TG THERAPEUTICS, INC.
Form 10-Q
November 14, 2013

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 September 30, 2013

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.)

787 Seventh Avenue
New York, New York 10019
(Address including zip code of principal executive offices)

(212) 554-4484
(Registrant's telephone number, including area code)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).
x Yes ¨ No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definition of “large accelerated filer,” “accelerated filer” and “smaller reporting

company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ¨	Accelerated filer ¨
Non-accelerated filer ¨ (Do not check if smaller reporting company)	Smaller reporting company x

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 33,498,860 shares of the registrant's common stock, $0.001 par value, outstanding as of November 1, 2013.

TG THERAPEUTICS, INC.
FORM 10-Q
FOR THE QUARTER ENDED SEPTEMBER 30, 2013

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SPECIAL CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS

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

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

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

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

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

TG Therapeutics, Inc.
(a Development Stage Company)
Condensed Consolidated Balance Sheets

	September 30, 2013 (Unaudited)	December 31, 2012
Assets		
Current assets:		
Cash and cash equivalents	$ 50,183,397	$ 16,455,995
Prepaid research and development	311,500	1,990,759
Other current assets	118,437	29,128
Total current assets	50,613,334	18,475,882
Equipment, net	3,829	1,164
In-process research and development	2,797,600	2,797,600
Goodwill	799,391	799,391
Other assets	85,121	-
Total assets	$ 54,299,275	$ 22,074,037
Liabilities and equity		
Current liabilities:		
Notes payable, current portion	$ 677,778	$ 677,778
Accounts payable and accrued expenses	4,325,313	1,117,397
Accrued compensation	350,000	145,000
Current portion of deferred revenue	152,381	152,381
Interest payable	172,751	123,511
Total current liabilities	5,678,223	2,216,067
Deferred revenue, net of current portion	1,714,286	1,828,571
Notes payable, less current portion, at fair value	2,269,046	2,479,098
Total liabilities	9,661,555	6,523,736
Commitments and contingencies		
Equity:		
Preferred stock, $0.001 par value per share (10,000,000 shares authorized, no shares issued and outstanding as of September 30, 2013 and December 31, 2012)		
Common stock, $0.001 par value per share (500,000,000 shares authorized, 33,414,135 and 25,820,738 shares issued, 33,400,609 and 25,807,212 shares outstanding at September 30,2013 and December 31, 2012, respectively)	33,414	25,821
Contingently issuable shares	6	6
Additional paid-in capital	78,428,989	34,534,805
Treasury stock, at cost, 13,526 shares at September 30, 2013 and December 31, 2012	(84,538)	(84,538)

Deficit accumulated in development stage		(33,740,151)		(18,925,793)
Total equity		44,637,720		15,550,301
Total liabilities and equity	$	54,299,275	$	22,074,037

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

TG Therapeutics, Inc.

(a Development Stage Company)

Condensed Consolidated Statements of Operations

(Unaudited)

	Three months ended September 30,		Nine months ended September 30,		Cumulative period ending September 30,
	2013	2012	2013	2012	2013
License revenue	$ 38,096	$	$ 114,286	$	$ 133,334
Costs and expenses:					
Research and development:					
Noncash stock expense associated with in-licensing agreement				16,578,000	16,875,000
Noncash compensation	171,442	127,091	892,313	236,289	1,348,122
Other research and development	3,138,119	1,433,711	9,014,776	3,133,960	13,039,241
Total research and development	3,309,561	1,560,802	9,907,089	19,948,249	31,262,363
General and administrative:					
Noncash compensation	825,313	690,999	3,363,687	1,942,301	6,416,554
Other general and administrative	550,639	462,425	1,833,733	1,313,960	4,117,013
Total general and administrative	1,375,952	1,153,424	5,197,420	3,256,261	10,533,567
Impairment of in-process research and development					1,104,700
Total costs and expenses	4,685,513	2,714,226	15,104,509	23,204,510	42,900,630
Operating loss	(4,647,417)	(2,714,226)	(14,990,223)	(23,204,510)	(42,767,296)
Other (income) expense:					
Interest income	(12,375)	(4,951)	(15,054)	(12,711)	(30,841)
Other income				(272,232)	(272,232)
Interest expense	240,530	228,585	712,016	676,843	1,624,857
Change in fair value of notes payable	(319,377)	(227,659)	(872,827)	(915,512)	(2,532,699)
Total other income	(91,222)	(4,025)	(175,865)	(523,612)	(1,210,915)
Loss before income taxes	(4,556,195)	(2,710,201)	(14,814,358)	(22,680,898)	(41,556,381)
Income taxes					330,000
Consolidated net loss	(4,556,195)	(2,710,201)	(14,814,358)	(22,680,898)	(41,886,381)

Net loss attributable to noncontrolling interest		(247,962)		(8,067,916)	(8,146,230)
Net loss attributable to TG Therapeutics, Inc. and subsidiaries	$ (4,556,195)	$ (2,462,239)	$ (14,814,358)	$ (14,612,982)	$ (33,740,151)
Basic and diluted net loss per common share	$ (0.16)	$ (0.16)	$ (0.62)	$ (1.34)	
Weighted average shares used in computing basic and diluted net loss per common share	27,684,802	15,810,299	24,057,200	10,901,070	

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

TG Therapeutics, Inc.
(a Development Stage Company)
Condensed Consolidated Statement of Equity
for the nine months ended September 30, 2013 (Unaudited)

	Preferred stock		Common stock		Contingently Issuable Shares	Additional paid-in Capital	Treasury Stock		Deficit accumulated in the Development stage	Total
	Shares	Amount	Shares	Amount			Shares	Amount		
Balance at January 1, 2013		$	25,820,738	$25,821	$6	$34,534,805	13,526	$(84,538)	$(18,925,793)	$15,550,301
Issuance of common stock in connection with exercise of warrants			887,109	887		1,996,611				1,997,498
Issuance of common stock in connection with cashless exercise of warrants			2,244	2		(3)				(1)
Issuance of restricted stock			149,044	149		(149)				
Issuance of common stock in public offering (net of offering costs of $2,664,970)			6,555,000	6,555		37,641,725				37,648,280
Compensation in respect of restricted stock and stock options granted to employees, directors and						4,256,000				4,256,000

consultants								
Net loss							(14,814,358)	(14,814,358)
Balance at September 30, 2013	$	33,414,135	$33,414	$6	$78,428,989	13,526	$(84,538)	$(33,740,151)	$44,637,720

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

TG Therapeutics, Inc.
(a Development Stage Company)
Condensed Consolidated Statements of Cash Flows
(Unaudited)

	Nine months ended September 30,		Cumulative period ended September 30,
	2013	2012	2013
CASH FLOWS FROM OPERATING ACTIVITIES:			
Consolidated net loss	$ (14,814,358)	$ (22,680,898)	$ (41,886,381)
Adjustments to reconcile consolidated net loss to net cash used in operating activities:			
Stock compensation expense	4,256,000	2,178,590	7,764,676
Noncash stock expense associated with in-licensing agreement		16,578,000	16,875,000
Impairment of in-process research and development			1,104,700
Depreciation	634	118	869
Change in fair value of notes payable	(210,052)	(284,297)	(1,025,751)
Changes in assets and liabilities, net of effects of acquisition:			
Decrease (increase) in other current assets	1,589,950	(1,697,304)	(339,167)
Increase in other assets	(85,121)		(85,121)
Increase in accounts payable and accrued expenses	3,412,916	1,505,531	4,416,983
Increase in interest payable	49,240	45,628	117,908
(Decrease) increase in deferred revenue	(114,286)		1,866,666
Net cash used in operating activities	(5,915,077)	(4,354,632)	(11,189,618)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchases of property, plant and equipment	(3,299)	(1,399)	(4,698)
Cash acquired in connection with acquisition			10,386
Net cash (used in) provided by investing activities	(3,299)	(1,399)	5,688
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from the exercise of warrants	1,997,498		1,997,498
Payments of short-term loans		(200,000)	(200,001)
Proceeds from sale of common stock, net	37,648,280		47,472,962
Proceeds from sale of preferred stock, net		12,257,309	12,257,309
Offering costs paid		(75,903)	(75,903)
Purchase of treasury stock			(84,538)
Net cash provided by financing activities	39,645,778	11,981,406	61,367,327

NET INCREASE IN CASH AND CASH EQUIVALENTS	33,727,402	7,625,375	50,183,397
Cash and cash equivalents at beginning of period	16,455,995	9,748,491	
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 50,183,397	$ 17,373,866	$ 50,183,397
NONCASH TRANSACTIONS:			
Conversion of notes payable to preferred stock	$	$	$ 55,271
Accrued financing costs	$	$	$ 61,138

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

TG Therapeutics, Inc.
(a Development Stage Company)
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 innovative and medically important pharmaceutical products for the treatment of cancer and other underserved therapeutic needs. We aim to acquire rights to these technologies by licensing or otherwise acquiring an ownership interest, funding their research and development and eventually either out-licensing or bringing the technologies to market. Currently, the Company is developing therapies for hematologic malignancies: TG-1101 (ublituximab), a novel, glycoengineered monoclonal antibody that targets a specific and unique epitope on the CD20 antigen found on mature B-lymphocytes; and TGR-1202, an orally available PI3K delta inhibitor. We also hold the development rights to AST-726, a nasally delivered product for the treatment of Vitamin B12 deficiency.

The accompanying unaudited condensed consolidated financial statements were prepared in accordance with U.S. generally accepted accounting principles ("GAAP") for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they may not include all of the information and footnotes required by GAAP for complete financial statements. All adjustments that are, in the opinion of management, of a normal recurring nature and are necessary for a fair presentation of the consolidated financial statements have been included. Nevertheless, these consolidated financial statements should be read in conjunction with the audited consolidated financial statements contained in our Annual Report on Form 10-K for the year ended December 31, 2012. The results of operations for the three and nine months ended September 30, 2013 are not necessarily indicative of the results that may be expected for the entire fiscal year or any other interim period.

On December 29, 2011, the Company consummated an exchange transaction (the "Exchange Transaction") with Opus Point Partners, LLC ("Opus") and TG Biologics, Inc. (formerly known as TG Therapeutics, Inc.) ("TG Bio"). The stockholders of TG Bio received the majority of the voting shares of the Company, therefore, the transaction was accounted for as a reverse acquisition whereby TG Bio was the accounting acquirer (legal acquiree) and the Company was the accounting acquiree (legal acquirer) under the acquisition method of accounting. TG Bio was incorporated in Delaware in November 2010, but did not commence operations until April 2011.

On April 30, 2012, the Company filed a Certificate of Amendment to its Certificate of Incorporation to change its name from Manhattan Pharmaceuticals, Inc. ("Manhattan") to TG Therapeutics, Inc. In conjunction with this change, the subsidiary formerly named TG Therapeutics, Inc. filed a Certificate of Amendment changing its name to TG Biologics, Inc.

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 we may never become profitable. As of September 30, 2013, we have an accumulated deficit of $33,740,151.

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

In July 2013, we raised approximately $37.6 million, net of underwriting discounts and offering expenses of approximately $2.7 million, in an underwritten public offering. See Note 3 for additional information.

We currently anticipate that our cash and cash equivalents at September 30, 2013 are sufficient to fund our anticipated operating cash requirements for at least 24 months. The actual amount of cash that we will need to operate is subject to many factors, including, but not limited to, the timing, design and conduct of clinical trials for our drug candidates. We are dependent upon significant future financing to provide the cash necessary to execute our current operations, including the commercialization of any of our drug candidates.

Our Common Stock is quoted on the NASDAQ Capital Market and trades under the symbol “TGTX.”

Cash and Cash Equivalents

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

Revenue Recognition

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

Research and Development Costs

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

In-Process Research and Development

All acquired research and development projects are recorded at their fair value as of the date of acquisition. The fair values are assessed as of the balance sheet date to ascertain if there has been any impairment of the recorded value. If there is an impairment, the asset is written down to its current fair value by the recording of an expense. Impairment is tested on an annual basis, and consists of a comparison of the fair value of the in-process research and development with its carrying amount.

Income Taxes

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

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

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

Stock-Based Compensation

We recognize all share-based payments to employees and to non-employee directors for services as compensation expense in the consolidated financial statements based on the fair values of such payments. Stock-based compensation expense recognized each period is based on the value of the portion of share-based payment awards that is ultimately expected to vest during the period. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.
For share-based payments to consultants and other third-parties, compensation expense is determined at the "measurement date." The expense is recognized over the vesting period of the award. Until the measurement date is reached, the total amount of compensation expense remains uncertain. We record compensation expense based on the fair value of the award at the reporting date. The awards to consultants and other third-parties are then revalued, or the total compensation is recalculated based on the then current fair value, at each subsequent reporting date.

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

Basic net income (loss) per share of Common Stock is calculated by dividing net income (loss) applicable to the Common Stock by the weighted-average number of shares of the Common Stock outstanding for the period. Diluted net loss per share of Common Stock is the same as basic net income (loss) per share of Common Stock since potentially dilutive securities from stock options, stock warrants and convertible preferred stock would have an antidilutive effect either because the Company incurred a net loss during the period presented or because such potentially dilutive securities were out of the money and the Company realized net income during the period presented. The amounts of potentially dilutive securities excluded from the calculation were 9,994,297 and 7,484,689 at September 30, 2013 and 2012, respectively. During the three and nine months ended September 30, 2013 and 2012, the Company incurred a net loss; therefore, all of the dilutive securities are excluded from the computation of diluted earnings per share.

Long-Lived Assets and Goodwill

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

assumptions in determining the impairment amount. If the carrying amount of an asset exceeds its estimated future cash flows, an impairment charge is recognized.

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

NOTE 2 FAIR VALUE MEASUREMENTS

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

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

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

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

As of September 30, 2013 and December 31, 2012, the fair values of cash and cash equivalents, accounts payable, accrued expenses, and notes and interest payable approximate their carrying value.

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

In connection with the Exchange Transaction in December 2011, the Company performed a valuation of the assets and liabilities of Manhattan immediately prior to the transaction. The cumulative liability including accrued and unpaid interest of the 5% Notes was approximately $16,876,000 immediately prior to the Exchange Transaction, $17,727,000 at December 31, 2012 and $18,390,000 at September 30, 2013. As the 5% Notes are tied directly to net product cash flows derived from the preexisting products of the Company, the 5% Notes and accrued interest were recorded at fair value of $3,287,700 as of the date of the Exchange Transaction. No payments have been made on the 5% Notes as of September 30, 2013.

We elected the fair value option for valuing the 5% Notes upon the completion of the Exchange Transaction with TG Bio, as discussed above. The Company elected the fair value option in order to reflect in our financial statements the assumptions that market participants use in evaluating these financial instruments.

The valuation method used to estimate the 5% Notes’ fair value is a discounted cash flow model, where the expected cash flows of AST-726 are discounted to the present using a yield that incorporates compensation for the probability of success in clinical development and marketing, among other factors. The discount rate used in this discounted cash flow model approximated 20% at December 31, 2012 and September 30, 2013. The assumptions, assessments and projections of future revenues are subject to uncertainties, are difficult to predict and require significant judgment. The use of different assumptions, applying different judgment to inherently subjective matters and changes in future market conditions could result in significantly different estimates of fair value and the differences could be material to our consolidated financial statements.

The following table provides the fair value measurements of applicable financial liabilities as of December 31, 2012 and September 30, 2013:

	Financial liabilities at fair value as of December 31, 2012			
	Level 1	Level 2	Level 3	Total
5% Notes	$	$	$ 2,479,098	$ 2,479,098
Totals	$	$	$ 2,479,098	$ 2,479,098

	Financial liabilities at fair value as of September 30, 2013			
	Level 1	Level 2	Level 3	Total
5% Notes	$	$	$ 2,269,046	$ 2,269,046
Totals	$	$	$ 2,269,046	$ 2,269,046

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 nine months ended September 30, 2013:

Fair value at December 31, 2012	$2,479,098
Interest accrued on face value of 5% Notes	662,775
Change in fair value of Level 3 liabilities	(872,827)
Fair value at September 30, 2013	$2,269,046

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 3 - STOCKHOLDERS' EQUITY

Preferred Stock

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

Common Stock

Our amended and restated certificate of incorporation authorizes the issuance of up to 500,000,000 shares of $0.001 par value Common Stock.

On July 18, 2013, we announced the pricing of an underwritten public offering of 5,700,000 shares of our Common Stock at a price of $6.15 per share for gross proceeds of approximately $35 million. We also granted to the underwriters a 30-day option to acquire an additional 855,000 shares to cover overallotments in connection with the offering. Total net proceeds from this offering, including the overallotment, were approximately $37.6 million, net of underwriting discounts and offering expenses of approximately $2.7 million. The shares were sold under a shelf registration statement on Form S-3 (File No. 333-189015) that was previously filed and declared effective by the SEC on June 17, 2013.

We currently have one shelf registration statement on Form S-3, filed and declared effective by the SEC (File No. 333-189015). Subsequent to the July 2013 offering, this shelf registration statement provides for the offering of up to approximately $135 million of common stock. We may offer the securities under our shelf registration statement from time to time in response to market conditions or other circumstances if we believe such a plan of financing is in the best interests of our stockholders. We believe that this shelf registration statement provides us with the flexibility to raise additional capital to finance our operations as needed.

Equity Incentive Plans

Shares available for the issuance of stock options or other stock-based awards under our stock option and incentive plans were 1,903,213 shares at September 30, 2013.

Stock Options

The following table summarizes stock option activity for the nine months ended September 30, 2013:

	Number of shares	Weighted-average exercise price	Weighted-average Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2012	46,904	$ 61.08	9.44	$
Granted				
Exercised				
Forfeited	(313)	2,249.85		
Expired				

Outstanding at September 30, 2013	46,591	$	46.37	8.75	$	29,440
Vested and expected to vest at September 30, 2013	9,591	$	208.30	8.41	$	5,760
Exercisable at September 30, 2013	9,591	$	208.30	8.41	$	5,760

As of September 30, 2013, there is no unrecognized compensation cost related to unvested time-based option awards. This amount does not include, as of September 30, 2013, 37,000 non-employee options outstanding which are milestone-based and vest upon certain corporate milestones. Stock-based compensation will be measured and recorded if and when a milestone occurs.

Restricted Stock

Certain employees, directors and consultants have been awarded restricted stock under the 2012 Incentive Plan. The restricted stock vesting consists of milestone and time-based vesting. The following table summarizes restricted share activity for the nine months ended September 30, 2013:

	Number of Shares	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2012	6,614,243	$ 4.49
Granted	149,044	6.04
Vested	(398,750)	2.55
Forfeited		
Outstanding at September 30, 2013	6,364,537	$ 4.65

Total expense associated with restricted stock grants was $4,199,595 during the nine months ended September 30, 2013. As of September 30, 2013, there was approximately $7,227,000 of total unrecognized compensation cost related to unvested time based restricted stock, which is expected to be recognized over a weighted-average period of 2.1 years. This amount does not include, as of September 30, 2013, unrecognized compensation expense related to 1,517,500 shares of restricted stock outstanding which are milestone-based and vest upon certain corporate milestones; and 2,481,375 shares of restricted stock outstanding issued to non-employees. Milestone based noncash compensation expense will be measured and recorded if and when a milestone occurs.

Warrants

The following table summarizes warrant activity for the nine months ended September 30, 2013:

	Warrants	Weighted-Average exercise price	Aggregate Intrinsic Value
Outstanding at December 31, 2012	6,781,007	$1.58	$14,563,539
Issued			
Exercised	(890,644)	2.25	
Expired	(53)	562.50	
Outstanding at September 30, 2013	5,890,310	$1.47	$21,799,376

Stock-Based Compensation

The fair value of stock options granted is estimated at the date of grant using the Black-Scholes pricing model. The expected term of options granted is derived from historical data and the expected vesting period. Expected volatility is based on the historical volatility of our common stock. The risk-free interest rate is based on the U.S. Treasury yield for a period consistent with the expected term of the option in effect at the time of the grant. We have assumed no expected dividend yield, as dividends have never been paid to stock or option holders and will not be paid for the foreseeable future. The Company did not grant any stock options during the nine months ended September 30, 2013.

The following table summarizes stock-based compensation expense information about stock options and restricted stock for the three and nine months ended September 30, 2013:

	Three months ended September 30, 2013	Nine months ended September 30, 2013
Stock-based compensation expense associated with restricted stock	$ 996,755	$ 4,199,595
Stock-based compensation expense associated with option grants	-	56,405
	$ 996,755	$ 4,256,000

NOTE 4 NOTES PAYABLE

The following is a summary of notes payable:

	September 30, 2013			December 31, 2012		
	Current portion, net	Non-current portion, net	Total	Current portion, net	Non-current portion, net	Total
Convertible 5% Notes Payable	$ -	$ 2,269,046	$ 2,269,046	$ -	$ 2,479,098	$ 2,479,098
ICON Convertible Note	677,778	-	677,778	677,778	-	677,778
Total	$ 677,778	$ 2,269,046	$ 2,946,824	$ 677,778	$ 2,479,098	$ 3,156,876

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

Convertible 5% Notes Payable

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

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

In connection with the Exchange Transaction in December 2011, the Company performed a valuation of the assets and liabilities of Manhattan immediately prior to the transaction. The cumulative liability including accrued and unpaid interest of the 5% Notes was approximately $16,876,000 immediately prior to the Exchange Transaction, $17,727,000 at December 31, 2012 and $18,390,000 at September 30, 2013. As the 5% Notes are tied directly to net product cash flows derived from the preexisting products of the Company, the 5% Notes and accrued interest was recorded at fair value as of the date of the Exchange Transaction. No payments have been made on the 5% Notes as of September 30, 2013. See Note 2 for further details.

ICON Convertible Note Payable

In connection with the merger with Ariston as discussed above, Ariston satisfied an account payable of $1,275,188 to ICON Clinical Research Limited ("ICON") through the payment of $275,188 in cash and the issuance of a three-year 5% note payable (the "ICON Note"). The principal was to be repaid in 36 monthly installments of $27,778 commencing in April 2010. Interest was payable monthly in arrears. On March 1, 2011, Ariston entered into an amended and restated convertible promissory note (the "Amended ICON Note") with ICON. The principal terms of the Amended ICON Note are that monthly payments of principal and interest will be waived for the thirteen month period ended

December 31, 2011 (the “Waiver Period”) in exchange for a single payment of $100,000 on March 31, 2011, an increase in the interest on the Amended ICON Note from 5% to 8% per annum during the Waiver Period and a balloon payment on January 31, 2012. The Amended ICON Note is convertible at the option of the holder into the Company’s Common Stock at the conversion price of $562.50 per share. During the nine months ended September 30, 2013, the Company recorded $49,240 of interest expense on the Amended ICON Note. At September 30, 2013, the principal amount of the Amended ICON Note was $677,778, of which the entire balance has been classified as current, and interest payable on the Amended ICON Note was $172,751. This note is currently in default as the Company did not make the balloon payment due on January 31, 2012, or any subsequent payments. The Company is currently attempting to negotiate a settlement or alternative arrangement in satisfaction of this note.

NOTE 5 LICENSE AGREEMENTS

In November 2012, we entered into an exclusive (within the territory) sublicense agreement with Ildong Pharmaceutical Co. Ltd, ("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 foreign income tax withheld, is being recognized as license revenue on a straight-line basis over the life of the agreement, which is through the expiration of the last licensed patent right or 15 years after the first commercial sale of a product in such country, unless the agreement is earlier terminated. The upfront payment 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. The Company recorded license revenue of approximately $114,000 and $38,000 for the nine and three months ended September 30, 2013, respectively, and has deferred revenue of approximately $1,867,000 associated with this $2,000,000 payment (approximately $152,000 of which has been classified as a current liability) at September 30, 2013.

The Company 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 the Company on net sales of TG-1101 in the sublicense territory.

NOTE 6 RELATED PARTY TRANSACTIONS

On January 30, 2012, the Company 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 TG-1101 (the "License Agreement"). In connection with the License Agreement, LFB Group was issued 5,000,000 shares of Company Common Stock and a warrant to purchase 2,500,000 shares of Company Common stock at a purchase price of $0.001 per share. In addition, on November 9, 2012, the Company nominated Dr. Yann Echelard to the Company's 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 Company Common Stock.

Under the terms of the Company's License Agreement with LFB Group, the Company utilizes LFB Group for certain development and manufacturing services. The Company incurred approximately $6,068,000 and $2,034,000 during the nine and three months ended September 30, 2013, respectively, for manufacturing and development services, which have been included in other research and development expenses in the accompanying condensed consolidated statements of operations. As of September 30, 2013, the Company has approximately $3,079,000 recorded in accounts payable related to the aforementioned agreements with LFB Group.

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 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, 2012.

OVERVIEW

We are a biopharmaceutical company focused on the acquisition, development and commercialization of innovative and medically important pharmaceutical products for the treatment of cancer and other underserved therapeutic needs. We aim to acquire rights to these technologies by licensing or otherwise acquiring an ownership interest, funding their research and development and eventually either out-licensing or bringing the technologies to market. Currently, the Company is developing two therapies for hematologic malignancies: TG-1101 (ublituximab), a novel, glycoengineered monoclonal antibody that targets a specific and unique epitope on the CD20 antigen found on mature B-lymphocytes; and TGR-1202, an orally available PI3K delta inhibitor.

We 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 located on the surface of B-lymphocytes. Administration of anti-CD20 antibodies such as TG-1101 results in rapid depletion of circulating CD20 positive B-cells which is thought to aid in the treatment of various B-cell lymphoproliferative diseases. We hold exclusive worldwide rights (except France/Belgium) to develop and commercialize TG-1101 for all indications. Manufacturing of TG-1101 is currently performed by our partner, LFB Biotechnologies.

Generally, anti-CD20 antibodies are believed to exert their B-cell depleting effects through three primary mechanisms of action: 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 increase 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 2012 of approximately $7 billion.

TG-1101 has demonstrated activity in both *in vitro* and *in vivo* assays as an efficient and selective B-cell targeting anti-CD20 antibody with the ability to effectively deplete B-lymphocytes in both malignant laboratory cell models as well as non-Hodgkin's Lymphoma (NHL) and Chronic Lymphocytic Leukemia (CLL) patient donor cell lines.

Two single-agent, dose-escalation, Phase I studies were undertaken with TG-1101 to establish an optimal dose in patients with NHL and CLL. A two part first-in-human Phase I clinical trial was first completed in France in which TG-1101 was introduced in relapsed or refractory CLL patients in doses as high as 450mg per infusion. Preliminary results from Part 2 of this study were presented at the 53rd Annual American Society of Hematology Meeting in December 2011 and recently presented again at the 2013 European Hematology Annual Meeting. Subsequently, a single-agent Phase I study was undertaken in the US enrolling patients with both NHL and CLL, dosing patients up to 1200mg per infusion. In oncology settings, anti-CD20 therapy is generally used in combination with other anti-cancer agents where it demonstrates maximum activity. As a result, clinical development for TG-1101 has focused on combination therapy with a subsequent Phase I clinical study undertaken evaluating the combination of TG-1101 with lenalidomide (trade name Revlimid®), an immunomodulatory agent, also for patients with NHL and CLL. Future combinations studies with novel agents are planned.

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

TG-1101-101- Single Agent study in NHL and CLL

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

We have completed the dose escalation portion of this study, with three patients enrolled into four dose cohorts each (450mg, 600mg, 900mg, and 1200mg), with preliminary safety and efficacy data for these patients presented at the American Society of Clinical Oncology Annual Meeting in June 2013 and at the European Hematology Association Annual Meeting in June 2013. Cohort expansions were undertaken at the 900 and 1200 mg doses for NHL patients and at the 600 and 900 mg doses for CLL patients. As of November 2013, enrollment has completed for this study.

TG-1101-102 Combination study with Lenalidomide in NHL and CLL

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

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

Presently we have completed enrollment in this study, with the highest cohort dosing patients at 900mg of TG-1101 in combination with Revlimid® starting at 10mg and titrated based on tolerability in 5mg increments per cycle to a maximum dose of 20mg for patients with NHL and 15mg for patients with CLL.

TGR-1202

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

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

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

The Company’s Investigational New Drug (“IND”) application for TGR-1202 was accepted by the FDA in December 2012 and in January 2013, the Company 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, and is expected to enroll approximately 30 patients during the initial dose escalation phase, followed by up to an additional 30 patients in an expansion phase once the optimal dose has been determined. Enrollment in the dose escalation portion of this study continues currently in Cohort 6 (1200mg QD or once per day) and is open to patients with relapsed or refractory NHL, CLL, Peripheral T-Cell Lymphoma ("PTCL"), and other select hematologic malignancies. Michael R. Savona, MD, the Director of Leukemic Research, Sarah Cannon Research Institute, is acting as Study Chair for the Phase I study.

AST-726

AST-726 is a nasally delivered form of hydroxocobalamin for the treatment of Vitamin B12 deficiency. The Company acquired global rights to AST-726 as part of the Ariston acquisition. AST-726 has demonstrated pharmacokinetic equivalence to a marketed intramuscular injection product for Vitamin B12 remediation.

The Company is currently reviewing its development plans for AST-726, which may include: (1) ceasing further development and attempting to sell or license AST-726, (2) continuing development as originally contemplated under the SPA or (3) evaluating and implementing alternative development plans. No decision has been made as to which approach to execute, and a timeline for a decision is uncertain. If the Company is unable to determine a development plan for AST-726, it is probable that an impairment of in-process research and development would be recognized in

future periods, as the intellectual property for AST-726 begins to expire in 2014.

RECENT DEVELOPMENTS

TG-1101 (ublituximab)

In September 2013, the Company was notified of Orphan Drug Designation acceptance for TG-1101 for the treatment of Nodal and Extra-nodal Marginal Zone Lymphoma. Orphan drug designation is granted by the FDA Office of Orphan Drug Products to novel drugs or biologics that treat a rare disease or condition affecting fewer than 200,000 patients in the U.S.

In June of 2013, the Company presented preliminary data from TG-1101-101, the Phase I single agent study of TG-1101 in patients with rituximab relapsed and refractory B-cell lymphoma, at the 2013 American Society of Clinical Oncology (ASCO) annual meeting in Chicago, IL and at the 2013 European Hematology Association (EHA) annual meeting in Stockholm, Sweden. As of the presentation date, three patients had been treated at each dose level (12 patients total), and no dose-limiting-toxicities had been observed. TG-1101 was well tolerated with the majority of adverse events being Grade 1 or 2 in severity, with only one Grade 3 event observed: Grade 3 anemia in a Cohort 1 patient deemed possibly related to study drug. All patients received all planned infusions. As of November 2013, enrollment has been completed into this study.

In June 2013, preliminary data was also presented from TG-1101-102, the Phase I study of TG-1101 in combination with lenalidomide for patients with rituximab relapsed and refractory B-cell lymphoma at the 18th annual congress of the European Hematology Association (EHA) in Stockholm, Sweden. As of the date of presentation, six patients had been enrolled in the study, and it was reported that the combination regimen has been well tolerated to date. No DLTs have been observed, and Grade $\geq$3 adverse events deemed to be at least possibly related to either study drug have been limited. As of November 2013, enrollment has been completed into this study.

TGR-1202

In September 2013, pre-clinical data on TGR-1202 was presented at the 15th Annual International Workshop on Chronic Lymphocytic Leukemia (iwCLL) held in Cologne, Germany. The poster presentation entitled “The PI3K-inhibitor TGR-1202 induces cytotoxicity and inhibits phosphorylation of AKT in 17p deleted and non-17p deleted CLL cells in vitro,” was presented by Daphne Friedman, MD and Mark Lanasa, MD, PhD from Duke University Medical Center.

In June 2013, the Company presented pre-clinical data at the 12th International Conference on Malignant Lymphomas in Lugano, Switzerland, on the combination of TGR-1202 and TG-1101 in models of B-cell lymphoma demonstrating synergy against select lymphoma cell lines tested. The oral presentation was delivered by Changchun Deng, MD, PhD, of Columbia University Medical Center in New York, NY.

The first-in-human Phase I clinical trial of TGR-1202 (TGR-1202-101) was initiated in January 2013. TGR-1202-101 is ongoing and enrolling patients in the dose escalation component of the study evaluating once-daily doses of TGR-1202. To date, treatment with TGR-1202 has been generally well tolerated. Enrollment continues at the 1200mg once per day or QD dose (Cohort 6). Provided a maximum tolerated dose is not reached, additional cohorts evaluating the sequentially higher doses of TGR-1202 are planned.

In September 2012, preliminary pharmacokinetic (PK) data was presented from initial cohorts in the ongoing Phase 1 study. TGR-1202 demonstrated rapid absorption and linear pharmacokinetics through the 800mg QD dose level. An extended half-life and observed accumulation were supportive of the once daily (QD) dosing regimen. Pharmacodynamic indicators such as compartmental lymphocyte shift (lymphocytosis) in patients with CLL, a hallmark of BCR targeted agents, were also reported to have been observed. While the Company believes this early data may provide preliminary information about the drug properties of TGR-1202, there can be no assurances given

that TGR-1202 will continue to exhibit sufficient pharmaceutical properties to support further development. While we do have potential back-up compounds, if we were to decide to terminate the development of TGR-1202 our PI3K Delta program would be significantly delayed or terminated. The Company plans to present updated safety, efficacy and PK data at the upcoming 55th American Society of Hematology Meeting (ASH), being held December 7 10, 2013 in New Orleans, LA.

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 expense 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 becomes 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 September 30, 2013 and September 30, 2012

License Revenue. License revenue was $38,096 for the three months ended September 30, 2013, as compared to $0 in the comparable period in 2012. License revenue for the three months ended September 30, 2013 was related to the amortization of an upfront payment of $2.0 million 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 Compensation Expense (Research and Development). Noncash compensation expense (research and development) related to equity incentive grants equaled $171,442 for the three months ended September 30, 2013, as compared to $127,091 during the comparable period in 2012. The noncash compensation expense was related to the period's expense for restricted stock grants to research and development personnel.

Other Research and Development Expenses. Other research and development expenses increased by $1,704,408 to $3,138,119 for the three months ended September 30, 2013, as compared to $1,433,711 for the three months ended September 30, 2012. The increase in other research and development expenses was due primarily to an increase of approximately $2,124,000 for research and development expenses related to TG-1101, and an increase of approximately $491,000 for research and development expenses related to TGR-1202. We expect our other research and development costs to increase modestly for the remainder of 2013 due primarily to the enrollment of additional patients on our clinical trials.

Noncash Compensation Expense (General and Administrative). Noncash compensation expense (general and administrative) related to equity incentive grants increased by $134,314 to $825,313 for the three months ended September 30, 2013, as compared to $690,999 for the three months ended September 30, 2012. The noncash compensation expense in both periods was related to restricted stock grants to general and administrative personnel.

Other General and Administrative Expenses. Other general and administrative expenses increased by $88,214 to $550,639 for the three months ended September 30, 2013, as compared to $462,425 for the three months ended September 30, 2012. The increase was due primarily to additional general and administrative personnel. We expect our other general and administrative expenses to remain at a comparable level for the remainder of 2013.

Other (Income) Expense. Other income increased by $87,197 to $91,222 for the three months ended September 30, 2013, as compared to $4,025 for the three months ended September 30, 2012. The other income for the period in 2012 was primarily due to the change in the fair value of our notes payable, partially offset by interest expense on our short-term note payable.

Nine months ended September 30, 2013 and September 30, 2012

License Revenue. License revenue was $114,286 for the nine months ended September 30, 2013, as compared to $0 in the comparable period in 2012. License revenue for the nine months ended September 30, 2013 was related to the amortization of an upfront payment of $2.0 million 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. Noncash stock expense associated with in-licensing agreement decreased by $16,578,000 to $0 for the nine months ended September 30, 2013, as compared to $16,578,000 for the nine months ended September 30, 2012. The expense during the nine months ended September 30, 2012 related to a noncash expense of $16,578,000 recorded in conjunction with the stock issued to LFB Group for the license to TGTX-1101.

Noncash Compensation Expense (Research and Development). Noncash compensation expense (research and development) related to equity incentive grants equaled $892,313 for the nine months ended September 30, 2013, as compared to $236,289 during the comparable period in 2012. The noncash compensation expense was related to the period’s expense for restricted stock grants to research and development personnel.

Other Research and Development Expenses. Other research and development expenses increased by $5,880,816 to $9,014,776 for the nine months ended September 30, 2013, as compared to $3,133,960 for the nine months ended September 30, 2012. The increase in other research and development expenses was due primarily to the commencement of the Company’s clinical development programs for TG-1101 and TGR-1202. We expect our other research and development costs to increase modestly for the remainder of 2013 due primarily to the enrollment of additional patients on our clinical trials.

Noncash Compensation Expense (General and Administrative). Noncash compensation expense (general and administrative) related to equity incentive grants increased by $1,421,386 to $3,363,687 for the nine months ended September 30, 2013, as compared to $1,942,301 for the nine months ended September 30, 2012. The increase in noncash compensation expense (general and administrative) was primarily due to the vesting of certain milestone-based restricted stock awards during the nine months ended September 30, 2013.

Other General and Administrative Expenses. Other general and administrative expenses increased by $519,773 to $1,833,733 for the nine months ended September 30, 2013, as compared to $1,313,960 for the nine months ended September 30, 2012. The increase was due primarily to business insurance, the NASDAQ entry fee, and expenses related to additional general and administrative personnel. We expect our other general and administrative expenses to remain at a comparable level for the remainder of 2013.

Other (Income) Expense. Other income decreased by $347,747 to $175,865 for the nine months ended September 30, 2013, as compared to $523,612 for the nine months ended September 30, 2012. The other income for the period in 2012 was primarily due to a refund of New York State Franchise tax of approximately $272,000 and the change in the fair value of our notes payable, partially offset by interest expense on our short-term note payable.

LIQUIDITY AND CAPITAL RESOURCES

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

On July 18, 2013, we announced the pricing of an underwritten public offering of 5,700,000 shares of Common Stock at a price of $6.15 per share for gross proceeds of approximately $35 million. We also granted to the underwriters a 30-day option to acquire an additional 855,000 shares to cover overallotments in connection with the offering. Total net proceeds from this offering, including the overallotment, were approximately $37.6 million, net of underwriting discounts and offering expenses of approximately $2.7 million. The shares were sold under a shelf registration statement on Form S-3 (File No. 333-189015) that was previously filed and declared effective by the SEC on June 17, 2013.

As of September 30, 2013, we had $50,183,397 in cash and cash equivalents. We currently anticipate that our cash and cash equivalents as of September 30, 2013 to be sufficient to fund our anticipated operating cash requirements for at least 24 months from September 30, 2013. 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 nine months ended September 30, 2013 was $5,915,077, as compared to $4,354,632 for the nine months ended September 30, 2012. 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 nine months ended September 30, 2013, net cash provided by financing activities of $39,645,778 related to net proceeds from the issuance of Common Stock as part of our underwritten public offering in July 2013, as well as proceeds from the exercise of warrants. For the nine months ended September 30, 2012, net cash provided by financing activities of $11,981,406 related primarily to net proceeds from the issuance of the preferred stock, partially offset by the repayment of a short-term loan.

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 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.

In-process research and development. All acquired research and development projects are recorded at their fair value as of the date acquisition. The fair values are assessed as of the balance sheet date to ascertain if there has been any impairment of the recorded value. If there is an impairment the asset is written down to its current fair value by the recording of an expense.

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 September 30, 2013 and December 31, 2012, 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 condensed consolidated statements 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 upon the completion of the reverse merger with TG Bio, as discussed above. The Company elected the fair value option in order to reflect in our financial statements the assumptions that market participants use in evaluating these financial instruments.

The valuation methods used to estimate the 5% Notes’ fair value is a discounted cash flow model, where the expected cash flows of AST-726 and AST-915 are discounted to the present using a yield that incorporates compensation for the probability of success in clinical development and marketing, among other factors. The discount rate used in this discounted cash flow model approximated 20% at December 31, 2012 and September 30, 2013. The assumptions, assessments and projections of future revenues are subject to uncertainties, are difficult to predict and require significant judgment. The use of different assumptions, applying different judgment to inherently subjective matters and changes in future market conditions could result in significantly different estimates of fair value and the differences could be material to our consolidated financial statements.

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 September 30, 2013, our portfolio of financial instruments consists of cash equivalents, including bank deposits. 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 September 30, 2013, 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 September 30, 2013, 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 September 30, 2013, 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 Investigational New Drug application ("IND"), Biologics License Application ("BLA"), or New Drug Application ("NDA") to the FDA, it is necessary to submit all information on the clinical, non-clinical, chemistry, manufacturing, controls and quality aspects of the product candidate. We rely on our third party contractors and our licensing partners to provide a significant portion of this data. If we are unable to obtain this data, or the data is not sufficient to meet the regulatory requirements, we may experience significant delays in our development programs. Additionally, an IND must be active in each division in which we intend to conduct clinical trials. While we maintain an active IND for TG-1101 and TGR-1202 enabling the conduct of studies in the FDA's Division of Hematology and Oncology; there can be no assurance given that we will be successful in obtaining an active IND for TG-1101 or TGR-1202 in any other division under whose supervision we may seek to develop our product candidates, or that the FDA will allow us to continue the development of our product candidates in those divisions where we maintain an active IND.

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

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

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

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

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

We plan on conducting additional Phase I, II and III clinical trials for TG-1101. Early clinical results seen with TG-1101 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, 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.

TGR-1202 has only recently entered into a first-in-human Phase I clinical trial. As such, preliminary human data is only available from a small number of patients from the ongoing Phase I clinical trial. There can be no assurances given that TGR-1202 will exhibit sufficient pharmacologic properties following review of the data from this first Phase 1 study to support further development of TGR-1202. In addition, the pharmacologic and pharmacokinetic properties demonstrated by TGR-1202 in early cohorts and at lower doses may not be consistent with those demonstrated at higher doses of TGR-1202. Furthermore, such pharmacologic data arising from this first Phase 1 study may be inconclusive or not reproducible in later clinical trials. In such situation, we may conduct additional clinical trials only to learn later that TGR-1202 lacks adequate pharmacologic properties. Additionally, even if we believed that TGR-1202 possessed adequate pharmacologic properties, that still does not ensure that TGR-1202 will be a safe and effective pharmaceutical agent. If TGR-1202 were ultimately determined to lack adequate pharmacologic properties or fail to be a safe and effective pharmaceutical agent, we would have to cease development, which could have a material adverse effect on our business. In such event, despite the rights we retain to back-up compounds, our PI3k Delta program would be significantly delayed or terminated.

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.

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

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

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

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

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

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

Any one or a combination of these events could prevent us from obtaining or maintaining regulatory approval and achieving or maintaining market acceptance of the affected product or could substantially increase the costs and

expenses of commercializing the affected product, which in turn could delay or prevent us from generating any revenues from the sale of the affected product.

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

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

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

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

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

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

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

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

- unexpected safety findings.

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

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

Once a clinical trial has begun, patient recruitment and enrollment may be slower than we anticipate. Clinical trials may also be delayed as a result of ambiguous or negative interim results. Further, a clinical trial may be suspended or terminated by us, an Institutional Review Board ("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, 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.

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

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

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

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

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

If approved, we expect TG-1101 to compete directly with Roche Group's Rituxan® (Rituximab) and Gazyva (obinutuzumab or GA-101), Spectrum Pharmaceutical's Zevalin® (Y^{90}-Ibritumomab Tiuxetan), and Genmab and GlaxoSmithKline's Arzerra® (Ofatumumab) among others, each of which is currently approved for the treatment of various diseases including NHL and CLL. In addition, a number of pharmaceutical companies are developing anti-CD20 antibodies which, if approved, would potentially compete with TG-1101. New developments, including the development of other pharmaceutical technologies and methods of treating disease, occur in the pharmaceutical and life sciences industries at a rapid pace.

With respect to TGR-1202, although no PI3K delta inhibitors have been approved by the FDA, there are several PI3K delta targeted compounds in development, including, but not limited to, Gilead's idelalisib (formerly known as GS-1101 or CAL-101), Infinity Pharmaceuticals IPI-145 and Amgen's AMG-319, which if approved we would expect to compete directly with TGR-1202. In addition, there are numerous other novel therapies targeting similar pathways to TGR-1202 in development, which if approved would also compete with TGR-1202 in similar indications, such as the BTK inhibitor, ibrutinib (under clinical development by Pharmacyclics/JNJ), or the blc-2 inhibitor ABT-199 (under clinical development by Abbott Laboratories/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 at an appropriate scale and cost to make it commercially feasible. If they are unable to do so, it could have a material adverse impact on our business.

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

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

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

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

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

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

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

- the efficacy and safety as demonstrated in clinical trials;
- the clinical indications for which the product is approved;
- acceptance by physicians, major operators of cancer clinics and patients of the product as a safe and effective treatment;
- the potential and perceived advantages of product candidates over alternative treatments;
- the safety of product candidates seen in a broader patient group, including its use outside the approved indications;
- the cost of treatment in relation to alternative treatments;
- the availability of adequate reimbursement and pricing by third parties and government authorities;
- relative convenience and ease of administration;
- the prevalence and severity of adverse events; and
- the effectiveness of our sales and marketing efforts.

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

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

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

- decreased demand for our product candidates;
- impairment to our business reputation;
- withdrawal of clinical trial participants;
- costs of related litigation;
- distraction of management’s attention from our primary business;

- substantial monetary awards to patients or other claimants;
- the inability to commercialize our product candidates; and
- loss of revenues.

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

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

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

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

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

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

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

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

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

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

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

As of September 30, 2013, we had six full and part time employees. Over time, we will need to expand our managerial, operational, financial and other resources in order to manage and obtain funds for 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 and other pharmaceutical development functions. Our growth strategy may also entail expanding our group of contractors or consultants to implement these tasks going forward. Because we rely on a substantial number of consultants, effectively outsourcing many key functions of our business, we will need to be able to effectively manage these consultants to ensure that they successfully carry out their contractual obligations and meet expected deadlines. However, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for our product candidates or otherwise advance its business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all. If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may be unable to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals.

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

We will need to expand and effectively manage our managerial, operational, financial and other resources in order to successfully pursue our clinical development and commercialization efforts for our product candidates and future product candidates. We are highly dependent on the development, regulatory, commercial and financial expertise of the members of our senior management. The loss of the services of any of our senior management could delay or

prevent the further development and potential commercialization of our product candidates and, if we are not successful in finding suitable replacements, could harm our business. We do not maintain “key man” insurance policies on the lives of these individuals. We will need to hire additional personnel as we continue to expand our manufacturing, research and development activities.

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

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

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

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

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

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

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

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

Risks Relating to Acquisitions

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

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

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

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

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

Risks Relating to our Intellectual Property

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

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

Currently, the composition of matter patent and several method of use patents for TG-1101 and TGR-1202 in various indications and settings have been applied for but have not yet been issued. The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or our partners will be successful in protecting our product candidates by obtaining and defending patents.

These risks and uncertainties include the following:

- the patent applications that we or our partners file may not result in any patents being issued;
- patents that may be issued or in-licensed may be challenged, invalidated, modified, revoked or circumvented, or otherwise may not provide any competitive advantage;
- as of March 16, 2013, the U.S. converted from a “first to invent” to a “first to file” system. Going forward, if we do not win the filing race, we will not be entitled to inventive priority;
- our competitors, many of which have substantially greater resources than we do, and many of which have made significant investments in competing technologies, may seek, or may already have obtained, patents that will limit, interfere with, or eliminate its ability to make, use, and sell our potential products either in the United States or in international markets;

- there may be significant pressure on the U.S. government and other international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful as a matter of public policy regarding worldwide health concerns; and
- countries other than the United States may have less restrictive patent laws than those upheld by United States courts, allowing foreign competitors the ability to exploit these laws to create, develop, and market competing products.

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

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

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

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

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

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

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

- obtain licenses, which may not be available on commercially reasonable terms, if at all;
- abandon an infringing product candidate or redesign its products or processes to avoid infringement;
- pay substantial damages, including treble damages and attorneys' fees, which we may have to pay if a court decides that the product or proprietary technology at issue infringes on or violates the third party's rights;
- pay substantial royalties, fees and/or grant cross licenses to our technology; and/or

- defend litigation or administrative proceedings which may be costly whether we win or lose, and which could result in a substantial diversion of our financial and management resources.

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

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

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

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

Interference proceedings provoked by third parties or brought by the U.S. Patent and Trademark Office ("PTO") may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our collaborators or licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract its management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States. Moreover, as of March 16, 2013, the U.S. will convert from a "first to invent" to a "first to file" system. After that time, should there be any innovations that we invented first, but on which we filed the patent application second, we will have limited options available to reclaim invention priority.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

We may be subject to claims that our consultants or independent contractors have wrongfully used or disclosed alleged trade secrets of their other clients or former employers to it.

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

Risks Relating to Our Finances and Capital Requirements

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

As of September 30, 2013, we had net cash on hand of approximately $50,183,000. We believe that our cash on hand will sustain our operations for at least the next 24 months. As a result, we will need additional capital to continue our operations beyond that time. We will need to seek additional sources of financing in the future, which might not be available on favorable terms, if at all, to continue our operations. If we do not succeed in raising additional funds on acceptable terms, we might be unable to complete planned preclinical and clinical trials or obtain approval of any of our product candidates from the FDA or any foreign regulatory authorities. In addition, we could be forced to discontinue product development, reduce or forego sales and marketing efforts and forego attractive business opportunities. Any additional sources of financing will likely involve the issuance of our equity securities, which would have a dilutive effect on your holdings of our capital stock.

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

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

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

We have never been profitable, and, as of September 30, 2013, we had an accumulated deficit of $33,740,151. We have generated operating losses in all periods since we were incorporated. We expect to make substantial expenditures resulting in increasing operating costs in the future and our accumulated deficit may increase significantly as we expand development and clinical trial efforts for our product candidates. Our losses have had, and are expected to continue to have, an adverse impact on our working capital, total assets and stockholders' equity. Because of the risks and uncertainties associated with product development, we are unable to predict the extent of any future losses or when we will become profitable, if ever. Even if we achieve profitability, we may not be able to sustain or increase profitability on an ongoing basis.

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

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

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

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

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

We expect to spend substantial amounts on development, including significant amounts on conducting clinical trials for our product candidates, manufacturing clinical supplies and expanding our pharmaceutical development

programs. We expect that our monthly cash used by operations will continue to increase for the next several years. We anticipate that we will continue to incur operating losses for the foreseeable future.

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

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

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

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

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

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

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

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

Following our July 2013 offering, our directors, executive officers, their affiliates, and our principal stockholders beneficially own approximately 45% percent of our outstanding voting stock, including shares underlying outstanding

options and warrants. Our directors, officers and principal stockholders, taken as a whole, have the ability to exert substantial influence over the election of our Board of Directors and the outcome of issues submitted to our stockholders.

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

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

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

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

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

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

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

ITEM 6. EXHIBITS

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

3.1	Amended and Restated Certificate of Incorporation, of TG Therapeutics, Inc. dated April 26, 2012 (incorporated by reference to Exhibit 3.2 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2012).
3.2	Restated Bylaws of TG Therapeutics, Inc. dated May 14, 2012 (incorporated by reference to Exhibit 3.2 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2012).
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated November 14, 2013.

31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated November 14, 2013.
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated November 14, 2013.
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated November 14, 2013.

SIGNATURES

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

TG THERAPEUTICS, INC.

Date: November 14, 2013	By:	/s/ Sean A. Power Chief Financial Officer Principal Financial and Accounting Officer

EXHIBIT INDEX

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

31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated November 14, 2013.
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