UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended June 30, 2014

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	**36-3898269**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

3 Columbus Circle, 15th 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 x 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).
x 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 38,120,655 shares of the registrant's common stock, $0.001 par value, outstanding as of July 21, 2014.

TG THERAPEUTICS, INC.
FORM 10-Q
FOR THE QUARTER ENDED JUNE 30, 2014

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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, (“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;
- 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;
- availability 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;
- volatility of stock price;
- 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

	June 30, 2014 (Unaudited)	December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	$ 37,077,977	$ 40,485,466
Short-term investment securities	7,959,652	—
Interest receivable	74,682	27,169
Prepaid research and development	3,976,742	1,742,824
Other current assets	197,855	47,804
Total current assets	49,286,908	42,303,263
Long-term investment securities	6,110,309	4,918,897
Equipment, net	7,326	5,718
Goodwill	799,391	799,391
Other assets	98,365	85,121
Total assets	$ 56,302,299	$ 48,112,390
Liabilities and equity		
Current liabilities:		
Notes payable, current portion	$ 159,214	$ 677,778
Accounts payable and accrued expenses	1,899,389	4,764,502
Accrued compensation	395,500	532,500
Current portion of deferred revenue	152,381	152,381
Interest payable	—	190,017
Total current liabilities	2,606,484	6,317,178
Deferred revenue, net of current portion	1,600,000	1,676,191
Notes payable, less current portion, at fair value	—	64,529
Total liabilities	4,206,484	8,057,898
Commitments and contingencies		
Equity:		
Preferred stock, $0.001 par value per share (10,000,000 shares authorized, 0 issued and outstanding as of June 30, 2014 and December 31, 2013)	—	—
Common stock, $0.001 par value per share (150,000,000 and 500,000,000 shares authorized, 38,161,964 and 34,336,235 shares issued, 38,120,655 and 34,294,926 shares outstanding at June 30, 2014 and December 31, 2013, respectively)	38,162	34,336
Contingently issuable shares	6	6
Additional paid-in capital	111,229,666	79,658,490
Treasury stock, at cost, 41,309 shares at June 30, 2014 and December 31, 2013	(234,337)	(234,337)
Accumulated deficit	(58,937,682)	(39,404,003)
Total equity	52,095,815	40,054,492
Total liabilities and equity	$ 56,302,299	$ 48,112,390

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

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

	Three months ended June 30,		Six months ended June 30,	
	2014	**2013**	**2014**	**2013**
License revenue	$ 38,095	$ 38,095	$ 76,190	$ 76,190
Costs and expenses:				
Research and development:				
Noncash stock expense associated with in-licensing agreement	1,211,250	—	1,211,250	—
Noncash compensation	3,300,111	366,168	5,201,721	720,871
Other research and development	2,336,771	4,661,455	4,845,029	5,876,657
Total research and development	6,848,132	5,027,623	11,258,000	6,597,528
General and administrative:				
Noncash compensation	4,438,735	1,007,600	6,768,563	2,538,374
Other general and administrative	706,725	631,637	1,610,249	1,283,094
Total general and administrative	5,145,460	1,639,237	8,378,812	3,821,468
Total costs and expenses	11,993,592	6,666,860	19,636,812	10,418,996
Operating loss	(11,955,497)	(6,628,765)	(19,560,622)	(10,342,806)
Other (income) expense:				
Interest income	(12,727)	(1,177)	(26,201)	(2,679)
Other income	—	—	(95,427)	—
Interest expense	234,787	240,014	461,127	471,486
Change in fair value of notes payable	(191,127)	(283,050)	(366,442)	(553,450)
Total other (income) expense	30,933	(44,213)	_(26,943)	(84,643)
Consolidated net loss	$ (11,986,430)	$ (6,584,552)	$ (19,533,679)	$ (10,258,163)
Basic and diluted net loss per common share	$ (0.36)	$ (0.29)	$ (0.62)	$ (0.46)
Weighted average shares used in computing basic and diluted net loss per common share	32,985,130	22,483,394	31,546,060	22,213,335

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

TG Therapeutics, Inc.
Condensed Consolidated Statement of Equity
for the six months ended June 30, 2014 (Unaudited)

	Preferred stock		Common stock		Contingently issuable	Additional paid-in	Treasury Stock		Accumulated	
	Shares	Amount	Shares	Amount	shares	capital	Shares	Amount	Deficit	Total
Balance at January 1, 2014	—	$ —	34,336,235	$ 34,336	$ 6	$ 79,658,490	41,309	$ (234,337)	$ (39,404,003)	$ 40,054,492
Issuance of common stock in connection with exercise of warrants			700,230	700		1,601,360				1,602,060
Issuance of restricted stock			297,690	298		(298)				—
Issuance of common stock in public offering (net of offering costs of $1,344,440)			2,702,809	2,703		16,788,705				16,791,408
Compensation in respect of restricted stock granted to employees, directors and consultants						11,970,284				11,970,284
Common stock issued in connection with in-licensing agreement			125,000	125		1,211,125				1,211,250
Net loss									(19,533,679)	(19,533,679)
Balance at June 30, 2014	—	$ —	38,161,964	$ 38,162	$ 6	$ 111,229,666	41,309	$ (234,337)	$ (58,937,682)	$ 52,095,815

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

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

	Six months ended June 30,	
	2014	**2013**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Consolidated net loss	$ (19,533,679)	$ (10,258,163)
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	11,970,284	3,259,245
Noncash stock expense associated with in-licensing agreement	1,211,250	—
Depreciation	1,558	309
Amortization of premium on investment securities	66,943	—
Change in fair value of notes payable	94,685	(114,282)
Changes in assets and liabilities:		
(Increase) decrease in other current assets	(2,383,969)	1,267,843
Increase in accrued interest receivable	(47,513)	—
Increase in other assets	(13,244)	(90,058)
(Decrease) increase in accounts payable and accrued expenses	(3,002,113)	1,217,871
(Decrease) increase in interest payable	(94,590)	32,318
Decrease in deferred revenue	(76,191)	(76,190)
Net cash used in operating activities	(11,902,006)	(4,761,107)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of equipment	(3,165)	(1,672)
Investment in held-to-maturity long-term securities	(6,127,539)	—
Investment in held-to-maturity short-term securities	(3,090,469)	—
Net cash used in investing activities	(9,221,173)	(1,672)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from the exercise of warrants	1,602,060	1,723,736
Payment of notes payable	(677,778)	—
Proceeds from sale of common stock, net	16,791,408	—
Net cash provided by financing activities	17,715,690	1,723,736
NET DECREASE IN CASH AND CASH EQUIVALENTS	(3,407,489)	(3,039,043)
Cash and cash equivalents at beginning of period	40,485,466	16,455,995
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 37,077,977	$ 13,416,952

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.) 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 cancer and autoimmune diseases. We aim to acquire rights to these technologies by licensing or otherwise acquiring an ownership interest, funding their research and development, and eventually either out-licensing or bringing the technologies to market. Currently, we are developing two therapies targeting hematological malignancies:

- TG-1101 (ublituximab) a novel, glycoengineered monoclonal antibody that targets a specific and unique epitope on the CD20 antigen found on mature B-lymphocytes; and
- TGR-1202, an orally available PI3K delta inhibitor.

We are also developing a portfolio of inhibitors of IRAK-4 (interleukin-1 receptor-associated kinase 4), which is currently in pre-clinical development.

The accompanying unaudited condensed consolidated financial statements were prepared in accordance with U.S. generally accepted accounting principles ("GAAP") for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. 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 consolidated financial statements have been included. Nevertheless, these 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, 2013. The results of operations for the three and six months ended June 30, 2014 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 June 30, 2014, we have an accumulated deficit of $58,937,682.

Our major sources of cash have been proceeds from the private placement and public offering of equity securities, the upfront payment from our Sublicense Agreement with Ildong Pharmaceutical Co. Ltd. ("Ildong"), and warrant exercises. 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.

In March 2014, we raised approximately $16.8 million, net of underwriting discounts and offering expenses of approximately $1.3 million, in an underwritten public offering. See Note 5 for additional information.

As of June 30, 2014, we had $51,222,620 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 approximately 24 months from June 30, 2014. 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 operations, including the commercialization of any of our drug candidates.

Our Common Stock is quoted on the Nasdaq Capital Market and trades under the symbol "TGTX."

Recently Issued Accounting Standards

In May 2014, the FASB issued an update to ASC 606, Revenue from Contracts with Customers. This update to ASC 606 provides a five-step process to determine when and how revenue is recognized. The core principle of the guidance is that a Company should recognize revenue upon transfer of promised goods or services to customers in an amount that reflects the expected consideration to be received in exchange for those goods or services. This update to ASC 606 will also result in enhanced disclosures about revenue, providing guidance for transactions that were not previously addressed comprehensively, and improving guidance for multiple-element arrangements. This update to ASC 606 is effective for the Company beginning in fiscal 2017. The Company is currently evaluating the impact of this update on its consolidated financial statements.

On June 10, 2014, FASB issued Accounting Standards Update No. 2014-10, Development Stage Entities: Elimination of Certain Financial Reporting Requirements. The update removes the definition of a development stage entity from FASB ASC 915 and eliminates the requirement for development stage entities to present inception-to-date information on the statements of operations, cash flows and stockholders' equity. The Company early adopted this standard for the period covered by the report herein.

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

Cash and Cash Equivalents

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

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 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 to non-employee directors as compensation for service as 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, 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.

Basic and Diluted Net Income (Loss) Per Share of Common Stock

Basic net income (loss) per share of Common Stock is calculated by dividing net income (loss) applicable to the Common Stock by the weighted-average number of the Common Stock outstanding for the period. Diluted net loss per share of Common Stock is the same as basic net income (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 the Company 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 9,702,633 and 10,114,847 at June 30, 2014 and 2013, respectively. During the three and six months ended June 30, 2014 and 2013, the Company 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

	June 30, 2014	December 31, 2013
Money market funds	$ 6,361,558	$ 554,069
Checking and bank deposits	30,716,419	39,931,397
Total	$ 37,077,977	$ 40,485,466

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 June 30, 2014 and December 31, 2013:

	June 30, 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 June 2015) (held-to-maturity)	$ 7,959,652	$ 3,533	$ 156	$ 7,963,029
Long-term investments:				
Obligations of domestic governmental agencies (maturing between July 2015 and September 2015) (held-to-maturity)	$ 6,110,309	$ 368	$ 1,017	$ 6,109,660

	December 31, 2013			
	Amortized cost, as adjusted	Gross unrealized holding gains	Gross unrealized holding losses	Estimated fair value
Long-term investments:				
Obligations of domestic governmental agencies (maturing between January 2015 and April 2015) (held-to-maturity)	$ 4,918,897	$ —	$ 650	$ 4,918,247

NOTE 4 – FAIR VALUE MEASUREMENTS

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 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 June 30, 2014 and December 31, 2013, the fair values of cash and cash equivalents, and notes and interest payable approximate their carrying value.

Upon the merger between the Company (then known as Manhattan Pharmaceuticals, Inc., "Manhattan") and 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. The Company has 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 reverse merger transaction (the "Exchange Transaction") with TG Biologics, Inc. ("TGBio") in December 2011, the Company 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 Exchange Transaction, and $18,614,000 at December 31, 2013 and $19,075,000 at June 30, 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. No payments have been made on the 5% Notes as of June 30, 2014.

We elected the fair value option for valuing the 5% Notes upon the Exchange Transaction with TG Bio. 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.

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 June 30, 2014 and December 31, 2013. The assumptions, assessments and projections of future revenues are subject to uncertainties, are 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 June 30, 2014 and December 31, 2013:

	Financial liabilities at fair value as of June 30, 2014			
	Level 1	**Level 2**	**Level 3**	**Total**
5% Notes	$ —	$ —	$ 159,214	$ 159,214
Totals	$ —	$ —	$ 159,214	$ 159,214

	Financial liabilities at fair value as of December 31, 2013			
	Level 1	**Level 2**	**Level 3**	**Total**
5% Notes	$ —	$ —	$ 64,529	$ 64,529
Totals	$ —	$ —	$ 64,529	$ 64,529

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 six months ended June 30, 2014:

Fair value at December 31, 2013	$	64,529
Interest accrued on face value of 5% Notes		461,127
Change in fair value of Level 3 liabilities		(366,442)
Fair value at June 30, 2014	$	159,214

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, the Company 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. At the annual shareholder meeting on June 6, 2014, an amendment to the Company's Certificate of Incorporation to decrease its authorized share capital by 350,000,000 shares from 500,000,000 to 150,000,000 was approved.

On March 11, 2014, we announced the pricing of an underwritten sale of 2,702,809 shares of our Common Stock at a price of $6.71 per share for gross proceeds of approximately $18.1 million. Total net proceeds from this offering were approximately $16.8 million, net of underwriting discounts and offering expenses of approximately $1.3 million. The shares were sold under a shelf registration statement on Form S-3 (File No. 333-189015) that was previously filed and declared effective by the SEC on June 17, 2013.

We currently have one shelf registration statement on Form S-3 filed and declared effective by the SEC (File No. 333-189015). Subsequent to the March 2014 offering, there remains available under this shelf registration statement up to approximately $117 million of Common Stock. We may offer the securities under our shelf registration statement 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 this shelf registration statement provides 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 810,103 shares at June 30, 2014.

Stock Options

The following table summarizes stock option activity for the six months ended June 30, 2014:

	Number of shares	Weighted-average exercise price	Weighted-average Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2013	46,591	$ 46.37	8.50	$ —
Granted	—	—		
Exercised	—	—		
Forfeited	—	—		
Expired	(359)	4,640.63		
Outstanding at June 30, 2014	46,232	$ 10.70	8.07	$ 229,540
Vested and expected to vest at June 30, 2014	37,232	$ 12.22	8.07	$ 184,630
Exercisable at June 30, 2014	37,232	$ 12.22	8.07	$ 184,630

As of June 30, 2014, the total compensation cost related to unvested time-based option awards not yet recognized was $0. This amount does not include, as of June 30, 2014, 9,000 non-employee options outstanding which are milestone-based and vest upon certain corporate milestones. Stock-based compensation will be measured and recorded if and when a milestone occurs.

Restricted Stock

Certain employees, directors and consultants have been awarded restricted stock under the 2012 Incentive Plan. The restricted stock vesting consists of milestone and time-based vesting provisions. The following table summarizes restricted share activity for the six months ended June 30, 2014:

	Number of Shares	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2013	7,034,957	$ 4.60
Granted	297,690	8.14
Vested	(502,124)	6.88
Forfeited	—	—
Outstanding at June 30, 2014	6,830,523	$ 4.65

Total expense associated with restricted stock grants was $11,717,774 during the six months ended June 30, 2014. As of June 30, 2014, there was approximately $6,749,000 of total unrecognized compensation cost related to unvested time based restricted stock, which is expected to be recognized over a weighted-average period of 1.5 years. The unrecognized compensation cost does not include, as of June 30, 2014, 1,663,460 shares of restricted stock outstanding which are milestone-based and vest upon certain corporate milestones; and 2,417,250 shares of restricted stock outstanding issued to non-employees. Milestone based noncash compensation expense will be measured and recorded if and when a milestone occurs.

Warrants

The following table summarizes warrant activity for the six months ended June 30, 2014:

	Warrants	Weighted-average exercise price	Aggregate Intrinsic Value
Outstanding at December 31, 2013	5,718,947	$ 1.34	$ 14,809,030
Issued	—	—	
Exercised	(700,230)	2.29	
Expired	(9,795)	20.92	
Outstanding at June 30, 2014	5,008,922	$ 1.17	$ 41,163,640

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. The Company did not grant any stock options during the six months ended June 30, 2014.

The following table summarizes stock-based compensation expense information about stock options and restricted stock for the three and six months ended June 30, 2014:

	Three months ended June 30, 2014	Six months ended June 30, 2014
Stock-based compensation expense associated with restricted stock	$ 7,486,336	$ 11,717,774
Stock-based compensation expense associated with option grants	252,510	252,510
	$ 7,738,846	$ 11,970,284

NOTE 6 – NOTES PAYABLE

The following is a summary of notes payable:

	June 30, 2014			December 31, 2013		
	Current portion, net	Non-current portion, net	Total	Current portion, net	Non-current portion, net	Total
Convertible 5% Notes Payable	$ 159,214	$ -	$ 159,214	$ -	$ 64,529	$ 64,529
ICON Convertible Note	-	-	-	677,778	-	677,778
Total	$ 159,214	$ -	$ 159,214	$ 677,778	$ 64,529	$ 742,307

We assumed the preceding notes payable as the result of the Exchange Transaction between the Company and TG Bio. Accordingly, a valuation using the guidance in the accounting literature for business combinations (ASC 805) was performed and these notes have been presented 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 set forth in 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 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 $19,075,000 at June 30, 2014 and $18,614,000 at December 31, 2013. 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 June 30, 2014.

ICON Convertible Note Payable

As of December 31, 2013 the principal amount of the Amended ICON Note was $677,778, of which the entire balance had been classified as current and was reflected as notes payable, current portion, in the accompanying consolidated balance sheets. Interest payable on the Amended ICON Note was $190,017 as of December 31, 2013, and was reflected as interest payable in the accompanying consolidated balance sheets. In January 2014, we entered into a settlement and release agreement with ICON related to this note, under which we agreed to pay $772,369 in full settlement of the principal and interest due on this note, resulting in a gain of $95,427.

NOTE 7 – LICENSE AGREEMENTS

IRAK-4

On June 23, 2014, we entered into an exclusive licensing agreement with Ligand Pharmaceuticals Incorporated ("Ligand") for the development and commercialization of Ligand's interleukin-1 receptor associated kinase-4 ("IRAK-4") inhibitor technology, which currently is in preclinical development for potential use against certain cancers and autoimmune diseases. IRAK-4 is a serine/threonine protein kinase that is a key downstream signaling component of the interleukin-1 receptor and multiple toll-like receptors.

Under the terms of the license agreement, Ligand received 125,000 shares of our Common Stock as an upfront license fee. Ligand will also be eligible to receive maximum potential milestone payments of approximately $207 million upon the achievement of specific clinical, regulatory and commercial milestone events. Additionally, Ligand will be entitled to royalties on our future net sales of licensed products containing IRAK-4 inhibitors. The basic royalty rate for licensed products covered by Ligand's issued patents will be 6% for annual sales of up to $1 billion and 9.5% for annual sales in excess of that threshold.

In connection with the license agreement, we recognized $1,211,250 of noncash research and development expense during the three months ended June 30, 2014 in connection with the issuance of the above mentioned Common Stock.

Additionally, Opus Point Partners, LLC, who identified the opportunity and advised the Company on the transaction, will also be entitled to receive a 1% royalty for annual sales of up to $1 billion. Michael S. Weiss, our Executive Chairman and Interim Chief Executive Officer, is a Managing Member of Opus Point Partners, LLC.

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 withheld, 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 $76,000 for each of the six months ended June 30, 2014 and 2013, and, at June 30, 2014 and December 31, 2013, have deferred revenue of approximately $1,752,381 and $1,829,000, respectively, associated with this $2,000,000 payment (approximately $152,000 of which has been classified in current liabilities at June 30, 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 “License Agreement”). In connection with the 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.

Under the terms of the License Agreement, we utilize LFB Group for certain development and manufacturing services. We incurred approximately $183,000 and $4,035,000 in expenses for such services during the six months ended June 30, 2014 and 2013, respectively, which have been included in other research and development expenses in the accompanying consolidated statements of operations. As of June 30, 2014 and December 31, 2013, we had approximately $760,000 and $1,745,000, respectively, recorded in accounts payable related to the 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 June 30, 2014 and December 31, 2013, we recorded $2,810,175 and $1,629,340, 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 agree to share a rented facility and costs for certain other services. Michael S. Weiss, our Executive Chairman and Interim Chief Executive Officer, is a Managing Member of Opus. During the six months ended June 30, 2014, we incurred expenses of approximately $40,000, principally for rent, related to this agreement.

As discussed in Note 7 above, in connection with the licensing agreement with Ligand Pharmaceuticals, Opus Point Partners, LLC, who identified the opportunity and advised the Company on the transaction, will be entitled to receive a 1% royalty for annual sales of up to $1 billion. Michael S. Weiss, our Executive Chairman and Interim Chief Executive Officer, is a Managing Member of Opus Point Partners, LLC.

NOTE 9 – SUBSEQUENT EVENTS

Stockholder Rights Plan

On July 18, 2014, we adopted a stockholder rights plan. The stockholder rights plan is embodied in the Stockholder Protection Rights Agreement dated as of July 18, 2014 (the "Rights Agreement"), between the Company and American Stock Transfer & Trust Company, LLC, as rights agent (the "Rights Agent").

Accordingly, the Board of Directors declared a distribution of one right (a "Right") for each outstanding share of the Common Stock, to stockholders of record at the close of business on July 28, 2014, for each share of Common Stock issued (including shares distributed from treasury) by the Company thereafter and prior to the Separation Time (as defined in the Rights Agreement), and for certain shares of Common Stock issued after the Separation Time. Following the Separation Time, each Right entitles the registered holder to purchase from the Company one one-thousandth (1/1,000) of a share of Series A Junior Participating Preferred Stock, par value $0.001 per share (the "Preferred Stock"), at a purchase price of $100.00 (the "Exercise Price"), subject to adjustment. The description and terms of the Rights are set forth in the Rights Agreement. Each one one-thousandth of a share of Preferred Stock has substantially the same rights as one share of Common Stock. Subject to the terms and conditions of the Rights Agreement, Rights become exercisable ten days after the public announcement that a "Person" has become an "Acquiring Person" (as each such term is defined in the Rights Agreement). Any Rights held by an Acquiring Person are void and may not be exercised.

If a Person becomes an Acquiring Person, all holders of Rights, except the Acquiring Person, may purchase at the Right's then-current exercise price, the Company's common stock having a market value equal to twice the exercise price. Moreover, at any time after a Person becomes an Acquiring Person (unless such Person acquires 50 percent or more of the common stock of the Company then outstanding, as more fully described in the Rights Agreement), the Board of Directors may exchange all (but not less than all) of the then outstanding Rights (other than rights owned by such Person, which would have become void) for shares of Common Stock at an exchange ratio of one share of Common Stock per Right, appropriately adjusted in order to protect the interests of holders of Rights.

The Rights Agreement was approved by our Board of Directors on July 18, 2014. The Rights will expire at the close of business on the ten year anniversary of the Date of Adoption, unless earlier exchanged or terminated by the Company.

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, 2013.

OVERVIEW

We are a biopharmaceutical company focused on the acquisition, development and commercialization of novel treatments for cancer and autoimmune diseases. We aim to acquire rights to these technologies by licensing or otherwise acquiring an ownership interest, funding their research and development and eventually either out-licensing or bringing the technologies to market. Currently, we are developing two therapies for hematologic malignancies: TG-1101 (ublituximab), a novel, glycoengineered monoclonal antibody that targets a specific and unique epitope on the CD20 antigen found on mature B-lymphocytes; and TGR-1202, an orally available PI3K delta inhibitor. We are also developing a portfolio of inhibitors of IRAK4 (interleukin-1 receptor-associated kinase 4, which is currently in pre-clinical development.

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 Pharmaceutical Co. Ltd ("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®, the leading anti-CD20 monoclonal antibody, which had worldwide sales in 2013 of approximately $8 billion.

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"). A two part first-in-human Phase I clinical trial was first completed in France in which TG-1101 was evaluated in relapsed or refractory CLL patients at doses as high as 450mg per infusion. Preliminary results from Part 2 of this study were presented at the 53rd Annual American Society of Hematology Meeting in December 2011 and again at the 2013 European Hematology Annual Meeting. Subsequently, a single-agent Phase I study was undertaken in the US enrolling patients with both NHL and CLL, dosing patients up to 1200mg per infusion. 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™), a BTK inhibitor, for patients with CLL and Mantle Cell Lymphoma (MCL); and
- TG-1101 in combination with TGR-1202, the Company's development stage PI3Kδ inhibitor, for patients with CLL and NHL.

Prior to commencing the above combination trials, we studied the combination of TG-1101 and lenalidomide. Additional combinations studies with novel agents may be undertaken in the future.

Manufacturing of ublituximab is currently performed by our partner, LFB Biotechnologies.

Four Phase I/II trials with TG-1101 are currently ongoing, as follows:

Single Agent TG-1101 in Relapsed/Refractory NHL & CLL

Our first US based trial, entitled "An Open Label Phase I/II Trial of the Efficacy and Safety of TG-1101 in Patients with B-cell Non-Hodgkin Lymphoma who have Relapsed or are Refractory After CD20 Directed Antibody Therapy," was launched in the 3rd quarter of 2012. As of July 2014, this trial has completed enrollment of 35 patients, including 12 patients in the dose escalation component and 23 patients in various expansion cohorts. All enrolled patients were relapsed or refractory to Rituxan® or a Rituxan® containing regimen, and in most cases multiple other lines of therapy. Dr. Owen O'Connor, Professor of Medicine and Director, Center for Lymphoid Malignancies at New York Presbyterian Columbia Medical Center is the Principal Investigator for the multi-center study.

Data from this study was presented at the 50th American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, IL, and is summarized below:

Safety and Tolerability

TG-1101 was well tolerated at all dose levels tested in the 35 patients evaluable for safety, with Day 1 infusion related reactions (IRR) being the most frequently reported adverse event. All IRR's were Grade 1 or 2 in severity, were manageable, and occurred more frequently in patients with CLL. Infusion times for the fourth and later infusions of TG-1101 averaged approximately 90 minutes.

Clinical Activity

The combined overall response rate (ORR) for the Phase 1 dose escalation component and expansion cohorts was 43% (30% PR, 13% CR) among the 30 rituximab relapsed/refractory patients evaluable for efficacy. TG-1101 displayed marked clinical activity as a single agent in a variety of lymphoma subtypes, reporting a 67% (4/6) response rate in patients with CLL and 44% (8/18) response rate in iNHL (22% CR, 22% PR). Responses were durable, with a median duration of progression free survival (PFS) among patients who achieved SD or better not yet reached, and a median PFS for all patients on study of 34 weeks (n=30).

TG-1101 in Combination with Lenalidomide for Relapsed/Refractory NHL & CLL

In December of 2012, we initiated our second US based clinical trial entitled "TG-1101-102: A Phase I/II Study of Ublituximab in Combination with Lenalidomide (Revlimid®) in Patients with B-Cell Lymphoid Malignancies who have Relapsed or are Refractory After CD20 Directed Antibody Therapy".

The trial was designed as a Phase I dose escalation study with the potential to enroll one or more expansion cohorts once the optimal dose was determined. All enrolled patients were relapsed or refractory to a prior anti-CD20 antibody containing regimen. The patients enrolled into this study were heavily pre-treated, most of which were refractory to Rituxan or a Rituxan-containing regimen. This multicenter trial was being led by Dr. Marshall Schreeder of the Clearview Cancer Institute in Huntsville, AL.

Enrollment in this study has been completed, with updated data from this study presented in June 2014 at the 19th Annual Congress of the European Hematology association (EHA) in Milan, Italy. The majority of adverse events observed in this study were grade 1/2 in severity and managed by dose reductions and delays, and a titrating regimen for lenalidomide. Responses were observed in this heavily refractory patient population (70% rituximab refractory and 30% were refractory to either a BTK inhibitor or PI3K inhibitor) with a > 90% median reduction in ALC was observed in patients with CLL following 1 Cycle of therapy.

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, PI3Kδ 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.

The trial, entitled "A Multi-center Phase I/Ib Study Evaluating the Efficacy and Safety of TG-1101 (Ublituximab), a novel Glycoengineered Anti-CD20 Monoclonal Antibody, in Combination with TGR-1202, a Novel PI3k Delta Inhibitor, in Patients with B-cell Malignancies," is enrolling CLL and NHL patients whose disease is relapsed from or refractory to prior therapies, including prior anti-CD20 monoclonal antibodies, PI3Kδ inhibitors, and/or BTK inhibitors. The MD Anderson Cancer Center is the lead center for the trial. Susan O'Brien, MD, Professor in the Department of Leukemia, is the Study Chair for the CLL patient group, and Nathan Fowler, MD, Assistant Professor and Co-Director of Clinical Research in the Department of Lymphoma, is the Study Chair for the NHL patient group.

Preliminary data from this study was presented at the at the 2014 Pan Pacific Lymphoma Conference in Kohala Coast, Hawaii. and is summarized below:

Safety and Tolerability

TG-1101 in combination with TGR-1202 appeared to be well tolerated in the 21 patients evaluable for safety, with day 1 infusion related reactions (IRR) being the most frequently reported adverse event. All IRR events were manageable without dose reductions, and all but one event was Grade 1 or 2 in severity. Other observed adverse events included neutropenia, nausea, and diarrhea, with neutropenia being the only Grade 3/4 adverse event reported in > 10% of patients (24%). One CLL patient required a dose delay for neutropenia in Cycle 1, which met the criteria for a dose-limiting toxicity (DLT) necessitating additional patients to be enrolled into the CLL Cohort 1. No additional DLT's have been observed with full enrollment completed in the first two dose cohorts.

Clinical Activity

Of the 21 patients evaluable for safety, 15 (5 CLL, 5 DLBCL, 4 FL and 1 Richter's) were also evaluable for efficacy, with the remaining patients too early for assessment. A breakdown of the clinical activity is as follows:

- Of the 5 CLL/SLL patients evaluable, 4 achieved a PR per the IWCLL (Hallek, et. al.) or Cheson criteria (SLL) at first efficacy assessment. The remaining patient, a CLL patient with both 17p and 11q del, achieved SD with a 44% nodal reduction at first assessment and >50% reduction in ALC and remains on study. In addition, all 5 patients (100%) achieved a > 50% reduction in ALC by the first efficacy assessment.
- Of the 13 NHL or Richter's patients enrolled to date, 10 were evaluable for efficacy (5 DLBCL, 4 FL and 1 Richter's). The disease control rate (Stable Disease or better) at first efficacy assessment was 90% (9 of 10), in this population of high risk relapsed/refractory patients. In DLBCL, 2 of 5 patients had a partial response, including one GCB-subtype that was refractory to prior therapy.

Patients in the NHL/Richter's group were heavily pre-treated, with 50% refractory to their prior treatment regimen. In the DLBCL group, patients had a median of 3 prior lines and 3 of the 5 patients had the GCB subtype, with one patient classified as "triple-hit" lymphoma (overexpression of BCL2, BCL6 and MYC rearrangements). In the Follicular Lymphoma group, patients had a median of 6 prior lines of therapy and for the entire study population patients had a median of 2 prior lines of Rituxan-based therapy with a high of 7 prior lines of Rituxan-based therapy.

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 (IMBRUVICA™) 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 which was recently granted approval by the U.S. Food and Drug Administration (FDA).

The trial, entitled "A Multi-center Phase 2 Study with Safety Run-in Evaluating the Efficacy and Safety of Ublituximab in Combination with Ibrutinib in Patients with Select B-Cell Malignancies," is enrolling patients with CLL and MCL who are eligible to receive ibrutinib. Jeff Sharman, MD, Medical Director for Hematology Research, US Oncology Network, is the Study Chair for the CLL patient group, while Owen A. O'Connor, MD, PhD, Professor and Director of the Center for Lymphoid Malignancies, Columbia University Medical Center is the Study Chair for the MCL patient group.

Preliminary data from this study was presented at the 19th Annual Congress of the European Hematology association (EHA) in Milan, Italy and is summarized below:

Safety and Tolerability

TG-1101 in combination with ibrutinib was well tolerated in the 28 patients evaluable for safety, with Day 1 infusion related reactions (IRR) being the most frequently reported adverse event for TG-1101. All but one IRR were Grade 1 or 2 in severity and were manageable without dose reductions. Ibrutinib related adverse events included diarrhea and rash with one patient discontinuing treatment due to ibrutinib related diarrhea (only patient to discontinue from the study at the time of data presentation).

Clinical Activity

The overall response rate (ORR) for the first 10 evaluable patients was 100%. The breakdown of responses is as follows:

- CLL patients (including 4 with high risk cytogenetics such as 17p del and 11q del): 100% (7/7) achieved a partial response (PR); and
- MCL patients: 100% (3/3) achieved a response (1 CR and 2 PRs).

TGR-1202

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.

TGR-1202 is being developed jointly with Rhizen Pharmaceuticals, S A, a Switzerland based drug discovery and biotechnology company. We and Rhizen are jointly developing the product on a worldwide basis, excluding India, initially focusing on indications in the area of hematologic malignancies and autoimmune disease. Rhizen holds rights to manufacture and supply the product, we have responsibility for all clinical and regulatory development for TGR-1202 globally.

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™) and chlorambucil in patients with previously untreated CLL; and
- TGR-1202 in combination with the anti-CD30 antibody drug conjugate, brentuximab vedotin (Adcetris®), in patients with relapsed or refractory Hodgkin's lymphoma.

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. Enrollment is open to patients with relapsed or refractory NHL, CLL, Peripheral T-Cell Lymphoma, and Hodgkin's Lymphoma.

Interim data from this ongoing study was presented at the 50th American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, IL in May 2014 with updated data presented again at the 19th Annaul Congress of the European Hematology Association (EHA). As of the data cutoff for this presentation, 40 patients had been evaluated with single agent TGR-1202 at doses ranging from 50 mg to 1800 mg QD, including expansion cohorts evaluating fed state dosing of TGR-1202 opened at doses of 800 mg and 1200 mg QD. A summary of the data presented is below:

Safety and Tolerability

TGR-1202 appears to be well-tolerated with no dose-related trends in adverse events observed and no MTD reached to date. Grade 3 events were limited. Notably, of the 40 patients evaluable for safety, no drug related transaminase elevations or events of colitis have been observed, with several patients on daily TGR-1202 for over 1 year.

Clinical Activity

Clinical activity was observed in patients with CLL treated at doses ≥ 800 mg with all (9/9) patients exhibiting significant nodal reductions. Eight of nine evaluable patients (89%) exhibited a nodal response (> 50% reduction in nodal size) of which four of these patients achieved a partial response per the IWCLL 2008 criteria. The remaining patient had stable disease and exhibited a > 40% reduction in nodal size at first efficacy assessment and remained on study awaiting upcoming efficacy assessments.

Among all disease types, 26 patients had been treated at doses ≥ 800 mg and were evaluable for efficacy (including patients who started at lower doses and were escalated), with 20/26 (77%) achieving a reduction in nodal size with TGR-1202. In addition to CLL, responses were observed in patients with follicular lymphoma and Hodgkin's lymphoma.

In May 2014, we announced that a micronized (smaller particle size) formulation of TGR-1202 had demonstrated improved absorption in healthy human testing. A second healthy human study also demonstrated improved absorption with fed-state dosing over dosing in the fasting state, which has to date been utilized in this ongoing study. Subsequently, the dose escalation portion of this study has been reinitiated at a dose of 200 mg of the micronized form of TGR-1202 in the fed state. Enrollment into the dose escalation portion of the study is ongoing, dosing patients at 400 mg of the micronized form of TGR-1202 as of July 2014.

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, and in combination with the anti-CD30 antibody drug conjugate, brentuximab vedotin, in patients with relapsed or refractory Hodgkin's lymphoma. It is anticipated that preliminary results from these studies will be presented at future medical conferences.

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 June 30, 2014 and June 30, 2013

License Revenue. License revenue was $38,095 for the three months ended June 30, 2014 and 2013. License revenue for the three months ended June 30, 2014 and 2013 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 the Company will have certain ongoing responsibilities under the sublicense agreement.

Noncash Stock Expense Associated with In-Licensing Agreement (Research and Development). Noncash stock expense associated with in-licensing agreement (research and development) amounted to $1,211,250 for the three months ended June 30, 2014, as compared to $0 during the comparable period in 2013. The expense during the three months ended June 30, 2014 was recorded in conjunction with the stock issued to Ligand Pharmaceuticals as an upfront payment for the license to the IRAK-4 inhibitors program.

Noncash Compensation Expense (Research and Development). Noncash compensation expense (research and development) related to equity incentive grants totaled $3,300,111 for the three months ended June 30, 2014, as compared to $366,168 during the comparable period in 2013. The increase in noncash compensation expense was primarily related to milestone-based vesting of restricted stock grants to non-executive personnel during the period ended June 30, 2014.

Other Research and Development Expenses. Other research and development expenses decreased by $2,324,684 to $2,336,771 for the three months ended June 30, 2014, as compared to $4,661,455 for the three months ended June 30, 2013. The decrease in other research and development expenses was due primarily to a decrease of approximately $3,042,000 for research and development expenses related to TG-1101, offset by an increase of approximately $717,000 for research and development expenses related to TGR-1202. The decrease in other research and development expenses related to TG-1101 was related to the timing of manufacturing costs. We expect our other research and development costs to increase modestly for the remainder of 2014 as enrollment of additional patients increases in our clinical trials.

Noncash Compensation Expense (General and Administrative). Noncash compensation expense (general and administrative) related to equity incentive grants increased by $3,431,135 to $4,438,735 for the three months ended June 30, 2014, as compared to $1,007,600 for the three months ended June 30, 2013. The increase in noncash compensation expense was primarily related to milestone-based vesting of restricted stock grants to personnel during the period ended June 30, 2014.

Other General and Administrative Expenses. Other general and administrative expenses increased by $75,088 to $706,725 for the three months ended June 30, 2014, as compared to $631,637 for the three months ended June 30, 2013. The increase was due primarily to Nasdaq listing fees and legal fees. We expect our other general and administrative expenses to remain at a comparable level for the remainder of 2014.

Other (Income) Expense. Other income decreased by $75,146 to $30,933 of expenses for the three months ended June 30, 2014, as compared to $(44,213) of income for the three months ended June 30, 2013. The decrease is mainly due to the decrease in the change in the fair value of notes payable, partially offset by interest income.

Six months ended June 30, 2014 and June 30, 2013

License Revenue. License revenue was $76,190 for the six months ended June 30, 2014 and 2013. License revenue for the six months ended June 30, 2014 and 2013 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 the Company will have certain ongoing responsibilities under the sublicense agreement.

Noncash Stock Expense Associated with In-Licensing Agreement (Research and Development). Noncash stock expense associated with in-licensing agreement (research and development) amounted to $1,211,250 for the six months ended June 30, 2014, as compared to $0 during the comparable period in 2013. The expense during the six months ended June 30, 2014 was recorded in conjunction with the stock issued to Ligand Pharmaceuticals as an upfront payment for the license to the IRAK-4 inhibitors program.

Noncash Compensation Expense (Research and Development). Noncash compensation expense (research and development) related to equity incentive grants totaled $5,201,721 for the six months ended June 30, 2014, as compared to $720,871 during the comparable period in 2013. The increase in noncash compensation expense was primarily related to milestone-based vesting of restricted stock grants to non-executive personnel during the period ended June 30, 2014.

Other Research and Development Expenses. Other research and development expenses decreased by $1,031,628 to $4,845,029 for the six months ended June 30, 2014, as compared to $5,876,657 for the six months ended June 30, 2013. The decrease in other research and development expenses was due primarily to a decrease of approximately $2,521,000 for research and development expenses related to TG-1101, offset by an increase of approximately $1,490,000 for research and development expenses related to TGR-1202. The decrease in other research and development expenses related to TG-1101 was related to the timing of manufacturing costs. We expect our other research and development costs to increase modestly for the remainder of 2014 as enrollment of additional patients increases on our clinical trials.

Noncash Compensation Expense (General and Administrative). Noncash compensation expense (general and administrative) related to equity incentive grants increased by $4,230,189 to $6,768,563 for the six months ended June 30, 2014, as compared to $2,538,374 for the six months ended June 30, 2013. The increase in noncash compensation expense was primarily related to milestone-based vesting of restricted stock grants to personnel during the period ended June 30, 2014.

Other General and Administrative Expenses. Other general and administrative expenses increased by $327,155 to $1,610,249 for the six months ended June 30, 2014, as compared to $1,283,094 for the six months ended June 30, 2013. The increase was due primarily to Delaware franchise taxes and Nasdaq listing fees. We expect our other general and administrative expenses to remain at a comparable level for the remainder of 2014.

Other (Income) Expense. Other income decreased by $57,700 to $(26,943) of income for the six months ended June 30, 2014, as compared to $(84,643) of income for the six months ended June 30, 2013. The decrease is mainly due to the decrease in the change in the fair value of notes payable, partially offset by interest income.

LIQUIDITY AND CAPITAL RESOURCES

Our primary source of cash has been proceeds from the private placement and public offering of equity securities and from 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.

On March 11, 2014, we announced the pricing of an underwritten sale of 2,702,809 shares of our Common Stock at a price of $6.71 per share for gross proceeds of approximately $18.1 million. Total net proceeds from this offering were approximately $16.8 million, net of underwriting discounts and offering expenses of approximately $1.3 million. The shares were sold under a shelf registration statement on Form S-3 (File No. 333-189015) that was previously filed and declared effective by the SEC on June 17, 2013.

As of June 30, 2014, we had $51,222,620 in cash, cash equivalents, investment securities, and interest receivable. We currently anticipate that our cash and cash equivalents and investments as of June 30, 2014 to be sufficient to fund our anticipated operating cash requirements for approximately 24 months from June 30, 2014. 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 six months ended June 30, 2014 was $11,902,006, as compared to $4,761,107 for the six months ended June 30, 2013. 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 six months ended June 30, 2014, net cash provided by financing activities of $17,715,690 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, net of payment of notes payable of $677,778. For the six months ended June 30, 2013, net cash provided by financing activities of $1,723,736 related to 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 June 30, 2014 and December 31, 2013, there was approximately $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.

For the year ended December 31, 2012, the valuation method used to estimate the 5% Notes’ fair value was a discounted cash flow model, where the expected cash flows of AST-726 and AST-915 were discounted to the present using a yield that incorporated compensation for the probability of success in clinical development and marketing, among other factors. The discount rate used in this discounted cash flow model approximated 20% at December 31, 2012. 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 December 31, 2013 and June 30, 2014. The assumptions, assessments and projections of future revenues are subject to uncertainties, are 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.

RECENTLY ISSUED ACCOUNTING STANDARDS

In May 2014, the FASB issued an update to ASC 606, Revenue from Contracts with Customers. This update to ASC 606 provides a five-step process to determine when and how revenue is recognized. The core principle of the guidance is that a Company should recognize revenue upon transfer of promised goods or services to customers in an amount that reflects the expected consideration to be received in exchange for those goods or services. This update to ASC 606 will also result in enhanced disclosures about revenue, providing guidance for transactions that were not previously addressed comprehensively, and improving guidance for multiple-element arrangements. This update to ASC 606 is effective for the Company beginning in fiscal 2017. The Company is currently evaluating the impact of this update on its consolidated financial statements.

On June 10, 2014, FASB issued Accounting Standards Update No. 2014-10, Development Stage Entities: Elimination of Certain Financial Reporting Requirements. The update removes the definition of a development stage entity from FASB ASC 915 and eliminates the requirement for development stage entities to present inception-to-date information on the statements of operations, cash flows and stockholders' deficit. The Company early adopted this standard for the period covered by the report herein.

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

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 June 30, 2014, 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 June 30, 2014, 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 June 30, 2014, 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 June 30, 2014 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, Biologics License Application ("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 recently acquired. Additionally, there can be no assurance given that any of the molecules under development in our IRAK4 inhibitor 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 given 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 attrition from the 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.

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 its 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 recently introduced micronized formulation of TGR-1202 which has only been studied in a limited number of healthy subjects to date and recently introduced into patients. Further, with respect to TGR-1202, to date only a small number of patients have been dosed in the ongoing first-in-human dose-escalation Phase I study, the full adverse effect profile of TGR-1202 is not known. Limited data is available on the drug’s adverse event profile at lower doses, and as the dose escalation continues with higher doses of TGR-1202, 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 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 the Company 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 its 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 its 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, the Company 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, that 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® (Rituximab) and Gazyva (obinutuzumab or GA-101), Spectrum Pharmaceutical's Zevalin® (Y^{90}-Ibritumomab Tiuxetan), and Genmab and GlaxoSmithKline's Arzerra® (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, although no PI3K delta inhibitors have been approved by the FDA, there are several PI3K delta targeted compounds in development, including, but not limited to, Gilead's idelalisib (formerly known as GS-1101 or CAL-101), Infinity Pharmaceuticals IPI-145, and Amgen's AMG-319, 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 and CLL and marketed by Pharmacyclics/ and Janssen), or the blc-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 meets 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 or 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.

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

As of June 30, 2014, we had fourteen 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 the Company is not able to attract and retain the necessary personnel to accomplish its 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, par value $0.001 ("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 and TGR-1202 in various indications and settings have been applied for but have not yet been issued, and no patents to date have been issued for our IRAK4 inhibitor program. 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 its 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. Moreover, as of March 16, 2013, the U.S. has converted from a "first to invent" to a "first to file" system. As such, should there be any innovations that we invented first, but on which we filed the patent application second, we have limited options available to reclaim invention priority.

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 June 30, 2014, we had net cash, cash equivalents, investment securities and interest receivable of approximately $51,223,000. We believe that our cash on hand and investments will sustain our operations for approximately 24 months from June 30, 2014. As a result, we will need additional capital to continue our operations beyond that time. We will need to seek additional sources of financing in the future, which might not be available on favorable terms, if at all, to continue our operations. 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 on your holdings of our capital stock.

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.

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 prospect 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 June 30, 2014, we had an accumulated deficit of $58,937,682. 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.

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

Our directors, executive officers, their affiliates, and our principal stockholders beneficially own approximately 60% percent 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:

- the global economic crisis, which affected stock prices of many companies, and particularly many small pharmaceutical companies like ours;
- 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.

ITEM 6. EXHIBITS

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

3.1	Amended and Restated Certificate of Incorporation of TG Therapeutics, Inc., dated April 26, 2012 (incorporated by reference to Exhibit 3.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2012).
3.2	Certificate of Amendment of Amended and Restated Certificate Incorporation of TG Therapeutics, Inc., dated June 9, 2014.
3.3	Amended and Restated Bylaws of TG Therapeutics, Inc. (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on July 21, 2014).
10.1	License Agreement, dated June 23, 2014, by and between Ligand Pharmaceuticals Incorporated and TG Therapeutics, Inc.*
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 July 24, 2014.
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 July 24, 2014.
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 July 24, 2014.
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 July 24, 2014.
*	Confidential treatment has been requested with respect to omitted portions of this exhibit.

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: July 24, 2014

By: /s/ 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:

3.2	Certificate of Amendment of Amended and Restated Certificate Incorporation of TG Therapeutics, Inc., dated June 9, 2014.
10.1	License Agreement, dated June 23, 2014, by and between Ligand Pharmaceuticals Incorporated and TG Therapeutics, Inc.*
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 July 24, 2014.
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 July 24, 2014.
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 July 24, 2014.
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 July 24, 2014.
*	Confidential treatment has been requested with respect to omitted portions of this exhibit.

CERTIFICATE OF AMENDMENT
OF
AMENDED AND RESTATED CERTIFICATE OF INCORPORATION
OF
TG THERAPEUTICS, INC.

TG Therapeutics, Inc., a corporation organized and existing under and by virtue of the Delaware General Corporation Law (the "Corporation"), does hereby certify:

FIRST: That on March 3, 2014, the Board of Directors of the Corporation adopted resolutions setting forth a proposed amendment to the Amended and Restated Certificate of Incorporation of the Corporation and declaring its advisability. The proposed amendment is as follows:

RESOLVED, that the Corporation's Amended and Restated Certificate of Incorporation be amended by deleting Article FOURTH in its entirety and by substituting in lieu thereof the following:

"FOURTH: A. The Corporation is authorized to issue two classes of stock designated "Common Stock" and "Preferred Stock," respectively. The total number of shares of Common Stock authorized to be issued is 150,000,000, and each such share will have a par value of $0.001. The total number of shares of Preferred Stock authorized to be issued is 10,000,000, and each such share will have a par value of $0.001.

B. No fractional shares of Common Stock of the Corporation shall be issued. No stockholder of the Corporation shall transfer any fractional shares of Common Stock of the Corporation. The Corporation shall not recognize on its stock record books any purported transfer of any fractional share of Common Stock of the Corporation.

C. Shares of Preferred Stock may be issued from time to time in one or more series. The Board of Directors is hereby authorized, by adopting appropriate resolutions and causing one or more certificates of amendment to be signed, verified and delivered in accordance with the General Corporation Law, to establish from time to time the number of shares to be included in such series, and to fix the designations, relative rights, preferences and limitations of the shares of each such series. Such designations, relative rights, preferences and limitations may include, but are not limited to, the fixing or alteration of the dividend rights, dividend rate, conversion rights, exchange rights, voting rights, rights and terms of redemption (including sinking fund provisions), the redemption price or prices, and the liquidation preferences of any wholly unissued series of shares of Preferred Stock, or any of them. In accordance with the authority hereby granted, the Board of Directors may increase or decrease the number of shares of any series subsequent to the issue of shares of that series, but not above the total number of authorized shares of Preferred Stock and not below the number of shares of such series then outstanding. In case the number of shares of any series shall be so decreased, the shares constituting such decrease shall resume the status that they had prior to the adoption of the resolution originally fixing the number of shares of such series. Except as may otherwise be required by law or this Certificate of Incorporation, the terms of any series of Preferred Stock may be amended without the consent of the holders of any other series of Preferred Stock, or Common Stock.

SECOND: That said amendment was duly adopted in accordance with the provisions of Section 242 of the Delaware General Corporation Law.

IN WITNESS WHEREOF, the Corporation has caused this certificate to be signed by a duly authorized officer this 9th day of June, 2014.

By: /s/ Sean A. Power
Sean A. Power
Chief Financial Officer

CONFIDENTIAL TREATMENT REQUESTED. Confidential portions of this document have been redacted and have been separately filed with the Commission.

Exhibit No. 10.1

LICENSE AGREEMENT

Dated as of June 23, 2014

by and between

Ligand Pharmaceuticals Incorporated

and

TG Therapeutics, Inc.

LICENSE AGREEMENT

THIS LICENSE AGREEMENT (the "**Agreement**") is dated as of June 23, 2014 (the "**Effective Date**") by and between Ligand Pharmaceuticals Incorporated, a Delaware corporation organized having its place of business at 11119 North Torrey Pines Road, Suite 200, La Jolla, California 92037 (including its successors and permitted assigns, "**Licensor**"), and TG Therapeutics, Inc., a Delaware corporation with its place of business at 3 Columbus Circle, 15th Floor, New York, New York 10019 (including its successors and permitted assigns and all of its Affiliates, "**TGTX**"). TGTX, on the one hand, and Licensor, on the other hand, shall each be referred to herein as a "**Party**" or, collectively, as the "**Parties**."

RECITALS:

WHEREAS, TGTX is engaged in the research, development, manufacturing and commercialization of pharmaceutical products, and TGTX is interested in developing and commercializing products containing or comprising the Compounds; and

WHEREAS, TGTX desires to license from Licensor and Licensor wishes to license to TGTX, on an exclusive basis, the right to use, develop and commercialize Licensor Technology in and for a defined field of use.

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

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.

1.2 **"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.

1.3 **"Calendar Year"** means the period beginning on the 1st of January and ending on the 31st 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.

1.4 **"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.

1.5 **"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.

1.6 **"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.

1.7 "**Compounds**" means Licensor's proprietary Interleukin-1 Receptor Associated Kinase-4 (IRAK-4) inhibitors set forth on Schedule 1 and any other salts, solvates, esters, metabolites, hydrates, intermediates, stereoisomers, polymorphs, and derivatives of such compounds, and any other IRAK-4 inhibitors discovered or developed by Licensor during the first six months after the Effective Date and any other salts, solvates, esters, metabolites, hydrates, intermediates, stereoisomers, polymorphs, and derivatives of such compounds.

1.8 **"Controlled**" means, with respect to (a) Patent Rights, (b) Know-How or (c) biological, chemical or physical material, that a Party or one of its Affiliates owns or has a license or sublicense to such Patent Rights, Know-How or material (or in the case of 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 Patent Rights, Know-How or material as provided for in this Agreement without violating the terms of any agreement or other arrangement with any Third Party.

1.9 **"Covered"** means, with respect to a Licensed Product, that the manufacturing, importing, using, selling, or offering for sale of such Licensed Product would, but for ownership of or a license granted hereunder under Licensor's relevant Patent Rights, infringe a Valid Claim of Licensor's relevant Patent Rights in the country in which the activity occurs.

1.10 **"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.

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

1.12 **"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.

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

1.14 **"Field"** means all prophylactic, palliative, therapeutic or diagnostic uses in humans.

1.15 **"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 such country to a Third Party by TGTX, an Affiliate of TGTX or a Sublicensee after Regulatory Approval therefor has been obtained in such country.

1.16 "**GAAP**" means United States generally accepted accounting principles.

1.17 **"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.

1.18 **"Know-How"** means any scientific or technical information, results and data of any type whatsoever, in any tangible or intangible form whatsoever, that is not in the public domain or otherwise publicly known, including, without limitation, discoveries, inventions, trade secrets, databases, practices, protocols, regulatory filings, methods, processes, techniques, software, works of authorship, plans, concepts, ideas, biological and other materials, reagents, specifications, formulations, formulae, data (including, but not limited to, pharmacological, biological, chemical, toxicological, clinical and analytical information, quality control, trial and stability data), case reports forms, 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, results and data, whether or not patentable, all to the extent not claimed or disclosed in a patent or pending patent application. 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" includes any rights including copyright, moral, trade-secret, database or design rights protecting such Know-How. "Know-How" excludes Patent Rights.

1.19 **"Indication"** means a generally acknowledged disease or condition, a significant manifestation of a disease or condition, or symptoms associated with a disease or condition or a risk for a disease or condition, which a Licensed Product is intended to address; provided, however, that with respect to the each of the Product Milestone Events, if each of the first two Indications for which a particular Product Milestone Event has been achieved both involve oncology, no further indication shall (with regard to such particular Product Milestone Event) be deemed to be an Indication unless the further indication is for a non-oncology indication. For the avoidance of doubt, in the event the first two Indications for which a particular Product Milestone Event has been achieved both involve oncology, no additional milestones shall be due under Section 5.2 for any subsequent, oncology-related Indication.

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

1.21 **"Licensed Product"** means any pharmaceutical product, in any dosage form, preparation, composition, formulation, presentation or package configuration, that is Commercialized or undergoing research or preclinical or clinical Development that contains or comprises, in part or in whole, a Compound. For clarity: if a product is described by the foregoing sentence it is a "Licensed Product" for all purposes hereof whether or not it is Covered and whether or not the manufacturing, importing, using, selling, or offering for sale of such product would, but for a license granted under this Agreement under the Licensor Technology, infringe any Licensor Technology in the country in which the activity occurs.

1.22 **"Licensor Know-How**" means any and all Know-How that (a) is Controlled by Licensor or any of its Affiliates as of the Effective Date or at any time thereafter during the Term and (b) pertains directly and particularly to the Compounds and (c) is from time to time expressly identified in writing by Licensor to TGTX as constituting Licensor Know-How. For clarity: any and all Know-How which Licensor determines, in its reasonable discretion, not to so expressly identify as being within the definition of Licensor Know-How shall not constitute Licensor Know-How. The Licensor Know-How shall include, but not be limited to, the Know-How listed on Schedule 2 hereto.

1.23 **"Licensor Patents"** means all Patent Rights that are Controlled by Licensor or any of its Affiliates as of the Effective Date or at any time thereafter during the Term and that pertain directly and particularly to the Compounds, other inhibitors of IRAK-4 and/or IRAK-4 inhibition. The Licensor Patents shall include, but not be limited to, all Patent Rights set forth on Schedule 3 hereto.

1.24 **"Licensor Technology"** means the Licensor Patents and the Licensor Know-How.

1.25 "**Major Market**" means any of the (a) United States, (b) the European Union (either in its entirety or including at least one Major Market EU Country, as determined by TGTX in its sole discretion), or (c) Japan.

1.26 "**Major Market EU Country**" means any of France, Germany and the United Kingdom.

1.27 **"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.

1.28 **"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.

1.29 **"Net Sales"** means the gross amount invoiced or otherwise charged by TGTX, its Affiliates and Sublicensees to unrelated Third Parties for a Licensed Product, less:

(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 (other than such which have already diminished the gross amount invoiced such as those outlined in Section 1.29(a) above), 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 production, 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; and

(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).

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.

In the event that a Licensed Product is commercialized as part of a Combination Product for a single price, then for the purpose of determining Net Sales the gross amount invoiced or otherwise charged by TGTX for such Licensed Product shall be calculated by multiplying the sales price of such Combination Product by the fraction A/(A+B) where A is the fair market value of the Licensed Product and B is the fair market value of the other product(s) in the Combination Product; and the applicable deductions from the gross amount invoiced or otherwise charged by TGTX shall be allocated between the Licensed Product and the other product(s) in the Combination Product in the same proportion.

1.30 **"Patent Right"** means: (a) an issued or granted patent, including any extension, supplemental protection certificate, registration, confirmation, reissue, reexamination, extension or renewal thereof; (b) a pending patent application, including any continuation, divisional, continuation-in-part, substitute or provisional application thereof; and (c) all counterparts or foreign equivalents of any of the foregoing issued by or filed in any country or other jurisdiction, provided however that, with respect to items (b) and (c), no patent application shall be pending for a period of greater than seven years from its actual date of filing.

1.31 **"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.

1.32 **"Phase I Trial"** means a clinical trial of a Licensed Product in human patients 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.

1.33 **"Phase III Trial"** means a clinical trial of a Licensed Product in human patients, which trial 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. Provided that, and for avoidance of doubt: any pivotal trial, which is intended to be or is in fact used as one of the adequate and well-controlled trials for registration in any jurisdiction, shall be deemed to be a Phase III Trial.

1.34 **"Product Milestone Events"** means the second, third, fourth, fifth, sixth and seventh milestone events specified in Section 5.2.

1.35 **"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.

1.36 **"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.

1.37 **"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 (a) expiry of the last-to-expire Licensor Patent containing a Valid Claim to the Compound in such country; or (b) the 10^{th} anniversary of the First Commercial Sale of such Licensed Product in such country. In a country where no Licensor Patent containing a Valid Claim with respect to the Compound has ever existed nor ever exists, the Royalty Term means on a product-by-product and country-by-country basis, the period from the First Commercial Sale of such product in such country until the 10^{th} anniversary of such First Commercial Sale of such product in such country.

1.38 **"Sales Milestone Events"** means the eighth and ninth milestone events specified in Section 5.2.

1.39 "**Share Value**" as of a particular date means the mean average of the respective trading days' closing sale prices of the Shares on the Shares' principal United States securities exchange for each of the eighteen trading days immediately preceding such date; it being understood that any such closing sale prices shall be adjusted appropriately to reflect the occurrence of any stock split, reverse stock split, recapitalization, reorganization or other such event.

1.40 "**Shares**" means shares of TGTX's common stock, par value $0.001 per share, as constituted on the Effective Date; the meaning of such term shall be adjusted appropriately to reflect the occurrence of any stock split, reverse stock split, recapitalization, reorganization or other such event.

1.41 **"Sublicensee"** means a Person, other than an Affiliate of TGTX, to which TGTX (or its Affiliate) has, pursuant to Section 2.2, granted sublicense rights under any of the license rights granted under Section 2.1. "**Sublicense**" shall be construed accordingly.

1.42 **"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.

1.43 **"Third Party"** means any Person other than Licensor, TGTX or Affiliates of either of them, or any Sublicensees.

1.44 **"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.

1.45 **"United States"** or **"US"** means the United States of America and its territories and possessions.

1.46 "**Upfront Shares**" means 125,000 Shares.

1.47 "**Valid Claim**" means a claim of an issued and unexpired patent which has not lapsed or been revoked, abandoned or held unenforceable or invalid by a final decision of a court or governmental agency of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, and which has not been disclaimed, denied or admitted to be invalid or unenforceable through reissue, reexamination or disclaimer or otherwise.

1.48 The definition of each of the following terms is set forth in the section of the Agreement indicated below:

"Action" has the meaning set forth in Section 6.5(b).

"Claim" has the meaning set forth in Section 9.1.

"Confidential Information" has the meaning set forth in Section 7.1.

"Controlling Party" has the meaning set forth in Section 6.6(c).

"Development Program" has the meaning set forth in Section 3.1.

"Disclosing Party" has the meaning set forth in Section 7.1.

"Generic Supply" has the meaning set forth in Section 5.4(b).

"Indemnified Party" has the meaning set forth in Section 9.4.

"Indemnifying Party" has the meaning set forth in Section 9.4.

"Licensor Indemnitees" has the meaning set forth in Section 9.1.

"**Notice**" has the meaning set forth in Section 7.6.

"**Publishing Party**" has the meaning set forth in Section 7.6.

"Receiving Party" has the meaning set forth in Section 7.1.

"Term" has the meaning set forth in Section 10.1.

"TGTX Indemnitees" has the meaning set forth in Section 9.2.

ARTICLE II
LICENSES AND OTHER RIGHTS

2.1 **Grant of License to TGTX**. Subject to the terms and conditions of this Agreement, Licensor hereby grants to TGTX and its Affiliates, and TGTX and its Affiliates hereby accept, an exclusive (even as to Licensor), worldwide, royalty-bearing right and license (with the right to sublicense, and to further sublicense, subject to the provisions of Section 2.2) under the Licensor Technology to research, Develop, manufacture, have manufactured, use, import and Commercialize and have Commercialized the Licensed Products in and for the Field. Licensor and its Affiliates grant no licenses or rights to use other than as expressly set forth herein.

2.2 **Grant of Sublicenses by TGTX**. 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 all of the duties, obligations, restrictions and acknowledgements hereunder of TGTX (with Licensor being an express third-party beneficiary thereof), and stating that the Sublicense shall (except as otherwise expressly provided in Section 10.3 or 10.4(c)) automatically terminate upon the expiration or earlier termination of this Agreement. Notwithstanding the foregoing sentence, it is not required that a Sublicense include provisions for the Sublicensee to pay Royalties or make milestone payments directly to Licensor or to provide royalty reports directly to Licensor. TGTX shall ensure that all of its Sublicensees shall comply with the terms and conditions of this Agreement (as applicable to them) and TGTX shall be and remain fully responsible for the compliance by such Sublicensees with the terms and conditions of this Agreement (as applicable to them) as if such Sublicensees were TGTX hereunder. Except for Sublicenses as expressly allowed herein, TGTX acknowledges that it has no right to, and agrees not to purport to, grant to anyone a sublicense under the Licensor Technology.

2.3 **Bankruptcy Code**. All rights and licenses granted under or pursuant to this Agreement by Licensor to TGTX are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the US Bankruptcy Code, licenses of rights to "intellectual property" as defined under Section 101 of the US Bankruptcy Code. The Parties agree that TGTX, as a licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the US Bankruptcy Code.

2.4 **Service Agreement.** The Parties acknowledge that the Parties may choose in the future to negotiate toward a research agreement in support of the Development Program; however, neither Party shall be obligated to negotiate toward, or to enter into, such a research agreement, and in the absence of any such definitive written research agreement Licensor shall have no obligation to assist TGTX's research and development.

ARTICLE III
DEVELOPMENT, MANUFACTURE AND COMMERCIALIZATION

3.1 **Diligence by TGTX.** TGTX shall use Commercially Reasonable Efforts to Develop and to Commercialize at least one Licensed Product in and for the Field in at least one Major Market. In connection therewith, TGTX shall formulate and execute a preclinical and clinical development program to Develop one or more Licensed Products in and for the Field in at least one Major Market (the "**Development Program**").

3.2 **No Guaranty of Favorable Results**. Licensor does not warrant that the Development Program, TGTX's other preclinical studies and evaluation (if any) and/or TGTX's clinical studies (if any) will produce any particular results or any favorable results.

3.3 **TGTX Responsibility and Authority for Development**. TGTX shall have the exclusive right, and sole responsibility and decision-making authority, to research and Develop any Licensed Products in and for the Field and to conduct (either itself or through its Affiliates, agents, subcontractors and/or Sublicensees) all clinical trials and non-clinical studies TGTX believes appropriate to obtain Regulatory Approval for Licensed Products in and for the Field.

3.4 **Commercialization**. TGTX shall have the exclusive right, and sole responsibility and decision-making authority, to Commercialize any Licensed Products in and for the Field itself or through one or more Sublicensees or other Third Parties selected by TGTX and shall have the sole decision-making authority and responsibility in all matters relating to the Commercialization of Licensed Products.

3.5 **Manufacturing**. TGTX shall have the exclusive right, and sole responsibility and decision-making authority, to manufacture, at the clinical and/or commercial stage, any Licensed Product in and for the Field itself or through one or more Sublicensees selected by TGTX.

3.6 **Reporting to Licensor**. TGTX shall, at least once each Calendar Year, provide to Licensor an update report regarding the progress of all research and Development efforts toward Licensed Products and regarding the progress of Commercialization of Licensed Products.

3.7 **Right to Subcontract of TGTX**. Subject to any required compliance with Section 2.2, TGTX may exercise any of the rights or obligations that TGTX may have under this Agreement (including, without limitation, any of the rights licensed in Section 2.1 hereof) by Sublicensing, but any Sublicense granted or entered into by TGTX as contemplated by this Section 3.7 or any Sublicensee's exercise or performance of all or any portion of the rights or obligations that TGTX may have under this Agreement shall not relieve TGTX from any of its obligations under this Agreement.

3.8 **Compliance with Law**. TGTX undertakes and agrees that the conduct of the Development Program, the use of the Licensor Technology, and all Development, manufacture and Commercialization of Licensed Products by it and its Affiliates and Sublicensees shall comply in all material respects with all applicable international, federal, state and local laws, rules and regulations, including, but not limited to, environmental, occupational safety/health, safety and import/export restrictions, laws, rules and regulations.

3.9 **Costs and Expenses**. As between Licensor and TGTX, TGTX shall be solely responsible for all costs and expenses related to Development, manufacture 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 Product.

3.10 .**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 Licensor Patents.

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

ARTICLE IV
REGULATORY MATTERS

4.1 **Regulatory Filings.** As between TGTX and Licensor, 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.

4.2 **Communications with Authorities.** TGTX (or one of its Affiliates or Sublicensees) shall be responsible for and act as the sole point of contact for communications with Regulatory Authorities in connection with the Development, Commercialization, and manufacturing of Licensed Products. At the request of TGTX, Licensor shall make available to TGTX, at no more than a reasonable charge, a qualified representative who shall, together with the representatives of TGTX, participate in and contribute to meetings with the Regulatory Authorities with respect to regulatory matters relating solely to the Licensor Technology.

4.3 **Adverse Event Reporting.** TGTX agrees to comply with any and all Laws that are applicable to it as of the Effective Date and thereafter during the Term in connection with Licensed Product safety data collection and reporting (and, if applicable, recalls). TGTX shall provide annually to Licensor a listing of each serious untoward medical occurrence in a patient or subject who is administered a Licensed Product and shall, should Licensor expressly so request and TGTX approve (such approval not to be unreasonably withheld), provide Licensor with additional detail as to such ones of such occurrences as Licensor may designate.

ARTICLE V
Financial Provisions

5.1 **Upfront Fee**. TGTX becomes obligated on the Effective Date to pay Licensor the Upfront Shares in partial consideration of the rights granted to Company under this Agreement. TGTX shall deliver to Licensor a stock certificate representing the Upfront Shares on the Effective Date or within five business days thereafter, provided that in any event such stock certificate is delivered on or before June 30, 2014. Such stock certificate shall be unlegended except for a standard securities-law restrictive legend.

5.2 **Commercial Milestone Payments.** As further partial consideration for Licensor's grant of the rights and licenses to TGTX hereunder, TGTX shall pay to Licensor the following one-time, non-refundable milestone payments (a) with regard to the first Licensed Product to achieve the respective Product Milestone Event, for each of the first * Indications for which a Licensed Product achieves the respective Product Milestone Event, and (b) upon achievement of each respective Sales Milestone Event by TGTX or its Affiliate or Sublicensee. TGTX shall promptly, but in no event later than 15 days following TGTX or its Affiliate's receipt of actual knowledge of each achievement of a milestone event, notify Licensor in writing of the achievement of such milestone event and shall pay the relevant milestone payment within 20 days thereafter. All milestone and other Article V payments shall be paid in cash except that in the case of any achievement of the second Product Milestone Event (Enrollment of at least 100 patients (combined) in all clinical trials for the indication), TGTX shall have the right to elect (but only within the notice of achievement referred to in the preceding sentence, and only if such notice of achievement is not delivered untimely) to pay any amounts owed not in the form of cash but rather in the form of a number of Shares equal to amount owed divided by the Share Value as of the date such notice of achievement is delivered; or some portion (designated and specified by TGTX in its discretion within such notice of achievement, which such notice of achievement is not delivered untimely) of the amount owed in cash and the remainder in the form of a number of Shares equal to such remainder divided by the Share Value as of the date such notice of achievement is delivered. (Any such election shall be irrevocable.) If TGTX makes such election it shall deliver to Licensor a stock certificate representing the Shares on the date such notice of achievement is delivered or within five business days thereafter; such stock certificate shall be unlegended except for a standard securities-law restrictive legend.

Milestone Event	**Milestone Payment**	**Total Milestone Payments (if achieved with three Indications)**
First dosing of any patient in any Phase I Trial	* Shares	n/a
Enrollment of at least 100 patients (combined) in all clinical trials for the Indication	$* (per Indication)	$ *
Enrollment of first patient in first Phase III Trial	$* (per Indication)	$ *
NDA filing in the United States for a Licensed Product	$* (per Indication)	$ *
Regulatory Approval in the United States for a Licensed Product	$* (per Indication)	$ *
Regulatory Approval in or for a Major Market EU Country for a Licensed Product	$* (per Indication)	$ *
Regulatory Approval in Japan for a Licensed Product	$* (per Indication)	$ *
The first time aggregate worldwide Net Sales for all Licensed Products exceeds $1,000,000,000 in any Calendar Year	$*	n/a
The first time aggregate worldwide Net Sales for all Licensed Products exceeds $3,000,000,000 in any Calendar Year	$*	n/a

* Confidential material redacted and filed separately with the Commission.

For avoidance of doubt: it is possible that the first three Indications to achieve a particular milestone event might not be identical with the first three Indications to achieve a different particular milestone event; this non-identity would not affect the validity of the three-time milestone event achievement for either of the milestone events. For the avoidance of doubt, in the event the first two Indications for which a particular Product Milestone Event has been achieved both involve oncology, no additional milestones shall be due under Section 5.2 for any subsequent, oncology-related Indication.

5.3 **Deemed Achievement of Commercial Milestones**. Upon achievement of any respective Product Milestone Event with regard to a particular Indication, all "prior" milestone events shall be deemed to be thereby achieved as to such Indication; and if the milestone payment for any such "prior" milestone events so deemed to be thereby achieved has not previously been paid, it shall thereupon also be paid, forthwith (unless the deemed-achieved milestone event has already been achieved and paid for three times).

5.4 **Royalty, Etc. Payments for Licensed Products**.

(a) With respect to Net Sales of all Licensed Products which are Covered under a Licensor Patent as of the time of the Net Sales: As further consideration for Licensor's grant of the rights and licenses to TGTX hereunder, TGTX shall pay to Licensor a royalty 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:

Annual Worldwide Net Sales of All (Covered) Licensed Products per Calendar Year (US Dollars)	**Incremental Royalty Rate**
For Net Sales of such Licensed Products from $0 up to and including $1,000,000,000	6%
For that portion of Net Sales of such Licensed Products that is greater than $1,000,000,000	9.5%

By way of illustration, assume in a Calendar Year that aggregate worldwide annual Net Sales of all such Licensed Products total $1,950,000,000. The total royalties due and payable by TGTX to Licensor for such Net Sales would be $150,250,000, calculated as follows:

$1,000,000,000 x 6% = $60,000,000
$950,000,000 x 9.5% = $90,250,000
Total Royalty = $150,250,000

(b) With respect to Net Sales of all Licensed Products which are not Covered under any Licensor Patent as of the time of the Net Sales: In addition, as further consideration for Licensor's grant of the Licensed Know-How rights and licenses to TGTX hereunder, TGTX shall pay to Licensor a payment in the nature of royalties 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:

Annual Worldwide Net Sales of All (Uncovered) Licensed Products per Calendar Year (US Dollars)	Incremental Royalty Rate
For Net Sales of such Licensed Products from $0 up to and including $1,000,000,000	4.5%
For that portion of Net Sales of such Licensed Products that is greater than $1,000,000,000	7.125%

Provided, that for the purposes of this Section 5.4(b), only *% of the Net Sales of a Licensed Product in a country during the time period when a Generic Supply of such Licensed Product is being lawfully Commercialized in such country, shall be subject to such payment in the nature of royalties and the other *% shall be excluded. A "**Generic Supply**" of a Licensed Product shall be deemed to be being Commercialized in a country if and only if the aggregate market share of all generic versions of such Licensed Product in such country in the calendar year in question is at least *%.

(c) In establishing the royalty/payment in the nature of royalties structure hereunder, the Parties recognize, and TGTX acknowledges, the substantial value of the various obligations being undertaken by Licensor under this Agreement, in addition to the grant of the license under the Licensor Patents, to enable the rapid and effective market introduction of the Licensed Products. The Parties have agreed to the payment structure set forth herein as a convenient and fair mechanism to compensate Licensor for these obligations.

(d) For purposes of determining whether the Section 5.4(a) or Section 5.4(b) royalty/payment in the nature of royalties threshold has been attained, only Net Sales that are subject to a Section 5.4(a) payment or a Section 5.4(b) payment, respectively, shall be included in the total amount of Net Sales and any Net Sales that are not subject to such a respective payment shall be excluded. In addition, 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 Licensor under Section 5.4(a) is imposed only once with respect to the same unit of Licensed Product regardless of the number of Licensor Patents pertaining thereto or the number of times such Licensed Product has been sold or transferred to a Person.

(e) 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, transferable (to the extent not transferable previously), perpetual and irrevocable.

5.5 **Timing of Payment.** Royalties/payments in the nature of royalties payable under Section 5.4 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 30 days after the end of each Calendar Quarter during which the royalty/payment in the nature of royalties obligation accrued; provided that within 50 days after the conclusion of each Calendar Year TGTX shall provide notice to Licensor 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 5.7 hereof.

* Confidential material redacted and filed separately with the Commission.

5.6 **Royalty (Etc.) Reports and Records Retention.** Within 60 days after the end of each Calendar Quarter during which Licensed Products have been sold, TGTX shall deliver to Licensor, 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) 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), (b) amounts deducted by category (following the definition of Net Sales) from such gross invoiced amounts to calculate Net Sales, (c) Net Sales subject to royalty or royalty/payment in the nature of royalties payments for such Calendar Quarter and Calendar Year to date and (d) the corresponding royalty or royalty/payment in the nature of royalties. 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.

5.7 **Audits**.

(a) From the First Commercial Sale (of the first Licensed Product to have a First Commercial Sale) until one Calendar Year after the conclusion of the final Royalty Term, upon the written request of Licensor, and not more than once in each Calendar Year, TGTX shall permit, shall cause its Affiliates and Sublicensees to permit, an independent certified public accounting firm of nationally recognized standing selected by Licensor (who has not been engaged by Licensor 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 or Sublicensee, to have access to and to review, during normal business hours upon reasonable prior written notice, the applicable records of TGTX and its Affiliates or Sublicensees to verify the accuracy of the royalty and payment in the nature of royalties reports and payments under this Article V. Such review may cover: (i) the records for sales made in any 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 royalties and/or royalties/payment in the nature of royalties 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 or at TGTX's request, shall be reimbursed to TGTX within 30 days after the date such public accounting firm delivers such report to TGTX. 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. Licensor shall pay for the cost of any audit by Licensor, unless TGTX has underpaid Licensor by 5% or more for a specific royalty period, in which case TGTX shall pay for the reasonable costs of audit.

(c) Each Party shall treat all information that it receives under this Section 5.7 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.

5.8 **Mode of Payment and Currency**. All payments to Licensor 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 such bank account as Licensor may from time to time designate by advance written notice to TGTX. 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.

5.9 **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 500 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.

5.10 **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 Licensor'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 Licensor under this Agreement. To the extent TGTX is required to withhold taxes on any payment to Licensor, TGTX shall pay the amounts of such taxes to the proper governmental authority in a timely manner and promptly transmit to Licensor official receipts issued by the appropriate taxing authority and/or an official tax certificate, or such other evidence as Licensor may reasonably request, to establish that such taxes have been paid. Licensor 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. Licensor 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 Licensor 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. Licensor 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 Licensor) to withhold or by reduction (at the express request of Licensor) in its withholding.

ARTICLE VI
Inventions and Patents

6.1 **Third Party Inventions and Know-How.** As between Licensor and TGTX, all inventions and Know-How made by a Third Party in the course of the Development Program shall be owned by TGTX.

6.2 **Patent Prosecution and Maintenance.**

(a) **Licensor Patents**. Licensor shall have the first right to file, prosecute and maintain Licensor Patents in Licensor's name.

(b) **New or Revised Applications**. Licensor will, upon forming an intention to file or revise one or more patent applications which would become or are Licensor Patent Rights 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 Licensor patent application before so filing or revising. Licensor shall consider any such reasonable TGTX comments in good faith.

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

(d) **Election Not to File/Prosecute/Maintain Licensor Patents**. TGTX acknowledges and agrees that Licensor shall not be required to file, prosecute or maintain Patent Rights for the Licensor Patents, provided, however, if Licensor decides to not pursue or maintain any such Patent Rights then Licensor shall provide TGTX with at least 30 days' notice before discontinuing the filing, prosecution or maintenance of such Patent Rights so that TGTX may assume responsibility for such activities in Licensor's name but at TGTX's expense. In such event, TGTX will no longer owe any royalty obligation on account of such (country-level) Patent Rights assumed by TGTX.

6.3 **Certification under Drug Price Competition and Patent Restoration Act.** Each of Licensor and TGTX shall immediately give 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 Licensor Patents covering a Compound or 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.

6.4 **Listing of Patents.** TGTX shall have the sole right to determine which of the Licensor 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. Licensor will co-operate with TGTX to list any of said Licensor Patents.

6.5 **Enforcement of Patents.**

(a) **Notice.** If either Licensor or TGTX believes that a Licensor Patent is being infringed in the Field, or that Licensor Know-How has been misappropriated in the Field, by a Third Party or if a Third Party claims that any Licensor 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) **Right to Bring an Action for Licensor's Patents.** If such infringement, misappropriation or claim is in one or more of the Major Markets in respect of Licensor Patents, Licensor shall have the right to attempt to resolve such infringement, misappropriation or claim, including by filing an infringement suit, defending against or bringing a declaratory judgment action as to such claim or taking other similar action (each, "initiation" of an "**Action**") and (subject to Section 6.5(e)) to compromise or settle such infringement or claim. TGTX may, in its sole discretion and at its expense, join in any such Action and in such case shall reasonably cooperate with Licensor. If Licensor does not intend to initiate an Action, Licensor shall promptly inform TGTX. If Licensor does not initiate an Action with respect to such an infringement or claim within 180 days following notice thereof, TGTX shall have the right to attempt to resolve such infringement, misappropriation or claim, including by initiating an Action, and (subject to Section 6.5(e)) to compromise or settle such infringement, misappropriation or claim. At TGTX's request, Licensor shall immediately provide TGTX with all relevant documentation (as may be requested by TGTX) evidencing that TGTX is validly empowered by the Licensor to initiate an Action. Licensor shall be under the obligation to join TGTX in its Action if TGTX determines that this is necessary to demonstrate "standing to sue." The Party initiating such Action shall have the sole and exclusive right to select counsel for any suit initiated by it pursuant to this Section 6.5. If a Party initiates an Action but then elects not to pursue the Action, the other Party shall have the right (but not the obligation) to take over the Action, in which case the second Party shall be deemed to have been the initiating Party.

(c) **Costs of an Action.** Subject to the respective indemnity obligations of the Parties set forth in Article IX and subject to Section 6.5(f), each Party involved in an Action under Section 6.5(b) shall pay its own costs and expenses incurred in connection with such Action.

(d) **Settlement**. No Party shall settle or otherwise compromise (or resolve by consent to the entry of judgment upon) any Action by admitting that any Licensor Patent is to any extent invalid or unenforceable, or that any Licensor Know-How is not protected or has not been misappropriated, without the other Party's prior written consent, and, in the case of Licensor, Licensor may not settle or otherwise compromise (or resolve by consent to the entry of judgment upon) an Action in a way that adversely affects or would be reasonably expected to adversely affect any of TGTX's rights or benefits hereunder with respect to any Licensor Technology or any Licensed Product, without TGTX's prior written consent.

(e) **Reasonable Assistance.** Each Party (if it is not the Party enforcing or defending Licensor's Patent Rights) shall provide reasonable assistance to the other Party, including providing access to relevant documents and other evidence and making its employees and consultants available, subject to the other Party's reimbursement of any reasonable out-of-pocket expenses incurred on an on-going basis by the non-enforcing or non-defending Party in providing such assistance.

(f) **Distribution of Amounts Recovered.** Any amounts recovered by the Party initiating an Action pursuant to this Section 6.5, whether by settlement or judgment, shall be allocated in the following order: (i) to reimburse the Party initiating such Action for any costs incurred; (ii) to reimburse the Party not initiating such Action for its costs incurred in such Action, if it joins (as opposed to taking over) such Action; and (iii) the remaining amount of such recovery shall (A) if TGTX initiated the Action, the remainder shall be allocated to TGTX and the portion thereof attributable to "lost sales" 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 Licensor a royalty on such portion based on the royalty rates set forth in Section 5.4(a), and the portion thereof not attributable to "lost sales" shall be allocated to TGTX and (B) if Licensor initiated the Action, the remainder shall be allocated to TGTX and the portion thereof attributable to "lost sales" 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 Licensor a royalty on such portion based on the royalty rates set forth in Section 5.4(a), and the portion thereof not attributable to "lost sales" shall be allocated to 50% to Licensor and 50% to TGTX.

6.6 **Third Party Actions Claiming Infringement**.

(a) **Notice**. If either Licensor or TGTX becomes aware of any Third Party Action, such Party shall promptly notify the other of all details regarding such claim or action that is reasonably available to such Party.

(b) **Right to Defend.** TGTX shall have the right, at its sole expense, but not the obligation, to defend a Third Party Action described in Section 6.6(a) and (subject to Section 6.6(f)) to compromise or settle such Third Party Action. If TGTX declines or fails to assert its intention to defend such Third Party Action within 40 days of receipt/sending of notice under Section 6.6(a), then Licensor shall have the right, at its sole expense, to defend such Third Party Action and (subject to Section 6.6(f)) to compromise or settle such Third Party Action. The Party defending such Third Party Action shall have the sole and exclusive right to select counsel for such Third Party Action.

(c) **Consultation.** The Party defending a Third Party Action pursuant to Section 6.6(b) shall be the **"Controlling Party"**. The Controlling Party shall consult with the non-Controlling Party, pursuant to an appropriate joint defense or common interest agreement, on all material aspects of the defense. The non-Controlling Party shall have a reasonable opportunity for meaningful participation in decision-making and formulation of defense strategy. The Parties shall reasonably cooperate with each other in all such actions or proceedings. The non-Controlling Party will be entitled to join the Third Party Action and be represented by independent counsel of its own choice at its own expense.

(d) **Appeal**. In the event that a judgment in a Third Party Action is entered against either Party and an appeal is available, the Controlling Party shall have the first right, but not the obligation, to file such appeal. In the event the Controlling Party does not desire to file such an appeal, it will promptly, in a reasonable time period (i.e., with sufficient time for the non-Controlling Party to take whatever action may be necessary) before the date on which such right to appeal will lapse or otherwise diminish, permit the non-Controlling Party to pursue such appeal at such non-Controlling Party's own cost and expense. If applicable Law requires the other Party's involvement in an appeal, the other Party shall be a nominal party in the appeal and shall provide reasonable cooperation to such Party at such Party's expense.

(e) **Costs of an Action**. Subject to the respective indemnity obligations of the Parties set forth in Article IX, the Controlling Party shall pay all costs and expenses associated with such Third Party Action other than the expenses of the other Party if the other Party elects to join such Third Party Action (as provided in the last sentence of Section 6.6(c)).

(f) **No Settlement without Consent.** Neither Licensor or TGTX shall settle or otherwise compromise (or resolve by consent to the entry of judgment upon) any Third Party Action by admitting that any Licensor Patent is to any extent invalid or unenforceable or that any Licensed Product, or its use, Development, importation, manufacture or sale infringes such Third Party's intellectual property rights, in each case without the other Party's prior written consent, and, in the case of Licensor, Licensor may not settle or otherwise compromise (or resolve by consent to the entry of judgment upon) a Third Party Action in a way that adversely affects or would be reasonably expected to adversely affect TGTX's rights and benefits hereunder with respect to any Licensor Technology or any Licensed Product, without TGTX's prior written consent.

ARTICLE VII
CONFIDENTIALITY

7.1 **Definitions**. The Parties recognize that disclosures of Confidential Information between them before the Effective Date were subject to the Confidential Disclosure Agreement between them dated April 29, 2014. TGTX and Licensor 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 TGTX nor Licensor 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**. Licensor and TGTX 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. TGTX and Licensor 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 Releases and Disclosure.** Either Party may make press releases or public announcements regarding this Agreement or any matter covered by this Agreement, including the Development or Commercialization of Licensed Products, but such Party shall use Commercially Reasonable Efforts to 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.) Notwithstanding the above, once a public disclosure has been made, either Party shall be free to disclose to third parties any information contained in said public disclosure, without further pre-review.

7.6 **Publication Rights**. Until the first anniversary of the Effective Date, the following restrictions shall apply with respect to possible disclosure by either Party of the other Party's Confidential Information relating to Licensed Products in any publication or presentation. A Party (the "**Publishing Party**") shall provide the other Party with a copy of any proposed publication or presentation at least 30 days before submission for publication by the Publishing Party or its Affiliates so as to provide such other Party with an opportunity to recommend any changes it reasonably believes are necessary to continue to maintain the Confidential Information disclosed by the other Party to the Publishing Party in accordance with the requirements of this Agreement. The incorporation of such recommended changes shall not be unreasonably refused; and if such other Party notifies ("**Notice**") the Publishing Party in writing, within 30 days after receipt of the copy of the proposed publication or presentation, that such publication or presentation in its reasonable judgment (a) contains an invention, solely or jointly conceived or reduced to practice by the other Party, for which the other Party reasonably desires to obtain patent protection or (b) could be expected to have a material adverse effect on the commercial value of any Confidential Information disclosed by the other Party to the Publishing Party, the Publishing Party shall prevent such publication or delay such publication for a mutually agreeable period of time. In the case of inventions, a delay shall be for a period reasonably sufficient to permit the timely preparation and filing of a patent application(s) on such invention, and in no event less than 90 days after the date of the Notice. In the case of Confidential Information, any of the non-publishing Party's Confidential Information shall be deleted as requested. The Parties hereby agree that the need for such publication review may diminish over time and agree, every six months, to discuss and attempt to agree upon whether and/or when the obligations under this Section 7.6 may be discontinued.

ARTICLE VIII
REPRESENTATIONS, WARRANTIES AND COVENANTS

8.1 **Representations and Warranties.** (a) TGTX represents and warrants to Licensor, and (b) Licensor represents and warrants 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 and will 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 and will 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 **Additional Representations and Warranties of Licensor.** Licensor represents and warrants to TGTX that:

(a) No consent by any Third Party or Governmental Body is required with respect to the execution and delivery of this Agreement by Licensor or the consummation by Licensor of the transactions contemplated hereby;

(b) No claims have been asserted or threatened by any Person (i) challenging the validity, effective status, or ownership of Licensor Technology, and/or (ii) to the effect that the use, reproduction, modification, manufacturing, distribution, licensing, sublicensing, sale or any other exercise of rights in any of Licensor Technology infringes or will infringe on any intellectual property right of any Person; and no such claims have been asserted or are threatened;

(c) The Licensor Patents are subsisting and are not the subject of any litigation procedure, discovery process, interference, reissue, reexamination, opposition, appeal proceedings or any other legal dispute;

(d) The Licensor Patents constitute all Patent Rights owned or Controlled by Licensor that pertain directly and particularly to the research, Development, manufacture, use and Commercialization of the Licensed Products as currently envisioned; and

(e) No Third Party has filed, pursued or maintained or threatened in writing to file, pursue or maintain any claim, lawsuit, charge, complaint or other action alleging that any Licensor Technology is invalid or unenforceable.

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 Compounds can be successfully Developed or Commercialized. The representations and warranties set forth in this Article VIII are provided in lieu of, and **EACH PARTY HEREBY DISCLAIMS**, all other warranties, express and implied, relating to the subject matter of this Agreement, the Licensor Technology, the Compounds and/or the Licensed Products, including but not limited to **the implied warranties of merchantability and fitness for a particular purpose, title and non-infringement of third party rights**. Each Party's representations and warranties under this Agreement are solely for the benefit of the other Party and may be asserted only by the other Party and not by any Affiliate, Sublicensee or any customer of the other Party, its Affiliates or Sublicensees. Each Party, its Affiliates and Sublicensees shall be solely responsible for all representations and warranties that it, its Affiliates or Sublicensees make to any customer, Affiliates or Sublicensees.

ARTICLE IX
INDEMNIFICATION; LIMITATION OF LIABILITY; INSURANCE

9.1 **Indemnification by TGTX.** TGTX shall indemnify, defend and hold Licensor and its Affiliates, and each of their respective employees, officers, directors and agents (the "**Licensor Indemnitees**") harmless from and against any and all actions, judgments, settlements, liabilities, damages, penalties, fines, losses, costs and expenses (including reasonable attorneys' fees and expenses) to the extent arising out of any Third Party claim, demand, action or other proceeding (each, a "**Claim**") related to (a) TGTX's performance of its obligations or exercise (by it or its Affiliates or Sublicensees) of its rights under this Agreement; or (b) breach by TGTX of its representations and warranties set forth in Article VIII; provided, however, that TGTX's obligations pursuant to this Section 9.1 shall not apply (x) to the extent such claims or suits result from the gross negligence or willful misconduct of any of the Licensor Indemnitees, or (y) with respect to claims or suits arising out of breach by Licensor of this Agreement, including without limitation of its or their representations and warranties set forth in Article VIII.

9.2 **Indemnification by Licensor.** Licensor shall indemnify, defend and hold TGTX and its Affiliates and each of their respective agents, employees, officers and directors (the "**TGTX Indemnitees**") harmless from and against any and all actions, judgments, settlements, liabilities, damages, penalties, fines, losses, costs and expenses (including reasonable attorneys' fees and expenses) to the extent arising out of any and all Claims related to (a) Licensor's performance of its obligations or exercise (by it or its Affiliates) of its or their rights under this Agreement; or (b) breach by Licensor of its representations and warranties set forth in Article VIII; provided, however, that Licensor's obligations pursuant to this Section 9.2 shall not apply (x) to the extent that such claims or suits result from the gross negligence or willful misconduct of any of the TGTX Indemnitees or (y) with respect to claims or suits arising out of a breach by TGTX of this Agreement, including without limitation its representations and warranties set forth in Article VIII.

9.3 **No Consequential, Etc., Damages**. EXCEPT FOR DAMAGES FOR WHICH A PARTY IS RESPONSIBLE PURSUANT TO ITS INDEMNIFICATION OBLIGATIONS SET FORTH IN ARTICLE IX, EACH PARTY SPECIFICALLY DISCLAIMS ALL LIABILITY FOR AND SHALL IN NO EVENT BE LIABLE TO ANY OTHER PARTY OR TO ANY OTHER PARTY'S AFFILIATES FOR ANY INCIDENTAL, SPECIAL, INDIRECT OR CONSEQUENTIAL DAMAGES, EXPENSES, LOST PROFITS, LOST SAVINGS, INTERRUPTIONS OF BUSINESS OR OTHER DAMAGES OF ANY KIND OR CHARACTER WHATSOEVER ARISING OUT OF OR RELATED TO THIS AGREEMENT OR THE DEVELOPMENT PROGRAM OR THE LICENSED TECHNOLOGY OR RESULTING FROM THE MANUFACTURE, HANDLING, MARKETING, SALE, DISTRIBUTION OR USE OF LICENSED PRODUCTS, REGARDLESS OF THE FORM OF ACTION, WHETHER IN CONTRACT, TORT, STRICT LIABILITY OR OTHERWISE, EVEN IF SUCH PARTY WAS ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

9.4 **Procedure**.

(a) The Party or other Person intending to claim indemnification under this Article IX (an "Indemnified Party") shall promptly notify the opposed Party (the "Indemnifying Party") of any Claim in respect of which the Indemnified Party intends to claim such indemnification (provided, that no delay or deficiency on the part of the Indemnified Party in so notifying the Indemnifying Party will relieve the Indemnifying Party of any liability or obligation under this Agreement except to the extent the Indemnifying Party has suffered actual prejudice directly caused by the delay or other deficiency), and the Indemnifying Party shall assume the defense thereof (with counsel selected by the Indemnifying Party and reasonably satisfactory to the Indemnified Party) whether or not such Claim is rightfully brought; provided, however, that an Indemnified Party shall have the right to retain its own counsel and to participate in the defense thereof, with the fees and expenses to be paid by the Indemnified Party unless the Indemnifying Party does not assume the defense or unless a representation of both the Indemnified Party and the Indemnifying Party by the same counsel would be inappropriate due to the actual or potential differing interests between them, in which case the reasonable fees and expenses of counsel retained by the Indemnified Party shall be paid by the Indemnifying Party. (Provided, that in no event shall the Indemnifying Party be required to pay for more than one separate counsel no matter the number or circumstances of all Indemnified Parties.)

(b) If the Indemnifying Party shall fail to timely assume the defense of and reasonably defend such Claim, the Indemnified Party shall have the right to retain or assume control of such defense and the Indemnifying Party shall pay (as incurred and on demand) the fees and expenses of counsel retained by the Indemnified Party.

(c) The Indemnifying Party shall not be liable for the indemnification of any Claim settled (or resolved by consent to the entry of judgment) without the written consent of the Indemnifying Party. Also, if the Indemnifying Party shall control the defense of any such Claim, the Indemnifying Party shall have the right to settle such Claim; provided, that the Indemnifying Party shall obtain the prior written consent (which shall not be unreasonably withheld or delayed) of the Indemnified Party before entering into any settlement of (or resolving by consent to the entry of judgment upon) such Claim unless (i) there is no finding or admission of any violation of law or any violation of the rights of any person by an Indemnified Party, no requirement that the Indemnified Party admit negligence, fault or culpability, and no adverse effect on any other claims that may be made by or against the Indemnified Party and (ii) the sole relief provided is monetary damages that are paid in full by the Indemnifying Party and such settlement does not require the Indemnified Party to take (or refrain from taking) any action.

(d) The Indemnified Party, and its employees and agents, shall cooperate fully with the Indemnifying Party and its legal representatives in the investigations of any Claim.

(e) Regardless of who controls the defense, each Party hereto shall reasonably cooperate in the defense as may be requested.

9.5 **Expenses**. As the Parties intend complete indemnification, all costs and expenses of enforcing any provision of this Article IX shall also be reimbursed by the Indemnifying Party..

9.6 **Limitation of Liability**. EACH PARTY SHALL HAVE NO REMEDY, AND EACH PARTY SHALL HAVE NO LIABILITY, OTHER THAN AS EXPRESSLY SET FORTH IN THIS AGREEMENT. EXCEPT WITH RESPECT TO THE INDEMNIFICATION SPECIFICALLY PROVIDED IN ARTICLE IX OR CLAIMS FOR NON-PAYMENT, IN NO EVENT SHALL A PARTY'S TOTAL AGGREGATE LIABILITY FOR ALL CLAIMS ARISING OUT OF OR RELATED TO THIS AGREEMENT EXCEED 50% OF THE AMOUNT PAID BY TGTX TO LICENSOR UNDER THIS AGREEMENT IN THE CASE OF LICENSOR OR EXCEED ONE MILLION DOLLARS IN THE CASE OF TGTX. NO ACTION, REGARDLESS OF FORM, ARISING OUT OF OR RELATED TO THIS AGREEMENT MAY BE BROUGHT BY EITHER PARTY MORE THAN TWO YEARS AFTER SUCH PARTY HAS KNOWLEDGE OF THE OCCURRENCE THAT GAVE RISE TO THE CAUSE OF ACTION OR AFTER EXPIRATION OF THE APPLICABLE STATUTORY LIMITATIONS PERIOD, WHICHEVER IS SOONER.

9.7 **Insurance.** During the Term and for three years thereafter, TGTX shall obtain and maintain, at its own cost and expense, product liability insurance (or TGTX's parent company shall obtain and maintain coverage for TGTX under its own product liability insurance policies) in amounts, that are reasonable and customary in the United States pharmaceutical and biotechnology industry for companies engaged in comparable activities, with Licensor identified as an additional named insured. It is understood and agreed that this insurance shall not be construed to limit TGTX's liability with respect to its indemnification obligations hereunder. TGTX shall upon request provide to Licensor upon request a certificate evidencing the insurance TGTX is required to obtain and keep in force under this Section 9.7.

ARTICLE X
TERM AND TERMINATION

10.1 **Term and Expiration.** 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 Licensor Patents have expired or been invalidated.

10.2 **Termination upon Material Breach.** If a Party breaches any of its material obligations under this Agreement, the Party not in default may give to the breaching Party a written notice specifying the nature of the default, requiring it to cure such breach, and, if desired, stating its intention to terminate this Agreement if such breach is not cured. If such breach is not capable of being cured, or is capable of being cured but nonetheless has not within 45 days after the receipt of such notice been cured, then the Party not in default shall (in addition to and not in lieu of all other available rights and remedies) be entitled to at its option either (a) terminate this Agreement immediately by written notice to the other Party, or (b) continue this Agreement in full force and effect and seek any legal or equitable remedies that the non-breaching Party may have. In case of a breach of an obligation to pay money, which obligation to pay is not disputed in good faith, the cure period shall be 15 days instead of 45 days. The Parties agree that any failure by TGTX to pay when due 100% of such portion of any amount of money owing from TGTX to Licensor as is not disputed in good faith by TGTX (subject to the 15-day cure period) shall conclusively be deemed to constitute a "material" breach. Notwithstanding the foregoing provisions, in the event of a good-faith dispute as to whether any alleged breach is in fact a breach, termination under this Section 10.2 in respect of such alleged breach shall not take effect unless and until (y) such dispute is resolved (by court or arbitration decision or otherwise) in favor of the Party alleging the breach or (z) the breaching Party's denial that the alleged breach is in fact a breach ceases to be in good faith.

10.3 **Termination for Bankruptcy.** Licensor may terminate this Agreement immediately upon written notice to TGTX in the event that TGTX has a petition in bankruptcy filed against it that is not dismissed within 60 days of such filing, files a petition in bankruptcy, or makes an assignment for the benefit of creditors. If TGTX has before such filing or such assignment entered into a written Sublicense which complies with Section 2.2, then the Sublicensee thereunder shall have the right to, by but only by delivering to Licensor within 30 days after such termination a written election to do so and a written assumption of all of TGTX's past and future obligations, liabilities and duties under this Agreement, convert its Sublicense into a direct of license from Licensor of the same technology, for the same field and for the same territory, as had been provided for in the Sublicense and otherwise on the same terms and conditions as are set forth in this Agreement as if such Sublicensee were TGTX hereunder. TGTX may terminate this Agreement immediately upon written notice to Licensor in the event that Licensor has a petition in bankruptcy filed against it that is not dismissed within 60 days of such filing, files a petition in bankruptcy, or makes an assignment for the benefit of creditors.

10.4 **Effects of Termination/Expiration.**

(a) Articles I (Definitions), VII (Confidentiality), IX (Indemnification; Limitation of Liability; Insurance) and XI (Miscellaneous Provisions) and Sections 5.6 (Royalty Reports and Records Retention**)**, 5.7 (Audits), 5.9 (Late Payments), 5.10 (Taxes) and 10.4 (Effects of Termination/Expiration) hereof shall survive the expiration or termination of this Agreement for any reason. In addition, upon termination of this Agreement by TGTX pursuant to Sections 10.2 or 10.3, then Section 6.6 (Third Party Actions Claiming Infringement) shall survive the expiration or termination of this Agreement.

(b) Termination or expiration of this Agreement shall not relieve the Parties of any liability that accrued hereunder before the effective date of such termination or expiration. In addition, termination or expiration of this Agreement shall not preclude either Party from pursuing all rights and remedies it may have hereunder or at Law or in equity with respect to any breach of this Agreement nor prejudice either Party's right to obtain performance of any obligation.

(c) Upon termination of this Agreement by Licensor pursuant to Section 10.2, all licenses granted to TGTX hereunder shall terminate. If TGTX has before the breach entered into a written Sublicense which complies with Section 2.2, then the Sublicensee thereunder shall have the right to, by but only by delivering to Licensor within 30 days after such termination a written election to do so and a written assumption of all of TGTX's past and future obligations, liabilities and duties under this Agreement and a tender of funds or other action to directly and fully cure TGTX's breach, convert its Sublicense into a direct of license from Licensor of the same technology, for the same field and for the same territory, as had been provided for in the Sublicense and otherwise on the same terms and conditions as are set forth in this Agreement as if such Sublicensee were TGTX hereunder. In the event of termination by TGTX pursuant to Section 10.2, the licenses granted to TGTX hereunder shall continue in effect but become fully paid-up, royalty-free, transferable (to the extent not transferable previously), perpetual and irrevocable.

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 Licensor, which consent shall not be unreasonably withheld, conditioned or delayed; *provided that,* notwithstanding the foregoing, TGTX may assign its rights or licenses and/or delegate its obligations under this Agreement to an Affiliate or to a successor to all or substantially all of TGTX's assets, whether by way of merger, sale of all or substantially all of its assets, sale of stock or otherwise, without Licensor's prior written consent. As a condition to any permitted assignment hereunder, the assignee must expressly assume, in a writing delivered to Licensor (and in a form reasonably acceptable to Licensor) all of TGTX's obligations under this Agreement, whether arising before, at or after the assignment.

(d) Licensor may not transfer or assign its rights 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 TGTX, which consent shall not be unreasonably withheld, conditioned or delayed; *provided that*, notwithstanding the foregoing, Licensor may, without TGTX's prior written consent, assign its rights and/or delegate its obligations under this Agreement to an Affiliate, or to any person in a transaction in which Licensor also assigns all of its right, title and interest in all or substantially all of its Licensor Technology assets, including without limitation, intellectual property rights, to the same party contemporaneous with the assignment of this Agreement, or to a successor, whether by way of merger, sale of all or substantially all of its assets, sale of stock or otherwise. As a condition to any permitted assignment hereunder, the assignee must expressly assume, in a writing delivered to TGTX (and in a form reasonably acceptable to TGTX) all of Licensor'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 TGTX, addressed to:

TG Therapeutics, Inc.
3 Columbus Circle, 15th Floor
New York, NY 10019
Attention: Michael S. Weiss, Executive Chairman, Interim President and Chief Executive Officer
Email: msw@opuspointpartners.com

If to Licensor, addressed to:

General Counsel
Ligand Pharmaceuticals Incorporated
11119 North Torrey Pines Road, Suite 200
La Jolla, CA 92037
Email: cberkman@ligand.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 10.2 and 10.4(c), 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 Licensor under this Agreement shall only be pursued by TGTX or such Indemnified Party, and not Sublicensees (except as set forth in Sections 10.2 and 10.4(c)).

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 Licensor or its Affiliates, except by an express license granted hereunder. No right or license is granted to Licensor 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 Section 5.7(b) of this Agreement, TGTX shall not have a right to set-off any royalties, milestones or other amount due to Licensor under this Agreement against any damages incurred by TGTX for a breach by Licensor 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 License Agreement to be executed and delivered by their respective duly authorized officers as of the day and year first above written.

LIGAND PHARMACEUTICALS INCORPORATED

By: /s/ Matthew W. Foehr

Name: Matthew W. Foehr

Title: EVP/COO

TG THERAPEUTICS, INC.

By: /s/ Michael S. Weiss

Name: Michael S. Weiss

Title: Executive Chairman, Interim President and Chief Executive Officer

Schedule 1

Compounds*

* Confidential material redacted and filed separately with the Commission.

Schedule 2

Licensor Know-How*

* Confidential material redacted and filed separately with the Commission.

Schedule 3

Licensor Patent Rights*

* Confidential material redacted and filed separately with the Commission.

Exhibit 31.1

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: July 24, 2014

/s/ Michael S. Weiss
Michael S. Weiss
Executive Chairman, Interim Chief Executive Officer and President
Principal Executive Officer

Exhibit 31.2

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: July 24, 2014

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

Exhibit 32.1

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 June 30, 2014 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: July 24, 2014

/s/ Michael S. Weiss
Michael S. Weiss
Executive Chairman, Interim Chief Executive Officer and President
Principal Executive Officer

Exhibit 32.2

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 June 30, 2014 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: July 24, 2014

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