TG THERAPEUTICS, INC.
Form 10-Q
August 10, 2015

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, 2015

OR

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

For the transition period from _____ to _____

Commission File Number 000-30929

TG THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**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 x
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 x

There were 52,547,286 shares of the registrant's common stock, $0.001 par value, outstanding as of August 4, 2015.

TG THERAPEUTICS, INC.

FORM 10-Q

FOR THE QUARTER ENDED JUNE 30, 2015

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SPECIAL CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS

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

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

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

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

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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

TG Therapeutics, Inc.

Condensed Consolidated Balance Sheets

	June 30, 2015 (Unaudited)	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$60,300,086	$55,713,784
Short-term investment securities	31,765,910	23,062,034
Interest receivable	190,313	85,516
Prepaid research and development	10,921,958	6,179,743
Other current assets	548,776	173,952
Total current assets	103,727,043	85,215,029
Restricted cash	577,110	575,012
Long-term investment securities	18,311,340	--
Equipment, net	34,833	20,357
Goodwill	799,391	799,391
Other assets	155,564	137,101
Total assets	$123,605,281	$86,746,890
Liabilities and equity		
Current liabilities:		
Accounts payable and accrued expenses	$8,254,189	$3,991,625
Accrued compensation	506,000	702,000
Current portion of deferred revenue	152,381	152,381
Notes payable	295,360	275,190
Total current liabilities	9,207,930	5,121,196
Deferred revenue, net of current portion	1,447,619	1,523,810
Total liabilities	10,655,549	6,645,006
Commitments and contingencies		
Equity:		
Preferred stock, $0.001 par value per share (10,000,000 shares authorized, none issued and outstanding as of June 30, 2015 and December 31, 2014)	--	--
Common stock, $0.001 par value per share (150,000,000 shares authorized, 51,697,864 and 44,974,248 shares issued, 51,656,555 and 44,932,939 shares	51,698	44,974

outstanding at June 30, 2015 and December 31, 2014, respectively)		
Contingently issuable shares	6	6
Additional paid-in capital	239,998,563	175,476,521
Treasury stock, at cost	(234,337)	(234,337)
Accumulated deficit	(126,866,198)	(95,185,280)
Total equity	112,949,732	80,101,884
Total liabilities and equity	$123,605,281	$86,746,890

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,	
	2015	2014	2015	2014
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	1,359,446	3,300,111	2,697,354	5,201,721
Other research and development	9,902,214	2,336,771	18,181,645	4,845,029
Total research and development	11,261,660	6,848,132	20,878,999	11,258,000
General and administrative:				
Noncash compensation	4,883,540	4,438,735	8,902,660	6,768,563
Other general and administrative	1,004,475	706,725	2,008,962	1,610,249
Total general and administrative	5,888,015	5,145,460	10,911,622	8,378,812
Total costs and expenses	17,149,675	11,993,592	31,790,621	19,636,812
Operating loss	(17,111,580)	(11,955,497)	(31,714,431)	(19,560,622)
Other (income) expense:				
Interest income	(31,551)	(12,727)	(53,683)	(26,201)
Other income	--	--	--	(95,427)
Interest expense	246,526	234,787	484,183	461,127
Change in fair value of notes payable	(223,372)	(191,127)	(464,013)	(366,442)
Total other (income) expense	(8,397)	30,933	(33,513)	(26,943)
Net loss	$(17,103,183)	$(11,986,430)	$(31,680,918)	$(19,533,679)
Basic and diluted net loss per common share	$(0.38)	$(0.36)	$(0.73)	$(0.62)
Weighted average shares used in computing basic and diluted net loss per common share	45,320,637	32,985,130	43,216,385	31,546,060

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, 2015 (Unaudited)

	Preferred stock		Common stock		Contingently issuable shares	Additional paid-in capital	Treasury Stock		Accumulated Deficit	Total
	Shares	Amount	Shares	Amount			Shares	Amount		
Balance at January 1, 2015	--	$--	44,974,248	$44,974	$6	$175,476,521	41,309	$(234,337)	$(95,185,280)	$80,101,884
Issuance of common stock in connection with exercise of warrants			2,914,703	2,915		989,729				992,644
Issuance of common stock in connection with cashless exercise of warrants			2,915	3		(3)				--
Issuance of restricted stock			471,592	471		(471)				--
Forfeiture of restricted stock			(1,166)	(1)		1				--
Issuance of common stock to affiliate for cash (See Note 8)			114,855	115		749,888				750,003
Issuance of common stock in At the Market offering (net of offering costs of $965,188)			3,220,717	3,221		51,182,884				51,186,105
						11,600,014				11,600,014

Compensation in respect of restricted stock granted to employees, directors and consultants										
Net loss									(31,680,918)	(31,680,918)
Balance at June 30, 2015	--	$--	51,697,864	$51,698	$6	$239,998,563	41,309	$(234,337)	$(126,866,198)	$(112,949,732)

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,	
	2015	2014
CASH FLOWS FROM OPERATING ACTIVITIES:		
Consolidated net loss	$(31,680,918)	$(19,533,679)
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	11,600,014	11,970,284
Noncash stock expense associated with in-licensing agreement	--	1,211,250
Depreciation	5,805	1,558
Amortization of premium on investment securities	205,409	66,943
Change in fair value of notes payable	20,170	94,685
Changes in assets and liabilities:		
Increase in restricted cash	(2,098)	--
Increase in other current assets	(5,117,040)	(2,383,969)
Increase in accrued interest receivable	(104,797)	(47,513)
Increase in other assets	--	(13,244)
Increase (decrease) in accounts payable and accrued expenses	4,018,767	(3,002,113)
Decrease in interest payable	--	(94,590)
Decrease in deferred revenue	(76,191)	(76,191)
Net cash used in operating activities	(21,130,879)	(11,902,006)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of equipment	(20,280)	(3,165)
Investment in held-to-maturity long-term securities	(18,324,355)	(6,127,539)
Investment in held-to-maturity short-term securities	(16,746,270)	(3,090,469)
Proceeds from maturity of short-term securities	7,850,000	--
Net cash used in investing activities	(27,240,905)	(9,221,173)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from the exercise of warrants	992,644	1,602,060
Payment of notes payable	--	(677,778)
Proceeds from sale of common stock, net	51,984,879	16,791,408
Deferred financing costs paid	(19,437)	--
Net cash provided by financing activities	52,958,086	17,715,690
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	4,586,302	(3,407,489)
Cash and cash equivalents at beginning of period	55,713,784	40,485,466
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$60,300,086	$37,077,977

NONCASH TRANSACTIONS		
Accrued financing costs	$47,797	$--
Reclassification of deferred financing costs to additional paid-in capital	$(48,771)	$--

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

TG Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements (unaudited)

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

NOTE 1 – ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Description of Business

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

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

The accompanying unaudited condensed consolidated financial statements were prepared in accordance with U.S. generally accepted accounting principles, or GAAP, for interim financial information and with the instructions to Quarterly Report on Form 10-Q and Article 10 of Regulation S-X of the Exchange Act. Accordingly, they may not include all of the information and footnotes required by GAAP for complete financial statements. All adjustments that are, in the opinion of management, of a normal recurring nature and are necessary for a fair presentation of the condensed consolidated financial statements have been included. Nevertheless, these condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements contained in our Annual Report on Form 10-K for the year ended December 31, 2014. The accompanying December 31, 2014 balance sheet has been derived from these statements. The results of operations for the three and six months ended June 30, 2015 are not necessarily indicative of the results that may be expected for the entire fiscal year or any other interim period.

Liquidity and Capital Resources

We have incurred operating losses since our inception and expect to continue to incur operating losses for the foreseeable future and, may never become profitable. As of June 30, 2015, we have an accumulated deficit of $126,866,198.

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

As of June 30, 2015, we had approximately $110.6 million in cash, cash equivalents, investment securities, and interest receivable. We anticipate that our cash and cash equivalents and investments will be sufficient to fund our anticipated operating cash requirements for more than 24 months from June 30, 2015. The actual amount of cash that we will need to operate is subject to many factors, including, but not limited to, the timing, design and conduct of clinical trials for our drug candidates. We are dependent upon significant future financing to provide the cash necessary to execute our current strategic plan, including the commercialization of any of our drug candidates.

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

Recently Issued Accounting Standards

In May 2014, the Financial Accounting Standards Board ("FASB") issued an Accounting Standards 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 us beginning in fiscal 2018. We are currently evaluating the impact of this update on our consolidated financial statements.

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

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

Use of Estimates

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

Cash and Cash Equivalents

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

Restricted Cash

We record cash pledged or held in trust as restricted cash. As of June 30, 2015, we have approximately $0.6 million of restricted cash pledged to secure a line of credit as a security deposit for a Desk Space Agreement (see Note 8).

Investment Securities

Investment securities at June 30, 2015 and December 31, 2014 consist of short-term and long-term government securities. We classify these securities as held-to-maturity. Held-to-maturity securities are those securities in which we have the ability and intent to hold the security until maturity. Held-to-maturity securities are recorded at amortized cost, adjusted for the amortization or accretion of premiums or discounts. Premiums and discounts are amortized or accreted over the life of the related held-to-maturity security as an adjustment to yield using the effective interest method.

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

Credit Risk

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

Revenue Recognition

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

Research and Development Costs

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

policy is to match the recording of expenses in our financial statements to the actual services received and efforts expended. As such, expense accruals related to clinical site costs are recognized based on our estimate of the degree of completion of the event or events specified in the specific clinical study or trial contract.

Income Taxes

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

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

Stock-Based Compensation

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

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

Basic and Diluted Net Loss Per Common Share

Basic net loss per share of our common stock is calculated by dividing net loss applicable to the common stock by the weighted-average number of our common stock outstanding for the period. Diluted net loss per share of common stock is the same as basic net loss per share of common stock since potentially dilutive securities from stock options, stock warrants and convertible preferred stock would have an antidilutive effect either because we incurred a net loss during the period presented or because such potentially dilutive securities were out of the money and the Company realized net income during the period presented. The amounts of potentially dilutive securities excluded from the calculation were 5,668,134 and 9,702,633 at June 30, 2015 and 2014, respectively. During the three and six months ended June 30, 2015 and 2014, we incurred a net loss; therefore, all of the dilutive securities are excluded from the computation of diluted earnings per share.

Long-Lived Assets and Goodwill

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

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

NOTE 2 – CASH AND CASH EQUIVALENTS

The following tables summarize our cash and cash equivalents at June 30, 2015 and December 31, 2014:

	June 30, 2015	December 31, 2014
Money market funds	$5,267,687	$12,364,537
Checking and bank deposits	55,032,399	43,349,247
Total	$60,300,086	$55,713,784

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, 2015 and December 31, 2014:

	June 30, 2015			
	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 July 2015 and June 2016) (held-to-maturity)	$31,765,910	$ 6,781	$ 1,326	$31,771,365
Long-term investments:				
Obligations of domestic governmental agencies (maturing between July 2016 and June 2017) (held-to-maturity)	18,311,340	17,165	470	18,328,035
Total short-term and long-term investment securities	$50,077,250	$ 23,946	$ 1,796	$50,099,400

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

NOTE 4 – FAIR VALUE MEASUREMENTS

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

- Level 1 – quoted prices in active markets for identical assets and liabilities;

- Level 2 – inputs other than Level 1 quoted prices that are directly or indirectly observable; and

- Level 3 – unobservable inputs that are not corroborated by market data.

As of June 30, 2015 and December 31, 2014, the fair values of cash and cash equivalents, restricted cash, and notes and interest payable, current portion approximate their carrying value.

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

The cumulative liability including accrued and unpaid interest of the 5% Notes was approximately $19.5 million at December 31, 2014 and $20.0 million at June 30, 2015. No payments have been made on the 5% Notes as of June 30, 2015.

In December 2011 we elected the fair value option for valuing the 5% Notes. The fair value option was elected in order to reflect in our financial statements the assumptions that market participants use in evaluating these financial instruments.

As of December 31, 2013, as a result of expiring intellectual property rights and other factors, it was determined that net product cash flows from AST-726 were unlikely. As we have no other obligations under the 5% Notes aside from the net product cash flows and the conversion feature, the conversion feature was used to estimate the 5% Notes' fair value as of June 30, 2015 and December 31, 2014. The assumptions, assessments and projections of future revenues are subject to uncertainties, difficult to predict, and require significant judgment. The use of different assumptions, applying different judgment to inherently subjective matters and changes in future market conditions could result in significantly different estimates of fair value and the differences could be material to our consolidated financial statements.

The following tables provide the fair value measurements of applicable financial liabilities as of June 30, 2015 and December 31, 2014:

	Financial liabilities at fair value as of June 30, 2015			
	Level 1	Level 2	Level 3	Total
5% Notes	$--	$ --	$295,360	$295,360
Totals	$--	$ --	$295,360	$295,360

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

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

The following table summarizes the changes in Level 3 instruments during the six months ended June 30, 2015:

Fair value at December 31, 2014	$275,190
Interest accrued on face value of 5% Notes	484,183
Change in fair value of Level 3 liabilities	(464,013)
Fair value at June 30, 2015	$295,360

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

NOTE 5 - STOCKHOLDERS' EQUITY

Preferred Stock

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

Common Stock

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

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

During the six months ended June 30, 2015, we sold a total of 3,220,717 shares of common stock under the 2015 ATM for aggregate total gross proceeds of approximately $52.2 million at an average selling price of $16.19 per share, resulting in net proceeds of approximately $51.2 million after deducting commissions and other transaction costs.

From July 1, 2015 through August 6, 2015, we sold an aggregate of 873,781 shares of common stock pursuant to the 2015 ATM for total gross proceeds of approximately $16.1 million at an average selling price of $18.38 per share, resulting in net proceeds of approximately $15.8 million after deducting commissions and other transaction costs.

We currently have two shelf registration statements on Form S-3 filed and declared effective by the SEC (File No. 333-189015 and File No. 333-201339). After deducting shares already sold, approximately $248.3 million of common stock remains available for sale under these shelf registration statements. We may offer the securities under our shelf registration statements from time to time in response to market conditions or other circumstances if we believe such a plan of financing is in the best interests of our stockholders. We believe that these shelf registration statements provide us with the flexibility to raise additional capital to finance our operations as needed.

Equity Incentive Plans

An amendment to the TG Therapeutics, Inc. Amended and Restated 2012 Incentive Plan ("2012 Incentive Plan") was approved by stockholders in June 2015. Pursuant to this amendment, 6,000,000 shares were added to the 2012

Incentive Plan. Shares available for the issuance of stock options or other stock-based awards under our 2012 Incentive Plan were 5,655,574 shares at June 30, 2015.

Stock Options

The following table summarizes stock option activity for the three months ended June 30, 2015:

	Number of shares	Weighted-average exercise price	Weighted-average Contractual Term	Aggregate Intrinsic Value
			(in years)	
Outstanding at December 31, 2014	194	$ 971.70	3.50	$ --
Granted	--	--		
Exercised	--	--		
Forfeited	--	--		
Expired	(42)	2,811.53		
Outstanding at June 30, 2015	152	$ 463.32	3.97	$ --
Exercisable at June 30, 2015	152	$ 463.32	3.97	$ --

As of June 30, 2015, there are no unvested option awards and no unrecognized compensation cost related to option awards.

Restricted Stock

Certain employees, directors and consultants have been awarded restricted stock. The restricted stock vesting consists of milestone and time-based vesting. The following table summarizes restricted share activity for the six months ended June 30, 2015:

	Number of Shares	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2014	6,400,001	$ 5.86
Granted	471,592	16.03
Vested	(813,997)	4.99
Forfeited	(1,166)	10.53
Outstanding at June 30, 2015	6,056,430	$ 6.77

Total expense associated with restricted stock grants was approximately $11.6 million during the six months ended June 30, 2015. As of June 30, 2015, there was approximately $21.0 million of total unrecognized compensation cost related to unvested time-based restricted stock, which is expected to be recognized over a weighted-average period of 2.2 years. This amount does not include, as of June 30, 2015, 1,863,167 shares of restricted stock outstanding issued to non-employees. The expense for non-employee shares is determined at the “measurement date.” The expense is recognized over the vesting period of the award. Until the measurement date is reached, the total amount of compensation expense remains uncertain. We record compensation expense based on the fair value of the award at the reporting date.

Warrants

The following table summarizes warrant activity for the six months ended June 30, 2015:

	Warrants	Weighted-average	Aggregate Intrinsic Value

		exercise price	
Outstanding at December 31, 2014	4,148,228	$ 0.94	$61,792,184
Issued	--	--	
Exercised	(2,918,115)	0.34	
Expired	(11,364)	2.25	
Outstanding at June 30, 2015	1,218,749	$ 2.37	$17,327,944

Stock-Based Compensation

The fair value of stock options granted is estimated at the date of grant using the Black-Scholes pricing model. The expected term of options granted is derived from historical data and the expected vesting period. Expected volatility is based on the historical volatility of our common stock. The risk-free interest rate is based on the U.S. Treasury yield for a period consistent with the expected term of the option in effect at the time of the grant. We have assumed no expected dividend yield, as dividends have never been paid to stock or option holders and will not be paid for the foreseeable future. We did not grant any stock options during the six months ended June 30, 2015 and 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, 2015:

	Three months ended June 30, 2015	**Six months ended June 30, 2015**
Stock-based compensation expense associated with restricted stock	$6,242,986	$11,600,014
Stock-based compensation expense associated with option grants	--	--
	$6,242,986	$11,600,014

NOTE 6 – NOTES PAYABLE

The following is a summary of notes payable:

	June 30, 2015			December 31, 2014		
	Current portion, net	Non-current portion, net	Total	Current portion, net	Non-current portion, net	Total
Convertible 5% Notes Payable	$295,360	$ -	$295,360	$275,190	$ -	$275,190
Total	$295,360	$ -	$295,360	$275,190	$ -	$275,190

Convertible 5% Notes Payable

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

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

The cumulative liability including accrued and unpaid interest of these notes was approximately $20.0 million at June 30, 2015 and $19.5 million at December 31, 2014. No payments have been made on the 5% Notes as of June 30, 2015.

In December 2011 we elected the fair value option for valuing the 5% Notes. The fair value option was elected in order to reflect in our financial statements the assumptions that market participants use in evaluating these financial instruments (See Note 4 for further details).

NOTE 7 – LICENSE AGREEMENTS

Anti-PD-L1 and anti-GITR

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

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

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

TG-1101

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

An upfront payment of $2,000,000, which was received in December 2012, net of $330,000 of income tax withholdings, is being recognized as license revenue on a straight-line basis over the life of the agreement, which is through the expiration of the last licensed patent right or 15 years after the first commercial sale of a product in such country, unless the agreement is earlier terminated, and represents the estimated period over which we will have certain ongoing responsibilities under the sublicense agreement. We recorded license revenue of approximately $76,000 for each of the six months ended June 30, 2015 and 2014 and, at June 30, 2015 and December 31, 2014, have deferred revenue of approximately $1.6 million and $1.7 million, respectively, associated with this $2,000,000 payment (approximately $152,000 of which has been classified in current liabilities at June 30, 2015 and December 31, 2014).

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

NOTE 8 – RELATED PARTY TRANSACTIONS

LFB Biotechnologies

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

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

Under the terms of the LFB License Agreement, we utilize LFB Group for certain development and manufacturing services. We incurred approximately $2.3 million and $183,000 in expenses for such services during the six months ended June 30, 2015 and 2014, respectively, which have been included in other research and development expenses in the accompanying consolidated statements of operations. As of June 30, 2015 and December 31, 2014, we had approximately $1.8 million and $52,000, respectively, recorded in accounts payable related to the LFB License Agreement. In conjunction with the development and manufacturing services discussed above, certain agreements between us and LFB Group require payments in advance of services performed or goods delivered. Accordingly, as of June 30, 2015 and December 31, 2014, we recorded $5,707,223 and $1,886,518, respectively, in prepaid research and development for such advance payments.

Other Parties

In March 2014, we entered into a shared services agreement with Opus Point Partners Management, LLC (“Opus”) in which the parties agreed to share the costs of a rented facility and certain other services. Our Executive Chairman and Interim Chief Executive Officer, is a Managing Member of Opus. During the six months ended June 30, 2015, we incurred expenses of approximately $116,000, principally for rent, related to this agreement. As of June 30, 2015, we had approximately $37,000 recorded in accounts payable related to this shared services agreement.

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

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

In connection with the Desk Agreement, we paid $80,000 in advance rent payments, which is recorded in other current assets in the accompanying consolidated balance sheets as of June 30, 2015 and December 31, 2014. Also in connection with this lease, in October 2014 we pledged $0.6 million to secure a line of credit as a security deposit for the Desk Agreement, which has been recorded as Restricted Cash in the accompanying consolidated balance sheets.

NOTE 9 – SUBSEQUENT EVENTS

From July 1, 2015 through August 6, 2015, we sold an aggregate of 873,781 shares of common stock pursuant to the 2015 ATM for total gross proceeds of approximately $16.1 million at an average selling price of $18.38 per share, resulting in net proceeds of approximately $15.8 million after deducting commissions and other transaction costs.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

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

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

OVERVIEW

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

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

TG-1101 (ublituximab)

Overview

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

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

Clinical Trials Overview and Recent Developments

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

- TG-1101 in combination with ibrutinib (trade name IMBRUVICA®), a Bruton's Tyrosine Kinase ("BTK") inhibitor, for patients with CLL; and
- TG-1101 in combination with TGR-1202, our development stage PI3K inhibitor, for patients with CLL and NHL.

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

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

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

The MD Anderson Cancer Center is the lead center for the trial with Nathan Fowler, MD, Assistant Professor and Co-Director of Clinical Research in the Department of Lymphoma, as the Study Chair for the NHL patient group and Susan O'Brien, MD, formerly of MD Anderson and now Professor and Medical Director for Cancer Clinical Trials and Research at UC Irvine as the Study Chair for the CLL patient group. As of July 2015, enrollment into this study is ongoing in select expansion cohorts.

Preliminary data from this study was presented at the 51st American Society of Clinical Oncology (ASCO) Annual Meeting held in Chicago, IL in May/June 2015, and again in June 2015 at both the 20th European Hematology Association (EHA) Meeting held in Vienna, Austria as well as at the 13th International Congress on Malignant Lymphoma (ICML), held in Lugano, Switzerland.

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

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

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

Preliminary data from this study was presented at the 56th Annual American Society of Hematology (ASH) meeting held in San Francisco, CA in December 2014, and most recently updated at the 13th International Congress on Malignant Lymphoma (ICML), held in Lugano, Switzerland in June 2015.

TG-1101 + Ibrutinib Phase 3 Study Program – The GENUINE Trial

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

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

TGR-1202

Overview

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

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

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

Clinical Trials Overview and Recent Developments

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

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

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

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

Preliminary data from this study was presented at the 51st American Society of Clinical Oncology (ASCO) Annual Meeting held in Chicago, IL in May/June 2015, and again in June 2015 at both the 20th European Hematology Association (EHA) Meeting held in Vienna, Austria as well as at the 13th International Congress on Malignant Lymphoma (ICML), held in Lugano, Switzerland.

TGR-1202 Combination Trials

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

IRAK4

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

PD-L1 and GITR

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

GENERAL CORPORATE

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

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

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

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

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

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

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

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

RESULTS OF OPERATIONS

Three months ended June 30, 2015 and June 30, 2014

License Revenue. License revenue was $38,095 for each of the three months ended June 30, 2015 and 2014. License revenue for the three months ended June 30, 2015 and 2014 was related to the amortization of an upfront payment of $2.0 million received in 2012 associated with our license agreement with Ildong. The upfront payment from Ildong will be recognized as license revenue on a straight-line basis through December 2025, which represents the estimated period over which 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 $0 for the three months

ended June 30, 2015, as compared to $1,211,250 during the comparable period in 2014. 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 IRAK4 inhibitors program.

Noncash Compensation Expense (Research and Development). Noncash compensation expense (research and development) related to equity incentive grants totaled $1,359,446 for the three months ended June 30, 2015, as compared to $3,300,111 during the comparable period in 2014. The decrease in noncash compensation expense was primarily related to milestone-based vesting of restricted stock grants to personnel that occurred during the period ended June 30, 2014.

Other Research and Development Expenses. Other research and development expenses increased by $7,565,443 to $9,902,214 for the three months ended June 30, 2015, as compared to $2,336,771 for the three months ended June 30, 2014. Due to increased clinical trials, increased number of patients on study, and increased manufacturing and clinical trial expenses, research and development expenses related to TG-1101 and TGR-1202 increased by approximately $5.8 million and $1.3 million, respectively. We expect our other research and development costs to increase modestly for the remainder of 2015 due primarily to the enrollment of additional patients in our clinical trials.

Noncash Compensation Expense (General and Administrative). Noncash compensation expense (general and administrative) related to equity incentive grants increased by $444,805 to $4,883,540 for the three months ended June 30, 2015, as compared to $4,438,735 for the three months ended June 30, 2014. The increase in noncash compensation expense was primarily related to the recording of the fair value of equity awards granted to general and administrative personnel and directors, which are expensed over the vesting periods of the individual awards.

Other General and Administrative Expenses. Other general and administrative expenses increased by $297,750 to $1,004,475 for the three months ended June 30, 2015, as compared to $706,725 for the three months ended June 30, 2014. We expect our other general and administrative expenses to remain at a comparable level for the remainder of 2015.

Other (Income) Expense. Other income increased by $39,330 to $8,397 of income for the three months ended June 30, 2015, as compared to $30,933 of expenses for the three months ended June 30, 2014.

Six months ended June 30, 2015 and June 30, 2014

License Revenue. License revenue was $76,190 for each of the six months ended June 30, 2015 and 2014. License revenue for the six months ended June 30, 2015 and 2014 was related to the amortization of an upfront payment of $2.0 million received in 2012 associated with our license agreement with Ildong.

Noncash Stock Expense Associated with In-Licensing Agreement (Research and Development). Noncash stock expense associated with in-licensing agreement (research and development) amounted to $0 for the six months ended June 30, 2015 compared to $1,211,250 for the six months ended June 30, 2014. 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 IRAK4 inhibitors program.

Noncash Compensation Expense (Research and Development). Noncash compensation expense (research and development) related to equity incentive grants totaled $2,697,354 for the six months ended June 30, 2015, as compared to $5,201,721 during the comparable period in 2014. The decrease 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 increased by $13,336,616 to $18,181,645 for the six months ended June 30, 2015, as compared to $4,845,029 for the six months ended June 30, 2014. The increase in other research and development expenses was due primarily to increases of approximately $9.8 million and $2.5 million for research and development expenses related to TG-1101 and TGR-1202, respectively. We expect our other research and development costs to increase modestly for the remainder of 2015 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 $2,134,097 to $8,902,660 for the six months ended June 30, 2015, as compared to $6,768,563 for the six months ended June 30, 2014. The increase in noncash compensation expense was primarily related to the recording of the fair value of equity awards granted to general and administrative personnel and directors, which are expensed over the vesting periods of the individual awards.

Other General and Administrative Expenses. Other general and administrative expenses increased by $398,713 to $2,008,962 for the six months ended June 30, 2015, as compared to $1,610,249 for the six months ended June 30, 2014. We expect our other general and administrative expenses to remain at a comparable level for the remainder of 2015.

Other (Income) Expense. Other income increased by $6,570 to $33,513 for the six months ended June 30, 2015, as compared to $26,943 for the six months ended June 30, 2014.

LIQUIDITY AND CAPITAL RESOURCES

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

As of June 30, 2015, we had $110,567,649 in cash and cash equivalents, investment securities, and interest receivable. Subsequent to the quarter ended June 30, 2015, we sold a total of 873,781 shares of common stock under the 2015 ATM for aggregate net proceeds of approximately $15.8 million.

We anticipate that our cash and cash equivalents as of June 30, 2015 plus the amounts raised subsequent to the end of the quarter are sufficient to fund our anticipated operating cash requirements for more than 24 months from June 30, 2015. The actual amount of cash that we will need to operate is subject to many factors, including, but not limited to, the timing, design and conduct of clinical trials for our drug candidates. We are dependent upon significant financing to provide the cash necessary to execute our current operations, including the commercialization of any of our drug candidates.

Cash used in operating activities for the six months ended June 30, 2015 was $21,130,879 as compared to $11,902,006 for the six months ended June 30, 2014. The increase in cash used in operating activities was due primarily to increased expenditures associated with our clinical development programs for TG-1101 and TGR-1202.

For the six months ended June 30, 2015, net cash used in investing activities was $27,240,905 as compared to $9,221,173 for the six months ended June 30, 2014. The increase in net cash used in investing activities was primarily due to purchases of investment in held-to-maturity treasury securities.

For the six months ended June 30, 2015, net cash provided by financing activities of $52,958,086 related to our ATM program, as well as proceeds from the exercise of warrants. 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.

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

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

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

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

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

RECENTLY ISSUED ACCOUNTING STANDARDS

In May 2014, the FASB issued an Accounting Standards 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 us beginning in fiscal 2018. We are currently evaluating the impact of this update on our consolidated financial statements.

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

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

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The primary objective of our investment activities is to preserve principal while maximizing our income from investments and minimizing our market risk. We invest in government and investment-grade corporate debt in accordance with our investment policy. Some of the securities in which we invest have market risk. This means that a change in prevailing interest rates, and/or credit risk, may cause the fair value of the investment to fluctuate. For example, if we hold a security that was issued with a fixed interest rate at the then-prevailing rate and the prevailing interest rate later rises, the fair value of our investment will probably decline. As of June 30, 2015, our portfolio of financial instruments consists of cash equivalents, including bank deposits, and investments. Due to the short-term nature of our investments, we believe there is no material exposure to interest rate risk, and/or credit risk, arising from our investments.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

As of June 30, 2015, management carried out, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Our disclosure controls and procedures are designed to provide reasonable assurance that information we are required to disclose in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in applicable rules and forms. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of June 30, 2015, our disclosure controls and procedures were effective.

Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended June 30, 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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

ITEM 1A. RISK FACTORS

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

Risks Related to Our Business and Industry

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

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

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

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

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

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

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

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

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

Pharmaceutical development has inherent risk. We will be required to demonstrate through adequate and well-controlled clinical trials that our product candidates are effective with a favorable benefit-risk profile for use in diverse populations for their target indications before we can seek regulatory approvals for their commercial sale. Success in early clinical trials does not mean that later clinical trials will be successful because product candidates in later-stage clinical trials may fail to demonstrate sufficient safety or efficacy despite having progressed through initial

clinical testing. Companies frequently suffer significant setbacks in advanced clinical trials, even after earlier clinical trials have shown promising results. In addition, there is typically an extremely high rate of failure of pharmaceutical candidates proceeding through clinical trials.

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

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

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

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

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

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

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

FDA, and any other regulatory body around the world can delay, limit or deny approval of a product candidate for many reasons, including:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for any indication;

- the FDA may not accept clinical data from trials which are conducted by individual investigators or in countries where the standard of care is potentially different from the United States;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a BLA, NDA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we or our collaborators contract for clinical and commercial supplies; or
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

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

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

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

We have not completed testing of any of our product candidates for the treatment of the indications for which we intend to seek product approval in humans, and we currently do not know the extent that adverse events, if any, will be observed in patients who receive any of our product candidates. To date, clinical trials using TG-1101 and TGR-1202 have demonstrated a toxicity profile that was deemed acceptable by the investigators performing such studies. Such interpretation may not be shared by future investigators or by the FDA and in the case of TG-1101 and TGR-1202, even if deemed acceptable for oncology applications, it may not be acceptable for diseases outside the oncology setting, and likewise for any other product candidates we may develop. Additionally, the severity, duration and incidence of adverse events may increase in larger study populations. With respect to both TG-1101 and TGR-1202, the toxicity when manufactured under different conditions and in different formulations 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. Further, with respect to TGR-1202, although more than 50 patients have been dosed in the ongoing first-in-human dose-escalation Phase I single agent study, the full adverse effect profile of TGR-1202 is not known. It is unknown as the dose escalation continues and expansion cohorts are initiated and patients are exposed for longer durations to TGR-1202, whether greater frequency and/or severity of adverse events are likely to occur as a maximum tolerated dose is reached. Common toxicities of other drugs in the same class as TGR-1202 include high levels of liver toxicity and colitis, the latter of which notably has presented with later onset, with incidence increasing with duration of exposure. To date, the incidence of these events has been limited for TGR-1202, however, no assurance can be given that this safety and tolerability profile will continue to be demonstrated in the future as higher doses, longer durations of exposure, and multiple drug combinations are explored. 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, or even if approved for sale may lack differentiation from competitive products, which could have a material adverse impact on our business and operations.

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

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

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

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

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

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

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

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

We must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA places the IND on a clinical hold within that 30-day time period. In such a case, we must work with the FDA to resolve any outstanding concerns before the clinical trials can begin. The FDA may also impose clinical holds on a product candidate at any time before or during clinical trials due to safety concerns or non-compliance. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate such clinical trial.

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

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

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

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

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

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

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

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

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

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

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

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

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

Our product candidates are in the initial stages of development and are currently manufactured in small batches for use in pre-clinical and clinical studies. Process improvements implemented to date have changed, and process improvements in the future may change, the activity profile of the product candidates, which may affect the safety and efficacy of the products. No assurance can be given that the material manufactured from any of the optimized processes will perform comparably to the product candidates as manufactured to date and used in currently available pre-clinical data and or in early clinical trials reported in this or any previous filing. Additionally, future clinical trial results will be subject to the same level of uncertainty if, following such trials, additional process improvements are made. In addition, we are currently in the process of engaging a secondary manufacturer for TG-1101 to meet our current clinical and future commercial needs and anticipate engaging additional manufacturing sources for TGR-1202 to meet expanded clinical trial and 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 or TGR-1202 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, or if regulatory authorities impose unforeseen requirements with respect to product comparability from multiple manufacturing sources, we may experience delays in clinical development.

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

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

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

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

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

If approved, we expect TG-1101 to compete directly with Roche Group's Rituxan® (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, there are several PI3K delta targeted compounds both approved, such as Gilead's Zydelig™ (idelalisib), and in development, including, but not limited to, Infinity Pharmaceuticals' duvelisib (IPI-145), which if approved we would expect to compete directly with TGR-1202. In addition, there are numerous other novel therapies targeting similar pathways to TGR-1202 in development, which if approved would also compete with TGR-1202 in similar indications, such as the BTK inhibitor, ibrutinib (FDA approved for MCL, CLL, and WM and marketed by Pharmacyclics and Janssen), or the bcl-2 inhibitor ABT-199 (under clinical development by AbbVie and Roche).

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

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

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

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

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

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

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

In most cases, our manufacturing partners are single source suppliers. It is expected that our manufacturing partners will be sole source suppliers from single site locations for the foreseeable future. Given this, any disruption of supply from these partners could have a material, long-term impact on our ability to supply products for clinical trials or commercial sale. If our suppliers do not deliver sufficient quantities of our product candidates on a timely basis, or at all, and in accordance with applicable specifications, there could be a significant interruption of our supply, which would adversely affect clinical development and commercialization of our products. In addition, if our current or future supply of any 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. Additionally, while we may seek approval of our products in combination with each other, there can be no guarantee that we will obtain coverage and reimbursement for any of our products together, or that such reimbursement will incentivize the use of our products in combination with each other as opposed to in combination with other agents which may be priced more favorably to the medical community.

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

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

- the demand for any products for which we may obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;

- our ability to generate revenues and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

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

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

As of June 30, 2015, we had twenty-seven full and part time employees. Over time, we will need to expand our managerial, operational, financial and other resources in order to manage and fund our operations and clinical trials, continue research and development activities, and commercialize our product candidates. Our management and scientific personnel, systems and facilities currently in place may not be adequate to support our future growth. Our need to effectively manage our operations, growth, and various projects requires that we:

- manage our clinical trials effectively;
- manage our internal development efforts effectively while carrying out our contractual obligations to licensors, contractors and other third parties;

· continue to improve our operational, financial and management controls and reporting systems and procedures; and
· attract and retain sufficient numbers of talented employees.

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

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

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

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

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