire, or of discouraging a third party from attempting to acquire, or control us. These factors could limit the price that certain investors might be willing to pay in the future for shares of our common stock. Our amended and restated certificate of incorporation allows us to issue preferred stock without the approval of our stockholders. The issuance of preferred stock could decrease the amount of earnings and assets available for distribution to the holders of our common stock or could adversely affect the rights and powers, including voting rights, of such holders. In certain circumstances, such issuance could have the effect of decreasing the market price of our common stock. Our restated bylaws eliminate the right of stockholders to call a special meeting of stockholders, which could make it more difficult for stockholders to effect certain corporate actions. Any of these provisions could also have the effect of delaying or preventing a change in control.

On July 18, 2014, the Board of Directors declared a distribution of one right for each outstanding share of common stock. The rights may have certain anti-takeover effects. The rights will cause substantial dilution to a person or group that attempts to acquire us on terms not approved by the Board of Directors unless the offer is conditioned on a substantial number of rights being acquired. However, the rights should not interfere with any merger, statutory share exchange or other business combination approved by the Board of Directors since the rights may be terminated by us upon resolution of the Board of Directors. Thus, the rights are intended to encourage persons who may seek to acquire control of the Company to initiate such an acquisition through negotiations with the Board of Directors. However, the effect of the rights may be to discourage a third party from making a partial tender offer or otherwise attempting to obtain a substantial equity position in the equity securities of, or seeking to obtain control of, the Company. To the extent any potential acquirers are deterred by the rights, the rights may have the effect of preserving incumbent management in office.

## **ITEM 6. EXHIBITS**

The exhibits listed on the Exhibit Index are included with this report.

- 10.1 Collaboration Agreement by and between TG Therapeutics, Inc. and Checkpoint Therapeutics, Inc., dated March 3, 2015. Confidential Treatment Requested. Confidential portions of this document have been redacted and have been separately filed with the Commission.
- 31.1 Certification of Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated May 11, 2015.
- 31.2 Certification of Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated May 11, 2015.
- 32.1 Certification of Chief Executive Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated May 11, 2015.
- 32.2 Certification of Chief Financial Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated May 11, 2015.
- 101 The following financial information from the Company's Quarterly Report on Form 10-Q for the period ended March 31, 2015, formatted in Extensible Business Reporting Language (XBRL): (i) the Consolidated Balance Sheets, (ii) the Consolidated Statement of Operations, (iii) the Consolidated Statement of Equity, (iv) the Consolidated Statement of Cash Flows, and (v) Notes to the Consolidated Financial Statements (filed herewith).

**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.

TG THERAPEUTICS, INC.

Date: May 11, 2015

By: /s/ Sean A. Power  
Sean A. Power  
Chief Financial Officer  
Principal Financial and Accounting Officer

## EXHIBIT INDEX

The following exhibits are included as part of this Quarterly Report on Form 10-Q:

- 10.1 Collaboration Agreement by and between TG Therapeutics, Inc. and Checkpoint Therapeutics, Inc., dated March 3, 2015. Confidential Treatment Requested. Confidential portions of this document have been redacted and have been separately filed with the Commission.
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COLLABORATION AGREEMENT

**THIS COLLABORATION AGREEMENT** (the “**Agreement**”) is dated as of March 3, 2015 (the “**Effective Date**”) by and between Checkpoint Therapeutics, Inc., a Delaware corporation organized having its place of business at 3 Columbus Circle, New York, NY 10019 (“**CTI**”), and TG Therapeutics, Inc. located at 3 Columbus Circle, New York, NY 10019 (“**TGTX**”). CTI, on the one hand, and TGTX, on the other hand, shall each be referred to herein as a “**Party**” or, collectively, as the “**Parties**.”

**RECITALS:**

**WHEREAS**, CTI is party to that certain license agreement (the “License Agreement”) dated the date hereof with Dana Farber Cancer Institute (“DFCI”);

**WHEREAS**, DFCI is the owner of certain rights in the DFCI Technology; and

**WHEREAS**, DFCI has licensed rights to the DFCI Technology to CTI; and

**WHEREAS**, CTI is permitted to extend the rights granted to it under the DFCI Technology to Affiliates (as defined in the License Agreement); and

**WHEREAS**, TGTX, an Affiliate of CTI, is engaged in the research, development, manufacturing and commercialization of pharmaceutical products, and TGTX is interested in developing and commercializing products based on the DFCI Patents; and

**WHEREAS**, CTI desires to collaborate with TGTX and extend to TGTX the rights granted to it under the Licensed Technology in order to benefit the public by disseminating the results of its research via the commercial development, manufacture, distribution and use of Licensed Products (as defined below); and

**WHEREAS**, TGTX desires to collaborate with CTI and to exercise the rights granted to CTI, on an exclusive basis, so that it can exclusively use, develop and commercialize DFCI Patents in and for a defined field of use; and

**WHEREAS**, in the event TGTX is no longer an Affiliate of CTI, TGTX and CTI intend for the rights extended to TGTX hereunder to continue as a Sublicense (as defined in the License Agreement) as permitted by Section 2.3 of the License Agreement

**NOW, THEREFORE**, in consideration of the foregoing and of the various promises and undertakings set forth herein, the Parties agree as follows:

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## ARTICLE I DEFINITIONS

Unless otherwise specifically provided herein, the following terms shall have the following meanings:

**1.1 "Affiliate"** means a Person or entity that controls, is controlled by or is under common control with a Party, but only for so long as such control exists. For the purposes of this Section 1.1, the word "**control**" (including, with correlative meaning, the terms "**controlled by**" or "**under common control with**") means the actual power, either directly or indirectly through one or more intermediaries, to direct the management and policies of such Person or entity, whether by the ownership of at least 50% of the voting stock of such entity, or by contract or otherwise. TGTX and CTI acknowledge and agree that TGTX is an Affiliate of CTI.

**1.2 "Antibody"** means any antibody, any gene expressing such an antibody, any hybridoma producing such antibody, or any fragment, variant, derivative or construct thereof, or antibody fusion protein produced therefrom (including PEDgylated or multimeric versions thereof, whether polyclonal, monoclonal, multi-specific antibodies (e.g., bi-specific antibodies), human, humanized, chimeric, murine, synthetic, or from any other source), including without limitation (a) the full immunoglobulin molecules (e.g. the IgG, IgM, IgE, IgA, and IgD molecules), and (b) the antigen binding portions including Fab, Fab', F(ab')<sub>2</sub>, Fv, dAb, and CDR fragments, chimeric antibodies, diabodies, polypeptides, linear antibodies and single-chain antibodies (scFv) that contain any portion of an immunoglobulin that is sufficient to confer specific binding to an antigen.

**1.3 "Autoimmune Diseases"** means any disease which results from a loss of immune tolerance to self-antigens, including without limitation multiple sclerosis, rheumatoid arthritis, systemic lupus erythematosus, sjogren syndrome, celiac disease, Graves' disease, myasthenia gravis, Type I diabetes, idiopathic thrombocytopenic purpura, pemphigus vulgaris, among others, including any presentation or manifestation thereof.

**1.4 "Calendar Quarter"** means each three month period commencing January 1, April 1, July 1 or October 1, provided however that (a) the first Calendar Quarter of the Term shall extend from the Effective Date to the end of the first full Calendar Quarter thereafter, and (b) the last Calendar Quarter of the Term shall end upon the termination or expiration of this Agreement.

**1.5 "Calendar Year"** means the period beginning on the 1<sup>st</sup> of January and ending on the 31<sup>st</sup> of December of the same year, provided however that (a) the first Calendar Year of the Term shall commence on the Effective Date and end on December 31 of the same calendar year as the Effective Date, and (b) the last Calendar Year of the Term shall commence on January 1 of the Calendar Year in which this Agreement terminates or expires and end on the date of termination or expiration of this Agreement.

**1.6 "Combination Product"** means a product (a) containing a Licensed Product together with one or more other active ingredients, or (b) with one or more products, devices, pieces of equipment or components, but sold for an integrated price (e.g., with the purchase of one product the customer gets a coupon for the other) or for a single price.

**1.7 “Commercialization” or “Commercialize”** means any and all activities undertaken at any time for a particular Licensed Product and that relate to the manufacturing, marketing, promoting, distributing, importing or exporting for sale, offering for sale, and selling of the Licensed Product, and interacting with Regulatory Authorities regarding the foregoing.

**1.8 “Commercially Reasonable Efforts”** means, with respect to the efforts to be expended by a Party or such Party’s applicable Affiliate with respect to any objective, such reasonable, diligent, and good faith efforts normally used to accomplish a similar objective under similar circumstances by a similarly-situated company. Commercially Reasonable Efforts will not mean that a Party commits that it or such Party’s applicable Affiliate will actually accomplish the applicable task.

**1.9 “Controlled”** means, with respect to (a) DFCI Patents, (b) Know-How, (c) Antibodies, or (d) DFCI Materials, that a Party or one of its Affiliates owns or has a license or sublicense to such DFCI Patents, Know-How, Antibodies or DFCI Material (or in the case of DFCI Material, has the right to physical possession of such material) and has the ability to grant a license or sublicense to, or assign its right, title and interest in and to, such DFCI Patents, Know-How, Antibodies, or DFCI Material as provided for in this Agreement without violating the terms of any agreement or other arrangement with any Third Party.

**1.10 “Covered”** means, with respect to a Licensed Product, that the practicing, manufacturing, importing, using, selling, or offering for sale of such Licensed Product would, but for ownership of or a license granted hereunder under DFCI’s relevant DFCI Patents, infringe a Valid Claim of DFCI’s relevant DFCI Patents in the country in which the activity occurs (or, in the case of a Valid Claim that has not yet issued, would infringe such Valid Claim if it were to issue).

**1.11 “Derivative”** means a DFCI Antibody that has (a) been modified via isotype switching; (b) undergone a modification of effector function; (c) been adapted to enable the antibody to carry payloads; (d) been altered to change the expression characteristics, stability or biological half-life of the antibody; or (e) been mutated using an affinity maturation strategy designed to modify the affinity of either the variable regions and/or the constant regions of the antibody for any ligands, antigens or receptors. Derivatives may be full length antibodies, monoclonal and polyclonal antibodies, multispecific antibodies (e.g., bi-specific antibodies) and antibody fragments (including Fab, Fab’, F(ab’)<sub>2</sub>, F<sub>y</sub> fragments, diabodies, linear antibodies and single-chain antibodies), in each case, of any origin, whether human, humanized, chimeric or otherwise.

**1.12 “Development” or “Develop”** means, with respect to a Licensed Product, the performance of all preclinical and clinical development (including, without limitation, toxicology, pharmacology, test method development and stability testing, process development, formulation development, quality control development, statistical analysis), clinical trials, and manufacturing and regulatory activities that are required to obtain Regulatory Approval of such Licensed Product.

**1.13 DFCI Antibodies**" means the Antibodies supplied by or on behalf of DFCI to CTI under this Agreement as identified in Schedule 4.

**1.14 "DFCI Know-How"** means any and all Know-How that (a) is Controlled by DFCI or any of its Affiliates as of the Effective Date and (b) was developed in the laboratory of Dr. Wayne Marasco in the performance of research directly pertaining to the DFCI Patents and (c) is necessary for CTI to research, Develop, manufacture, use, or Commercialize Licensed Products. The DFCI Know-How is described in Schedule 2 hereto.

**1.15 "DFCI Materials"** means all materials Controlled by DFCI and supplied by DFCI to CTI under the License Agreement as identified in Schedule 3, together with any progeny or unmodified derivatives that may be developed by CTI or DFCI or TGTX. For the avoidance of doubt, "DFCI Materials" excludes the DFCI Antibodies and Derivatives.

**1.16 "DFCI Patents"** means (a) those patents and patent applications set forth on Schedule 3 hereto; (b) any additions, divisionals, continuations, conversion, supplemental examinations, extensions, term restorations, registrations, reinstatements, amendments, reissuances, corrections, substitutions, re-examinations, registrations, revalidations, supplementary protection certificates, renewals, and foreign counterparts of the patents and patent applications mentioned in clause (a) above; (c) all patents issuing from any of the patents and patent applications mentioned in clause (a) or (b) above and any foreign counterparts of any such patents and patent applications, and which shall include, in any case, patents surviving post grant review and inter partes review.

**1.17 "DFCI Technology"** means the DFCI Patents, DFCI Know-How, DFCI Antibodies, Derivatives, and DFCI Materials.

**1.18 "EMA"** means the European Medicines Agency or any successor agency.

**1.19 "European Commission"** means the authority within the European Union that has the legal authority to grant Regulatory Approvals in the European Union based on input received from the EMA or other competent Regulatory Authorities.

**1.20 "FDA"** means the United States Food and Drug Administration, or a successor federal agency thereto.

**1.21 "Field"** means all prophylactic, palliative, therapeutic or diagnostic uses in humans or animals for the prevention, diagnosis and treatment of hematological malignancies, including, without limitation, all Leukemia's, Lymphoma's, Multiple Myeloma and Waldentroms Macroglobulemia, but specifically excluding use in chimeric antigen receptor technology. Additionally, upon exercise of the Autoimmune Option, the Field shall include the prevention, diagnosis and treatment of Autoimmune Diseases.

**1.22 "First Commercial Sale"** means, with respect to a Licensed Product in any country, the first commercial transfer or disposition for value of such Licensed Product in the Field in such country to a Third Party, by TGTX, by an Affiliate of TGTX or by a Sublicensee after Regulatory Approval therefor has been obtained in such country, for cash or non-cash consideration to which a fair market value can be assigned for purposes of determining Net Sales.

**1.23 “GAAP”** means United States generally accepted accounting principles.

**1.24 “Governmental Body”** means any: (a) nation, principality, state, commonwealth, province, territory, county, municipality, district or other jurisdiction of any nature; (b) federal, state, local, municipal, foreign or other government; (c) governmental or quasi-governmental authority of any nature (including any governmental division, subdivision, department, agency, bureau, branch, office, commission, council, board, instrumentality, officer, official, representative, organization, unit, body or entity and any court or other tribunal); (d) multi-national or supranational organization or body; or (e) individual, entity, or body exercising, or entitled to exercise, any executive, legislative, judicial, administrative, regulatory, police, military or taxing authority or power of any nature.

**1.25 “Know-How”** means any scientific or technical information, results and data of any type whatsoever, in any intangible form whatsoever, that is not in the public domain or otherwise publicly known and is not claimed or disclosed in a patent or pending patent application, including practices, protocols, regulatory filings, scientific techniques, works of authorship, plans, data (including, but not limited to, pharmacological, biological, chemical, toxicological, clinical and analytical information, quality control, trial and stability data), data analyses, reports, studies and procedures, designs for experiments and tests and results of experimentation and testing (including results of research or development), summaries and information contained in submissions to and information from ethical committees, the FDA or other Regulatory Authorities, and manufacturing process and development information. The fact that an item is known to the public shall not be taken to exclude the possibility that a compilation including the item, and/or a development relating to the item, is (and remains) not known to the public. “Know-How” excludes DFCI Patents, DFCI Antibodies, and DFCI Materials.

**1.26 “Law” or “Laws”** means all applicable laws, statutes, rules, regulations, ordinances and other pronouncements having the binding effect of law of any Governmental Body.

**1.27 “Licensed Product”** means any pharmaceutical product, in any dosage form, preparation, composition, formulation, presentation or package configuration, (a) that is Covered in whole or in part by a Valid Claim in the DFCI Patents, (b) that incorporates, constitutes, or contains DFCI Antibodies or Derivatives as an active ingredient, or (c) that shares at least \*% of the amino acid sequence identity (combined or in the aggregate) to all the complementarity determining regions (CDRs) of any DFCI Antibodies or Derivatives and made using DFCI Technology.

**1.28 “Licensed Process”** means processes which, (a) in the course of being practiced, is Covered in whole or in part by a Valid Claim in the DFCI Patents, or (b) which incorporates or uses DFCI Antibodies or Derivatives in whole or in part.

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\* Confidential material redacted and filed separately with the Commission.

**1.29 “NDA”** means a New Drug Application submitted pursuant to the requirements of the FDA, as more fully defined in 21 U.S. CFR § 314.3 et seq., a Biologics License Application submitted pursuant to the requirements of the FDA, as more fully defined in 21 U.S. CFR § 601, and any equivalent application submitted in any country, including a European Marketing Authorization Application, together, in each case, with all additions, deletions or supplements thereto.

**1.30 “NDA Approval”** means the receipt of notice from the relevant US Regulatory Authority that an NDA for a Licensed Product has met all the criteria for marketing approval.

**1.31 “Net Sales”** means the gross income derived by TGTX or its Affiliates or Sublicensees to unrelated Third Parties for a Licensed Product in the Field in bona-fide arms-length transactions, less the following deductions, which may not exceed reasonable and customary amounts in the country in which the transaction occurs:

- (a) Normal and customary trade, quantity, cash and discounts and credits allowed and taken;
- (b) Discounts, refunds, rebates, chargebacks, retroactive price adjustments, and any other allowances given and taken which effectively reduce the net selling price, including, without limitation, Medicaid rebates, institutional rebates or volume discounts;
- (c) Product returns and allowances;
- (d) Administrative fees paid to group purchasing organizations (e.g., Medicare) and government-mandated rebates;
- (e) Shipping, handling, freight, postage, insurance and transportation charges, but all only to the extent included as a separate line item in the gross amount invoiced;
- (f) Any tax, tariff or duties imposed on the sale, delivery or use of the Licensed Product, including, without limitation, sales, use, excise or value added taxes and customs and duties, but all only to the extent included as a separate line item (e.g., “taxes”) in the gross amount invoiced.
- (g) Bad debt actually written off during the accounting period (provided, that any bad debt write-off so taken which is later reversed shall be added back to Net Sales in the accounting period in which the reversal occurs).

No deduction shall be made for any item of cost incurred by TGTX, its Affiliates or Sublicensees in Developing or Commercializing Licensed Products except as permitted pursuant to clauses (a) through (g) of the foregoing.

Net Sales includes the fair market value of any non-cash consideration from sale of Licensed Products received by TGTX, its Affiliates or Sublicensees. Licensed Products are considered “sold” when billed, invoiced, or payment is received, whichever occurs first.

Notwithstanding the foregoing, amounts invoiced by TGTX and its Affiliates and Sublicensees for sales of Licensed Products among TGTX and its Sublicensees and their respective Affiliates for resale shall not be included in the computation of Net Sales except where such purchasing party is an end user or consumer of Licensed Products.

Net Sales of any Combination Product (as defined below) for the purpose of calculating royalties due under this Agreement shall be determined on a country-by-country basis as follows: the Net Sales of the Combination Product (prior to application of the following adjustment) shall be multiplied by the fraction  $A/(A+B)$ , where A is the net selling price in such country of a Licensed Product without the additional active ingredient in the Combination Product, if sold separately for the same dosage as contained in the Combination Product, and B is the net selling price in such country of any other active ingredients (or delivery device) in the combination if sold separately for the same dosage (or form) as contained in the Combination Product. All net selling prices of the elements of such end-user product or service shall be calculated as the average net selling price of the said elements during the applicable accounting period for which the Net Sales are being calculated. In the event that, in any country, no separate sale of either such above-designated Licensed Product (containing only such Licensed Product and no other active ingredients) or any one or more of the active ingredients included in such Combination Product are made during the accounting period in which the sale was made or if the net selling price for an active ingredient cannot be determined for an accounting period, Net Sales for purposes of determining payments under this Agreement shall be calculated by multiplying the sales price of the Combination Product by the fraction  $C/(C+D)$  where C is the standard fully-absorbed manufacturing cost of the Licensed Product portion of the combination, and D is the standard fully-absorbed manufacturing cost of the other active ingredients or components included in the Combination Product, as determined by TGTX using its standard accounting procedures consistently applied. In the event that the standard fully-absorbed manufacturing cost of the Licensed Product and/or the other active ingredients or components included in such Combination Product cannot be determined, Net Sales allocable to the Licensed Product in each such country shall be determined by mutual agreement reached in good faith by the parties prior to the end of the accounting period in question based on an equitable method of determining same that takes into account, on a country-by-country basis, all relevant factors (including variations in potency, the relative contribution of each active ingredient in the combination, and relative value to the end user of each active ingredient).

**1.32 "Person"** means any natural person, corporation, firm, business trust, joint venture, association, organization, company, partnership or other business entity, or any government or agency or political subdivision thereof.

**1.33 "Phase I Trial"** means a clinical trial of a Licensed Product in human patients designated as a Phase I Trial and conducted primarily for the purpose of determining the safety of and/or the metabolism and pharmacologic actions of the Licensed Product in humans, as described under 21 CFR § 312.21(a) (as hereafter modified or amended) and any of its foreign equivalents. For purposes of this definition, Phase I Trial shall specifically exclude trials in healthy volunteers.

**1.34 "Phase II Trial"** means a clinical trial of a Licensed Product, designated as a Phase II Trial and the principal purpose of which is to make a preliminary determination that such Licensed Product is safe and active in a patient population for its intended use and is designed to obtain sufficient information about such Licensed Product's efficacy to permit the design of a Phase III Trial(s), and generally consistent with 21 CFR § 312.21(b). For purposes of this definition, Phase II trial shall specifically exclude expansion cohorts from Phase I Trial(s).

**1.35 “Phase III Trial”** means a clinical trial of a Licensed Product in human patients, which is designated as a Phase III Trial or a pivotal trial and is designed (a) to establish that the Licensed Product is safe and efficacious for its intended use; (b) to define warnings, precautions and adverse reactions that are associated with the Licensed Product in the dosage range to be prescribed; and (c) to be, either by itself or together with one or more other clinical trials having a comparable design and size, the final human clinical trial in support of Regulatory Approval of the Licensed Product, and (d) consistent with 21 CFR § 312.21(c) (as hereafter modified or amended) and any of its foreign equivalents.

**1.36 “Regulatory Authority”** means (a) the FDA, (b) the EMA or the European Commission, or (c) any regulatory body with similar regulatory authority over pharmaceutical or biotechnology products in any other jurisdiction anywhere in the world.

**1.37 “Regulatory Approval”** means any and all approvals, licenses, registrations, or authorizations of the relevant Regulatory Authority, necessary for the Development, manufacture, use, storage, import, transport and Commercialization of a given Licensed Product in a particular country or jurisdiction. For the avoidance of doubt, Regulatory Approval outside of the United States shall include any pricing or marketing approval needed prior to the sale of a Licensed Product in the Field.

**1.38 “Royalty Term”** means, on a Licensed Product-by-Licensed Product and country-by-country basis, the period from the First Commercial Sale of a given Licensed Product in such country until the later of (i) ten (10) years after First Commercial Sale of the applicable Licensed Product in such country, or (ii) the expiry of the last-to-expire DFCI Patent containing a Valid Claim to the Licensed Product in such country, provided that TGTX’s obligation to pay royalties hereunder shall not extend beyond the obligation of CTI to DFCI under the License Agreement.

**1.39 “Sublicensee”** means a Person, other than an Affiliate of TGTX, to which TGTX (or its Affiliate) has, pursuant to Section 2.3, granted sublicense rights under any of the license rights granted under Section 2.1. **“Sublicense”** shall be construed accordingly.

**1.40 “Sublicense Revenue”** means any payments or other consideration that CTI actually receives from a Sublicensee as consideration for the grant of a Sublicense, including, without limitation, milestone payments, license fees, license maintenance fees and equity. Sublicense Revenue excludes (i) purchases of equity or debt of TGTX, (ii) payments made for GTX’s performance of any research, Development, or Commercialization of any Licensed Product, (iii) (b) royalties on Net Sales (or, in the case of a profit sharing deal structure, shares of net profits) which are covered in Section 5.9, and (iv) any payment or reimbursement of any costs or expenses incurred by TGTX for filing, prosecution, maintenance, or defense of any DFCI Patents. In the event such consideration received from a Sublicensee is not cash, Sublicense Revenue shall be calculated by TGTX based on the fair market value of such consideration, at the time of the transaction, assuming an arm’s length transaction made in the ordinary course of business.

**1.41 “Tax” or “Taxes”** means any federal, state, local or foreign income, gross receipts, license, payroll, employment, excise, severance, stamp, occupation, premium, windfall profits, environmental, customs duties, capital stock, franchise, profits, withholding, social security, unemployment, disability, real property, personal property, sales, use, transfer, registration, value added, alternative or add-on minimum, estimated, or other tax of any kind whatsoever, including any interest, penalty, or addition thereto, whether disputed or not.

**1.42 “Third Party”** means any Person other than DFCI, CTI, or Affiliates of either of them, or any Sublicensees.

**1.43 “Third Party Action”** means any claim or action made by a Third Party against a Party that claims that a Licensed Product, or its use, Development, manufacture or sale infringes such Third Party’s intellectual property rights.

**1.44 “United States” or “US”** means the United States of America and its territories and possessions.

**1.45 “Valid Claim”** means (a) a claim of an issued and unexpired patent that has not been held permanently revoked, invalid or unenforceable by a patent office, court or other governmental agency of competent jurisdiction in a final and non-appealable judgment (or judgment from which no appeal was taken within the allowable time period) and that is not admitted to be invalid or unenforceable through reissue, disclaimer or otherwise (i.e. only to the extent the subject matter is disclaimed or is sought to be deleted or amended through reissue or (b) a claim of a pending patent application within DFCI Patents that has not been abandoned, finally rejected or expired without the possibility of appeal or refiling, provided that (i) Valid Claim shall exclude any such pending claim in an application that has not been granted within the latter of five (5) years after the Effective Date or seven (7) years following the earliest priority filing date for such application (unless and until such claim is granted) and (ii) Valid Claim will exclude any such pending claim that does not have a reasonable bona fide basis for patentability, in either case of (i) or (ii), unless and until such claim is granted. Notwithstanding the foregoing, in the event that a claim in a pending patent application is involved in an interference action declared by the US Patent and Trademark Office or any analogous patentability determination by any other national patent office, and, at the time such proceeding is filed or initiated such claim is a Valid Claim, the time period set forth in subsection (i) above will be stayed for the pendency of such proceeding.

## **ARTICLE II LICENSES AND OTHER RIGHTS**

### **2.1 Grant of License to TGTX.**

(a) Subject to the terms and conditions of this Agreement and the License Agreement, and the reserved rights described in Section 2.4 and Section 2.5 of the License Agreement, effective immediately at the time TGTX is no longer deemed to be an Affiliate of CTI, CTI hereby grants to TGTX, and TGTX hereby accepts, an exclusive, worldwide, royalty-bearing right and license (with the right to sublicense, subject to the provisions of Section 2.3) under the DFCI Patents to (i) research, Develop, manufacture, have manufactured, use, import and Commercialize and have Commercialized the Licensed Products, in and for the Field and (ii) to practice and have practiced any Licensed Processes, in and for the Field. CTI and its Affiliates grant no licenses or rights by implication, estoppel or otherwise under any other patent applications or patents owned in whole or in part by DFCI other than as expressly set forth herein.

(b) Subject to the terms and conditions of this Agreement, effective immediately at the time TGTX is no longer deemed to be an Affiliate of CTI, CTI hereby grants TGTX a non-exclusive license under DFCI's rights in and to the DFCI Materials listed in Schedule 3 solely in support of the exercise of TGTX's license rights under Section 2.1(a). TGTX shall not have the right and shall be prohibited from selling, transferring, or distributing the DFCI Materials to end users, except in the case where such end users are CTI Affiliates or Sublicensees under this Agreement. This Section 2.1(b) shall not affect the rights granted to TGTX hereunder to research, Develop, manufacture, have manufactured, use, import and Commercialize and have Commercialized Licensed Products made from or using such DFCI Materials.

**2.2 Affiliates.** Effective immediately at the time TGTX is no longer deemed to be an Affiliate of CTI, TGTX is entitled to extend its licenses under this Article II to its Affiliates, consistent with all of the terms and conditions of this Agreement. If TGTX does extend its license and an Affiliate assumes obligations under the Agreement, TGTX shall be responsible and liable for the acts or omissions of the Affiliate in the exercise of rights under this Agreement. If CTI has a claim arising under this Agreement against an Affiliate, CTI may seek a remedy directly against TGTX and may, but is not required to, seek a remedy against the Affiliate. Any termination of the Agreement under Article X as to TGTX also constitutes termination as to any Affiliates.

**2.3 Grant of Sublicenses by TGTX.** Effective immediately at the time TGTX is no longer deemed to be an Affiliate of CTI, TGTX shall have the right, in its sole discretion, to grant Sublicenses, in whole or in part, under the license granted in Section 2.1; provided, however, that the granting by TGTX of a Sublicense shall not relieve TGTX of any of its obligations hereunder; and provided, further, that TGTX's right to grant a Person a Sublicense shall be subject to TGTX including within such Sublicense express provisions binding the Sublicensee to terms and condition consistent with those contained herein. TGTX shall be and remain fully responsible and primarily liable for the compliance by Sublicensees with the terms and conditions of this Agreement (as applicable to them) as if such Sublicensees were TGTX hereunder. TGTX shall promptly provide a copy of each executed sublicense agreement and any modifications of the sublicense agreement (provided that such copy may be redacted to remove commercially sensitive terms that are not necessary to confirm compliance with the terms and conditions of this Agreement) following execution of such agreement.

**2.4 Delivery of DFCI Know-How, DFCI Antibodies, and DFCI Materials.** Effective immediately at the time TGTX is no longer deemed to be an Affiliate of CTI, CTI shall deliver to TGTX DFCI Know-How, DFCI Antibodies, and DFCI Materials within sixty (60) days of the Effective Date of this Agreement.

**2.5 Extension of Rights.** During such time as TGTX is deemed an Affiliate of CTI, CTI extends to TGTX all of its rights under the License Agreement subject to the terms and conditions of this Agreement and the License Agreement, provided that such rights shall be limited to the Field and shall exclude the right to make and have made Licensed Products. TGTX hereby assumes the obligations of CTI under the License Agreement with respect to its exercise of rights thereunder. Such extension of rights shall automatically terminate at the time TGTX is no longer deemed to be an Affiliate of CTI. It is the intention of TGTX and CTI for this Agreement to be consistent with the License Agreement. During the term of this Agreement, if CTI shall default on any obligations owed DFCI then TGTX shall have the right to cure such defaults and set any amounts incurred by TGTX in curing such defaults against any future payments TGTX may owe to CTI.

**ARTICLE III  
RIGHTS, DUTIES AND DILIGENCE**

**3.1 Diligence by TGTX.** TGTX shall use Commercially Reasonable Efforts to Develop and to Commercialize Licensed Products targeting PD-L1 and GITR in the Field. The Parties acknowledge that TGTX may Develop and Commercialize Licensed Products that are a Combination Product containing one or more DFCI Antibodies or Derivatives. Except as otherwise provided herein or agreed upon in writing, CTI agrees that it will not make, use or sell Licensed Products in the Field (“Exclusivity Covenant”). In addition, TGTX shall have the option (the “Autoimmune Option”) to include Autoimmune Diseases in the Field by providing notice to CTI and making a \$1,000,000 payment. Such Autoimmune Option can be exercised up to 3 years from the date hereof.

**3.2 Projected Milestone Dates.** TGTX shall use its commercially reasonable efforts to meet the following milestones (“Milestones”) by the dates specified in this paragraph, subject to annual adjustment as described below.

For purposes of this Section 3.2, CTI will consider efforts of an Affiliate or Sublicensee as efforts of TGTX.

(a) Milestone Dates for a Licensed Product Targeting PD-L1

<b>Milestone</b>	<b>Achievement Date</b>
- * for first PD-L1 Licensed Product	* years from the Effective Date
- * for first PD-L1 Licensed Product	* years from the Effective Date
- * for first PD-L1 Licensed Product	* years from the Effective Date
- * for first PD-L1 Licensed Product	* years from the Effective Date
- * for first PD-L1 Licensed Product	* years from the Effective Date
- * for first PD-L1 Licensed Product	* years from the Effective Date
- * for first PD-L1 Licensed Product	* Years from the Effective Date

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\* Confidential material redacted and filed separately with the Commission.

(b) Milestone Dates for a Licensed Product Targeting G1TR

Milestone	Achievement Date
- * for first G1TR Licensed Product	* years from the Effective Date
- * for first G1TR Licensed Product	* years from the Effective Date
- * for first G1TR Licensed Product	* years from the Effective Date
- * for first G1TR Licensed Product	* years from the Effective Date
- * for first G1TR Licensed Product	* years from the Effective Date
- * for first G1TR Licensed Product	* years from the Effective Date
- * for first G1TR Licensed Product	* Years from the Effective Date

**3.3 Adjustments.** The parties acknowledge that since the program is in early pre-clinical development that the dates included in the Milestone table above are rough estimates to provide DFCI and CTI a preliminary projection of what can be achieved by what dates, the accuracy of which the parties agree is impossible to predict and will be based on many factors completely outside the control of TGTX and its Diligence Efforts. On an annual basis, with its report contained below, TGTX will, in good faith, update the dates in the Milestones table above to provide CTI an updated assessment of the timing of the upcoming milestones. Upon providing such update, the table above shall be deemed amended notwithstanding Section 11.5 hereof.

**3.4 Development and Commercialization Reports.** Within 50 days of the Effective Date and at least 10 days before each anniversary of the Effective Date, TGTX shall provide to CTI a written report describing the efforts by TGTX, or any Affiliates or Sublicensees, to bring one or more Licensed Products to the marketplace. The report must be in sufficient detail to permit CTI to monitor TGTX' compliance with the due diligence provisions of this Agreement.

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\* Confidential material redacted and filed separately with the Commission.

TGTX shall include at least the following in these reports: (a) a summary of TGTX' progress toward meeting the goals and objectives that had been established for the previous year; (b) a summary of TGTX' goals and objectives for the ensuing year for developing and commercializing Licensed Products, including an identification of Licensed Products that TGTX intends to develop, if any; and (c) to the extent not covered by the foregoing, a summary of TGTX' progress in meeting the Milestone timelines above.

If multiple technologies are covered by this Agreement, the progress report must provide the information set forth above for each Licensed Product.

**3.5 Failure to Perform.** TGTX's failure to use commercially reasonable efforts to perform any due diligence requirement provided in Section 3.1 through 3.4 is grounds for CTI to terminate this Agreement according to Section 10.2(d); provided that CTI shall only have the right to terminate this Agreement with respect to the specific Licensed Product for which such failure is claimed and the Agreement shall remain in full force and effect for the remaining Licensed Products. In the alternative, CTI may terminate the Exclusivity Covenant (if such failure occurs while TGTX is an Affiliate of CTI) or convert the exclusive licenses granted under this Agreement to a non-exclusive license (if such failure occurs after the time TGTX ceases to be an Affiliate of CTI), as further provided in Section 3.6, as to the specific Licensed Product for which such failure is claimed.

**3.6 Conversion to Non-exclusive License.** If (i) the Exclusivity Covenant is terminated as provided in Section 3.5 or (ii) the exclusive license granted under this Agreement is converted to a non-exclusive license for any Licensed Product as provided in Section 3.5, this Agreement is automatically amended as follows as it relates to such Licensed Product; (a) the exclusive license of Section 2.1 becomes a non-exclusive license, (b) TGTX loses the right to grant sublicenses under Section 2.3; provided that any sublicense granted prior to such conversion shall continue and not be affected by such conversion, (c) the obligations of Sections 3.1 through 3.4 continue to apply, (d) the obligation under Section 3.10 no longer applies, (e) TGTX has no further rights or obligations under Article VI; provided that CTI shall keep TGTX apprised of any new filings of patent applications and issuance of patents that fall within the DFCI Patents, and (f) CTI has the sole right to pursue apparent infringements and the terms of Article VI no longer apply.

**3.7 Costs and Expenses.** As between CTI and TGTX, (a) TGTX shall be solely responsible for all costs and expenses related to Development, and Commercialization of the Licensed Products, including without limitation costs and expenses associated with all preclinical activities and clinical trials, and all regulatory filings and proceedings relating to Licensed Products in the Field and (b) CTI shall be the sole and exclusive manufacturer of Licensed Products for TGTX, such that TGTX shall purchase all of its requirements of Licensed Products from CTI and will not make or have made Licensed Products directly or through its Affiliates or Sublicensees) unless CTI is unable to provide sufficient supplies at competitive prices, the terms of which shall be negotiated in a manufacturing and supply agreement. CTI shall be solely responsible for all costs and expenses related to CMC including without limitation, CMC development and scale-up, CMC validation, analytical method development and validation, stability testing, manufacturing, finishing and release. TGTX shall reimburse CTI for CTI's out-of-pocket cost for Licensed Product used by TGTX for its Development activities and shall pay CTI a manufacturing transfer price for Commercial supplies equal to CTI's out-of-pocket cost of Licensed Product plus the lesser of: (a) 30% of such cost and (b) 3% of Net Sales generated by the materials supplied. The Parties agree to execute a manufacturing and supply agreement within a reasonable time after the execution of the Agreement on these terms and including such other customary and reasonable terms.

**3.8 Patent Marking.** TGTX agrees that with respect to each unit or package of Licensed Products sold in a given country, TGTX shall comply with the customary patent marking laws and practices of such country as to the applicable DFCI Patents.

**3.9 Trademarks.** As between TGTX and CTI, TGTX shall have the sole authority to select trademarks for Licensed Products and shall own all such trademarks. CTI does not grant TGTX the right to use any trademarks of CTI, DFCI or its Affiliates.

**3.10 U.S. Manufacture.** To the extent TGTX manufactures Licensed Products (e.g. if TGTX and CTI agree that CTI will no longer be the sole manufacturer of Licensed Products), TGTX shall manufacture Licensed Products leased, used or sold in the United States substantially in the United States as required by 35 U.S.C. 204 and 37 C.F.R. 401 et. seq., as amended. TGTX shall also require any Affiliate(s) or Sublicensee(s) to comply with this U.S. manufacture requirement. Notwithstanding the foregoing, if TGTX or its Affiliate(s) or Sublicensee(s) determines that it is not commercially feasible or reasonable to manufacture such Licensed Products in the United States or determines that it is necessary to have additional manufacturers outside the United States for back-up supply or to supply Licensed Products outside the United States, then CTI agrees to make reasonable efforts to assist TGTX, or its Affiliate(s) or Sublicensee(s), as applicable, at TGTX' expense, in obtaining any necessary permission from the appropriate government authorities to manufacture such Licensed Products outside the United States.

**3.11 Other Government Laws.** CTI shall comply with, and ensure that its Affiliates and Sublicensees comply with, all government statutes and regulations that relate to Licensed Products. These include but are not limited to FDA statutes and regulations, the Export Administration Act of 1979, as amended, codified in 50 App. U.S.C. 2041 et seq. and the regulations promulgated thereunder or other applicable export statutes or regulations.

**3.12 Publicity.** TGTX, its Affiliate and Sublicensees are not permitted to use the names of CTI, DFCI, its related entities or its employees, or any adaptations thereof, in any advertising, promotional or sales literature, or in any securities report required by the Securities and Exchange Commission (except as required by law), without the prior written consent of DFCI in each case. However TGTX may (a) refer to publications in the scientific literature by employees of DFCI or CTI or (b) state that a license from DFCI or CTI has been granted as provided in this Agreement.

**3.13 Other Agreements.** In the event that TGTX determines to conduct a clinical trial of a Licensed Product in the Field in the United States, TGTX shall consider in good faith and discuss with DFCI the potential of engaging DFCI to serve as a clinical site for such clinical trial; provided that (a) DFCI has the appropriate expertise and patient population to conduct the clinical trial, and (b) DFCI is economically competitive with other sites having substantially similar expertise and patient populations to conduct such clinical trial.

**ARTICLE IV  
REGULATORY MATTERS**

**4.1 Regulatory Filings.** As between CTI and TGTX, TGTX (or its applicable Affiliate) shall own and maintain all regulatory filings made after the Effective Date for Licensed Products and all Regulatory Approvals for Licensed Products. Once per year, representatives from CTI may visit TGTX and review all such regulatory filings, provided such representatives do not have a conflict of interest or involvement with any competitive companies or technologies and agree to TGTX's confidentiality agreement.

**ARTICLE V  
Financial Provisions**

**5.1 Upfront Fee.** Within twenty (20) days of the Effective Date, TGTX shall pay CTI an up-front, non-creditable, non-refundable fee in the amount of Five Hundred Thousand Dollars (\$500,000).

**5.2 Maintenance Fee.** Within thirty (30) days following the second anniversary of the Effective Date and each anniversary thereafter, TGTX shall pay CTI an annual license maintenance fee in the amount of \* Dollars (\$\*). Such fees are creditable against milestone payments due pursuant to Section 5.6, royalties due pursuant to Section 5.7 or Sublicense Revenue Share Payments (as defined in Section 5.9).

**5.3 Reserved**

**5.4 Milestone Payments.**

(a) **Product-based Milestones.** As further partial consideration for CTI's grant of the rights to TGTX hereunder, TGTX shall pay to CTI the following one-time, product-based milestone payments with regard to each Licensed Product (as specifically set forth below) to achieve the respective event, up to two (2) Licensed Products per product-based milestone. TGTX will pay the relevant milestone payment within 60 days of such achievement.

<b>Product-based Milestones</b>	<b>Milestone Payment</b>
Twelfth patient dosed in a Phase I Trial in the Field	\$*
First dosing of any patient in a Phase II Trial in the Field	\$*
First dosing of any patient in a Phase III Trial in the Field	\$*
First Commercial Sale in the United States	\$*
First Commercial Sale in the European Union	\$*
First Commercial Sale in Japan	\$*

\* Confidential material redacted and filed separately with the Commission.

If any of the above milestones are triggered as a result of a combination approval of two or more Licensed Products or combination clinical trial of two or more Licensed Products, only one milestone payment shall be due to CTI as if the combination was a single Licensed Product.

b. **Aggregate Net Sales Achievement Milestones:** As further consideration for CTI's grant of the rights to TGTX hereunder, TGTX shall pay to CTI the following one-time milestone payments upon first achievement of worldwide Net Sales (as specifically set forth below) by TGTX and its Affiliates and Sublicensees. TGTX will pay the relevant milestone payment within 90 days of such achievement.

<b>Aggregate Net Sales Achievement Milestones</b>	
The first time aggregate worldwide Net Sales for all Licensed Products exceeds \$* in any Calendar Year	\$*
The first time aggregate worldwide Net Sales for all Licensed Products exceeds \$* in any Calendar Year	\$*
The first time aggregate worldwide Net Sales for all Licensed Products exceeds \$* in any Calendar Year	\$*

#### **5.5 Royalty, Etc. Payments for Licensed Products.**

(a) With respect to Net Sales of all Licensed Products: As further consideration for CTI's grant of the rights to TGTX hereunder, TGTX shall pay to CTI a royalty of on aggregate annual worldwide Net Sales of all such Licensed Products by TGTX and its Affiliates and Sublicensees (but excluding Net Sales of a given Licensed Product after its applicable Royalty Term) at the percentage rates set forth below:

<b>Annual Worldwide Net Sales of All Licensed Products per Calendar Year (US Dollars)</b>	<b>Incremental Royalty Rate</b>
For Net Sales of such Licensed Products from \$0 up to and including \$*	*%
For that portion of Net Sales of such Licensed Products that is greater than \$*	*%

(b) In no event shall the manufacture of a Licensed Product give rise to a royalty/payment in the nature of royalties obligation until the particular unit of Licensed Product is sold; but if Net Sales of a particular unit of Licensed Product might or might not be subject to a royalty/payment in the nature of royalties payment (e.g., manufactured in Country A where the Royalty Term has expired but sold in Country B where the Royalty Term has not expired), the sale shall be deemed to be subject to a royalty/payment in the nature of royalties payment. For clarity, TGTX's obligation to pay royalties to CTI under Section 5.7(a) is imposed only once with respect to the same unit of Licensed Product regardless of the number of DFCI Patents pertaining thereto or the number of times such Licensed Product has been sold or transferred to a Person.

\* Confidential material redacted and filed separately with the Commission.

(c) On a Licensed Product by Licensed Product and country-by-country basis, upon expiration of the Royalty Term for a Licensed Product in a country, the rights, licenses and sublicenses granted to TGTX hereunder with respect to such Licensed Product in such country shall continue in effect but become fully paid-up, royalty-free, and perpetual.

(d) Reserved.

(e) In the event that the DFCI Patents do not contain any Valid Claim Covering the composition of matter for any of the active pharmaceutical ingredients of a Licensed Product in a particular country, royalties due to CTI will be reduced by \* percent (\*) of the applicable royalty rate as set forth in Section 5.7(a) for that Licensed Product in such country.

(f) In the event that a Licensed Product in a country is not Covered by a Valid Claim of a Licensed Patent, royalties with respect to such Licensed Product in such country shall be reduced by \* percent (\*) of the applicable royalty rate as set forth in Section 5.7(a) and shall be due for the period commencing with the First Commercial Sale of such Licensed Product in such country and ending ten (10) years from date of such First Commercial Sale.

(g) Notwithstanding the above, in no event shall the royalty rates set forth in Section 5.7(a) be reduced under 5.7(d), (e), and (f) above by more than \*% collectively.

**5.6 Timing of Royalty Payment.** Royalties/payments in the nature of royalties payable under Section 5.5 shall be payable on actual Net Sales and shall accrue at the time provided therefor by US GAAP. Royalty/payment in the nature of royalties obligations that have accrued during a particular Calendar Quarter shall be paid, on a Calendar Quarter basis, within 80 days after the end of each Calendar Quarter during which the royalty/payment in the nature of royalties obligation accrued; provided that within 40 days after the conclusion of each Calendar Year TGTX shall provide notice to CTI of any adjustments necessary to account for any royalties/payment in the nature of royalties which were overpaid or underpaid for such prior Calendar Year's Calendar Quarters, and the Parties shall promptly true-up based on such adjustments, provided however, the lapse of such 50-day period shall not impact the right of TGTX to credit any over-payments discovered during an audit against future royalties due under Section 5.5 hereof.

**5.7 Sublicense Revenue.** TGTX shall pay to CTI \* percent (\*) of all Sublicense Revenue received by TGTX ("**Sublicense Revenue Share Payments**"). Sublicense Revenue Share Payments shall be paid, on a Calendar Quarter basis, within 80 days after the end of each Calendar Quarter during which the respective Sublicense Revenue is received.

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\* Confidential material redacted and filed separately with the Commission.

**5.8 Royalty Reports and Records Retention.** Within 50 days after the end of each Calendar Quarter during which Licensed Products have been sold, TGTX shall deliver to CTI, together with the applicable royalty/payment in the nature of royalties payment due, a written report, on a Licensed Product-by-Licensed Product (and specifying non-Covered status, as applicable) and country-by-country basis, of (a) (a) Number of Licensed Products manufactured and sold by TGTX, and any Affiliates or Sublicensees, in each country; (b) gross invoiced (or otherwise charged) amounts of sales, by TGTX and its Affiliates and Sublicensees, of Licensed Products subject to royalty payments for such Calendar Quarter (and, if non-Covered, subject to royalty/payment in the nature of royalties payments for such Calendar Quarter), (c) amounts deducted by category (following the definition of Net Sales) from such gross invoiced amounts to calculate Net Sales, (d) Net Sales subject to royalty or royalty/payment in the nature of royalties payments for such Calendar Quarter and Calendar Year to date, and (e) the corresponding royalty or royalty/payment in the nature of royalties, and (f) the nature and amount of Sublicense Revenue received by TGTX. Such report shall be deemed “Confidential Information” of TGTX subject to the obligations of Article VII of this Agreement. For three years after each sale of a Licensed Product (whether Covered or not), TGTX shall keep (and shall ensure that its Affiliates and Sublicensees shall keep) complete and accurate records of such sale in sufficient detail to confirm the accuracy of the royalty or royalty/payment in the nature of royalties calculations hereunder.

**5.9** CTI shall be solely responsible for paying directly to DFCI all payments due to DFCI under Section 5 of the License Agreement that arise out of the exercise of rights by TGTX under this Agreement, including, without limitation, royalties on TGTX’s Net Sales.

**5.10 Books and Audits.**

TGTX shall keep, and shall require its Affiliates and Sublicensees to keep, true books of account containing an accurate record (together with supporting documentation) of all data necessary for determining the amounts payable to CTI. TGTX shall keep its records at its principal place of business or the principal place of business of the appropriate division of TGTX to which this Agreement relates and shall require its Affiliates and Sublicensees to keep their books and records in the same manner.

(a) Commencing on the earlier of (i) the First Commercial Sale (of the first Licensed Product to have a First Commercial Sale) or (ii) receipt of Sublicense Revenue, and continuing until one Calendar Year after the conclusion of the final Royalty Term, upon the written request of CTI, and not more than once in each Calendar Year, TGTX shall permit, shall cause its Affiliates to permit, an independent certified public accounting firm of nationally recognized standing selected by CTI (who has not been engaged by CTI to provide services in any other capacity at any time during the three-year period before such selection), and reasonably acceptable to TGTX or such Affiliate, to have access to and to review, during normal business hours upon reasonable prior written notice, the applicable records of TGTX and its Affiliates to verify the accuracy of the royalty payments and Sublicense Revenue Share Payments. Such review may cover: (i) the records for the Calendar Year ending not more than three years before the date of such request, and (ii) only those periods that have not been subject to a prior audit.

(b) If such accounting firm concludes that additional amounts were owed during such period, TGTX shall pay the additional royalties and/or royalties/payment in the nature of royalties within 15 days after the date such public accounting firm delivers to TGTX such accounting firm’s written report. If such accounting firm concludes that an overpayment was made, such overpayment shall be fully creditable against amounts payable in subsequent payment periods. If TGTX disagrees with such calculation, TGTX may contest such calculation in writing – at which point the parties will work in good faith to submit the matter to a mediator for resolution. If the parties are unable to reach an agreement via mediation, then TGTX may initiate a court action to seek to recover the additional payment or to increase the amount of credit or reimbursement. CTI shall pay for the cost of any audit by CTI, unless TGTX has underpaid CTI by 5% or more for a specific royalty period, in which case TGTX shall pay for the reasonable costs of audit, as well as any additional sum that would have been payable to CTI had the TGTX reported correctly, plus interest as set forth in Section 4.14.

(c) Each Party shall treat all information that it receives under this Section 5.10 in accordance with the confidentiality provisions of Article VII of this Agreement, and shall cause its accounting firm to enter into an acceptable confidentiality agreement with the audited Party obligating such firm to retain all such financial information in confidence pursuant to such confidentiality agreement, except to the extent necessary for a Party to enforce its rights under the Agreement.

**5.11 Mode of Payment and Currency.** All payments to CTI under this Agreement, whether or not in respect of Net Sales or milestone events, shall be made by deposit of US Dollars in the requisite amount to the following, which CTI may from time to time amend by advance written notice to TGTX.

**by check:**

Checkpoint Therapeutics, Inc.  
3 Columbus Circle  
  
New York, NY10019

**by wire transfer:**

[To be provided]

Conversion of sales or expenses recorded in local currencies to Dollars will be performed in a manner consistent with TGTX's normal practices used to prepare its audited financial statements for external reporting purposes, provided that such practices use a widely accepted source of published exchange rates. Based on the resulting Net Sales in US Dollars, the then applicable royalties/payment in the nature of royalties shall be calculated.

**5.12 Late Payments.** If a Party does not receive payment of any sum due to it on or before the due date therefor, simple interest shall thereafter accrue on the sum due to such Party from the due date until the date of payment at a rate equal to the lesser of (a) US dollar one-month LIBOR plus 300 basis points, or (b) the maximum rate permissible under applicable Law. Accrual and payment of interest shall not be deemed to excuse or cure breaches of contract arising from late payment or nonpayment. Waiver or deferral by CTI of any payment owed under any paragraph under this Article V may not be construed as a waiver or deferral of any subsequent payment owed by TGTX to CTI.

**5.13 Taxes.** All amounts due hereunder exclude all applicable sales, use, and other taxes and duties, and TGTX shall be responsible for payment of all such taxes (other than taxes based on CTI's income) and duties and any related penalties and interest, arising from the payment of amounts due under this Agreement. The Parties agree to cooperate with one another and use Commercially Reasonable Efforts to avoid or reduce tax withholding or similar obligations in respect of royalties, payments in the nature of royalties, milestone payments, and other payments made by TGTX to CTI under this Agreement. To the extent TGTX is required to withhold taxes on any payment to CTI, TGTX shall pay the amounts of such taxes to the proper governmental authority in a timely manner and promptly transmit to CTI official receipts issued by the appropriate taxing authority and/or an official tax certificate, or such other evidence as CTI may reasonably request, to establish that such taxes have been paid. CTI shall provide TGTX any tax forms that may be reasonably necessary in order for TGTX to not withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty. CTI shall use Commercially Reasonable Efforts to provide any such tax forms to TGTX at least 45 days before the due date for any payment for which CTI desires that TGTX apply a reduced withholding rate. Each Party shall provide the others with reasonable assistance to enable the recovery, as permitted by applicable law, of withholding taxes, value added taxes, or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the Party bearing such withholding tax or value added tax. CTI shall indemnify and hold TGTX harmless from and against any penalties, interest or other tax liability arising from any failure by TGTX (at the express request of CTI) to withhold or by reduction (at the express request of CTI) in its withholding.

**5.14 Currency Conversion.** If any currency conversion is required in connection with any payment owed to CTI, the conversion will be made at the buying rate for the transfer of such other currency as quoted by the Wall Street Journal on the last business day of the applicable accounting period in the case of any payment payable with respect to a specified accounting period or, in the case of any other payment, the last business day before the date the payment is due.

## **ARTICLE VI**

### **Patents**

#### **6.1 Patent Prosecution and Maintenance.**

(a) **DFCI Patents.** TGTX shall reimburse CTI for \*% of the patent expenses incurred under the License Agreement.

(b) **New or Revised Applications.** CTI will, upon learning from DFCI of an intention to file or revise one or more patent applications which are DFCI Patents subject to the License grant in Article II, promptly inform TGTX of such intention, and will provide TGTX with the opportunity to comment on the content of such DFCI patent application before CTI sends comments to DFCI on such filing. CTI shall include any such reasonable TGTX comments in the comments to be sent to DFCI.

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\* Confidential material redacted and filed separately with the Commission.

(c) **Liaising.** CTI shall keep TGTX promptly and regularly informed of the course of the filing and prosecution of DFCI Patents or related proceedings (e.g. interferences, oppositions, reexaminations, reissues, revocations or nullifications) in a timely manner, and to reasonably take into consideration the advice and recommendations of TGTX.

(d) **Election Not to File/Prosecute/Maintain DFCI Patents.** TGTX acknowledges and agrees that DFCI shall not be required to file, prosecute or maintain the DFCI Patents, provided, however, if DFCI decides to not pursue or maintain any such DFCI Patents then CTI shall promptly notify TGTX so the Parties can determine if they would like to assume responsibility for such activities in DFCI's name but at the Parties expense. In such event, TGTX will no longer owe any royalty obligation on account of such (country-level) DFCI Patents assumed by the Parties. Similarly, to the extent CTI does not want to continue funding the patent costs of any portion of DFCI Patents, CTI will notify TGTX and give TGTX an opportunity to assume responsibility for such Patents at TGTX's expense and shall owe DFCI directly the royalties due under the License Agreement and shall no longer owe royalty obligation to CTI on account of such (country-level) DFCI Patents assumed by TGTX. TGTX acknowledges that if neither CTI or TGTX continue funding patent costs then such portion of DFCI Patents will no longer be included as DFCI Patents.

**6.2 Certification under Drug Price Competition and Patent Restoration Act.** Each of TGTX and CTI shall provide within a reasonable time written notice to the other of any certification of which they become aware filed pursuant to 21 U.S.C. Section 355(b)(2)(A) (or any amendment or successor statute thereto) claiming that any DFCI Patents covering a Licensed Product, or the manufacture or use of each of the foregoing, are invalid or unenforceable, or that infringement will not arise from the manufacture, use or sale in the US of a Licensed Product by a Third Party.

**6.3 Listing of Patents.** To the extent a DFCI Patent is applicable solely in the Field, TGTX shall have the sole right to determine which of such DFCI Patents, if any, shall be listed for inclusion in the Approved Drug Products with Therapeutic Equivalence Evaluations publication pursuant to 21 U.S.C. Section 355, or any successor Law in the United States, together with any comparable Laws in any other country. DFCI will co-operate with CTI to list any of said DFCI Patents.

#### **6.4 Enforcement of Patents.**

(a) **Notice.** If either TGTX or CTI believes that a DFCI Patent is being infringed in the Field by a Third Party or if a Third Party claims that any DFCI Patent is invalid or unenforceable, the Party possessing such knowledge or belief shall notify the other and provide it with details of such infringement, misappropriation or claim that are known by such Party.

**(b) Action by DFCI.**

(i) **Procedure.** TGTX acknowledges that DFCI is responsible for enforcing its DFCI Patents and prosecuting apparent infringers when, in DFCI's judgment, such action may be reasonably necessary and justified. TGTX may request that CTI request DFCI to take steps to protect the DFCI Patents from an apparent infringement. However, TGTX recognizes that before DFCI must respond to the request, TGTX shall supply CTI to provide to DFCI (i) an opinion of qualified legal counsel demonstrating to DFCI's reasonable satisfaction that an infringement of the DFCI Patents exists in a particular country and (ii) with written evidence demonstrating to DFCI's reasonable satisfaction that a Substantial Infringement of the DFCI Patents exists in a particular country ("Substantial Infringer").

(ii) DFCI has three months from the date of receiving satisfactory written evidence from CTI of a Substantial Infringement to decide whether it will seek to terminate the Substantial Infringement. DFCI shall give CTI notice of its decision by the end of this three-month period, which CTI shall promptly forward to TGTX. If DFCI notifies CTI that it intends to prosecute the alleged infringer, then DFCI has six (6) months from the date of its notice to CTI to either (a) cause the Substantial Infringement to terminate or (b) initiate legal proceedings against the infringer. If any such suit is brought by DFCI in its own name, or jointly with CTI if required by law, it will be at DFCI's expense and on its own behalf, but DFCI shall not be obligated to bring more than one such suit at a time.

(iii) **CTI's Right to Join.** If CTI shall exercise its rights to join any legal proceeding brought by DFCI under Section 6.4 of the License Agreement, then TGTX shall have the right to join CTI under the same terms and conditions of paragraph 6.4(b)(iii) of the License Agreement.

**(c) Action by CTI and TGTX.**

(i) **Procedure.** If CTI has the right to prosecute a Substantial Infringement under Section 6.4(c) of the License Agreement, then CTI shall promptly notify TGTX, and it may initiate a legal proceedings against the alleged infringer. If CTI decides that it will not commence any legal proceeding with respect to the Substantial Infringement, then TGTX shall be given the rights to prosecute granted to CTI under Section 6.4(c).

(ii) **TGTX's Right To Join.** TGTX independently has the right to join any legal proceeding brought by CTI under this Section 6.4 and fund up to fifty percent of the cost of the legal proceeding from the date of joining. If TGTX elects to join as a party plaintiff pursuant to this Section 6.4, TGTX may jointly participate in the action with CTI, but CTI's counsel will be lead counsel.

(iii) **Reduction of Royalties.** If CTI initiates legal proceedings under Section 6.4 of the License Agreement and TGTX joins pursuant to this Section 6.4, then TGTX shall have the same rights as CTI has under Section 6.4(c)(iii) of the License Agreement. Additionally, if TGTX prosecutes pursuant Section 6.4(i) of this Agreement after CTI decides not to prosecute and neither DFCI nor CTI independently join the proceeding, then TGTX may deduct up to \* percent (%) of TGTX's documented costs and expenses of the proceeding (including reasonable attorney fees) from running and minimum royalties payable to CTI under Section 5.7(a) of this Agreement from sales of Licensed Products covered by the patent(s)-in suit. However, TGTX may not reduce CTI's royalty payments by more than fifty percent of the amount otherwise due under Article V. If \* percent (%) of TGTX's costs and expenses exceed the amount of royalties deducted by TGTX for any calendar year, TGTX may, to that extent, reduce the royalties due to CTI in succeeding calendar quarters for so long as TGTX is actively engaged in legal proceedings to terminate the Substantial Infringement. However, TGTX may not reduce total royalties due to CTI in a given calendar quarter by more than \* percent (%). TGTX's right to reduce royalty payments to CTI under this paragraph 6.4(c)(iii) applies only for so long as the Substantial Infringement continues.

(iv) **Settlement.** Regardless of whether CTI or DFCI is joined or joins any legal proceeding initiated by TGTX, TGTX acknowledges and agrees that no settlement, consent judgment or other voluntary final disposition of the legal proceeding may be entered into without the consent of DFCI.

**6.5 Cooperation.** If one party initiates legal proceedings to enforce the DFCI Patents pursuant to this Article VI, the other party shall cooperate with and supply all assistance reasonably requested by the party initiating the proceedings, at the initiating party's request and expense.

**6.6 Distribution of Amounts Paid by Third Parties.** Any amounts recovered by the Party initiating an Action pursuant to this Section 6.6, whether by settlement or judgment, shall be allocated in the following order: to reimburse the Parties for all out-of-pocket costs and expenses incurred in connection therewith, including attorneys' fees. If such recovery is insufficient to cover all such costs and expenses of both Parties, it will be shared pro-rata in proportion to the relative amount of such costs and expenses incurred by each Party. If after such reimbursement any funds remain from such damages, the remaining amount of such recovery shall be allocated as follows: the portion thereof attributable to "lost sales" in the Field shall be retained by TGTX and shall be deemed to be Net Sales for the Calendar Quarter in which the amount is actually received by TGTX and TGTX shall pay to CTI a royalty on such portion based on the royalty rates set forth in Section 5.7(a), and the portion thereof not attributable to "lost sales" and is not allocated to DFCI under Section 6.6 of the License Agreement shall be allocated 50% to TGTX and 50% to CTI.

**6.7 Declaratory Judgment Actions.** In the event that any third party initiates a declaratory judgment action alleging the invalidity or unenforceability of the DFCI Patents with respect to claims relating solely to the Field, or if any third party brings an infringement action against TGTX or its Affiliates or Sublicensees because of the exercise of the rights granted TGTX under this Agreement, then TGTX shall have the right to defend such action under its own control and at its own expense; provided, however, that TGTX acknowledges that DFCI has the right to assume control of such defense, at its own expense, if DFCI in good-faith believes that assuming control of such defense is beneficial to CTI and DFCI. TGTX shall NOT enter into any settlement, consent judgment or other voluntary final disposition of any action under this Section 6.7 without the consent of the other party, which consent shall not be unreasonably withheld unless the settlement includes any express or implied admission of liability or wrongdoing on the other party's or DFCI's part, in which case the other party or DFCI's right to grant or deny consent is absolute and at its sole discretion. Any recovery shall be first applied to reimburse each party pro rata for any out-of-pocket expenses it may have incurred with respect to defense of such action and the remainder shall be retained entirely by the party controlling the action; provided, however, that any recovery for infringement will be distributed as described in Section 6.7.

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\* Confidential material redacted and filed separately with the Commission.

**ARTICLE VII  
CONFIDENTIALITY**

**7.1 Definitions.** CTI and TGTX each recognizes that during the Term, it may be necessary for a Party (the “**Disclosing Party**”) to provide Confidential Information (as defined herein) to another Party (the “**Receiving Party**”) that is highly valuable, the disclosure of which would be highly prejudicial to such Party. The disclosure and use of Confidential Information shall be governed by the provisions of this Article VII. Neither Party shall use the other’s Confidential Information except as expressly permitted in this Agreement. For purposes of this Agreement, “**Confidential Information**” means all information (including information relating to the business, operations and products of a Party or any of its Affiliates) disclosed by the Disclosing Party to the Receiving Party and which reasonably ought to have been understood to be confidential and/or non-public information at the time disclosed to the Receiving Party, or which is designated in writing by the Disclosing Party as “Confidential” (or equivalent), or which when disclosed orally to the Receiving Party is declared to be confidential by the Disclosing Party and is so confirmed in a writing delivered to the Receiving Party within 30 days after such oral disclosure, including but not limited to any technical information, Know-How, trade secrets, or inventions (whether patentable or not), that such Party discloses to another Party under this Agreement, or otherwise becomes known to another Party by virtue of or that relates to this Agreement.

**7.2 Obligation.** The Parties agree that they will disclose the other Party’s Confidential Information to its own (or its respective Affiliate’s, or with respect to TGTX, its Sublicensees’) officers, employees, consultants and agents only if and to the extent necessary to carry out their respective responsibilities under this Agreement or in accordance with the exercise of their rights under this Agreement, and such disclosure shall be limited to the maximum extent possible consistent with such responsibilities and rights. Except as set forth in the foregoing sentence, no Party shall disclose Confidential Information of the other to any Third Party without the other’s prior written consent. In all events, however, any and all disclosure to a Third Party (or to any such Affiliate or Sublicensee) shall be pursuant to the terms of a non-disclosure/nonuse agreement no less restrictive than this Article VII. The Party which disclosed Confidential Information of the other to any Third Party (or to any such Affiliate or Sublicensee) shall be responsible and liable for any disclosure or use by such Third Party, Affiliate or Sublicensee (or its disclosees) which would have violated this Agreement if committed by the Party itself. No Party shall use Confidential Information of the other except as expressly allowed by and for the purposes of this Agreement. Each Party shall take such action to preserve the confidentiality of each other’s Confidential Information as it would customarily take to preserve the confidentiality of its own Confidential Information (but in no event less than a reasonable standard of care). Upon expiration or termination of this Agreement, each Party, upon the other’s request, shall return or destroy (at Disclosing Party’s discretion) all the Confidential Information disclosed to the other Party pursuant to this Agreement, including all copies and extracts of documents, within 60 days after the request, except for one archival copy (and such electronic copies that exist as part of the Party’s computer systems, network storage systems and electronic backup systems) of such materials solely to be able to monitor its obligations that survive under this Agreement.

**7.3 Exceptions.** The non-use and non-disclosure obligations set forth in this Article VII shall not apply to any Confidential Information, or portion thereof, that the Receiving Party can demonstrate by competent evidence:

(a) at the time of disclosure is in the public domain;

(b) after disclosure, becomes part of the public domain, by publication or otherwise, through no fault of the Receiving Party or its disclosees;

(c) is made available to the Receiving Party by an independent Third Party without obligation of confidentiality; provided, however, that to the Receiving Party's knowledge, such information was not obtained by said Third Party, directly or indirectly, from the Disclosing Party hereunder; or

(d) is independently developed by an employee of the Receiving Party not accessing or utilizing the Disclosing Party's information.

In addition, the Receiving Party may disclose information that is required to be disclosed by law, by a valid order of a court or by order or regulation of a governmental agency including but not limited to, regulations of the SEC or in the course of arbitration or litigation; provided, however, that in all cases the Receiving Party shall give the other party prompt notice of the pending disclosure and make a reasonable effort to obtain, or to assist the Disclosing Party in obtaining, a protective order or confidential-treatment order preventing or limiting (to the greatest possible extent and for the longest possible period) the disclosure and/or requiring that the Confidential Information so disclosed be used only for the purposes for which the law or regulation required, or for which the order was issued.

**7.4 Third Party Information.** The Parties acknowledge that the defined term "Confidential Information" shall include not only a Disclosing Party's own Confidential Information but also Confidential Information of a Third Party which is in the possession of a Disclosing Party. The Parties agree not to disclose to the other any Confidential Information of a Third Party which is in the possession of such Party, unless the other has given an express prior written consent (which specifies the owner of such Confidential Information) to receive such particular Confidential Information.

**7.5 Press Release Announcing the Execution of the License Agreement and Related Disclosures.** Either Party may make an initial press release announcing the execution of this Agreement, including any matter covered by this Agreement, and the Development or Commercialization of Licensed Products, but such Party shall provide the text of such planned disclosure to the other Party sufficiently in advance of the scheduled disclosure to afford such other Party a reasonable opportunity to review and comment upon the proposed text and the timing of such disclosure, and shall consider all reasonable comments of the other Party regarding such disclosure. (Provided, that no Party shall use the trademark or logo of the other Party, its Affiliates or their respective employee(s) in any publicity, promotion, news release or public disclosure relating to this Agreement or its subject matter, except as may be required by Law or required by the rules of an applicable US national securities exchange or except with the prior express written permission of such other Party, such permission not to be unreasonably withheld.)

## **ARTICLE VIII REPRESENTATIONS, WARRANTIES AND COVENANTS**

**8.1 Representations and Warranties.** (a) TGTX represents and warrants to CTI, and (b) CTI represents to TGTX, in each case as of the Effective Date:

(a) Such Party is a corporation duly organized and validly existing under the Laws of the jurisdiction of its incorporation;

(b) Such Party has all right, power and authority to enter into this Agreement, and to perform its obligations under this Agreement;

(c) Such Party has taken all action necessary to authorize the execution and delivery of this Agreement and the performance of its obligations under this Agreement;

(d) This Agreement is a legal and valid obligation of such Party, binding upon such Party and enforceable against such Party in accordance with the terms of this Agreement, except as enforcement may be limited by applicable bankruptcy, fraudulent conveyance, insolvency, reorganization, moratorium and other Laws relating to or affecting creditors' rights generally and by general equitable principles;

(e) To the best of such party's knowledge, the execution, delivery and performance of this Agreement by such Party does not conflict with, breach or create in any Third Party the right to accelerate, terminate or modify any agreement or instrument to which such Party is a party or by which such Party is bound;

(f) To the best of such party's knowledge, all consents, approvals and authorizations from all governmental authorities or other Third Parties required to be obtained by such Party in connection with the execution and delivery of this Agreement have been obtained; and the execution, delivery and performance of this Agreement by such Party does not violate any Law of any Governmental Body having authority over such Party;

(g) No person or entity has or will have, as a result of the execution and delivery of or as a result of the transactions contemplated by this Agreement, any right, interest or valid claim against or upon such Party for any commission, fee or other compensation as a finder or broker because of any act by such Party or its Affiliates, agents or Sublicensees; and

(h) To the best of such party's knowledge, no agreement between it and any Third Party is in conflict with the rights granted to any other party pursuant to this Agreement.

#### **8.2 Reserved.**

**8.3 Disclaimer.** Notwithstanding the representations and warranties set forth in this Article VIII, TGTX acknowledges and accepts the risks inherent in attempting to Develop and Commercialize any pharmaceutical product. There is no implied representation that the Licensed Products can be successfully Developed or Commercialized.

**8.4 CTI MAKES NO WARRANTY, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE WITH RESPECT TO ANY PATENT, TRADEMARK, SOFTWARE, NON-PUBLIC OR OTHER INFORMATION, DFCI MATERIALS, DFCI ANTIBODIES, KNOW-HOW, OR TANGIBLE RESEARCH PROPERTY, LICENSED OR OTHERWISE PROVIDED TO TGTX HEREUNDER AND HEREBY DISCLAIMS THE SAME.**

**8.5 TGTX DOES NOT WARRANT THE VALIDITY OF THE DFCI PATENTS LICENSED HEREUNDER AND MAKES NO REPRESENTATION WHATSOEVER WITH REGARD TO THE SCOPE OF THE LICENSED DFCI PATENTS OR THAT SUCH DFCI PATENTS MAY BE EXPLOITED BY TGTX, AFFILIATE OR SUBLICENSEE WITHOUT INFRINGING OTHER PATENTS. CTI MAKES NO REPRESENTATION THAT DFCI ANTIBODIES, DFCIMATERIALS OR THE METHODS USED IN MAKING OR USING SUCH DFCI MATERIALS OR DFCI ANTIBODIES ARE FREE FROM LIABILITY FOR PATENT INFRINGEMENT.**

### **ARTICLE IX INDEMNIFICATION; LIMITATION OF LIABILITY; INSURANCE**

#### **Indemnification and Defense.**

**9.1** TGTX shall indemnify, defend and hold harmless (i) DFCI and its trustees officers, medical and professional staff, employees, and agents and their respective successors, heirs and assigns and (ii) CTI and its directors, officers, employees, agents and contractors (the "CTI Indemnitees"), against any liability, damage, loss or expense (including reasonable attorneys' fees and expenses of litigation) incurred by or imposed upon the CTI Indemnitees, or any one of them, in connection with any claims, suits, actions, demands or judgments arising out any theory of product liability ( including but not limited to action in the form of tort, warranty, strict liability) concerning any product, process or service relating to, or developed by TGTX, its Affiliates or Sublicensees pursuant to (a) any right or license granted under this Agreement or (b) arising out of any other activities to be carried out by TGTX pursuant to this agreement. TGTX's indemnification under Section 9.1 does not apply to any liability, damage, loss or expense to the extent that it is attributable to (x) the grossly negligent activities of the CTI Indemnitees, or (y) the intentional wrongdoing or intentional misconduct of the CTI Indemnitees TGTX shall, at its own expense, provide attorneys reasonably acceptable to CTI to defend against any actions brought or filed against any party indemnified hereunder with respect to the subject of indemnity contained herein, whether or not such actions are rightfully brought.

9.2 CTI shall indemnify, defend and hold harmless TGTX and its directors, officers, employees, agents and contractors (the "TGTX Indemnitees"), against any liability, damage, loss or expense (including reasonable attorneys' fees and expenses of litigation) incurred by or imposed upon the TGTX Indemnitees, or any one of them, in connection with any claims, suits, actions, demands or judgments arising out any theory of product liability ( including but not limited to action in the form of tort, warranty, strict liability) concerning (a) any product, process or service relating to, or developed by CTI, its Affiliates or Sublicensees pursuant to the License Agreement or (b) any other activities to be carried out by CTI pursuant to this agreement. CTI's indemnification under Section 9.1 does not apply to any liability, damage, loss or expense to the extent that it is attributable to (x) the grossly negligent activities of the TGTX Indemnitees, or (y) the intentional wrongdoing or intentional misconduct of the TGTX Indemnitees. CTI shall, at its own expense, provide attorneys reasonably acceptable to DFCI and TGTX to defend against any actions brought or filed against any party indemnified hereunder with respect to the subject of indemnity contained herein, whether or not such actions are rightfully brought

9.3 If any such action is commenced or claim made or threatened against a DFCI Indemnitee or CTI Indemnitee (collectively, "Indemnitees") as to which the other Party (the "Indemnifying Party") is obligated to indemnify it (them) or hold it (them) harmless, the Indemnitee shall promptly notify Indemnifying Party of such event. Indemnifying Party shall assume the defense of, and may settle, that part of any such claim or action commenced or made against an Indemnitee which relates to the Indemnifying Party's indemnification and CTI may take such other steps as may be necessary to protect it. Indemnifying Party will not be liable to Indemnitees on account of any settlement of any such claim or litigation affected without Indemnifying Party's consent. The right of Indemnifying Party to assume the defense of any action is limited to that part of the action commenced against Indemnitees that relates to Indemnifying Party's obligation of indemnification and holding harmless.

9.4 TGTX shall require any Affiliates or Sublicensee(s) to indemnify, hold harmless and defend DFCI and CTI under the same terms set forth in Sections 9.1 – 9.4.

#### **Insurance.**

9.5 At such time as any product, process or service relating to, or developed pursuant to, this Agreement is being commercially distributed or sold (other than for the purpose of obtaining regulatory approvals) by TGTX or by a Sublicensee, Affiliate or agent of TGTX, TGTX shall, at its sole cost and expense, procure and maintain policies of commercial general liability insurance in amounts not less than \$2,000,000 per incident and \$2,000,000 annual aggregate and naming the Indemnitees as additional insureds. Such commercial general liability insurance must provide (a) product liability coverage and (b) contractual liability coverage for TGTX's indemnification under Sections 9.1 through 9.5 of this Agreement. If TGTX elects to self-insure all or part of the limits described above (including deductibles or retentions which are in excess of \$250,000 annual aggregate), such self-insurance program must be acceptable to the CTI, DFCI and the DFCI's associated Risk Management Foundation. The minimum amounts of insurance coverage required under these provisions may not be construed to create a limit of TGTX's liability with respect to its indemnification obligation under Sections 9.1 through 9.5 of this Agreement.

**9.6** TGTX shall provide CTI with written evidence of such insurance upon request of CTI. TGTX shall provide CTI with written notice at least fifteen (15) days prior to the cancellation, non-renewal or material change in such insurance; if TGTX does not obtain replacement insurance providing comparable coverage within such fifteen (15) day period, CTI has the right to terminate this Agreement effective at the end of such fifteen (15) day period without any notice or additional waiting periods.

**9.7** TGTX shall maintain such comprehensive general liability insurance beyond the expiration or termination of this Agreement during (a) the period that any product, process, or service, relating to, or developed pursuant to, this Agreement is being commercially distributed or sold (other than for the purpose of obtaining regulatory approvals) by TGTX or by a Sublicensee, Affiliate or agent of TGTX and (b) a reasonable period after the period referred to in 9.8 (a) above which in no event shall be less than fifteen (15) years.

**9.8** TGTX shall require any of its Affiliates or Sublicensee(s) to, maintain insurance in favor of CTI, DFCI and the Indemnitees under the same terms set forth in Sections 9.5 – 9.7 of this Agreement.

## **ARTICLE X TERM AND TERMINATION**

**10.1 Term.** The term of this Agreement shall commence on the Effective Date and, unless earlier terminated as provided in this Article X, shall continue in full force and effect, on a country-by-country and Licensed Product-by-Licensed Product basis until the Royalty Term in such country with respect to such Licensed Product expires, at which time this Agreement shall expire in its entirety with respect to such Licensed Product in such country. (The “**Term**” shall mean the period from the Effective Date until the earlier of termination of this Agreement as provided in this Article X or expiration of this Agreement upon the expiration of the last-to-expire Royalty Term.) The Parties confirm that subject to the foregoing sentence, this Agreement shall not be terminated or invalidated by any future determination that any or all of the DFCI Patents have expired or been invalidated.

**10.2 Termination by CTI.** CTI has the right to immediately terminate this Agreement, the extension of rights (if such termination occurs while TGTX is an Affiliate of CTI), and all licenses granted hereunder (if such failure occurs after the time TGTX ceases to be an Affiliate of CTI), or at CTI’s option to convert the exclusive license granted in Article 2.1 to a non-exclusive license (if such failure occurs after the time TGTX ceases to be an Affiliate of CTI) in accordance with Section 3.6, by providing TGTX with written notice of such, upon the occurrence of any of the following events.

(a) TGTX's Board of Director's has agreed that TGTX will cease to carry on its business with respect to Licensed Products.

(b) TGTX fails to pay when due any undisputed royalty or other undisputed payment that has become due and is payable under Article V of this Agreement and has not cured the default by making the required payment, together with interest due, within ninety days of receiving a written notice of default from CTI requesting such payment.

(c) An officer of TGTX is convicted of a felony relating to the manufacture, use, sale or importation of Licensed Products.

(d) TGTX materially breaches any other provision of this Agreement (including but not limited to due diligence obligations under Article III and insurance obligations under Section 9.7 – Section 9.10), unless TGTX has cured the breach within ninety days of receiving written notice from CTI specifying the nature of the breach; provided, however, that the due diligence obligations shall be determined on a Licensed Product by Licensed Product basis.

**10.3 Termination for insolvency.** TGTX or CTI may terminate this Agreement immediately upon written notice, with no further notice obligation or opportunity to cure, if TGTX or CTI shall become insolvent, shall make an assignment for the benefit of creditors, or shall have a petition in bankruptcy filed for or against it (which is not dismissed within 60 days of such filing).

**10.4** Notwithstanding Sections 10.2 and 10.3, in the event of a good-faith dispute as to whether any alleged breach, default, failure or any other act or omission gives rise to a right of termination under this Agreement, is in fact a breach, default, failure or other act or omission that gives rise to a right of termination under this Agreement, termination of this Agreement in respect of such alleged breach, default, failure or other act or omission shall not take effect unless and until (y) such dispute is resolved in accordance with Section 10.7 below in favor of the Party alleging such breach, default, failure or other act or omission or (z) the non-terminating Party's denial that the alleged breach, default, failure or other act or omissions is in fact a breach, default, failure or other act or omission giving rise to a right of termination hereunder ceases to be in good faith.

**10.5 Termination by TGTX.** TGTX has the right to terminate this Agreement without cause by giving CTI one hundred and eighty days prior written notice in whole or on a Licensed Product by Licensed Product basis. Any milestones achieved by TGTX during this one hundred and eight day period will be due and payable to CTI.

#### **10.6 Effect of Termination**

(a) **No release.** Upon termination of this Agreement for any reason, nothing in this Agreement may be construed to release either party from any obligation that matured prior to the effective date of the termination.

(b) **Survival.** The provisions of Section 6.1(a) (patent expenses) Article V (Financial Provisions), Section 3.1.2 (Publicity –paragraph 10.6(c) (Inventory), Article IX (Indemnification), Sections 9.7 – 9.10 (Insurance), Article VIII (Representations and Warranties) and Section 10.7 (Dispute Resolution) survive termination or expiration of this Agreement.

(c) **Inventory.** TGTX, any Affiliate(s) and any Sublicensees whose sublicenses are not converted as provided in paragraph 10.6(d) below, may, after the effective date of termination, sell all Licensed Products that are in inventory as of the date of written notice of termination, and complete and sell Licensed Products which the licensed entity(ies) can reasonably demonstrate were in the process of manufacture as of the date of written notice of termination, provided that TGTX shall pay to CTI the royalties thereon as required by Article V and shall submit the reports required by Section 5.10 on the sales of Licensed Products.

(d) **Sublicenses.** Any Sublicenses will terminate contemporaneously with this Agreement; provided, however, that any Sublicenses that are not in default under the sublicense agreement shall, upon DFCI's and CTI's written approval, survive and remain in full force and effect so long as the Sublicensee agrees to be bound by all of the provisions of this Agreement, if not otherwise already provided for in the sublicense agreement. Such approval by DFCI and CTI shall not be unreasonably withheld and shall not require the payment of additional consideration.

(e) If (i) this Agreement is in effect at the time of the termination of the License Agreement and (ii) TGTX is not an Affiliate of CTI at such time then, upon the written approval by DFCI, this Agreement survive and remain in full force and TGTX hereby agrees to be bound by the terms of the License Agreement pursuant to Section 10.6(d) of the License Agreement. If DFCI does not approve such survival, then this Agreement shall terminate upon termination of the License Agreement. Such approval by DFCI shall not be unreasonably withheld and shall not require the payment of additional consideration.

(f) Pursuant to the License Agreement, TGTX is deemed an Affiliate of CTI, and thus at the time the License Agreement is terminated, this Agreement shall automatically terminate at such time; provided, that pursuant to Section 2.5, TGTX shall have the right to cure any breach and that CTI will not voluntarily terminate the License Agreement with TGTX's prior written consent.

### **10.7 Dispute Resolution.**

(a) **Negotiation between the Parties.** The parties shall first attempt to resolve any controversy that arises from this Agreement, or claim for breach of the Agreement, by good faith negotiations, first between their respective business development representatives and then, if necessary, between senior representatives for the Parties.

(b) **Non-Binding Mediation.** If the controversy or claim cannot be settled through good faith negotiation between the parties, the parties agree first to try in good faith to settle their dispute by non-binding mediation under the Mediation Rules of the American Arbitration Association, before resorting to arbitration, litigation or other dispute resolution procedure.

**ARTICLE XI  
MISCELLANEOUS PROVISIONS**

**11.1 Relationship of the Parties.** Nothing in this Agreement is intended or shall be deemed to constitute a partnership, agency, joint venture or employer-employee relationship between the Parties. No Party shall have any right or authority to commit or legally bind any other Party in any way whatsoever including, without limitation, the making of any agreement, representation or warranty and each Party agrees to not purport to do so.

**11.2 Assignment.**

(a) Any assignment not in accordance with this Section 11.2 shall be void.

(b) No assignment shall relieve the assigning Party of any of its responsibilities or obligations hereunder.

(c) TGTX may not transfer or assign its rights or licenses or delegate its obligations under this Agreement, in whole or in part, by operation of law or otherwise, to any Third Party without the prior written consent of CTI, which consent shall not be unreasonably withheld, conditioned or delayed; *provided that*, notwithstanding the foregoing, TGTX may, without such consent, assign its rights or licenses and/or delegate its obligations under this Agreement to (i) an Affiliate or (ii) a Third Party in connection with a Sale Event (and for the avoidance of doubt, at such time the extension of rights set forth in Section 2.5 shall terminate and the licenses granted to TGTX in Section 2 shall become effective). As a condition to any permitted assignment hereunder, the assignee must expressly assume, in a writing delivered to CTI and signed by a duly authorized officer of the assignee (and in a form reasonably acceptable to CTI) all of TGTX's obligations under this Agreement, whether arising before, at or after the assignment.

**11.3 Further Actions.** Each Party agrees to execute, acknowledge and deliver such further instruments and to do all such other acts as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

**11.4 Force Majeure.** No Party shall be liable to any other Party or be deemed to have breached or defaulted under this Agreement for failure or delay in the performance of any of its obligations under this Agreement (other than obligations for the payment of money) for the time and to the extent such failure or delay is caused by or results from acts of God, earthquake, riot, civil commotion, terrorism, war, strikes or other labor disputes, fire, flood, failure or delay of transportation, omissions or delays in acting by a governmental authority, acts of a government or an agency thereof or judicial orders or decrees or restrictions or any other like reason which is beyond the control of the respective Party. The Party affected by force majeure shall provide the other Party with full particulars thereof as soon as it becomes aware of the same (including its best estimate of the likely extent and duration of the interference with its activities), and shall use Commercially Reasonable Efforts to overcome the difficulties created thereby and to resume performance of its obligations hereunder as soon as practicable, and the time for performance shall be extended for a number of days equal to the duration of the force majeure.

**11.5 Entire Agreement of the Parties; Amendments.** This Agreement and the Schedules hereto constitute and contain the entire understanding and agreement of the Parties respecting the subject matter hereof and cancel and supersede any and all prior or contemporaneous negotiations, correspondence, understandings and agreements between the Parties, whether oral or written, regarding such subject matter (provided, that any and all previous nondisclosure/nonuse obligations are not superseded and remain in full force and effect in addition to the nondisclosure/nonuse provisions hereof). Each Party acknowledges that it has not relied, in deciding whether to enter into this Agreement on this Agreement's expressly stated terms and conditions, on any representations, warranties, agreements, commitments or promises which are not expressly set forth within this Agreement. No modification or amendment of any provision of this Agreement shall be valid or effective unless made in a writing referencing this Agreement and signed by a duly authorized officer of each Party.

**11.6 Governing Law.** This Agreement shall be governed by and interpreted in accordance with the laws of the State of New York, excluding application of any conflict of laws principles.

**11.7 Notices and Deliveries.** Any notice, request, approval or consent required or permitted to be given under this Agreement shall be in writing and shall be deemed to have been sufficiently given if and only if delivered in person, by email or by express courier service to the Party to which it is directed at its physical or email address shown below or such other physical or email address as such Party shall have last given by such written notice to the other Party.

If to CTI, addressed to:

Checkpoint Therapeutics, Inc.  
3 Columbus Circle, 15<sup>th</sup> Floor  
New York, NY 10019  
Attention: Michael S. Weiss, Executive Chairman  
Email: msw@opuspointpartners.com

If to TGTX, addressed to:

TG Therapeutics, Inc.  
3 Columbus Circle, 15<sup>th</sup> Floor  
New York, NY 10019  
Attention: Sean Power, CFO  
Email: sp@tgtxinc.com

**11.8 Waiver.** No waiver of any provision of this Agreement shall be valid or effective unless made in a writing referencing this Agreement and signed by a duly authorized officer of the waiving Party. A waiver by a Party of any of the terms and conditions of this Agreement in any instance shall not be deemed or construed to be a waiver of such term or condition for the future, or of any other term or condition hereof.

**11.9 Rights and Remedies are Cumulative.** Except to the extent expressly set forth herein, all rights, remedies, undertakings, obligations and agreements contained in or available upon violation of this Agreement shall be cumulative and none of them shall be in limitation of any other remedy or right authorized in law or in equity, or any undertaking, obligation or agreement of the applicable Party.

**11.10 Severability.** This Agreement is severable. When possible, each provision of this Agreement will be interpreted in such manner as to be effective and valid under applicable Law, but if any provision of this Agreement is held to be to any extent prohibited by or invalid under applicable Law, such provision will be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of this Agreement (or of such provision). The Parties shall make a good faith effort to replace the invalid or unenforceable provision with a valid one which in its economic effect is most consistent with the invalid or unenforceable provision.

**11.11 Third Party Beneficiaries.** Except for the rights of Indemnified Parties pursuant to Article IX hereof and the rights of Sublicensees set forth in Sections 2.3 and 10.6(d), the terms and provisions of this Agreement are intended solely for the benefit of each Party hereto and their respective successors or permitted assigns and it is not the intention of the Parties to confer third-party beneficiary rights upon any other person, including without limitation Sublicensees. The enforcement of any obligation of CTI under this Agreement shall only be pursued by TGTX or such Indemnified Party, and not Sublicensees (except as set forth in Sections 2.3 and 10.6(d)).

**11.12 No Implied License.** No right or license is granted to TGTX hereunder by implication, estoppel, or otherwise to any know-how, patent or other intellectual property right owned or controlled by CTI or its Affiliates, except by an express license granted hereunder. No right or license is granted to CTI hereunder by implication, estoppel, or otherwise to any know-how, patent or other intellectual property right owned or controlled by TGTX or its Affiliates, except by an express license granted hereunder.

**11.13 No Right of Set-Off.** Except as expressly provided in Article 5 of this Agreement, TGTX shall not have a right to set-off any royalties, milestones or other amount due to CTI under this Agreement against any damages incurred by TGTX for a breach by CTI of this Agreement.

**11.14 Equitable Relief.** Each Party recognizes that the covenants and agreements herein and their continued performance as set forth in this Agreement are necessary and critical to protect the legitimate interests of the other Party, that the other Party would not have entered into this Agreement in the absence of such covenants and agreements and the assurance of continued performance as set forth in this Agreement, and that a Party's breach or threatened breach of such covenants and agreements may cause the opposed Party irreparable harm and significant injury, the amount of which will be extremely difficult to estimate and ascertain, thus potentially making any remedy at law or in damages inadequate. Therefore, each Party agrees that an opposed Party shall be entitled to seek specific performance, an order restraining any breach or threatened breach of Article VII and all other provisions of this Agreement, and any other equitable relief (including but not limited to temporary, preliminary and/or permanent injunctive relief). This right shall be in addition to and not exclusive of any other remedy available to such other Party at law or in equity.

**11.15 Interpretation.** The language used in this Agreement is the language chosen by the Parties to express their mutual intent, and no provision of this Agreement shall be interpreted for or against a Party because that Party or its attorney drafted the provision.

**11.16 Construction.** The words “include,” “includes” and “including” shall be deemed to be followed by the phrase “without limitation.” All references herein to Articles, Sections and Schedules shall be deemed references to Articles and Sections of, and Schedules to, this Agreement unless the context shall otherwise require.

**11.17 Counterparts.** This Agreement may be executed in counterparts, each of which will be deemed an original, and all of which together will be deemed to be one and the same instrument. A facsimile or a portable document format (.pdf) copy of this Agreement, including the signature pages, will be deemed an original.

*[the remainder of this page has been left blank intentionally]*

**IN WITNESS WHEREOF**, the Parties have caused this Collaboration Agreement to be executed and delivered by their respective duly authorized officers as of the day and year first above written.

**CHECKPOINT THERAPEUTICS, INC.**

By: */s/* \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

**TG THERAPEUTICS, INC.**

By: */s/* \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

**CERTIFICATION OF PERIODIC REPORT PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Michael S. Weiss, certify that:

1. I have reviewed this quarterly report on Form 10-Q of TG Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 11, 2015

/s/ Michael S. Weiss

Michael S. Weiss

Executive Chairman, Interim Chief Executive Officer and President

Principal Executive Officer

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## CERTIFICATION OF PERIODIC REPORT PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Sean A. Power, certify that:

1. I have reviewed this quarterly report on Form 10-Q of TG Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 11, 2015

/s/ Sean A. Power

Sean A. Power

Chief Financial Officer

Principal Financial and Accounting Officer

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**STATEMENT OF CHIEF EXECUTIVE OFFICER OF  
TG THERAPEUTICS, INC.  
PURSUANT TO 18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the quarterly report of TG Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended March 31, 2015 as filed with the Securities and Exchange Commission (the "Report"), I, Michael S. Weiss, 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, that, based on my knowledge:

- 1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- 2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 11, 2015

/s/ Michael S. Weiss

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Michael S. Weiss

Executive Chairman, Interim Chief Executive Officer and President

Principal Executive Officer

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**STATEMENT OF CHIEF FINANCIAL OFFICER OF  
TG THERAPEUTICS, INC.  
PURSUANT TO 18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the quarterly report of TG Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended March 31, 2015 as filed with the Securities and Exchange Commission (the "Report"), I, Sean A. Power, 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, that, based on my knowledge:

- 1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- 2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 11, 2015

/s/ Sean A. Power

Sean A. Power

Chief Financial Officer

Principal Financial and Accounting Officer

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