TG THERAPEUTICS, INC.
Form 10-Q
November 14, 2012

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, 2012

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 25,058,995 shares of the registrant's common stock, $0.001 par value, outstanding as of November 12, 2012.

TG THERAPEUTICS, INC.

FORM 10-Q

FOR THE QUARTER ENDED SEPTEMBER 30, 2012

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SPECIAL CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS

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

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

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

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

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	September 30, 2012 (Unaudited)	December 31, 2011 (See Note 1)
Assets		
Current assets:		
Cash and cash equivalents	$ 17,373,866	$ 9,748,491
Prepaid research and development	1,719,828	—
Other current assets	64,652	87,176
Total current assets	19,158,346	9,835,667
Equipment, net	1,281	—
In-process research and development	5,441,839	5,441,839
Goodwill	629,752	629,752
Total assets	$ 25,231,218	$ 15,907,258
Liabilities and equity		
Current liabilities:		
Notes payable, current portion	$ 677,778	$ 877,778
Accounts payable - related party	1,799,424	—
Other accounts payable and accrued expenses	372,747	666,640
Interest payable, current portion	107,569	61,941
Total current liabilities	2,957,518	1,606,359
Notes payable, noncurrent portion, at fair value	4,380,400	4,664,697
Total liabilities	7,337,918	6,271,056
Commitments and contingencies		
Equity:		
TG Therapeutics, Inc. and subsidiaries:		
Preferred stock, $0.001 par value per share (10,000,000 shares authorized, 0 and 413,388 issued and outstanding as of September 30, 2012 and December 31, 2011, respectively, aggregate liquidation value of $0 and $8,267,760 at September 30, 2012 and December 31, 2011, respectively)	—	413
Common stock, $0.001 par value per share (500,000,000 shares authorized, 20,058,995 and 5,061,399 shares issued and outstanding at September 30, 2012 and December 31, 2011, respectively)	20,059	5,061
Contingently issuable shares	6	6

Additional paid-in capital	24,817,526	10,472,115
Deficit accumulated in development stage	(15,466,056)	(853,074)
Total TG Therapeutics, Inc. and subsidiaries equity	9,371,535	9,624,521
Noncontrolling interest in subsidiary	8,521,765	11,681
Total equity	17,893,300	9,636,202
Total liabilities and equity	$ 25,231,218	$ 15,907,258

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,
	2012	2011	2012	2011	2012
Costs and expenses:					
Research and development:					
Noncash stock expense associated with in-licensing agreement	$—	$—	$16,578,000	$297,000	$16,875,000
Noncash compensation	127,091	—	236,289	—	236,289
Other research and development	1,433,711	15,940	3,133,960	15,940	3,164,243
Total research and development	1,560,802	15,940	19,948,249	312,940	20,275,532
General and administrative:					
Noncash compensation	690,999	—	1,942,301	—	2,028,795
Other general and administrative	462,425	14,175	1,313,960	14,175	1,782,157
Total general and administrative	1,153,424	14,175	3,256,261	14,175	3,810,952
Total costs and expenses	2,714,226	30,115	23,204,510	327,115	24,086,484
Operating loss	(2,714,226)	(30,115)	(23,204,510)	(327,115)	(24,086,484)
Other (income) expense:					
Interest income	(4,951)	—	(12,711)	—	(12,711)
Other income	—	—	(272,232)	—	(272,232)
Interest expense	228,585	—	676,843	—	683,940
Change in fair value of notes payable	(227,659)	—	(915,512)	—	(915,512)
Total other income	(4,025)	—	(523,612)	—	(516,515)
Consolidated net loss	(2,710,201)	(30,115)	(22,680,898)	(327,115)	(23,569,969)
Net loss attributable to noncontrolling interest	(247,962)	(1,510)	(8,067,916)	(16,405)	(8,103,913)
Net loss attributable to TG Therapeutics, Inc. and subsidiaries	$(2,462,239)	$(28,605)	$(14,612,982)	$(310,710)	$(15,466,056)
Basic and diluted net loss per common share	$(0.16)	$(0.01)	$(1.34)	$(0.21)	
Weighted average shares used in computing basic and diluted net loss per common share	15,810,299	2,632,000	10,901,070	1,494,359	

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, 2012 (Unaudited)

	Preferred stock		Common stock		Contingently issuable shares	Additional paid-in capital	Deficit Accumulated in the development stage	Total TG Therapeutics, Inc. and subsidiaries equity	Noncontrol interest in subsidiary
	Shares	Amount	Shares	Amount					
Balance at January 1, 2012	413,388	$413	5,061,399	$5,061	$6	$10,472,115	$(853,074)	$9,624,521	$11,681
Changes during the period:									
Compensation in respect of restricted preferred stock granted to employees						188,509		188,509	
Preferred stock issued at $20.00 per share, net of expenses	695,428	696				12,180,710		12,181,406	
Shares issued in subsidiary to noncontrolling interest in connection with in-licensing agreement								—	16,578,00
Conversion of preferred stock to common stock in conjunction with reverse stock split	(1,108,816)	(1,109)	9,857,596	9,858		(8,749)		—	
Issuance of restricted stock			5,140,000	5,140		(5,140)		—	
						1,990,081		1,990,081	

Compensation in respect of restricted common stock granted to employees, directors and consultants									
Net loss							(14,612,982)	(14,612,982)	(8,067,916
Balance at September 30, 2012	—	$—	20,058,995	$20,059	$6	$24,817,526	$(15,466,056)	$9,371,535	$8,521,765

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,
	2012	2011	2012
CASH FLOWS FROM OPERATING ACTIVITIES:			
Consolidated net loss	$ (22,680,898)	$ (327,115)	$ (23,569,969)
Adjustments to reconcile consolidated net loss to net cash used in operating activities:			
Stock compensation expense	2,178,590	—	2,265,084
Stock issued in connection with in-licensing agreement	16,578,000	297,000	16,875,000
Depreciation	118	—	118
Change in fair value and accrued interest of notes payable	(284,297)	—	(284,297)
Changes in assets and liabilities, net of effects of acquisition:			
Increase in prepaid and other current assets	(1,697,304)	—	(1,693,711)
Increase in accounts payable related party, other accounts payable and accrued expenses	1,505,531	—	1,913,841
Increase in interest payable	45,628	—	52,725
Net cash used in operating activities	(4,354,632)	(30,115)	(4,441,209)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchases of property, plant and equipment	(1,399)		(1,399)
Cash acquired in connection with acquisition	—	—	10,386
Net cash (used in) provided by investing activities	(1,399)	—	8,987
CASH FLOWS FROM FINANCING ACTIVITIES:			
Payments of short-term loans	(200,000)	—	(200,000)
Proceeds from sale of common stock, net	—	30,115	9,824,682
Proceeds from sale of preferred stock, net	12,257,309	—	12,257,309
Offering costs paid	(75,903)	—	(75,903)
Net cash provided by financing activities	11,981,406	30,115	21,806,088
NET INCREASE IN CASH AND CASH EQUIVALENTS	7,625,375	—	17,373,866
Cash and cash equivalents at beginning of period	9,748,491	—	—
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 17,373,866	$ —	$ 17,373,866
NONCASH TRANSACTIONS:			

Conversion of notes payable to preferred stock	$ —	—	$ 55,271
Accrued financing costs	$ —	—	$ 116,626

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.) 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 two advanced therapies targeting hematological malignancies. TG-1101 (ublituximab), is a novel, third generation monoclonal antibody that targets a specific and unique epitope on the CD20 antigen found on mature B-lymphocytes. We are also developing TGR-1202, a highly specific, orally available PI3K delta inhibitor. We also hold the development rights to AST-726, a nasally delivered product for the treatment of Vitamin B_{12} deficiency, and AST-915, an orally delivered treatment for essential tremor.

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, 2011. The results of operations for the three and nine months ended September 30, 2012 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 entered into and consummated an exchange transaction agreement (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 merger 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 may never become profitable. As of September 30, 2012, we have an accumulated deficit of $15,466,056, including non-cash licensing and non-cash compensations expenses of approximately $19,140,000, prior to the allocation of noncontrolling interest.

Our primary source of cash has been proceeds from the private placement of equity securities. We have not yet commercialized any of our drug candidates and cannot be sure if we will ever be able to do so. Even if we commercialize one or more of our drug candidates, we may not become profitable. Our ability to achieve profitability depends on 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 December 30, 2011, we completed the first closing of the private placement of our securities, issuing 4,929,523 shares of Company $0.001 par value common stock (“Common Stock “) at a price per share of $2.25 for total gross proceeds, before placement commissions and expenses, of $11,091,425 (the “2011 Equity PIPE”). Investors also received warrants to purchase 1,232,381 shares of Common Stock. The warrants have an exercise price of $2.25 per share and are exercisable for five years.

In 2012, we completed two additional closings of the 2011 Equity PIPE. These closings were held on January 31, 2012, and February 24, 2012. In these closings, the Company issued 695,428 shares of our Series A preferred stock (“Company Preferred Stock”) at a price per share of $20.00, for total gross proceeds, before placement commissions and expenses, of $13,908,560. Each share of Company Preferred Stock was convertible into 8.89 shares of Common Stock, provided that such conversion rights were subject to sufficient available authorized shares of Common Stock. In connection with the reverse stock split effected by the Company on April 30, 2012 (as discussed below), all shares of preferred stock issued in the 2011 Equity PIPE were converted to Common Stock. Investors also received warrants to purchase 1,545,396 shares of Common Stock. The warrants have an exercise price of $2.25 per share and are exercisable for five years. The shares of Company Preferred Stock and warrants sold in these closings were offered and sold to accredited investors, including members of management, without registration under the Securities Act, or state securities laws, in reliance on the exemptions provided by Section 4(2) of the Securities Act, and Regulation D promulgated thereunder and in reliance on similar exemptions under applicable state laws. Accordingly, the securities issued in the Offering have not been registered under the Securities Act, and until so registered, these securities may not be offered or sold in the United States absent registration or availability of an applicable exemption from registration.

Our Common Stock is quoted on the OTC Bulletin Board and trades under the symbol “TGTX.”

Reverse Stock Split

On April 30, 2012, the Company effected a reverse split of its Common Stock at a ratio of 56.25 for 1, pursuant to a previously obtained stockholder authorization. All share amounts and per share prices in this Quarterly Report on Form 10-Q have been retroactively adjusted to reflect the effect of our reverse stock split, on a fifty six and one quarter (56.25) for one (1) basis, unless otherwise indicated. The exercise price for all stock options and warrants and the conversion price for convertible securities in the accompanying condensed consolidated financial statements have been adjusted to reflect the reverse stock split by multiplying the original exercise or conversion price by fifty six and one quarter (56.25).

Cash and Cash Equivalents

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

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

Acquired research and development projects are recorded at their fair value as of the date of acquisition. The fair values are assessed annually in the fourth quarter, or sooner, if there is an indicator of impairment, 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 testing 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 net operating loss carryforwards that are subject to examination for a number of years beyond the year in which they were generated. 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 service on our board of directors 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 Common Stock by the weighted-average number of shares of 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 7,484,689 at September 30, 2012. During the three and nine months ended September 30, 2012, the Company incurred a net loss; therefore, all of the dilutive securities are excluded from the computation of diluted earnings per share.

Impairment

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 for the difference between the carrying value and the estimated fair value.

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 goodwill 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 December 31, 2011 and September 30, 2012, the fair values of cash and cash equivalents, and notes and interest payable, current portion 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 these notes was approximately $16,876,000 immediately prior to the Exchange Transaction, $16,883,000 at December 31, 2011, and $17,515,000 at September 30, 2012. As these notes payable are tied directly to net product cash flows derived from the preexisting products of the Company, this note and accrued interest was recorded at fair value of $4,664,697 as of the date of the Exchange Transaction. No payments have been made on these notes as of September 30, 2012.

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 was 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, 2011 and September 30, 2012. 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, 2011 and September 30, 2012:

	Financial liabilities at fair value as of December 31, 2011			
	Level 1	Level 2	Level 3	Total
5% Notes	$—	$—	$4,664,697	$4,664,697
Totals	$—	$—	$4,664,697	$4,664,697

	Financial liabilities at fair value as of September 30, 2012			
	Level 1	Level 2	Level 3	Total
5% Notes	$—	$—	$4,380,400	$4,380,400
Totals	$—	$—	$4,380,400	$4,380,400

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, 2012:

Fair value at December 31, 2011	$4,664,697
Interest accrued on face value of 5% Notes	631,215
Change in fair value of Level 3 liabilities	(915,512)
Fair value at September 30, 2012	$4,380,400

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 - ACQUISITION

On December 29, 2011, the Company completed a reverse acquisition of privately held TG Bio, a Delaware Corporation. The acquisition was effected pursuant to an Exchange Transaction Agreement (the "Agreement") dated December 29, 2011 by and among the Company, TG Bio and Opus, the largest shareholder of TG Bio. In accordance with the terms of the Agreement, 95% of the holders of common stock of TG Bio (one (1) minority shareholder of TG Bio holding in aggregate 132,000 shares of common stock of TG Bio did not participate) surrendered their TG Bio common stock. The Agreement caused the Company to issue to TG Bio's shareholders 281,250 shares of Company Preferred Stock. Each share of Company Preferred Stock was convertible into 8.89 shares of the Common Stock provided that such conversion rights were subject to sufficient available authorized shares of Common Stock. In connection with the reverse stock split effected by the Company on April 30, 2012 (as discussed above), all shares of preferred stock issued in connection with the Agreement were converted to Common Stock. The Company Preferred Stock issued in connection with the Agreement provided the former TG Bio shareholders with direct and/or indirect ownership of approximately 95% of the Company's outstanding Company Common Stock immediately following the consummation of the transaction.

The shares of Common Stock issued upon the conversion of the Company Preferred Stock are not registered for resale and, therefore, shall remain subject to the rights and restrictions of Rule 144 under the Securities Act of 1933, as amended.

Based on fair value of the Company's Common Stock of $2.25 per share at December 29, 2011, the purchase price was $295,933, plus the fair value of restricted stock assumed of $82,305. In connection with the Exchange Transaction, the Company incurred $231,580 of acquisition related costs.

A summary of the purchase price calculation is as follows:

Number of shares of Manhattan common stock outstanding at the time of the transaction	131,526	
Multiplied by Manhattan's fair value of the Common Stock	$2.25	$295,933
Fair value of restricted stock assumed		82,305
Total purchase price		$378,238

The purchase price has been allocated as follows based on the fair values of the assets and liabilities acquired:

Cash and cash equivalents	$10,386
Other assets	90,770
In-process research and development acquired	5,441,839
Total identifiable assets	5,542,995
Accounts payable and accrued expenses	197,191
Notes payable (ICON and Swiss Pharma)	939,718
5% notes payable and accrued interest	4,657,600
Total identifiable liabilities	5,794,509
Net identifiable liabilities	(251,514)
Goodwill	629,752
Total	$378,238

A valuation was performed to determine the fair value of certain identifiable intangible assets of Manhattan.

The fair value of certain identifiable intangible assets was determined using the income approach. This method starts with a forecast of the expected future net cash flows. These cash flows are then adjusted to present value by applying an appropriate discount rate that reflects the risk of achieving the asset's projected cash flows. The present value of the estimated cash flows are then added to the present value equivalent of the residual value of the asset, if any, at the end of the discrete projection period to estimate the fair value.

The valuations are based on information that is available as of the acquisition date and the expectations and assumptions that have been deemed reasonable by our management. No assurance can be given, however, that the underlying assumptions or events associated with such assets will occur as projected. For these reasons, among others, the actual results may vary from the projected results.

The following supplemental pro forma information presents the financial results as if the transaction had occurred on January 1, 2011 for the three and nine months ended September 30, 2011. This supplemental pro forma information has been prepared for comparative purposes and does not purport to be indicative of what would have occurred had the acquisition been made on January 1, 2011, nor are they indicative of future results.

	Three months ended September 30, 2011	**Nine months ended September 30, 2011**
Revenue	$ —	$ —
Net loss	$ (581,854)	$ (29,010)
Basic and diluted loss per common share	$ (0.22)	$ (0.01)

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NOTE 4 - 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.

In conjunction with the reverse split effected on April 30, 2012 (as discussed in Note 1), all outstanding Company Preferred Stock automatically converted to 9,857,596 shares of Common Stock as of that date.

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 December 30, 2011, we completed the first closing of the private placement of our securities, issuing 4,929,523 shares of Common Stock at a price per share of $2.25 for total gross proceeds, before placement commissions and expenses, of $11,091,425 (the “2011 Equity PIPE”). Investors also received warrants to purchase 1,232,381 shares of Common Stock. The warrants have an exercise price of $2.25 per share and are exercisable for five years.

In 2012, we completed two additional closings of the 2011 Equity PIPE. These closings were held on January 31, 2012, and February 24, 2012. In these closings, the Company issued 695,428 shares of our Company Preferred Stock at a price per share of $20.00 for total gross proceeds, before placement commissions and expenses, of $13,908,560. Each share of Company Preferred Stock was convertible into 8.89 shares of Common Stock; provided that such conversion rights were subject to sufficient available authorized shares of Common Stock. In connection with the reverse stock split effected by the Company on April 30, 2012, all shares of preferred stock issued in the 2011 Equity PIPE were converted to Common Stock. Investors also received warrants to purchase 1,545,396 shares of Common Stock. The warrants have an exercise price of $2.25 per share and are exercisable for five years. The shares of Company Preferred Stock and warrants sold in these closings were offered and sold to accredited investors, including members of management, without registration under the Securities Act, or state securities laws, in reliance on the

exemptions provided by Section 4(2) of the Securities Act, and Regulation D promulgated thereunder and in reliance on similar exemptions under applicable state laws. Accordingly, the securities issued in the offering have not been registered under the Securities Act, and until so registered, these securities may not be offered or sold in the United States absent registration or availability of an applicable exemption from registration. The placement agent received cash commissions equal to 10% of the gross proceeds of the offering, five-year warrants to purchase shares of the Company's stock equal to 10% of shares sold in the offering, and a non-accountable expense allowance equal to two percent of the gross proceeds of the offering for their expenses.

Equity Incentive Plans

The TG Therapeutics, Inc. Amended and Restated 2012 Incentive Plan ("2012 Incentive Plan") was adopted in May 2012. Under the 2012 Incentive Plan, the compensation committee of the Company's board of directors is authorized to grant stock-based awards to directors, consultants, employees and officers. The 2012 Incentive Plan authorizes grants to purchase up to 6,000,000 shares of authorized but unissued common stock. As of September 30, 2012, up to an additional 2,814,000 shares may be issued under the 2012 Incentive Plan.

A summary of the status of the Company's stock options as of September 30, 2012 and changes during the period then ended is presented below:

Stock Options

The following table summarizes stock option activity for the nine months ended September 30, 2012:

	Number of shares	Weighted-average exercise price	Weighted-average Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2011	3,379	$ 1,315.62	6.39	
Granted	46,000	4.40		
Exercised	—	—		
Forfeited	(2,475)	720.45		
Expired	—	—		
Outstanding at September 30, 2012	46,904	$ 61.08	9.69	$ —
Vested and expected to vest at September 30, 2012	904	$ 2,945.09	1.99	$ —
Exercisable at September 30, 2012	898	$ 2,963.46	1.95	$ —

As of September 30, 2012, there was less than $1,000 of total unrecognized compensation cost related to non-vested stock options, which is expected to be recognized over approximately six months. This amount does not include, as of September 30, 2012, 46,000 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 - Preferred

Certain employees had been awarded restricted Company Preferred Stock. The restricted preferred stock vesting consisted of milestone and time-based vesting. The following table summarizes restricted preferred share activity for the nine months ended September 30, 2012:

	Number of Shares Restricted Series A Preferred Stock[1]	Weighted Average Grant Date Fair Value	Aggregate Intrinsic Value
Outstanding at December 31, 2011	129,375	$ 20.00	
Granted	—	—	
Vested	—	—	
Forfeited			
Conversion to restricted common stock	(129,375)	20.00	
Outstanding at September 30, 2012	—	$ —	$ —

[1] The restricted Company Preferred Stock listed in the table above was granted in connection with the Exchange Transaction to certain executives as discussed above. Each share of Company Preferred Stock was convertible into 8.89 shares of the Company's Common Stock. In conjunction with the reverse split effected on April 30, 2012 (as discussed in Note 1), all outstanding restricted Preferred Stock automatically converted to 1,150,000 shares of restricted Common Stock as of that date.

Restricted Stock - Common

Certain employees, directors and consultants have been awarded restricted Company Common Stock. 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, 2012:

	Number of Shares	Weighted Average Grant Date Fair Value	Aggregate Intrinsic Value
Outstanding at December 31, 2011	—	$ —	
Converted preferred stock	1,150,000	2.25	
Granted	5,140,000	4.95	
Vested	—	—	
Forfeited	—	—	
Outstanding at September 30, 2012	6,290,000	$ 4.46	$14,152,500

Total expense associated with restricted stock grants (both common and preferred) was $818,090 and $2,178,590 during the three and nine months ended September 30, 2012, respectively. As of September 30, 2012, there was approximately $8,635,000 of total unrecognized compensation cost related to non-vested time based restricted stock, which is expected to be recognized over a weighted-average period of 3.0 years. This amount does not include, as of September 30, 2012, 1,505,000 shares of restricted stock outstanding which are milestone-based and vest upon certain corporate milestones; and 2,505,000 shares of restricted stock outstanding issued to non-employees (see Note 7 for additional information). Milestone based non-cash 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, 2012:

	Warrants	**Weighted-average exercise price**	**Aggregate Intrinsic Value**
Outstanding at December 31, 2011	2,118,768	$ 4.62	
Issued	2,163,555	2.31	
Exercised	—	—	
Expired	(1,503)	2,739.75	
Outstanding at September 30, 2012	4,280,820	$ 2.49	$ —

During the nine months ended September 30, 2012, as part of the 2011 Equity PIPE, we issued warrants to purchase up to 1,545,396 shares of our Company Common Stock to investors in the 2011 Equity PIPE, none of which have been exercised as of September 30, 2012. The warrants have an exercise price of $2.25 per warrant share. In addition, we issued to the placement agent in the transaction warrants to purchase up to 618,159 shares of our Company Common Stock at an exercise price of $2.48 per warrant share, none of which have been exercised as of September 30, 2012.

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 following table summarizes stock-based compensation expense information about stock options and restricted stock for the three and nine months ended September 30, 2012:

	Three months ended September 30, 2012	**Nine months ended September 30, 2012**
Stock-based compensation expense associated with restricted stock	$ 818,090	$ 2,178,590
Stock-based compensation expense associated with option grants	—	—
	$ 818,090	$ 2,178,590

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NOTE 5 – NOTES PAYABLE

The following is a summary of notes payable:

	September 30, 2012			December 31, 2011		
	Current portion, net	Non-Current portion, net	Total	Current portion, net	Non-Current portion, net	Total
Non-interest Bearing Note Payable, Net	$—	$—	$—	$200,000	$—	$200,000
Convertible 5% Notes Payable	—	4,380,400	4,380,400	—	4,664,697	4,664,697
ICON Convertible Note	677,778	—	677,778	677,778	—	677,778
Total	$677,778	$4,380,400	$5,058,178	$877,778	$4,664,697	$5,542,475

We assumed the preceding notes payable as the result of the Exchange Transaction. Accordingly, a valuation was performed and these notes were recorded at their fair value on the date of the transaction.

Non-Interest Bearing Note Payable

In October 2009, Manhattan entered into a Settlement Agreement and Mutual Release with Swiss Pharma Contract LTD (“Swiss Pharma”) pursuant to which Manhattan agreed to pay Swiss Pharma $200,000 and issue to Swiss Pharma an interest free promissory note due on October 27, 2011 in the principal amount of $250,000 in full satisfaction of a September 5, 2008 arbitration award. In November 2011, Manhattan renegotiated the $250,000 promissory note due October 27, 2011 in which the amount of the promissory note was reduced to $200,000 and the maturity date was extended to February 15, 2012. This amount was paid on February 14, 2012 in full settlement of this note.

Convertible 5% Notes Payable

On March 8, 2010, Manhattan entered into an Agreement and Plan of Merger (the "Merger Agreement") by and among the Company, Ariston Pharmaceuticals, Inc., a Delaware corporation ("Ariston") and Ariston Merger Corp., a Delaware corporation and wholly-owned subsidiary of the Company (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 the Company.

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 these notes was approximately $16,876,000 immediately prior to the Exchange Transaction, $16,883,000 at December 31, 2011, and $17,515,000 at September 30, 2012. As these notes payable are tied directly to net product cash flows derived from the preexisting products of the Company, this note and accrued interest was recorded at fair value as of the date of the Exchange Transaction. No payments have been made on these notes as of September 30, 2012. 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 were 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 three and nine months ended September 30, 2012, the Company recorded $15,625 and $45,628, respectively, of interest expense on the Amended ICON Note. At September 30, 2012, 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 $107,569, and is reflected as notes payable, current portion, net, and interest payable, current portion, net, respectively, in the accompanying balance sheet as of September 30, 2012. 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 6 – LICENSE AGREEMENTS AND COLLABORATIONS

TG-1101

In April 2011, TG Bio acquired from LFB Biotechnologies, a fully owned subsidiary of France based LFB S.A., an option (the "License Option") for exclusive worldwide rights (except France/Belgium) to develop and market ublituximab ("TG-1101"), a monoclonal antibody that targets a specific epitope on the B-lymphocyte CD20 antigen. In exchange for the License Option, TG Bio issued 132,000 shares of its common stock to LFB.

On January 30, 2012, TG Bio exercised the License Option and entered into an exclusive license agreement with LFB Biotechnologies, GTC Biotherapeutics and LFB/GTC LLC, all wholly-owned subsidiaries of LFB Group, relating to the development of ublituximab (the "License Agreement"). Under the License Agreement, we have acquired the exclusive worldwide rights (exclusive of France/Belgium) for the development and commercialization of TG-1101 (ublituximab). To date, we have made no payments to LFB Group and LFB Group is eligible to receive payments of up to an aggregate of approximately $31.0 million upon our successful achievement of certain clinical development, regulatory and sales milestones, in addition to royalty payments on net sales of ublituximab. The license will terminate on a country by country basis upon 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.

In connection with the License Agreement, our subsidiary TG Bio issued 7,368,000 shares of its common stock to LFB, and the Company agreed to contribute $15 million, less applicable fees and expenses associated with the financing, to TG Bio to fund the development of ublituximab under the License Agreement in exchange for 7,500,000 shares of TG Bio common stock. The Company recognized approximately $16,578,000 of noncash research and development expense during the nine months ended September 30, 2012 in connection with the issuance of these shares. In addition, in connection with the issuance of 7,368,000 shares of TG Bio common stock, the Company and TG Bio provided LFB Group the option to, in its sole discretion, elect to convert all, and not less than all, of the shares of TG Bio common stock into 7,500,000 shares of the Company's Common Stock. This option may be exercised by LFB Group at any time before May 31, 2013.

Furthermore, should LFB Group choose to exercise the option for Company Common Stock, the Board of Directors of the Company shall appoint an individual designated by LFB Group to serve as a director of the Company until the next annual meeting of the stockholders and until his or her successor has been duly elected. Thereafter the Board of Directors of the Company shall nominate a designee named by LFB Group for election at each annual meeting of the stockholders until such time as LFB Group owns less than 10% of the outstanding Company Common Stock.

TGR-1202

On August 15, 2012, the Company and Rhizen Pharmaceuticals S A ("Rhizen") entered into an exclusive global agreement to collaborate on the development and commercialization of Rhizen's lead product candidate (the "Collaboration Agreement"), a novel P13K delta inhibitor, (" TGR-1202") (previously referred to as RP5264). The companies will jointly develop the product on a worldwide basis, excluding India, initially focusing on indications in the area of hematologic malignancies and autoimmune disease. Beyond TGR-1202, Rhizen would contribute backup molecules providing multiple opportunities for TG to develop differentiated therapies against hematologic cancers and autoimmune diseases.

The Company will make up-front licensing payments and milestones based on early clinical development, and will be responsible for the costs of clinical development of the product through Phase II, after which the Company and Rhizen will be jointly responsible for all development costs of the product. The Company and Rhizen will each maintain an exclusive option, exercisable at specific times during development, for the Company to license the rights to TGR-1202, in which case Rhizen would be eligible to receive upfront, development, and commercialization milestone payments in addition to milestone payments and royalties tied to net sales of the product, the aggregate of which could exceed $250 million. Rhizen shall maintain rights to manufacture and supply the product to the Company, and the Company will be responsible for all clinical and regulatory development for TGR-1202 globally.

In connection with the Collaboration Agreement, the Company recognized upfront milestone payments of $1,000,000 during the three and nine months ended September 30, 2012, which has been included in other research and development expenses in the accompanying condensed consolidated financial statements.

NOTE 7 – RELATED PARTY TRANSACTIONS

On December 30, 2011, OPN Capital Markets (“OPNCM”) and its affiliated broker-dealer, National Securities Corporation (“NSC” and collectively with OPNCM, “National”), both affiliates of National Holdings Corporation (“National Holdings”), entered into a Placement Agency Agreement (the “PAA”) with the Company in connection with the initial closing of the 2011 Equity PIPE, offering of up to $25 million of stock and warrants of the Company. Pursuant to the PAA, National acted as the Company’s placement agent for 2011 Equity PIPE.

Until April 2012, Michael S. Weiss was a director and Non-Executive Chairman of the Board of Directors of National Holdings. He is also a stockholder of National Holdings and, when combined with his ownership indirectly through Opus and its affiliates, beneficially owns 23.6% of National Holdings, the parent company of NSC. Mr. Weiss disclaims such beneficial ownership other than to the extent of his pecuniary interest. In addition, at the time, Opus and NSC were parties to a 50/50 joint venture that shared profits from OPNCM, the investment banking division of NSC that was responsible for managing the Offering. This joint venture was dissolved in April 2012.

As placement agent, National received cash commissions equal to 10% of the gross proceeds of the 2011 Equity PIPE, five-year warrants to purchase shares of Company Preferred Stock equal to 10% of shares sold in the 2011 Equity PIPE, and a non-accountable expense allowance equal to two percent of the gross proceeds of the 2011 Equity PIPE for National’s expenses (not including up to $80,000 of National’s legal expenses and any blue sky fees, both of which the Company also reimbursed). In addition to acting as placement, National provided advisory services in connection with the Exchange Transaction and received an advisory fee of $150,000 for such services.

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 recognized approximately $133,000 and $1,410,000 in such expenses during the three and nine months ended September 30, 2012, respectively, which have been included in other research and development expenses in the accompanying condensed consolidated financial statements. In conjunction with the development and manufacturing services discussed above, certain agreements between the Company and LFB Group require payments in advance of services performed or goods delivered. Accordingly, for the period ended September 30, 2012, the Company recorded $1,719,828 in prepaid research and development for such advance payments.

In connection with the Collaboration Agreement with Rhizen, the Company issued Opus 2,000,000 shares of Company common stock subject to certain vesting provisions based on the progress of the joint venture and future success of the products governed by the Collaboration Agreement. The issuance of the Company Common Stock was exempt from registration under the Securities Act of 1933 pursuant to Regulation D and Rule 506 promulgated thereunder. Accordingly, the securities issued in the offering have not been registered under the Securities Act, and until so registered, these securities may not be offered or sold in the United States absent registration or availability of an applicable exemption from registration. The Company recognized approximately $33,000 of noncash compensation (research and development) expense during the three and nine months ended September 30, 2012 in connection with the issuance of these shares.

NOTE 8 – SUBSEQUENT EVENTS

On November 9, 2012, the Company entered into a Securities Exchange Agreement (the "Agreement") by and between the Company and LFB Group. Pursuant to the terms of the Agreement, LFB Group agreed to exchange its 7,500,000 shares of the common stock of TG Bio, for 5,000,000 shares of Company Common Stock and a warrant (the "Warrant") to purchase an aggregate of 2,500,000 shares of Company Common Stock at a purchase price of US $0.001 per share. Further, upon the occurrence of certain financing conditions, the Agreement requires LFB Group to purchase at least $750,000 in additional shares of Company Common Stock at a purchase price per share equal to the then current Market Price (as defined therein). In connection with the Agreement, the Board of Directors (the "Board") of the Company appointed Yann Echelard to the Board. Dr. Echelard will serve as a director until his term expires at the 2013 annual meeting of stockholders, at which time he will stand for reelection by the Company's stockholders. The Company has not yet appointed Mr. Echelard to any Board committees.

In November 2012, the Company entered into a licensing agreement with Ildong Pharmaceutical Co. Ltd. ("Ildong"), under which Ildong obtained the exclusive rights for the development and commercialization of TG-1101 in South Korea and Southeast Asia. Under the terms of the agreement, the Company will receive an upfront payment of $2 million in addition to sales based milestone and royalty payments in exchange for exclusive rights to develop and commercialize TG-1101 for all therapeutic indications in the territory. The Company will retain all rights for the manufacture and supply of TG-1101 within the territory during clinical development and commercialization.

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, 2011.

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 advanced therapies targeting hematological malignancies. TG-1101 (ublituximab), is a novel, third generation monoclonal antibody that targets a specific and unique epitope on the CD20 antigen found on mature B-lymphocytes. We are also developing TGR-1202, a highly specific, orally available PI3K delta inhibitor.

Our portfolio of product candidates is summarized below:

- TG-1101 (ublituximab), an anti-CD20 monoclonal antibody for oncology and B-cell related disorders
- TGR-1202, highly specific PI3K delta inhibitor for hematologic malignancies and autoimmune disease
- AST-726, a nasally delivered form of hydroxocobalamin for the treatment of vitamin B12 deficiency

We also actively evaluate complimentary 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

Developed for the treatment of B-cell proliferative disorders, including Non-Hodgkin's Lymphoma ("NHL") and Chronic Lymphocytic Leukemia ("CLL"), anti-CD20 antibodies target and aid in the depletion of B- lymphocytes. Anti-CD20 antibodies have also been shown to be effective in treating select autoimmune diseases such as Rheumatoid Arthritis ("RA") and Systemic Lupus Erythematosus ("SLE"), along with the neurological disorder Multiple Sclerosis ("MS").

TG-1101 ("LFB-R603" or "R603") is a chimeric murine/human monoclonal antibody with the generic name "ublituximab" that targets the CD20 antigen found on the surface of B-lymphocytes and has been developed to aid in the depletion of circulating B-cells. We hold exclusive worldwide rights (excepting France/Belgium) to develop and commercialize ublituximab for all indications, including the treatment of cancer and autoimmune diseases such as Non-Hodgkin's Lymphoma ("NHL") and Chronic Lymphocytic Leukemia ("CLL").

Multiple preclinical studies both *in vitro* and *in vivo* produced data that support the activity and potency of ublituximab 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 NHL and CLL patient donor cell lines.

Generally, anti-CD20 antibodies are believed to exert their B-cell depleting effects through three primary mechanisms: direct or programmed cell death (“DCD” or “PCD”), complement dependent cytotoxicity (“CDC”), and antibody dependent cell-mediated cytotoxicity (“ADCC”). Ublituximab has been specifically bio-engineered to enhance the ADCC effects, which enhances its ability to deplete B-cells and may improve its anti-cancer effects as compared to Rituxan®, the leading anti-CD20 monoclonal antibody, which had worldwide sales in 2011 of approximately $7 billion.

A two part dose escalating Phase I clinical trial was completed in France in which ublituximab was introduced in relapsed or refractory CLL patients. In Part 1 of the study, 21 CLL patients in escalating dosage cohorts received once weekly infusions of ublituximab over the course of 4 weeks, with an additional 12 patients in Part 2 of the study receiving weekly infusions of ublituximab at a higher flat dose for 8 weeks. According to the investigators, results of Part 2 indicate single agent ublituximab therapy was well tolerated with primary adverse events including infusion related reactions, neutropenia, transient elevations in liver enzymes, pyrexia and thrombocytopenia. Though the primary endpoint of this Phase I clinical study was to assess the safety and tolerability of ublituximab in CLL patients, robust B-cell depletion and an encouraging rate of partial responses may suggest preliminary evidence of efficacy. A portion of the data from Part 2 of this study was presented at the 53rd Annual American Society of Hematology Meeting in San Diego, CA. The Company intends to utilize the data generated from patients in the recently completed Phase I clinical trial to design and conduct future Phase I, II and III studies in the United States and internationally.

Manufacturing of ublituximab is currently performed by our partner, LFB Biotechnologies, using mammalian cells with plans to explore a second manufacturing method utilizing a transgenic animal vector developed by GTC Biotherapeutics, a wholly owned subsidiary of LFB S.A.

TGR-1202

Overview

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

TGR-1202 is a highly specific and orally available PI3K delta inhibitor with nanomolar potency to the delta isoform and several fold selectivity over the alpha, beta, and gamma isoforms. TGR-1202 has demonstrated promising activity in numerous pre-clinical models and primary cells from patients with hematologic malignancies. Inhibition of PI3K delta signaling in pre-clinical evaluations of TGR-1202 has demonstrated:

- Potent inhibition of lipopolysaccharide (LPS) induced human B-cell proliferation;
- Direct inhibition of PI3K delta dependent CD63, a gene associated with tumor progression;
- Inhibition of steroid (dexamethasone) resistant Multiple Myeloma cell lines; and
- Significant reduction of AKT phosphorylation in several B-cell leukemic cell-lines.

Upon administration in various animal species, TGR-1202 has exhibited high oral bioavailability and low clearance as well as favorable pharmacokinetic properties.

The Company and Rhizen will jointly develop the product on a worldwide basis, excluding India, initially focusing on indications in the area of hematologic malignancies and autoimmune disease. Rhizen shall maintain rights to manufacture and supply the product to TG Therapeutics, while TG Therapeutics will be responsible for all clinical and regulatory development for TGR-1202 globally.

The Company is planning to submit an Investigational New Drug ("IND") application for TGR-1202 by YE 2012, with a first in-human Phase I clinical trial to begin in Q1 2013.

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. A final decision is expected to take 6-12 months, but may occur earlier or later.

AST-915

The Company has a sponsored research arrangement for AST-915, an orally delivered treatment for essential tremor. Patient enrollment, treatment, and follow-up concluded for a Phase 1 dose escalation trial of AST-915 in early June 2012. Upon analysis of the data from this study, it was determined that the Phase 1 dose escalation trial of AST-915 did not meet its primary efficacy endpoint of reduction in dominant hand tremor at a timepoint of 80 minutes following administration. Given the results from this Phase 1 study, the Company is currently evaluating the direction and scope of future development activities, if any, for AST-915.

RECENT DEVELOPMENTS

TG-1101 (ublituximab)

In March 2012, the Company submitted to the U.S. Food and Drug Administration (“FDA”) an Investigational New Drug Application (“IND”) for TG-1101 (ublituximab). The Company received notification of acceptance of this IND in April of 2012, permitting the initiation of clinical trials for TG-1101 in oncology patients in the US.

In September 2012, the Company announced that it had initiated a Phase I/II trial to evaluate the safety, tolerability and efficacy of TG-1101 (ublituximab), for patients with relapsed or refractory B-cell non-Hodgkin's lymphoma (“NHL”) who were previously treated with rituximab (Rituxan®). This is the Company's first clinical trial conducted in North America and the first trial of ublituximab in patients with NHL.

The trial, 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," will enroll up to 36 patients in the Phase I dose escalation component. Once the optimal dose is determined, up to 77 patients total will be enrolled for the Phase II component and stratified by subtype of B-cell Lymphoma, including Follicular Lymphoma, Diffuse Large B-cell Lymphoma, Marginal Zone Lymphoma and other NHL subtypes. All enrolled patients will be relapsed or refractory to Rituxan® or a Rituxan® containing regimen, and in most cases multiple other lines of therapy.

GENERAL CORPORATE

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

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 noncash 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 noncash compensation expenses.

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

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

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

RESULTS OF OPERATIONS

Three months ended September 30, 2012 and September 30, 2011

Noncash Compensation Expense (Research and Development). Noncash compensation expense (research and development) related to equity incentive grants equaled $127,091 for the three months ended September 30, 2012. The noncash compensation expense was related to the period’s expense for restricted stock grants to research and development personnel. We expect noncash compensation expense (research and development) to remain at a comparable level for the remainder of 2012.

Other Research and Development Expenses. Other research and development expenses increased by $1,417,771 to $1,433,711 for the three months ended September 30, 2012, as compared to $15,940 for the three months ended September 30, 2011. The increase in research and development expenses is primarily due to a $1,000,000 upfront

milestone payment paid to Rhizen in connection with the Collaboration Agreement for TGR-1202. In addition, research and development expenses related to TG-1101 have increased during the Company's preparations for and initiation of a U.S. based Phase I/II study. We expect our other research and development costs to increase for the remainder of 2012 due to the commencement of our clinical development programs for TG-1101 and TGR-1202.

Noncash Compensation Expense (General and Administrative). Noncash compensation expense (general and administrative) related to equity incentive grants equaled $690,999 for the three months ended September 30, 2012. The noncash compensation expense was related to the period's expense for restricted stock grants to general and administrative personnel. We expect noncash compensation expense (general and administrative) to remain at a comparable level for the remainder of 2012.

Other General and Administrative Expenses. Other general and administrative expenses increased by $448,250 to $462,425 for the three months ended September 30, 2012, as compared to $14,175 for the three months ended September 30, 2011. The increase in other general and administrative was primarily related to legal and personnel costs. We expect our other general and administrative expenses to remain at a comparable level during the remainder of 2012.

Other Income. Other income totaled $4,025 for the three months ended September 30, 2012.

Nine months ended September 30, 2012 and September 30, 2011

Noncash Stock Expense Associated with In-licensing Agreement. Noncash stock expense associated with in-licensing agreement increased by $16,281,000 to $16,578,000 for the nine months ended September 30, 2012, as compared to $297,000 for the nine months ended September 30, 2011. The expense during the nine months ended September 30, 2012 primarily related to a noncash expense of $16,578,000 recorded in conjunction with the stock issued to LFB Group for the license to TG-1101. The expense during the nine months ended September 30, 2011 primarily related to a noncash expense of $297,000 recorded in conjunction with the stock issued to LFB Group for the license option to TG-1101.

Noncash Compensation Expense (Research and Development). Noncash compensation expense (research and development) related to equity incentive grants equaled $236,289 for the nine months ended September 30, 2012. The noncash compensation expense was related to the period's expense for restricted stock grants to research and development personnel. We expect noncash compensation expense (research and development) to increase modestly during the remainder 2012.

Other Research and Development Expenses. Other research and development expenses increased by $3,118,020 to $3,133,960 for the nine months ended September 30, 2012, as compared to $15,940 for the nine months ended September 30, 2011. The increase in research and development expenses is primarily due to a $1,000,000 upfront milestone payment paid to Rhizen in connection with the Collaboration Agreement for TGR-1202. In addition, research and development expenses related to TG-1101 have increased during the Company's preparations for and initiation of a U.S. based Phase I/II study. We expect our other research and development costs to increase during the remainder of 2012 and into 2013 due to the commencement of our clinical development programs for TG-1101 and TGR-1202.

Noncash Compensation Expense (General and Administrative). Noncash compensation expense (general and administrative) related to equity incentive grants equaled $1,942,301 for the nine months ended September 30, 2012. The noncash compensation expense was related to the period's expense for restricted stock grants to general and administrative personnel. We expect noncash compensation expense (general and administrative) to decrease modestly during the remainder of 2012.

Other General and Administrative Expenses. Other general and administrative expenses general and administrative expenses increased by $1,299,785 totaled to $1,313,960 for the nine months ended September 30, 2012, as compared to $14,175 for the nine months ended September 30, 2011. This expense was primarily related to legal and personnel costs. We expect our other general and administrative expenses to remain at a comparable level during the remainder of 2012.

Other Income. Other income totaled $523,612 for the nine months ended September 30, 2012. The other income 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 private placement of equity securities. We have not yet commercialized any of our drug candidates and cannot be sure if we will ever be able to do so. Even if we commercialize one or more of our drug candidates, we may not become profitable. Our ability to achieve profitability

depends on a number of factors, including our ability to obtain regulatory approval for our drug candidates, successfully complete any post-approval regulatory obligations and successfully commercialize our drug candidates alone or in partnership. We may continue to incur substantial operating losses even if we begin to generate revenues from our drug candidates.

As of September 30, 2012, we had $17,373,866 in cash and cash equivalents. We currently anticipate that our cash and cash equivalents as of September 30, 2012 are sufficient to fund our anticipated operating cash requirements for approximately 18-21 months from September 30, 2012. 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, 2012 was $4,354,632, which primarily related to general and administrative and research and development expenses associated with TG commencing operations, the development of TG-1101, and milestone payments associated with the Collaboration Agreement for TGR-1202.

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 Company Preferred Stock, partially offset by the repayment of a short-term loan.

2011 Equity PIPE

On December 30, 2011, we completed the first closing of the private placement of our securities, issuing 4,929,523 shares of Common Stock at a price per share of $2.25 for total gross proceeds, before placement commissions and expenses, of $11,091,425 (the "2011 Equity PIPE"). Investors also received warrants to purchase 1,232,381 shares of Common Stock. The warrants have an exercise price of $2.25 per share and are exercisable for five years.

In 2012, we completed two additional closings of the 2011 Equity PIPE. These closings were held on January 31, 2012, and February 24, 2012. In these closings, the Company issued 695,428 shares of our Company Preferred Stock at a price per share of $20.00 for total gross proceeds, before placement commissions and expenses, of $13,908,560. Each share of Company Preferred Stock was convertible into 8.89 shares of Common Stock; provided that such conversion rights were subject to sufficient available authorized shares of Common Stock. In connection with the reverse stock split effected by the Company on April 30, 2012, all shares of preferred stock issued in the 2011 Equity PIPE were converted to Common Stock. Investors also received warrants to purchase 1,545,396 shares of Common Stock. The warrants have an exercise price of $2.25 per share and are exercisable for five years. The shares of Company Preferred Stock and warrants sold in these closings were offered and sold to accredited investors, including members of management, without registration under the Securities Act, or state securities laws, in reliance on the exemptions provided by Section 4(2) of the Securities Act, and Regulation D promulgated thereunder and in reliance on similar exemptions under applicable state laws. Accordingly, the securities issued in the offering have not been registered under the Securities Act, and until so registered, these securities may not be offered or sold in the United States absent registration or availability of an applicable exemption from registration. The placement agent received cash commissions equal to 10% of the gross proceeds of the offering, five-year warrants to purchase shares of the Company's stock equal to 10% of shares sold in the offering, and a non-accountable expense allowance equal to two percent of the gross proceeds of the offering for their expenses.

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. GAAP. 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:

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 (“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, 2012, there was approximately $630,000 of goodwill on our consolidated balance sheet. Goodwill is reviewed for impairment annually or when events arise that could indicate that an impairment exists. We test for goodwill impairment using a two-step process. The first step compares the fair value of the reporting unit with the unit's carrying value, including goodwill. When the carrying value of the reporting unit is greater than fair value, the unit’s goodwill may be impaired, and the second step must be completed to measure the amount of the goodwill impairment charge, if any. In the second step, the implied fair value of the reporting unit’s goodwill is compared with the carrying amount of the unit’s goodwill. If the carrying amount is greater than the implied fair value, the carrying value of the goodwill must be written down to its implied fair value.

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

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

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

We elected the fair value option for valuing our Convertible 5% Notes Payable 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.

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 these notes was approximately $16,876,000 immediately prior to the Exchange Transaction, $16,883,000 at December 31, 2011, and $17,515,000 at September 30, 2012. As these notes payable are tied directly to net product cash flows derived from the preexisting products of the Company, this note and accrued interest was recorded at fair value as of the date of the Exchange Transaction. No payments have been made on these notes as of September 30, 2012. The fair value of the 5% Notes Payable was approximately $4,664,697 as of December 31, 2011 and $4,380,400 at September 30, 2012.

The valuation methods used to estimate the 5% Notes' fair value was a discounted cash flow model, where the expected cash flows of AST-726 and AST-915 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, 2011 and September 30, 2012. 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, 2012, 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, 2012, 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, 2012, our disclosure controls and procedures were not effective. This conclusion was reached because a lack of segregation of duties exists, as all financial and accounting duties are performed by the Chief Financial Officer. The Company intends to address this deficiency by hiring additional accounting personnel to alleviate the segregation of duties issue.

Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended September 30, 2012, 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 the Company's Business and Industry

Because the Company has in-licensed its product candidates from third parties, any dispute with or non-performance by its licensors will adversely affect its 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 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 licensing partners and, in some cases, third parties, to provide 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 ublituximab 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 ublituximab in any other division under whose supervision we may seek to develop ublituximab, or that they FDA will allow us to continue the development of ublituximab in those divisions where we maintain an active IND. We have not yet submitted an IND for TGR-1202, and there can be no assurance we will be successful in obtaining an IND for TGR-1202 which would delay and or limit the conduct of future clinical trials for TGR-1202.

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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 and II clinical trials for ublituximab. If the results from these trials are different from those found in the completed Phase I clinical trial of ublituximab, 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 not been studied in humans. We plan on conducting Phase I and II trials for TGR-1202, and based on the results of those trials may need to terminate or revise our clinical development plan for TGR-1202, which could delay the clinical development program for TGR-1202 and could have a material adverse effect on our business.

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

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

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

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

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

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

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

We have not completed testing of any of our product candidates for the treatment of the indications for which we intend to seek product approval in humans, and we currently do not know the extent that adverse events, if any, will be observed in patients who receive any of its product candidates. To date, clinical trials using ublituximab 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 ublituximab, even if deemed acceptable for oncology applications, like the completed clinical trial, 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 ublituximab, the toxicity when manufactured under different conditions is not known, nor is the toxicity of transgenically derived ublituximab, 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, we are unfamiliar with the adverse event profile as it has not been dosed in humans. 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.

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, the Company and the FDA must 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 to the Company 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 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, including without limitation, the introduction of transgenically derived ublituximab.

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), Spectrum Pharmaceutical's Zevalin® (Y^{90}-Ibritumomab Tiuxetan), GlaxoSmithKline's Bexxar® (I^{131}-Tositumomab), Dr. Reddy's Laboratories' Reditux®, and Genmab and GlaxoSmithKline's Arzerra® (Ofatumomab) among others, each of which is currently approved for the treatment of various diseases including NHL and CLL. 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.

Although no PI3K delta inhibitors have been approved by the FDA, there are several PI3K delta targeted compounds in development including Gilead's GS-1101 (formerly known as 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.

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 specifications and 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. If that is the case, we may need to rely exclusively on transgenically manufactured material, which may introduce additional risk and uncertainty the extent of which cannot be fully determined today.

In addition, the Company does 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 the Company's 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 the Company's 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 Company's clinical development and commercialization of the product. Regarding ublituximab, the proprietary transgenic technology that supports the manufacture of transgenically derived ublituximab is not easily transferrable, if at all, and it is expected that GTC will be the sole supplier of transgenically derived ublituximab at a single site for the foreseeable future.

Clinical trials of our transgenically produced products may be unsuccessful or delayed, which may prevent us from meeting our anticipated development timeline.

The Company and its collaborators must demonstrate through preclinical and clinical trials that our transgenically produced products are safe and effective for use in humans. Clinical trials are expensive and may take several years. Several factors could prevent or delay completion of these trials, including an inability to enroll the required number of patients or demonstrate adequately the safety or efficacy of the product for humans. If safety concerns develop, regulatory authorities could stop or delay trials of transgenically derived ublituximab or any other product candidate evaluated by the Company. Furthermore, the results from early clinical trials are often not predictive of results in later clinical trials.

To our knowledge, Pharming Group N.V. and GTC Biotherapeutics, Inc. are the only other entities to have completed human clinical trials sufficient to support the filing for regulatory approval of a product produced from a transgenic mammal. If we are unable to complete all clinical trials and to satisfy any requirements that may be required by the FDA or the EMA for approval of transgenically derived ublituximab, it could have a material adverse effect on our business and operations.

Any transgenically produced products for which we obtain regulatory approval will be subject to continuing review and extensive regulatory requirements, which could affect their manufacture and marketing.

If and when the FDA or other foreign agencies approve our transgenically produced products under development, the manufacture and marketing of these products will be subject to continuing regulation and product approvals may be withdrawn if problems occur after initial approval. Post-approval regulation includes compliance with current Quality Systems Regulations and Good Manufacturing Practices, ("QSR/GMP"), adverse event reporting requirements and prohibitions on promoting a product for unapproved uses. In addition, the FDA could require us to conduct post-approval clinical trials or studies. We will also be required to obtain additional approvals for any significant alterations in the product's labeling or manufacturing process. Enforcement actions resulting from failure to comply with QSR/GMP requirements could result in fines, suspensions of approvals, recalls of products, operating restrictions and criminal prosecutions, and affect the manufacture and marketing of our transgenically produced products. The FDA or other regulatory agencies could withdraw a previously approved product from the market upon receipt of newly discovered information, including a failure to comply with regulatory requirements and the occurrence of unanticipated problems with products, including adverse events, manufacturing and quality problems, following approval. Any of these withdrawals could adversely affect our operating results.

The Company may face public concerns about genetic engineering in animals.

The activities of the Company's development and manufacturing affiliate involve genetic engineering in animals. The success of our potential commercial products will depend in part on public acceptance of the use of genetic engineering. Public attitudes may be influenced by claims and perceptions that these types of activities are unsafe and our products may not gain the acceptance of the public or the medical community. Negative public reaction to genetic engineering activities in general could result in greater restrictive legislation and regulations involving nuclear transfer and other methodologies which could impede our ability to conduct our business efficiently, delay preclinical studies or future clinical trials, or prevent us or our partners from obtaining regulatory approvals or commercializing transgenically produced products.

Our transgenically produced products may be subject to technology risks that may restrict or prevent their development and commercialization.

Developing products based on transgenic technology is subject to significant development risks. Each DNA construct is unique and it is possible that it might not be expressed in the transgenic animal's milk at a level that is commercially viable. Purifying the recombinant protein out of the milk to use as a biotherapeutic may be too difficult to be commercially feasible. In addition, production of the recombinant protein may have negative effects on the health of either the mammary gland or more systematically on the animal as a whole. This would compromise the ability of the animal to produce the recombinant protein. Directing the mammary gland to produce additional proteins in the milk could negatively affect lactation, thereby shutting down milk production. The mammary gland may also modify a protein in such a manner that it is non-functional or harmful in humans. It is also possible that there may be disease agents present in the animals that would prevent the use of products derived from these animals. If an as yet unknown disease was identified that could not be effectively mitigated, government agencies may confiscate or destroy the animals, or prevent the utilization of their milk. Any of these governmental actions would prevent the use of the recombinant proteins and may result in a material adverse effect on our business.

We may not be able to recover from any catastrophic event affecting our suppliers' animals or facilities.

While our suppliers have measures in place to minimize and recover from catastrophic events that may substantially destroy their animal herd(s), these measures may not be adequate to recover production processes quickly enough to support critical timelines, collaborator needs, or market demands. These catastrophic events may include, but are not limited to, animal diseases that breach biosecurity measures or weather events such as tornadoes, earthquakes or fires. In addition, these catastrophic events may render some or all of the products at the affected facilities unusable.

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 the Company or its 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 the Company successfully develops 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 the Company, 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 the Company 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 the Company could cause its stock price to decline and, if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

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

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

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

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

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

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

healthcare programs and will result in the development of new programs. An expansion in the government's role in the U.S. healthcare industry may further lower rates of reimbursement for pharmaceutical and biotechnology products.

There have been, and likely will continue to be, legislative and regulatory proposals at the federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare products and services. The Company 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 the Company is 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, 2012, the Company has 6 full and part time employees. Over time, we will need to expand our managerial, operational, financial and other resources in order to manage and fund our operations and clinical trials, continue research and development activities, and commercialize our product candidates. Our management and scientific personnel, systems and facilities currently in place may not be adequate to support our future growth. Our need to effectively manage our operations, growth, and various projects requires that we:

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

We may utilize the services of outside vendors or consultants to perform tasks including clinical trial management, statistics and analysis, regulatory affairs, formulation development 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 the Company is not able to effectively expand its organization by hiring new employees and expanding its 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 the Company fails 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 the Company continues to expand its 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 the Company fails to comply with healthcare regulations, it could face substantial penalties and its 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.

The Company uses 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 filing are based on the assumption of further financing.

The timelines and projections in this filing 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 the Company does 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, such as the Exchange Transaction between the Company and TG Bio. 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 the Company's Intellectual Property

The Company's 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 ublituximab 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. will convert from a “first to invent” to a “first to file” system. After this time 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 the Company or its 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 ublituximab. 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 ublituximab, 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 ublituximab or launch at the risk of litigation for patent infringement, which may have a material adverse effect on the Company.

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.

The Company may be subject to claims that its 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 the Company has 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 the Company's Finances and Capital Requirements

The Company will need to raise additional capital to continue to operate its business.

As of September 30, 2012, we had net cash on hand of approximately $17,374,000. We believe that our cash on hand will sustain our operations for the next 18-21 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 the Company's 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. The Company's prospects must be considered in light of the uncertainties, risks, expenses and difficulties frequently encountered by companies in their early stages of operations and the competitive environment in which we operate.

The Company has never been profitable, and, as of September 30, 2012, we had an accumulated deficit of approximately $15,466,000. We have generated operating losses in all periods since the Company was 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 the Company is 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 the Company 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.

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

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

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

Our directors, executive officers and principal stockholders beneficially own approximately 44% 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.

Our Common Stock is not listed on a national exchange and there is a limited market for the Common Stock which may make it more difficult for you to sell your stock.

Our Common Stock is quoted on the OTC Bulletin Board under the symbol "TGTX." There is a limited trading market for our Common Stock which negatively impacts the liquidity of our Common Stock not only in terms of the number of shares that can be bought and sold at a given price, but also through delays in the timing of transactions and reduction in security analysts' and the media's coverage of us. Accordingly, there can be no assurance as to the liquidity of any markets that may develop for the Common Stock, the ability of holders of our Common Stock to sell the Common Stock, or the prices at which holders may be able to sell the Common Stock.

The fact that our common stock is not listed on a national exchange may negatively impact our ability to attract investors and to use our common stock to raise capital to fund our operations.

In order to maintain liquidity in our common stock, we depend upon the continuing availability of a market on which our securities may be traded. We need to raise substantial additional funds in the future to continue our operations and the fact that our common stock is not listed on a national exchange may impact our ability to attract investors and to use our common stock to raise sufficient capital to continue to fund our operations.

If we fail to file periodic reports with the SEC our common stock may be removed from the OTCBB.

Pursuant to the Over-The-Counter Bulletin Board ("OTCBB") rules relating to the timely filing of periodic reports with the SEC, any OTCBB issuer which fails to file a periodic report (Form 10-Qs or 10-Ks) by the due date of such report (as extended by the filing of a Form 12b-25), three (3) times during any twenty-four (24) month period is automatically de-listed from the OTCBB. In the event an issuer is de-listed, such issuer would not be eligible to be re-listed on the OTCBB for a period of one-year, during which time any subsequent late filing would reset the one-year period of de-listing. If the Company is late in its filings three (3) times in any twenty-four (24) month period and is de-listed from the OTCBB, the Common Stock would likely be listed for trading only on the “Pink Sheets,” which generally provide an even less liquid market than the OTCBB. In such event, investors may find it more difficult to trade the Common Stock or to obtain accurate, current information concerning market prices for the Common Stock.

There is a risk of market fraud.

OTCBB securities are frequent targets of fraud or market manipulation. Not only because of their generally low price, but also because the OTCBB reporting requirements for these securities are less stringent than for listed or NASDAQ traded securities, and no exchange requirements are imposed. Dealers may dominate the market and set prices that are not based on competitive forces. Individuals or groups may create fraudulent markets and control the sudden, sharp increase of price and trading volume and the equally sudden collapse of market prices.

Penny stock regulations may impose certain restrictions on marketability of our securities.

The Securities and Exchange Commission has adopted Rule 15g-9 which establishes the definition of a “penny stock,” for the purposes relevant to us, as any equity security that has a market price of less than $5.00 per share or with an exercise price of less than $5.00 per share, subject to certain exceptions. For any transaction involving a penny stock, unless exempt, the rules require:

- that a broker or dealer approve a person’s account for transactions in penny stocks; and

- the broker or dealer receives from the investor a written agreement to the transaction, setting forth the identity and quantity of the penny stock to be purchased.

In order to approve a person's account for transactions in penny stocks, the broker or dealer must:

- obtain financial information and investment experience objectives of the person; and
- make a reasonable determination that the transactions in penny stocks are suitable for that person and the person has sufficient knowledge and experience in financial matters to be capable of evaluating the risks of transactions in penny stocks.

The broker or dealer must also deliver, prior to any transaction in a penny stock, a disclosure schedule prescribed by the Commission relating to the penny stock market, which, in highlight form:

- sets forth the basis on which the broker or dealer made the suitability determination; and
- that the broker or dealer received a signed, written agreement from the investor prior to the transaction.

Generally, brokers may be less willing to execute transactions in securities subject to the "penny stock" rules. This may make it more difficult for investors to dispose of our Common Stock and cause a decline in the market value of our stock.

Disclosure also must be made about the risks of investing in penny stocks in both public offerings and in secondary trading and about the commissions payable to both the broker-dealer and the registered representative, current quotations for the securities and the rights and remedies available to an investor in cases of fraud in penny stock transactions. Finally, monthly statements have to be sent disclosing recent price information for the penny stock held in the account and information on the limited market in penny stocks.

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 filed with this report.

3.1	Amended and Restated Certificate of Incorporation of TG Therapeutics, Inc., dated April 26, 2012, filed as Exhibit 3.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2012, File No. 001-32639, and incorporated herein by reference.
3.2	Restated Bylaws of TG Therapeutics, Inc. dated May 14, 2012, filed as Exhibit 3.2 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2012, file No. 001-32639, and incorporated herein by reference.
4.1	Warrant, dated as of November 9, 2012, filed as Exhibit 4.1 to the Registrants Current Report on Form 8-K, File No. 001-32639, and incorporated herein by reference.
10.1	Joint Venture Agreement between TG Therapeutics, Inc. and Rhizen Pharmaceuticals SA, dated August 15, 2012. *
10.2	Securities Exchange Agreement between TG Therapeutics, Inc. and LFB Biotechnologies S.A.S., dated November 9, 2012, filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, File No. 001-32639, and incorporated herein by reference.

* Confidential treatment has been requested with respect to omitted portions of this exhibit.

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, 2012.
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, 2012.
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, 2012.
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, 2012.

* Confidential treatment has been requested with respect to omitted portions of this exhibit.

SIGNATURES

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

TG THERAPEUTICS, INC.

Date: November 14, 2012 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:

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