UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2017

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.)

2 Gansevoort Street, 9th Floor
New York, New York 10014
(Address including zip code of principal executive offices)

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

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

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

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

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by checkmark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).
Yes ☐ No ☒

There were 70,652,267 shares of the registrant's common stock, $0.001 par value, outstanding as of November 1, 2017.

TG THERAPEUTICS, INC.
FORM 10-Q
FOR THE QUARTER ENDED SEPTEMBER 30, 2017

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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," "plan," "intend" and similar expressions are generally intended to identify forward-looking statements. Our actual results may differ materially from the results anticipated in these forward-looking statements due to a variety of factors, including, without limitation, those discussed under the captions "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this report, as well as other factors which may be identified from time to time in our other filings with the Securities and Exchange Commission, or the SEC, or in the documents where such forward-looking statements appear. All written or oral forward-looking statements attributable to us are expressly qualified in their entirety by these cautionary statements. Such forward-looking statements include, but are not limited to, statements about our

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

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

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

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

TG Therapeutics, Inc.
Condensed Consolidated Balance Sheets

	September 30, 2017 (Unaudited)	December 31, 2016 (Note 1)
Assets		
Current assets:		
Cash and cash equivalents	$ 91,842,167	$ 25,031,280
Short-term investment securities	--	19,853,860
Interest receivable	--	83,852
Prepaid research and development	5,022,846	5,678,755
Other current assets	796,283	216,397
Total current assets	97,661,296	50,864,144
Restricted cash	586,259	583,208
Leasehold interest, net	2,466,202	2,042,281
Equipment, net	268,366	328,148
Goodwill	799,391	799,391
Other assets	--	164,375
Total assets	$ 101,781,514	$ 54,781,547
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 18,179,772	$ 15,267,668
Accrued compensation	1,275,305	1,389,516
Current portion of deferred revenue	152,381	152,381
Notes payable	182,156	68,875
Total current liabilities	19,789,614	16,878,440
Deferred rent	1,341,372	816,257
Deferred revenue, net of current portion	1,104,762	1,219,048
Total liabilities	22,235,748	18,913,745
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value per share (10,000,000 shares authorized, none issued and outstanding as of September 30, 2017 and December 31, 2016)	--	--
Common stock, $0.001 par value per share (150,000,000 shares authorized, 70,693,576 and 56,820,422 shares issued; 70,652,267 and 56,779,113 shares outstanding at September 30, 2017 and December 31, 2016, respectively)	70,694	56,820
Additional paid-in capital	403,712,474	272,432,139
Treasury stock, at cost, 41,309 shares at September 30, 2017 and December 31, 2016	(234,337)	(234,337)
Accumulated deficit	(324,003,065)	(236,386,820)
Total stockholders' equity	79,545,766	35,867,802
Total liabilities and stockholders' equity	$ 101,781,514	$ 54,781,547

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

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

	Three months ended September 30,		Nine months ended September 30,	
	2017	**2016**	**2017**	**2016**
License revenue	$ 38,096	$ 38,096	$ 114,286	$ 114,286
Costs and expenses:				
Research and development:				
Noncash compensation	1,814,288	919,648	5,386,709	1,873,730
Other research and development	25,334,762	20,878,108	71,150,033	45,075,097
Total research and development	27,149,050	21,797,756	76,536,742	46,948,827
General and administrative:				
Noncash compensation	3,075,835	1,914,390	6,988,597	4,307,670
Other general and administrative	1,398,438	1,251,421	4,265,967	3,798,859
Total general and administrative	4,474,273	3,165,811	11,254,564	8,106,529
Total costs and expenses	31,623,323	24,963,567	87,791,306	55,055,356
Operating loss	(31,585,227)	(24,925,471)	(87,677,020)	(54,941,070)
Other (income) expense:				
Interest income	(79,163)	(87,965)	(174,056)	(265,456)
Other	29,588	(6,479)	113,281	(96,863)
Total other (income) expense, net	(49,575)	(94,444)	(60,775)	(362,319)
Net loss	$ (31,535,652)	$ (24,831,027)	$ (87,616,245)	$ (54,578,751)
Basic and diluted net loss per common share	$ (0.48)	$ (0.50)	$ (1.45)	$ (1.11)
Weighted average shares used in computing basic and diluted net loss per common share	65,079,128	49,203,277	60,552,084	48,961,582

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

TG Therapeutics, Inc.
Condensed Consolidated Statement of Stockholders' Equity
(Unaudited)

	Common Stock			Treasury Stock			
	Shares	Amount	Additional paid-in capital	Shares	Amount	Accumulated Deficit	Total
Balance at January 1, 2017	56,820,422	$ 56,820	$272,432,139	41,309	$(234,337)	$ (236,386,820)	$ 35,867,802
Issuance of common stock in connection with exercise of warrants	887,585	888	2,142,197	--	--	--	2,143,085
Issuance of restricted stock	1,112,131	1,112	(1,112)	--	--	--	--
Forfeiture of restricted stock	(26,625)	(27)	27	--	--	--	--
Issuance of common stock in public offering (net of offering costs of $3.6 million)	5,897,436	5,898	53,634,115	--	--	--	53,640,013
Issuance of common stock in At-the-Market offerings (net of offering costs of $1.1 million)	6,002,627	6,003	63,129,802	--	--	--	63,135,805
Compensation in respect of restricted stock granted to employees, directors and consultants	--	--	12,375,306	--	--	--	12,375,306
Net loss	--	--	--	--	--	(87,616,245)	(87,616,245)
Balance at September 30, 2017	70,693,576	$ 70,694	$403,712,474	41,309	$(234,337)	$ (324,003,065)	$ 79,545,766

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

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

	Nine months ended September 30,	
	2017	**2016**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (87,616,245)	$ (54,578,751)
Adjustments to reconcile net loss to net cash used in operating activities:		
Gain on sale of long-term securities	--	(33,042)
Noncash stock compensation expense	12,375,306	6,181,400
Depreciation	62,009	42,464
Amortization of premium on investment securities	53,860	367,673
Change in fair value of notes payable	113,281	(63,822)
Changes in assets and liabilities:		
Increase in restricted cash	(3,051)	(3,041)
Decrease (increase) in other current assets	147,826	(1,162,310)
Decrease (increase) in leasehold interest	88,179	(2,517,771)
Decrease in accrued interest receivable	83,852	77,563
Decrease (increase) in other assets	161,730	(3,523)
Increase in accounts payable and accrued expenses	2,666,164	6,447,215
Increase in deferred rent	72,942	793,968
Decrease in deferred revenue	(114,286)	(114,286)
Net cash used in operating activities	(71,908,433)	(44,566,263)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property, plant and equipment	(2,227)	(323,015)
Investment in held-to-maturity securities	--	(15,199,922)
Proceeds from the sale of long-term securities	--	18,000,000
Proceeds from maturity of short-term securities	19,800,000	12,589,219
Net cash provided by investing activities	19,797,773	15,066,282
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from the exercise of warrants	2,143,085	100,896
Proceeds from sale of common stock, net	116,778,462	3,504,261
Financing costs	--	(9,984)
Net cash provided by financing activities	118,921,547	3,595,173
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	66,810,887	(25,904,808)
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	25,031,280	55,061,329
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 91,842,167	$ 29,156,521
NONCASH TRANSACTIONS		
Reclassification of deferred financing costs to additional paid-in capital	$ (2,645)	$ (56,988)
Conversion of convertible notes payable to common stock	$ --	$ 30,601

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

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

NOTE 1 – ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Description of Business

We are a biopharmaceutical company focused on the acquisition, development and commercialization of novel treatments for B-cell malignancies and autoimmune diseases. Currently, we are developing two therapies targeting hematologic malignancies. TG-1101 (ublituximab) is a novel, glycoengineered monoclonal antibody that targets a specific and unique epitope on the CD20 antigen found on mature B-lymphocytes. We are also developing TGR-1202 (umbralisib), an orally available PI3K delta inhibitor. The delta isoform of PI3K is strongly expressed in cells of hematopoietic origin and is believed to be important in the proliferation and survival of B-lymphocytes. Both TG-1101 and TGR-1202, or the combination of which is referred to as "U2," are in Phase 3 clinical development for patients with hematologic malignancies, with TG-1101 also in Phase 3 clinical development for Multiple Sclerosis. Additionally, the Company has recently brought its anti-PD-L1 monoclonal antibody into Phase 1 development and aims to bring additional pipeline assets into the clinic in the future.

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

The accompanying unaudited condensed consolidated financial statements were prepared in accordance with U.S. generally accepted accounting principles, or GAAP, for interim financial information and with the instructions to Quarterly Report on Form 10-Q and Article 10 of Regulation S-X of the Exchange Act. Accordingly, they may not include all of the information and footnotes required by GAAP for complete financial statements. All adjustments that are, in the opinion of management, of a normal recurring nature and are necessary for a fair presentation of the condensed consolidated financial statements have been included. Nevertheless, these condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements contained in our Annual Report on Form 10-K for the year ended December 31, 2016. The accompanying condensed December 31, 2016 balance sheet has been derived from these statements. The results of operations for the three and nine months ended September 30, 2017 are not necessarily indicative of the results that may be expected for the entire fiscal year or any other interim period.

Liquidity and Capital Resources

We have incurred operating losses since our inception and expect to continue to incur operating losses for the foreseeable future and, may never become profitable. As of September 30, 2017, we have an accumulated deficit of approximately $324.0 million.

Our major sources of cash have been proceeds from the private placement and public offering of equity securities. We have not yet commercialized any of our drug candidates and cannot be sure if we will ever be able to do so. Even if we commercialize one or more of our drug candidates, we may not become profitable. Our ability to achieve profitability depends on many factors, including our ability to obtain regulatory approval for our drug candidates; successfully completing any post-approval regulatory obligations; and successfully commercializing 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, 2017, we had approximately $91.8 million in cash and cash equivalents. The Company believes its cash and cash equivalents on hand as of September 30, 2017 will be sufficient to fund the Company's planned operations through 2018. The actual amount of cash that we will need to operate is subject to many factors, including, but not limited to, the timing, design and conduct of clinical trials for our drug candidates. We are dependent upon significant future financing to execute our current strategic plan, including the commercialization of any of our drug candidates (see Note 5 for further details).

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

Recently Issued Accounting Standards

In May 2017, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2017-09, "Scope of Modification Accounting" ("ASU 2017-09"). ASU 2017-09 provides guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting. An entity should account for the effects of a modification unless all the following are met:

- The fair value (or calculated value or intrinsic value, if such an alternative measurement method is used) of the modified award is the same as the fair value (or calculated value or intrinsic value, if such an alternative measurement method is used) of the original award immediately before the original award is modified. If the modification does not affect any of the inputs to the valuation technique that the entity uses to value the award, the entity is not required to estimate the value immediately before and after the modification.
- The vesting conditions of the modified award are the same as the vesting conditions of the original award immediately before the original award is modified.
- The classification of the modified award as an equity instrument or a liability instrument is the same as the classification of the original award immediately before the original award is modified.

ASU 2017-09 is effective for annual and interim periods beginning on or after December 15, 2017. Early adoption is permitted for public business entities for reporting periods for which financial statements have not yet been issued, and all other entities for reporting periods for which financial statements have not yet been made available for issuance. The amendments should be applied prospectively to an award modified on or after the adoption date. The Company does not expect the adoption of ASU 2017-09 to have a material impact on the Company's condensed consolidated financial statements.

In January 2017, the FASB issued ASU No. 2017-04, "Simplifying the Test for Goodwill Impairment" ("ASU 2017-04"). ASU 2017-04 removes the requirement to compare the implied fair value of goodwill with its carrying amount as part of step 2 of the goodwill impairment test. As a result, under ASU 2017-04, an entity should perform its annual, or interim, goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount and should recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit's fair value; however, the loss recognized should not exceed the total amount of goodwill allocated to that reporting unit. In addition, ASU 2017-04:

- Clarifies the requirements for excluding and allocating foreign currency translation adjustments to reporting units in connection with an entity's testing of reporting units for goodwill impairment.
- Clarifies that an entity should consider income tax effects from any tax deductible goodwill on the carrying amount of the reporting unit when measuring the goodwill impairment loss, if applicable.
- Makes minor changes to the overview and background sections of certain Accounting Standards Codification ("ASC" or "Codification") subtopics and topics as part of the Board's initiative to unify and improve those sections throughout the Codification.

ASU 2017-04 is effective prospectively for annual and interim periods beginning on or after December 15, 2019, and early adoption is permitted on testing dates after January 1, 2017. The Company does not expect the adoption of ASU 2017-04 to have a material impact on the Company's condensed consolidated financial statements.

In January 2017, the FASB issued ASU No. 2017-01, "FASB Clarifies the Definition of a Business" ("ASU 2017-01"). ASU 2017-01 clarifies the definition of a business in ASC 805. The amendments in ASU 2017-01 are intended to make application of the guidance more consistent and cost-efficient. The amendments in ASU 2017-01:

- Provide a screen to determine when a set of assets and activities is not a business. The screen requires that when substantially all of the fair value of the gross assets acquired (or disposed of) is concentrated in a single identifiable asset or a group of similar identifiable assets, the set is not a business. This screen reduces the number of transactions that need to be further evaluated.
- Provide that if the screen is not met, (1) to be considered a business, a set must include, at a minimum, an input and a substantive process that together significantly contribute to the ability to create output and (2) remove the evaluation of whether a market participant could replace missing elements. The amendments provide a framework to assist entities in evaluating whether both an input and a substantive process are present. The framework includes two sets of criteria to consider that depend on whether a set has outputs. Although outputs are not required for a set to be a business, outputs generally are a key element of a business; therefore, the Board has developed more stringent criteria for sets without outputs.
- Narrow the definition of the term output so that the term is consistent with how outputs are described in Topic 606.

ASU 2017-01 is effective for annual and interim periods beginning after December 15, 2017, with early adoption permitted for transactions that occurred before the issuance date or effective date of the standard if the transactions were not reported in financial statements that have been issued or made available for issuance. The Company does not expect the adoption of ASU 2017-01 to have a material impact on the Company's condensed consolidated financial statements.

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606) ("ASU 2014-09"), which supersedes all existing revenue recognition requirements, including most industry-specific guidance. ASU 2014-09 provides a single set of criteria for revenue recognition among all industries. The new standard requires a company to recognize revenue when it transfers goods or services to customers in an amount that reflects the consideration that the Company expects to receive for those goods or services.

ASU 2014-09 includes guidance for determining whether a license transfers to a customer at a point in time or over time based on the nature of the entity's promise to the customer. To determine whether the entity's promise is to provide a right to access its intellectual property or a right to use its intellectual property, the entity should consider the nature of the intellectual property to which the customer will have rights.

ASU 2014-09 is effective for interim and annual periods beginning after December 15, 2017. The standard allows for two transition methods - full retrospective, in which the standard is applied to each prior reporting period presented, or modified retrospective, in which the cumulative effect of initially applying the standard is recognized at the date of initial adoption. The Company expects to elect the modified retrospective approach and is continuing to assess the impact of the new guidance on its accounting policies and procedures and is evaluating the new requirements. The Company does not expect the adoption of ASU 2014-09 to have a material impact on the Company's condensed consolidated financial statements.

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

Use of Estimates

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

Cash and Cash Equivalents

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

Restricted Cash

We record cash pledged or held in trust as restricted cash. As of September 30, 2017 and December 31, 2016, we have approximately $0.6 million of restricted cash pledged to secure a line of credit as a security deposit for an Office Agreement (see Note 8).

Investment Securities

Investment securities at December 31, 2016 consist of short-term government securities. We classify these securities as held-to-maturity. Held-to-maturity securities are those securities in which we have the ability and intent to hold the security until maturity. Held-to-maturity securities are recorded at amortized cost, adjusted for the amortization or accretion of premiums or discounts. Premiums and discounts are amortized or accreted over the life of the related held-to-maturity security as an adjustment to yield using the effective interest method.

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

Credit Risk

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

Revenue Recognition

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

Research and Development Costs

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

Prepaid research and development in our consolidated balance sheets includes, among other things, costs related to agreements with CROs, certain costs to third party service providers related to development and manufacturing services as well as clinical development. These agreements often require payments in advance of services performed or goods received. Accordingly, as of September 30, 2017 and December 31, 2016, we recorded approximately $5.0 million and $5.7 million, respectively, in prepaid research and development related to such advance agreements.

Income Taxes

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

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

Stock-Based Compensation

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

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

In addition, because some of the restricted stock issued to employees, consultants and other third-parties vest upon achievement of certain milestones, the total expense is uncertain. Compensation expense for such awards that vest upon the achievement of milestones is recognized when the achievement of such milestones becomes probable.

Basic and Diluted Net Loss Per Common Share

Basic net loss per share of our common stock is calculated by dividing net loss applicable to the common stock by the weighted-average number of our common stock outstanding for the period. Diluted net loss per share of common stock is the same as basic net loss per share of common stock since potentially dilutive securities from stock options, stock warrants and convertible preferred stock would have an antidilutive effect either because we incurred a net loss during the period presented or because such potentially dilutive securities were out of the money and the Company realized net income during the period presented. The amounts of potentially dilutive securities excluded from the calculation were 4,157,052 and 6,664,591 for the three and nine months ended September 30, 2017 and 2016, respectively. The following outstanding shares of common stock equivalents were excluded from the computation of net loss per share attributable to common stockholders for the periods presented because including them would have been antidilutive:

	Three and Nine Months Ended September 30,	
	2017	**2016**
Unvested restricted shares	4,141,680	5,507,250
Shares issuable upon note conversion	15,372	1,142,208
Warrants	--	15,133
Total	4,157,052	6,664,591

Long-Lived Assets and Goodwill

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

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

Rent Expense and Deferred Rent

Rent expense and lease incentives, including landlord construction allowances, are recognized on a straight-line basis over the lease term, commencing generally on the date the Company takes possession of the leased property. The Company records lease incentives as deferred rent and recognizes the lease incentives as reductions of rental expense. The unamortized portion of deferred rent is included in deferred rent in the condensed consolidated balance sheets.

NOTE 2 – CASH AND CASH EQUIVALENTS

The following tables summarize our cash and cash equivalents at September 30, 2017 and December 31, 2016:

	September 30, 2017	December 31, 2016
Money market funds	$ 29,055,021	$ 20,978,947
Checking and bank deposits	62,787,146	4,052,333
Total	$ 91,842,167	$ 25,031,280

NOTE 3 – INVESTMENT SECURITIES

Our investments as of December 31, 2016 are classified as held-to-maturity. Held-to-maturity investments are recorded at amortized cost.

The following table summarizes our investment securities at December 31, 2016:

	Amortized cost, as adjusted	Gross unrealized holding gains	Gross unrealized holding losses	Estimated fair value
Short-term investments:				
Obligations of domestic governmental agencies (maturing between February 2017 and September 2017) (held-to-maturity)	$ 19,853,860	$ 3,270	$ 2,492	$ 19,854,638
Total short-term investment securities	$ 19,853,860	$ 3,270	$ 2,492	$ 19,854,638

NOTE 4 – FAIR VALUE MEASUREMENTS

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

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

As of September 30, 2017 and December 31, 2016, the fair values of cash and cash equivalents, restricted cash, accounts payable, and notes and interest payable, current portion approximate their carrying value.

At the time of our merger (we were then known as Manhattan Pharmaceuticals, Inc. ("Manhattan")) with Ariston Pharmaceuticals, Inc. ("Ariston") in March 2010, Ariston issued $15.5 million of five-year 5% notes payable (the "5% Notes") in satisfaction of several note payable issuances. The 5% Notes and accrued and unpaid interest thereon are convertible at the option of the holder into common stock at the conversion price of $1,125 per share. Ariston agreed to make quarterly payments on the 5% Notes equal to 50% of the net product cash flow received from the exploitation or commercialization of Ariston's product candidates, AST-726 and AST-915. We have no obligations under the 5% Notes aside from (a) 50% of the net product cash flows from Ariston's product candidates, if any, payable to noteholders; and (b) the conversion feature, discussed above.

The cumulative liability including accrued and unpaid interest of the 5% Notes was approximately $17.3 million at September 30, 2017 and $16.7 million at December 31, 2016. No payments have been made on the 5% Notes as of September 30, 2017.

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

As of December 31, 2013, as a result of expiring intellectual property rights and other factors, it was determined that net product cash flows from AST-726 were unlikely. As we have no other obligations under the 5% Notes aside from the net product cash flows and the conversion feature, the conversion feature was used to estimate the 5% Notes' fair value as of September 30, 2017 and December 31, 2016. The assumptions, assessments and projections of future revenues are subject to uncertainties, difficult to predict, and require significant judgment. The use of different assumptions, applying different judgment to inherently subjective matters and changes in future market conditions could result in significantly different estimates of fair value and the differences could be material to our condensed consolidated financial statements.

The following tables provide the fair value measurements of applicable financial liabilities as of September 30, 2017 and December 31, 2016:

	Financial liabilities at fair value as of September 30, 2017			
	Level 1	Level 2	Level 3	Total
5% Notes	$ --	$ --	$ 182,156	$ 182,156
Total	$ --	$ --	$ 182,156	$ 182,156

	Financial liabilities at fair value as of December 31, 2016			
	Level 1	Level 2	Level 3	Total
5% Notes	$ --	$ --	$ 68,875	$ 68,875
Total	$ --	$ --	$ 68,875	$ 68,875

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, 2017:

Fair value at December 31, 2016	$ 68,875
Interest accrued on face value of 5% Notes	630,003
Conversion of 5% notes	--
Change in fair value of Level 3 liabilities	(516,722)
Fair value at September 30, 2017	$ 182,156

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

NOTE 5 - STOCKHOLDERS' EQUITY

Preferred Stock

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

Common Stock

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

In December 2014, we filed a shelf registration statement on Form S-3 (the "2015 S-3"), which was declared effective in January 2015. Under the 2015 S-3, the Company may sell up to a total of $250 million of its securities. In connection with the 2015 S-3, we amended our 2013 At-the-Market Issuance Sales Agreement with MLV & Co. LLC (the "2015 ATM") such that we may issue and sell additional shares of our common stock, having an aggregate offering price of up to $175.0 million, from time to time through MLV & Co. LLC ("MLV") and FBR Capital Markets & Co. ("FBR", each of MLV and FBR individually an "Agent" and collectively the "Agents"), acting as the sales agents. Under the 2015 ATM we pay the Agents a commission rate of up to 3.0% of the gross proceeds from the sale of any shares of common stock sold through the Agents.

During the nine months ended September 30, 2017, we sold a total of 3,104,253 shares of common stock under the 2015 ATM for total gross proceeds of approximately $31.6 million at an average selling price of $10.18 per share, resulting in net proceeds of approximately $31.0 million after deducting commissions and other transaction costs.

In March 2017, we completed an underwritten public offering of 5,128,206 shares of our common stock (plus a 30-day underwriter overallotment option to purchase up to an additional 769,230 shares of common stock, which was exercised) at a price of $9.75 per share. Net proceeds from this offering, including the overallotment option, were approximately $54 million, net of underwriting discounts and offering expenses of approximately $3.6 million.

In May 2017, we filed a shelf registration statement on Form S-3 (the "2017 S-3"), which was declared effective in June 2017, replacing the 2015 S-3. Under the 2017 S-3, the Company may sell up to a total of $300 million of its securities. In connection with the 2017 S-3, we entered into an At-the-Market Issuance Sales Agreement (the "2017 ATM") with Jefferies LLC, Cantor Fitzgerald & Co., FBR Capital Markets & Co., SunTrust Robinson Humphrey, Inc., Raymond James & Associates, Inc., Ladenburg Thalmann & Co. Inc. and H.C. Wainwright & Co., LLC (each a "2017 Agent" and collectively, the "2017 Agents"), relating to the sale of shares of our common stock. Under the 2017 ATM we pay the 2017 Agents a commission rate of up to 3.0% of the gross proceeds from the sale of any shares of common stock.

During the nine months ended September 30, 2017, we sold a total of 2,898,374 shares of common stock under the 2017 ATM for aggregate total gross proceeds of approximately $32.7 million at an average selling price of $11.30 per share, resulting in net proceeds of approximately $32.2 million after deducting commissions and other transactions costs.

The 2017 S-3 is currently our only active shelf registration statement. After deducting shares already sold there is approximately $267.3 million of common stock that remains available for sale under the 2017 S-3. We may offer the securities under the 2017 S-3 from time to time in response to market conditions or other circumstances if we believe such a plan of financing is in the best interests of our stockholders. We believe that the 2017 S-3 provides us with the flexibility to raise additional capital to finance our operations as needed.

Equity Incentive Plans

The TG Therapeutics, Inc. Amended and Restated 2012 Incentive Plan ("2012 Incentive Plan") was approved by stockholders in June 2015. As of September 30, 2017, no options were outstanding and up to an additional 1,201,258 shares may be issued under the 2012 Incentive Plan.

Effective as of January 1, 2017, we entered into an amendment (the "Amendment") to the employment agreement entered into as of December 15, 2011 (together with the Amendment, the "Employment Agreement") with Michael S. Weiss, our Executive Chairman and Chief Executive Officer and President. Under the Amendment, Mr. Weiss will remain as Chief Executive Officer and President, removing the interim status. Simultaneously, we entered into a Strategic Advisory Agreement (the "Advisory Agreement") with Caribe BioAdvisors, LLC (the "Advisor") owned by Mr. Weiss to provide the services of Mr. Weiss as Chairman of the Board and as Executive Chairman. As part of the Amendment, Mr. Weiss also agreed to forfeit 3,381,866 restricted shares previously granted under the Employment Agreement that were predominantly subject to time-based vesting over the next three years. Simultaneously, (i) Mr. Weiss was issued 418,371 restricted shares under the Employment Agreement that vest in 2018 and 2019 and (ii) the Advisor was issued 2,960,000 restricted shares under the Advisory Agreement that vested on market capitalization thresholds ranging from $375 million to $750 million. In accordance with GAAP, there was no incremental stock compensation expense recognition as a result of the modification.

Restricted Stock

Certain employees, directors and consultants have been awarded restricted stock. The restricted stock vesting consists of milestone and time-based vesting. The following table summarizes restricted share activity for the nine months ended September 30, 2017:

	Number of Shares	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2016	8,642,055	$ 7.20
Granted	1,112,131	6.10
Vested	(4,085,881)	5.23
Forfeited	(26,625)	6.72
Outstanding at September 30, 2017	5,641,680	$ 7.06

Total expense associated with restricted stock grants was approximately $4.9 million and $2.8 million during the three months ended September 30, 2017 and 2016, respectively, and $12.4 million, and $6.2 million during the nine months ended September 30, 2017 and 2016, respectively. As of September 30, 2017, there was approximately $14.9 million of total unrecognized compensation cost related to unvested time-based restricted stock, which is expected to be recognized over a weighted-average period of 0.9 years. The unrecognized compensation amount does not include, as of September 30, 2017, 180,000 shares of restricted stock outstanding which are milestone-based and vest upon certain corporate milestones; and 2,289,917 shares of restricted stock outstanding issued to non-employees, the expense for which is determined each reporting period at the measurement date. The expense for non-employee awards is recognized over the vesting period of the award. Until the measurement date is reached, the total amount of compensation expense remains uncertain. We record compensation expense based on the fair value of the award at the reporting date.

Warrants

The following table summarizes warrant activity for the nine months ended September 30, 2017:

	Warrants	Weighted-average exercise price	Aggregate Intrinsic Value
Outstanding at December 31, 2016	913,381	$ 2.41	$ 1,961,403
Issued	--	--	
Exercised	(887,585)	2.41	
Expired	(25,796)	--	
Outstanding at September 30, 2017	--	$ --	$ --

Stock-Based Compensation

We did not grant any stock options during the nine months ended September 30, 2017 and 2016.

The following table summarizes stock-based compensation expense information about restricted stock for the three and nine months ended September 30, 2017 and 2016:

	Three months ended September 30,		Nine months ended September 30,	
	2017	2016	2017	2016
Stock-based compensation expense associated with restricted stock	$ 4,890,123	$ 2,834,038	$ 12,375,306	$ 6,181,400
Total	$ 4,890,123	$ 2,834,038	$ 12,375,306	$ 6,181,400

NOTE 6 – NOTES PAYABLE

The following is a summary of notes payable:

	September 30, 2017			December 31, 2016		
	Current portion, net	Non-current portion, net	Total	Current portion, net	Non-current portion, net	Total
Convertible 5% Notes Payable	$ 182,156	$ -	$ 182,156	$ 68,875	$ -	$ 68,875
Total	$ 182,156	$ -	$ 182,156	$ 68,875	$ -	$ 68,875

Convertible 5% Notes Payable

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. We have no obligation under the 5% Notes aside from (a) 50% of the net product cash flows from Ariston's product candidates, if any, payable to noteholders; and (b) the conversion feature, discussed above. Interest accrues monthly, is added to principal on an annual basis, every March 8, and is payable at maturity, which was March 8, 2015 (see Note 4 for further details).

The cumulative liability including accrued and unpaid interest of these notes was approximately $17.3 million at September 30, 2017 and $16.7 million at December 31, 2016. No payments have been made on the 5% Notes as of September 30, 2017.

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

NOTE 7 – LICENSE AGREEMENTS

BET

In May 2016, as part of a broader agreement with Jubilant Biosys ("Jubilant"), an India-based biotechnology company, we entered into a sub-license agreement ("JBET Agreement") with Checkpoint Therapeutics, Inc. ("Checkpoint") (see Note 8) for the development and commercialization of Jubilant's novel BET inhibitor program in the field of hematological malignancies.

Under the terms of the JBET agreement, we paid Checkpoint an up-front licensing fee of $1.0 million and will make additional payments contingent on certain preclinical, clinical, and regulatory milestones, including commercial milestones totaling up to approximately $177 million and a single-digit royalty on net sales. TG will also provide funding to support certain targeted research efforts at Jubilant.

TG-1101

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

An upfront payment of $2.0 million, which was received in December 2012, net of $0.3 million of income tax withholdings, is being recognized as license revenue on a straight-line basis over the life of the agreement, which is through the expiration of the last licensed patent right or 15 years after the first commercial sale of a product in such country, unless the agreement is earlier terminated, and represents the estimated period over which we will have certain ongoing responsibilities under the sublicense agreement. We recorded license revenue of approximately $38,000 for each of the three months ended September 30, 2017 and 2016, and $114,000 for each of the nine months ended September 30, 2017 and 2016 and, at September 30, 2017 and December 31, 2016, have deferred revenue of approximately $1.3 million and $1.4 million, respectively, associated with this $2.0 million payment (approximately $0.2 million of which has been classified in current liabilities at September 30, 2017 and December 31, 2016).

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

NOTE 8 – RELATED PARTY TRANSACTIONS

LFB Biotechnologies

On January 30, 2012, we entered into an exclusive license agreement with LFB Biotechnologies, GTC Biotherapeutics and LFB/GTC LLC, all wholly-owned subsidiaries of LFB Group, relating to the development of ublituximab (the "LFB License Agreement"). In connection with the LFB License Agreement, we nominated Dr. Yann Echelard to our Board of Directors as LFB Group's nominee. LFB Group maintains the right to nominate a board member until such time as LFB Group owns less than 10% of the outstanding common stock.

Under the terms of the LFB License Agreement, we utilize LFB Group for certain development and manufacturing services. We incurred expenses of $1.8 million and $1.9 million during the three months ended September 30, 2017 and 2016, respectively, and $2.3 million and $4.3 million during the nine months ended September 30, 2017 and 2016, respectively, which have been included in other research and development expenses in the accompanying condensed consolidated statements of operations. As of September 30, 2017 and December 31, 2016, we had approximately $0 and $0.4 million, respectively, recorded in accounts payable related to the LFB License Agreement. In conjunction with the development and manufacturing services discussed above, certain agreements between us and LFB Group require payments in advance of services performed or goods delivered. Accordingly, as of September 30, 2017 and December 31, 2016, we recorded approximately $0 and $1.3 million, respectively, in prepaid research and development for such advance payments.

Other Parties

In March 2014, we entered into a shared services agreement (the "Opus Shared Services Agreement") with Opus Point Partners Management, LLC ("Opus") in which the parties agreed to share the costs of a rented facility and certain other services. Our Executive Chairman and Chief Executive Officer is a Managing Member of Opus. During the three and nine months ended September 30, 2017, we incurred no expenses related to this agreement, as compared to expenses incurred of approximately $0.02 million and $0.1 million during the three and nine months ended September 30, 2016, respectively. The Opus Shared Services Agreement is no longer in effect as we began occupying new office space in April 2016.

In October 2014, we entered into an agreement (the "Office Agreement") with Fortress Biotech, Inc. ("Fortress"), to occupy approximately 45% of the 24,000 square feet of New York City office space leased by Fortress, which is now our corporate headquarters. The Office Agreement requires us to pay our respective share of the average annual rent and other costs of the 15-year lease. We approximate an average annual rental obligation of $1.1 million under the Office Agreement. We began to occupy this new space in April 2016, with rental payments beginning in the third quarter of 2016. During the nine months ended September 30, 2017, we recorded rent expense of approximately $0.9 million and at September 30, 2017, have deferred rent of approximately $1.3 million. Mr. Weiss is also Executive Vice Chairman of Fortress.

Under the Office Agreement, we agreed to pay Fortress our portion of the build out costs, which have been allocated to us at the 45% rate mentioned above. The allocated build-out costs have been recorded in Leasehold Interest and will be amortized over the 15-year term of the Office Agreement. After an initial commitment of the 45% rate for a period of three (3) years, we and Fortress will determine actual office space utilization annually and if our utilization differs from the amount we have been billed, we will either receive credits or be assessed incremental utilization charges. As of September 30, 2017, we had approximately $131,000 recorded in accounts payable related to Fortress of which approximately $30,000 related to rent and build-out costs.

In July 2015, we entered into a Shared Services Agreement (the "Shared Services Agreement") with Fortress to share the cost of certain services such as facilities use, personnel costs and other overhead and administrative costs. This Shared Services Agreement requires us to pay our respective share of services utilized. In connection with the Shared Services Agreement, we incurred expenses of approximately $1.0 million and $0.5 million in shared services for the nine months ended September 30, 2017 and 2016, respectively, and expenses of approximately $0.3 million for each of the three months ended September 30, 2017 and 2016, primarily related to shared personnel.

In May 2016, as part of a broader agreement with Jubilant, an India-based biotechnology company, we entered into the JBET Agreement with Checkpoint, a subsidiary of Fortress, for the development and commercialization of Jubilant's novel BET inhibitor program in the field of hematological malignancies. We paid Checkpoint an up-front licensing fee of $1.0 million in July 2016 and incurred expenses of $0.2 million in March 2017 for the first milestone achievement as part of the JBET Agreement recorded in other research and development. As of September 30, 2017 and December 31, 2016, we had approximately $0.2 million and $0.8 million, respectively, recorded in accounts payable, related mostly to the JBET Agreement. Mr. Weiss is also the Executive Chairman of Checkpoint.

NOTE 9 – LITIGATION

On January 6, 2017, a purported securities class action complaint was filed in New York federal court against the Company and certain of its directors, officers or consultants on behalf of all shareholders who purchased or otherwise acquired TG Therapeutics common stock between September 15, 2014 and October 12, 2016 (the "Class Period"). The case was captioned *John Lyon v. TG Therapeutics, Michael S. Weiss, Sean A. Power and Robert Niecestro*, Case No. 1:17-cv-00112-VM (S.D.N.Y.). The complaint alleged that, throughout the Class Period various statements made by the Company regarding its GENUINE Phase 3 trial were materially false or misleading when made in violation of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder. On January 24, 2017, a second purported class action complaint was filed in New York federal court against the Company and certain of its directors, officers or consultants on behalf of all shareholders who purchased or otherwise acquired TG Therapeutics common stock between September 15, 2014 and October 12, 2016. The case was captioned *Kenneth C. Wyzgoski v. TG Therapeutics, Michael S. Weiss, Sean A. Power and Robert Niecestro*, Case No. 1:17-cv-00508-VM (S.D.N.Y.). The claims and allegations in the Wyzgoski complaint were substantially identical to those in the Lyon case. By order dated March 23, 2017, the court consolidated the Lyon and Wyzgoski cases into one action, captioned *In re TG Therapeutics Securities Litigation*, Case No. 1:17-cv-00112-VM (S.D.N.Y.), appointed lead plaintiffs in the case, and approved lead plaintiffs' selection of lead counsel. On April 5, 2017 the Court so ordered a stipulation pursuant to which lead plaintiffs voluntarily dismissed the consolidated action in its entirety without prejudice. The Company denies the allegations and claims made in the above-referenced actions and no consideration was given by the Company in connection with lead plaintiffs' voluntary dismissal of the consolidated action.

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

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

You should read the following discussion and analysis in conjunction with the unaudited condensed consolidated financial statements, and the related footnotes thereto, appearing elsewhere in this report, and in conjunction with management's discussion and analysis and the audited consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2016.

OVERVIEW

We are a biopharmaceutical company focused on the acquisition, development and commercialization of novel treatments for B-cell malignancies and autoimmune diseases. Currently, we are developing two therapies targeting hematologic malignancies. TG-1101 (ublituximab) is a novel, glycoengineered monoclonal antibody that targets a specific and unique epitope on the CD20 antigen found on mature B-lymphocytes. We are also developing TGR-1202 (umbralisib), an orally available PI3K delta inhibitor. The delta isoform of PI3K is strongly expressed in cells of hematopoietic origin and is believed to be important in the proliferation and survival of B-lymphocytes. Both TG-1101 and TGR-1202, or the combination of which is referred to as "U2," are in Phase 3 clinical development for patients with hematologic malignancies, with TG-1101 also in Phase 3 clinical development for Multiple Sclerosis. Additionally, the Company has recently brought its anti-PD-L1 monoclonal antibody into Phase 1 development and aims to bring additional pipeline assets into the clinic in the future.

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

TG-1101 (ublituximab)

Overview

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

Generally, anti-CD20 antibodies are believed to exert their B-cell depleting effects through three primary mechanisms: antibody dependent cell-mediated cytotoxicity ("ADCC"), complement dependent cytotoxicity ("CDC"), and direct or programmed cell death ("DCD" or "PCD"). TG-1101 has been specifically glycoengineered to enhance ADCC activity, which should enhance its ability to deplete B-cells and may improve its anti-cancer effects when compared to Rituxan®, the leading anti-CD20 monoclonal antibody, which had worldwide sales in 2016 of more than $7 billion.

Clinical Trials Overview and Recent Developments

Two single-agent, dose-escalation, Phase I studies were undertaken with TG-1101 to establish an optimal dose in patients with Non-Hodgkin's Lymphoma ("NHL") and Chronic Lymphocytic Leukemia ("CLL"). A two part first-in-human Phase I clinical trial was first completed in France in which TG-1101 was evaluated in relapsed or refractory CLL. Subsequently, a single-agent Phase I study was undertaken in the US enrolling patients with both NHL and CLL. In both studies, single agent therapy with TG-1101 was deemed well tolerated by treating investigators and displayed promising clinical activity in relapsed and refractory patients.

In oncology settings, anti-CD20 therapy is generally used in combination with other anti-cancer agents where it demonstrates maximum activity as opposed to single agent usage. As a result, subsequent clinical development for TG-1101 has focused on combination therapy. Currently, our priority combination trials for TG-1101 are:

- The GENUINE Trial – a randomized controlled Phase 3 trial evaluating TG-1101 in combination with ibrutinib, for previously treated CLL patients with high risk cytogenetics;

- The UNITY-CLL Trial – a randomized controlled Phase 3 trial evaluating TG-1101 in combination with TGR-1202, the Company's development stage PI3K delta inhibitor, for patients with front line and previously treated CLL;

- The UNITY-NHL Trial – registration-directed UNITY-NHL Phase 2b clinical study evaluating TG-1101, in combination with TGR-1202 with or without Bendamustine, as well as TGR-1202 alone, in patients with previously treated Non-Hodgkin's Lymphoma (NHL); and

- TG-1101 + TGR-1202 + Pembrolizumab for patients with CLL.

In non-oncology settings, anti-CD20 therapy has generally been used as monotherapy. In addition to the above oncology studies, TG-1101 is being evaluated in a Phase 2 study for the treatment of Multiple Sclerosis (MS) and in an investigator initiated Phase 1 study for the treatment of acute neuromyelitis optica (NMO) relapses, with additional autoimmune related indications planned to be studied. On August 1, 2017, we announced we had reached an agreement with the U.S. Food and Drug Administration (FDA) regarding a Special Protocol Assessment (SPA) on the design of two global Phase 3 clinical trials for TG-1101, referred to as the ULTIMATE I and ULTIMATE II Phase 3 clinical trials.

Manufacturing of TG-1101 is performed by both our partner, LFB Biotechnologies, and a contract manufacturer based in the US.

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

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

The GENUINE trial is a randomized controlled clinical trial in patients with previously treated CLL with specific high-risk cytogenetic abnormalities, with patients randomized to receive either TG-1101 plus ibrutinib or ibrutinib alone. In October 2016, we announced revisions to the design of the GENUINE study to accelerate its completion. Initially the study was being conducted pursuant to a Special Protocol Assessment (SPA) with the U.S. Food and Drug Administration (FDA), and was designed to enroll approximately 330 patients, with a two-part analysis of both overall response rate (ORR) and progression-free survival (PFS). The trial was amended in October 2016 to enroll approximately 120 patients, with the PFS analysis component removed. Following the revisions, the sole primary endpoint of the study is ORR, and the SPA is no longer in effect.

In June 2017, the positive results from our Phase 3 GENUINE trial were presented by Dr. Jeff Sharman, Medical Director, Hematology Research, US Oncology in an oral session during the 53rd American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, IL.

This presentation included data from the GENUINE Phase 3 trial, a multicenter, randomized trial, which assessed the efficacy and safety of TG-1101 plus ibrutinib versus ibrutinib alone in patients with high risk CLL. For the trial, high-risk was defined as having any one or more of the following centrally confirmed features: 17p deletion, 11q deletion or p53 mutation. The GENUINE study was designed to demonstrate the value of adding TG-1101 to ibrutinib monotherapy in high-risk CLL, and was powered to show a statistically significant improvement in ORR of 30%, with a minimal absolute detectable difference between the two arms of approximately 20%.

The trial met its primary endpoint, demonstrating a statistically significant improvement in Overall Response Rate (ORR), as assessed by blinded independent central radiology and hematology review by iwCLL (Hallek 2008) criteria, compared to ibrutinib alone in both the Intent to Treat (ITT) population ($p=0.001$) and Treated population ($p < 0.001$). Per iwCLL guidelines, all responders required confirmation of response for a minimum duration of 2 months. The ITT population included all 126 randomized patients (64 in the TG-1101 plus ibrutinib arm and 62 in the ibrutinib alone arm) while the Treated population includes all ITT patients that received at least one dose of either study drug (59 in the TG-1101 plus ibrutinib arm and 58 in the ibrutinib alone arm).

One hundred and seventeen (117) patients were evaluable for safety (59 patients in the TG-1101 plus ibrutinib arm, and 58 patients in the ibrutinib alone arm). The combination was well tolerated and, apart from infusion related reactions, the addition of TG-1101 did not appear to alter the safety profile of ibrutinib monotherapy. Neutropenia, occurring in 9% of patients, was the most commonly reported Grade 3/4 Adverse Event (AE) in the combination arm, followed by infusion related reactions and anemia, each reported in 5% of patients. Notably, the majority of infusion related reactions (IRR) were Grade 1 or 2 in severity, with only 5% Grade 3/4 IRR observed. Median follow-up for this study was approximately 11.4 months.

Response Rates

	TG-1101 plus Ibrutinib	Ibrutinib	P-value
Treated Population (n)	n=59	n=58	
Overall Response Rate (ORR)	78%	45%	P<0.001
Complete Response (CR)	7%	0%	NS
MRD-Negative	19% *(n=53) **	2% *(n=53) **	P<0.01

**Patients evaluable for MRD included those enrolled >4 months prior to data cutoff date of February 15, 2017. MRD analyzed by central lab, 7-color flow cytometry*

In October 2017, we announced the outcome of a meeting with the FDA regarding the use of the results from the GENUINE Phase 3 trial to support a Biologics License Application (BLA) filing for approval of TG-1101 in combination with ibrutinib. During the meeting, the FDA confirmed that accelerated approval based on ORR would be a review issue. As part of the discussion, the FDA encouraged us to consider future available therapy in its risk/benefit analysis as part of any potential future BLA filing that may impact accelerated approval.

The potential use of Progression Free Survival (PFS) results from the GENUINE trial to support the full approval of TG-1101 was also discussed. We plan to have a follow-up meeting with the FDA to discuss the use of the PFS endpoint in more detail before the end of the year and also plan to monitor the regulatory landscape for new approvals of agents for previously treated high-risk CLL while continuing to make preparations for a BLA filing as early as 2Q18.

TG-1101 in Combination with TGR-1202 Phase 3 Study Program – The UNITY-CLL Trial

In September 2015, we reached an agreement with the FDA regarding a SPA on the design, endpoints and statistical analysis approach of a Phase 3 clinical trial for the proprietary combination of TG-1101 plus TGR-1202, for the treatment of CLL. The SPA provides agreement that the Phase 3 trial design adequately addresses objectives that, if met, would support the regulatory submission for drug approval of both TG-1101 and TGR-1202 in combination.

The Phase 3 trial, called the UNITY-CLL trial, is a randomized controlled clinical trial that includes two key objectives: first, to demonstrate contribution of each agent in the TG-1101 + TGR-1202 regimen (the combination sometimes referred to as "1303"), and second, to demonstrate superiority in Progression Free Survival (PFS) over the standard of care to support the submission for full approval of the combination. The study will randomize patients into four treatment arms: TG-1101 + TGR-1202, TG-1101 alone, TGR-1202 alone, and an active control arm of obinutuzumab (GAZYVA®) + chlorambucil. An early interim analysis will assess contribution of each single agent in the TG-1101 + TGR-1202 combination regimen, which, if successful, will allow early termination of both single agent arms. A second interim analysis will be conducted following full enrollment into the study, which, if positive, we plan to utilize for accelerated approval. Assuming early termination of the TG-1101 and TGR-1202 single agent arms, the study will enroll approximately 450 patients to be utilized for the interim analysis and primary analysis data sets, not accounting for over enrollment anticipated in the single agent arms while the interim analysis data set is obtained.

In May 2017, we announced that the independent Data Safety Monitoring Board (DSMB) of the UNITY-CLL Phase 3 trial had successfully completed a pre-specified interim analysis to assess the contribution of TG-1101 and TGR-1202 in the combination regimen of TG-1101 plus TGR-1202. In conducting the analysis, the DSMB reviewed efficacy data from approximately 50 patients per arm in the UNITY-CLL study who were eligible for at least one response evaluation. Based on the overall response rate data available, and in accordance with the statistical analysis plan in the study's SPA, the DSMB determined that contribution has been established and recommended we cease enrollment into the single agent arms. Accordingly, in May the study began enrolling in a 1:1 ratio to only the two combination arms: the investigational arm of TG-1101 plus TGR-1202 and the control arm of obinutuzumab plus chlorambucil. Additionally, the DSMB reviewed safety data from all patients on study (n > 270) as of the data cut-off date, including patients with both treatment naive and relapsed/refractory Chronic Lymphocytic Leukemia (CLL), and again identified no safety concerns in any treatment group (treatment naive or previously treated) and recommended the continuation of the study without modification.

In September 2017, we announced that target enrollment in the UNITY-CLL trial was met and that we were extending enrollment until October 12, 2017 for any additional identified study patients to be allowed in the trial.

TG-1101 in Combination with TGR-1202 with or without bendamustine Phase 2b Registration-Directed Program – The UNITY-NHL Trial

In June 2016, we commenced a registration-directed UNITY-DLBCL Phase 2b clinical study evaluating TG-1101 in combination with TGR-1202, as well as TGR-1202 alone, in patients with previously treated DLBCL. In mid-2017, this study was expanded to allow enrollment of patients with follicular lymphoma (FL), small lymphocytic lymphoma (SLL), and marginal zone lymphoma (MZL), as well as to add a cohort evaluating the triplet regimen of TG-1101 + TGR-1202 + bendamustine which has previously been explored in Phase 1. The cohorts of DLBCL, FL/SLL, and MZL are each being enrolled to and evaluated independently.

The updated study is entitled "A Phase 2b Randomized Study to Assess the Efficacy and Safety of the Combination of Ublituximab + TGR-1202 with or without Bendamustine and TGR-1202 alone in Patients with Previously Treated Non-Hodgkin's Lymphoma." The DLBCL component is being led by Owen A. O'Connor, MD, PhD, Professor of Medicine and Experimental Therapeutics, and Director of the Center for Lymphoid Malignancies at Columbia University Medical Center, while the indolent NHL component of the study is being led by Nathan H. Fowler, MD, Associate Professor, Department of Lymphoma/Myeloma, The University of Texas MD Anderson Cancer Center. The primary objective of the study is to assess the efficacy of TGR-1202 alone, in combination with TG-1101, or in combination with TG-1101 and bendamustine in patients with previously treated NHL as measured by Overall Response Rate (ORR). The study will also provide important information as to the contribution of each agent, TGR-1202 and TG-1101, to the combination regimen of both agents, as well as the contribution of bendamustine to the combination regimen of both agents.

In August 2017, we announced that the study's Data Safety Monitoring Board (DSMB) had met and based on pre-set hurdles designed to evaluate ORR, the DSMB recommended continued enrollment in the TGR-1202 + TG-1101 ("U2") arm and no further enrollment into the single agent TGR-1202 arm for the DLBCL cohort. As set forth in the protocol, the single agent TGR-1202 arm was replaced with the triple combination of TG-1101 + TGR-1202 + bendamustine.

Single Agent TG-1101 in Relapsing Forms of Multiple Sclerosis

In May 2016, we commenced our first study of TG-1101 in patients with relapsing remitting multiple sclerosis (RRMS), a chronic demyelinating disease of the central nervous system (CNS).

The study, entitled "A Placebo-Controlled Multi-Center Phase 2 Dose Finding Study of Ublituximab, a Third-Generation Anti-CD20 Monoclonal Antibody, in Patients with Relapsing Forms of Multiple Sclerosis," is being led by Edward Fox, MD, PhD, Director of the Multiple Sclerosis Clinic of Central Texas and Clinical Assistant Professor at the University of Texas Medical Branch in Round Rock, TX. The primary objective of the study is to determine the optimal dosing regimen for TG-1101 with a focus on accelerating infusion times. In addition to monitoring for safety and tolerability at each dosing cohort, B-cell depletion and established MS efficacy endpoints will also be evaluated.

Updated data from this study was most recently presented at the 7th Joint ECTRIMS - ACTRIMS meeting in Paris, France, with additional data presentations expected at upcoming medical conferences.

TG-1101 in relapsing forms of Multiple Sclerosis Phase 3 Study Program – The ULITIMATE I and ULTIMATE II Trial

In August 2017, we reached an agreement with the FDA regarding an SPA on the design of two Phase 3 clinical trials for TG-1101, for the treatment of relapsing forms of Multiple Sclerosis (RMS). The SPA provides agreement that the two Phase 3 trial designs adequately address objectives that, if met, would support the regulatory submission for approval of TG-1101.

The RMS Phase 3 program consists of two trials, called the ULTIMATE I and ULTIMATE II trials. Each trial is a global, randomized, multi-center, double-blinded, double-dummy, active-controlled study comparing TG-1101 (ublituximab) to teriflunomide in subjects with RMS. The primary endpoint for each study is Annualized Relapse Rate (ARR) following 96 weeks of treatment. Each trial will enroll approximately 440 subjects, randomized in a 1:1 ratio, with approximately 880 patients to be enrolled across both trials.

Updates for the combination of TG-1101 and TGR-1202

In January 2017, we announced that the FDA has granted orphan drug designation covering the combination of TG-1101 and TGR-1202 for the treatment of patients with CLL and DLBCL.

TGR-1202

Overview

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

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

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

Clinical Trials Overview and Recent Developments

Initial clinical development of TGR-1202 was focused on establishing preliminary safety and efficacy in a wide variety of hematologic malignancies. Upon identification of safe and active doses of TGR-1202, a combination clinical trial program was opened, exploring TGR-1202 in combination with a variety of agents. In addition to the previously described study in combination with TG-1101 with or without the BTK inhibitor, ibrutinib, our current combination clinical trials for TGR-1202 include:

- TGR-1202 in combination with the BTK inhibitor, ibrutinib, in patients with previously treated CLL and MCL, as well as in patients with DLBCL;
- TGR-1202 in combination with the JAK inhibitor, ruxolitinib (JAKAFI®), in patients with previously treated Myelofibrosis or Polycythemia Vera; and
- TGR-1202 monotherapy in patients with CLL who were previously intolerant to prior BTK or PI3K inhibitor therapy.

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

In January 2013, the Company initiated a Phase I, open label, multi-center, first-in-human clinical trial of TGR-1202 in patients with hematologic malignancies. The study entitled TGR-1202-101, "A Phase I Dose Escalation Study Evaluating the Safety and Efficacy of TGR-1202 in Patients with Relapsed or Refractory Hematologic Malignancies," is being run in collaboration with the Sarah Cannon Research Institute in Nashville, TN with Howard "Skip" Burris, MD, Executive Director, Drug Development as the acting Study Chair. Enrollment is open to patients with relapsed or refractory NHL, CLL, and other select hematologic malignancies. As of February 2016, this study has closed to enrollment.

Data from this ongoing Phase I study was presented at the 57th Annual American Society of Hematology (ASH) meeting held in December 2015, with updated data presented as part of an integrated analysis as described below.

TGR-1202 Long-term Follow-up Integrated Analysis in Patients with Relapsed/Refractory Hematologic Malignancies

In June 2016, at the 52nd Annual Meeting of the American Society of Clinical Oncology (ASCO) and at the 21st Congress of the European Hematology Association (EHA), the Company presented integrated data with long term follow-up from 165 patients exposed to TGR-1202 monotherapy or the combination of TGR-1202 plus TG-1101, which continued to demonstrate high response rates in CLL, NHL, and DLBCL coupled with a favorable safety profile.

TGR-1202 Combination Trials

TGR-1202 has been evaluated in combination with the anti-CD30 antibody drug conjugate, brentuximab vedotin, in patients with relapsed or refractory Hodgkin's lymphoma; in combination with the anti-CD20 antibody obinutuzumab with chlorambucil in patients with CLL; in combination with the BTK inhibitor, ibrutinib, in patients with CLL and MCL; and in combination with the JAK inhibitor, ruxolitinib, in patients with Myelofibrosis or Polycythemia Vera. Additional investigator sponsored trials are also underway which are combining TGR-1202 with other approved agents for the treatment of B-cell malignancies.

Preliminary data from studies evaluating TGR-1202 + brentuximab vedotin and TGR-1202 + ibrutinib were presented at the 58th Annual American Society of Hematology (ASH) meeting held in December 2016. Both combinations appeared well tolerated. In particular, the combination of TGR-1202 + ibrutinib resulted in an 88% (15 of 17) Overall Response Rate (ORR) (including Complete Response (CR), Partial Response (PR), and Partial Response with lymphocytosis (PR-L)) in patients with CLL, with 1 patient achieving a bone marrow confirmed CR and 5 patients with a > 80% nodal reduction, nearing radiographic CR.

In November 2017, we announced that 6 abstracts for TGR-1202 (3 clinical and 3 pre-clinical) were accepted for poster presentation at the upcoming 59th American Society of Hematology Annual Meeting, being held in Atlanta, GA from December 9 – 12, 2017.

It is anticipated that results from these and additional combination studies will be presented or updated at future medical conferences.

IRAK4

We hold global rights to develop and commercialize the IRAK4 program, which was licensed from Ligand Pharmaceuticals. Our IRAK4 program is currently in pre-clinical development.

PD-L1 and GITR

In March 2015, we entered into a global collaboration agreement for the development and commercialization of anti-PD-L1 and anti-GITR antibody research programs in the field of hematological malignancies. Our anti-PD-L1 recently entered the clinic and our anti-GITR program is currently in pre-clinical development, with pre-clinical data most recently presented at the American Association for Cancer Research Annual Meeting in March 2017.

In October 2017, we announced that the first patient has been dosed in a Phase 1 clinical trial evaluating the safety and tolerability of our anti-PD-L1 monoclonal antibody, enrolling patients across sites in Australia and New Zealand.

BET

In May 2016, as part of a broader agreement with Jubilant Biosys ("Jubilant"), an India-based biotechnology company, we entered into a sub-license agreement ("JBET Agreement") with Checkpoint Therapeutics, Inc. ("Checkpoint"), a subsidiary of Fortress, for the development and commercialization of Jubilant's novel BET inhibitor program in the field of hematological malignancies. The BET inhibitor program is the subject of a family of patents covering compounds that inhibit BRD4, a member of the BET (Bromodomain and Extra Terminal) domain for cancer treatment. Our BET inhibitor program is currently in pre-clinical development.

GENERAL CORPORATE

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

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

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

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

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

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

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

Our clinical trials will be lengthy and expensive. Even if these trials show that our drug candidates are effective in treating certain indications, there is no guarantee that we will be able to record commercial sales of any of our drug candidates in the near future. In addition, we expect losses to continue as we fund in-licensing and development of new drug candidates. As we further our development efforts, we may enter into additional third-party collaborative agreements and incur additional expenses, such as licensing fees and milestone payments. In addition, we may need to establish a commercial infrastructure required to manufacture, market and sell our drug candidates following approval, if any, by the FDA or a foreign health authority, which would result in 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, 2017 and 2016

License Revenue. License revenue was approximately $38,000 for each of the three months ended September 30, 2017 and 2016. License revenue is related to the amortization of an upfront payment of $2.0 million received in 2012 associated with our license agreement with Ildong. The upfront payment from Ildong will be recognized as license revenue on a straight-line basis through December 2025, which represents the estimated period over which the Company will have certain ongoing responsibilities under the sublicense agreement.

Noncash Compensation Expense (Research and Development). Noncash compensation expense (research and development) related to equity incentive grants totaled $1.8 million for the three months ended September 30, 2017, as compared to $0.9 million during the comparable period in 2016. The increase in noncash compensation expense was primarily related to milestone-based vesting of restricted stock grants to personnel and an increase in the measurement date fair value of certain consultant restricted stock during the current 2017 period.

Other Research and Development Expenses. Other research and development expenses increased by $4.4 million to $25.3 million for the three months ended September 30, 2017, as compared to $20.9 million for the three months ended September 30, 2016. The increase was mainly due to new and ongoing clinical development programs and related manufacturing costs for TG-1101 and TGR-1202 during the three months ended September 30, 2017. We expect our other research and development costs to remain relatively consistent for the remainder of 2017.

Noncash Compensation Expense (General and Administrative). Noncash compensation expense (general and administrative) related to equity incentive grants increased by $1.2 million to $3.1 million for the three months ended September 30, 2017, as compared to $1.9 million for the three months ended September 30, 2016. The increase in noncash compensation expense was primarily due to greater compensation expense during the three months ended September 30, 2017 related to restricted stock granted to executive personnel.

Other General and Administrative Expenses. Other general and administrative expenses increased by $0.1 million to $1.4 million for the three months ended September 30, 2017, as compared to $1.3 million for the three months ended September 30, 2016. We expect our other general and administrative expenses to remain at a comparable level for the remainder of 2017.

Other (Income) Expense. Other income decreased by approximately $45,000 to approximately $50,000 for the three months ended September 30, 2017, as compared to $0.1 million for the three months ended September 30, 2016. The decrease is mainly due to a decrease in interest income for the three months ended September 30, 2017.

Nine months ended September 30, 2017 and 2016

License Revenue. License revenue was approximately $114,000 for each of the nine months ended September 30, 2017 and 2016. License revenue for the nine months ended September 30, 2017 and 2016 was related to the amortization of an upfront payment of $2.0 million received in 2012 associated with our license agreement with Ildong.

Noncash Compensation Expense (Research and Development). Noncash compensation expense (research and development) related to equity incentive grants totaled $5.4 million for the nine months ended September 30, 2017, as compared to $1.9 million during the comparable period in 2016. The increase in noncash compensation expense was primarily related to milestone-based vesting of restricted stock grants to personnel and an increase in the measurement date fair value of certain consultant restricted stock during the period ended September 30, 2017.

Other Research and Development Expenses. Other research and development expenses increased by $26.1 million to $71.2 million for the nine months ended September 30, 2017, as compared to $45.1 million for the nine months ended September 30, 2016. The increase in other research and development expenses was due primarily to new and ongoing clinical development programs and related manufacturing costs for TG-1101 and TGR-1202 during the nine months ended September 30, 2017. We expect our other research and development costs to increase modestly for the remainder of 2017 as the enrollment of additional patients in our Phase 3 clinical trials increases and we prepare for potential commercialization.

Noncash Compensation Expense (General and Administrative). Noncash compensation expense (general and administrative) related to equity incentive grants increased by $2.7 million to $7.0 million for the nine months ended September 30, 2017, as compared to $4.3 million for the nine months ended September 30, 2016. The increase in noncash compensation expense was primarily related to greater compensation expense during the nine months ended September 30, 2017 related to restricted stock granted to executive personnel.

Other General and Administrative Expenses. Other general and administrative expenses increased by $0.5 million to $4.3 million for the nine months ended September 30, 2017, as compared to $3.8 million for the nine months ended September 30, 2016. The increase was due primarily to rent related expenses of our new office space. We expect our other general and administrative expenses to remain at a comparable level for the remainder of 2017.

Other (Income) Expense. Other income decreased by $0.3 million to approximately $61,000 for the nine months ended September 30, 2017, as compared to $0.4 million for the nine months ended September 30, 2016. The decrease is mainly due to a decrease in interest income and a decrease in the change in fair value of notes payable for the nine months ended September 30, 2017.

LIQUIDITY AND CAPITAL RESOURCES

Our primary sources of cash have been from the sale of equity securities, warrant and option exercises, and the upfront payment from our Sublicense Agreement with Ildong. We have not 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, 2017, we had approximately $91.8 million in cash and cash equivalents. The Company believes its cash and cash equivalents on hand as of September 30, 2017 will be sufficient to fund the Company's planned operations through 2018. 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, 2017 was $71.9 million as compared to $44.6 million for the nine months ended September 30, 2016. The increase in cash used in operating activities was due primarily to increased expenditures associated with our clinical development programs for TG-1101 and TGR-1202.

For the nine months ended September 30, 2017, net cash provided by investing activities was $19.8 million as compared to $15.1 million for the nine months ended September 30, 2016. The increase in net cash provided by investing activities was primarily due to greater proceeds from maturity of investments during the nine months ended September 30, 2017.

For the nine months ended September 30, 2017, net cash provided by financing activities of $118.9 million related to proceeds from the issuance of common stock as part of our underwritten public offering in March 2017 and our ATM program, as well as proceeds from the exercise of warrants.

OFF-BALANCE SHEET ARRANGEMENTS

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

CRITICAL ACCOUNTING POLICIES

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

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

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

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

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

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

Accounting For Income Taxes. In preparing our condensed 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 statements of operations. Significant management judgment is required in determining our provision for income taxes, our deferred tax assets and liabilities and any valuation allowance recorded against our net deferred tax assets. We have fully offset our deferred tax assets with a valuation allowance. Our lack of earnings history and the uncertainty surrounding our ability to generate taxable income prior to the reversal or expiration of such deferred tax assets were the primary factors considered by management in maintaining the valuation allowance.

RECENTLY ISSUED ACCOUNTING STANDARDS

In May 2017, the FASB issued ASU No. 2017-09, "Scope of Modification Accounting" ("ASU 2017-09"). ASU 2017-09 provides guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting. An entity should account for the effects of a modification unless all the following are met:

- The fair value (or calculated value or intrinsic value, if such an alternative measurement method is used) of the modified award is the same as the fair value (or calculated value or intrinsic value, if such an alternative measurement method is used) of the original award immediately before the original award is modified. If the modification does not affect any of the inputs to the valuation technique that the entity uses to value the award, the entity is not required to estimate the value immediately before and after the modification.
- The vesting conditions of the modified award are the same as the vesting conditions of the original award immediately before the original award is modified.
- The classification of the modified award as an equity instrument or a liability instrument is the same as the classification of the original award immediately before the original award is modified.

ASU 2017-09 is effective for annual and interim periods beginning on or after December 15, 2017. Early adoption is permitted for public business entities for reporting periods for which financial statements have not yet been issued, and all other entities for reporting periods for which financial statements have not yet been made available for issuance. The amendments should be applied prospectively to an award modified on or after the adoption date. The Company does not expect the adoption of ASU 2017-09 to have a material impact on the Company's condensed consolidated financial statements.

In January 2017, the FASB issued ASU No. 2017-04, "Simplifying the Test for Goodwill Impairment" ("ASU 2017-04"). ASU 2017-04 removes the requirement to compare the implied fair value of goodwill with its carrying amount as part of step 2 of the goodwill impairment test. As a result, under ASU 2017-04, an entity should perform its annual, or interim, goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount and should recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit's fair value; however, the loss recognized should not exceed the total amount of goodwill allocated to that reporting unit. In addition, ASU 2017-04:

- Clarifies the requirements for excluding and allocating foreign currency translation adjustments to reporting units in connection with an entity's testing of reporting units for goodwill impairment.
- Clarifies that an entity should consider income tax effects from any tax deductible goodwill on the carrying amount of the reporting unit when measuring the goodwill impairment loss, if applicable.
- Makes minor changes to the overview and background sections of certain Accounting Standards Codification ("ASC" or "Codification") subtopics and topics as part of the Board's initiative to unify and improve those sections throughout the Codification.

ASU 2017-04 is effective prospectively for annual and interim periods beginning on or after December 15, 2019, and early adoption is permitted on testing dates after January 1, 2017. The Company does not expect the adoption of ASU 2017-04 to have a material impact on the Company's condensed consolidated financial statements.

In January 2017, the FASB issued ASU No. 2017-01, "FASB Clarifies the Definition of a Business" ("ASU 2017-01"). ASU 2017-01 clarifies the definition of a business in ASC 805. The amendments in ASU 2017-01 are intended to make application of the guidance more consistent and cost-efficient. The amendments in ASU 2017-01:

- Provide a screen to determine when a set of assets and activities is not a business. The screen requires that when substantially all of the fair value of the gross assets acquired (or disposed of) is concentrated in a single identifiable asset or a group of similar identifiable assets, the set is not a business. This screen reduces the number of transactions that need to be further evaluated.
- Provide that if the screen is not met, (1) to be considered a business, a set must include, at a minimum, an input and a substantive process that together significantly contribute to the ability to create output and (2) remove the evaluation of whether a market participant could replace missing elements. The amendments provide a framework to assist entities in evaluating whether both an input and a substantive process are present. The framework includes two sets of criteria to consider that depend on whether a set has outputs. Although outputs are not required for a set to be a business, outputs generally are a key element of a business; therefore, the Board has developed more stringent criteria for sets without outputs.
- Narrow the definition of the term output so that the term is consistent with how outputs are described in Topic 606.

ASU 2017-01 is effective for annual and interim periods beginning after December 15, 2017, with early adoption permitted for transactions that occurred before the issuance date or effective date of the standard if the transactions were not reported in financial statements that have been issued or made available for issuance. The Company does not expect the adoption of ASU 2017-01 to have a material impact on the Company's condensed consolidated financial statements.

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606) ("ASU 2014-09"), which supersedes all existing revenue recognition requirements, including most industry-specific guidance. ASU 2014-09 provides a single set of criteria for revenue recognition among all industries. The new standard requires a company to recognize revenue when it transfers goods or services to customers in an amount that reflects the consideration that the Company expects to receive for those goods or services.

ASU 2014-09 includes guidance for determining whether a license transfers to a customer at a point in time or over time based on the nature of the entity's promise to the customer. To determine whether the entity's promise is to provide a right to access its intellectual property or a right to use its intellectual property, the entity should consider the nature of the intellectual property to which the customer will have rights.

ASU 2014-09 is effective for interim and annual periods beginning after December 15, 2017. The standard allows for two transition methods - full retrospective, in which the standard is applied to each prior reporting period presented, or modified retrospective, in which the cumulative effect of initially applying the standard is recognized at the date of initial adoption. The Company expects to elect the modified retrospective approach and is continuing to assess the impact of the new guidance on its accounting policies and procedures and is evaluating the new requirements. The Company does not expect the adoption of ASU 2014-09 to have a material impact on the Company's condensed consolidated financial statements.

Other pronouncements issued by the FASB or other authoritative accounting standards with future effective dates are either not applicable or not significant to our condensed 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, 2017, 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, 2017, 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, 2017, our disclosure controls and procedures were effective.

Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended September 30, 2017 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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

ITEM 1A. RISK FACTORS

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

Risks Related to Our Business and Industry

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

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

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

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

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

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

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

If we are unable to develop, or receive regulatory approval for or successfully commercialize any of our product candidates, we will not be able to generate product revenues. Even if we are able to develop or receive regulatory approval for or successfully commercialize any of our product candidates, we may not be able to gain market acceptance for our product candidates and future products and may never become profitable.

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

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

We plan on conducting additional Phase I, II and III clinical trials for TG-1101 and TGR-1202. Early clinical results seen with TG-1101 and TGR-1202 in a small number of patients may not be reproduced in expanded or larger clinical trials. Additionally, individually reported outcomes of patients treated in clinical trials may not be representative of the entire population of treated patients in such studies. Further, larger scale Phase III studies, which are often conducted internationally, are inherently subject to increased operational risks compared to earlier stage studies, including the risk that the results could vary on a region to region, or country to country basis which could materially adversely affect the study's outcome or the opinion of the validity of the study results by applicable regulatory agencies. Early clinical trial results from interim analysis or from the review of a Data Safety Monitoring Board (DSMB) or similar safety committee may not be reflective of the results of the entire study, when completed. Additionally, many of the results reported in our early clinical trials rely on local investigator assessed safety and efficacy outcomes which may differ from results assessed in a blinded, independent, centrally reviewed manner, often required of adequate and well controlled registration directed clinical trials which may be undertaken at a later date. If the results from expansion cohorts or later trials are different from those found in the earlier studies of TG-1101 and TGR-1202, we may need to terminate or revise our clinical development plan, which could extend the time for conducting our development program and could have a material adverse effect on our business. Our IRAK4, BET, and anti-GITR programs are all in pre-clinical development and no assurance can be given that they will advance into clinical development. If the results from additional pre-clinical studies or early clinical trials differ from those found in earlier studies, our clinical development plans and timelines for this program could be adversely affected which could have a material adverse effect on our business. Many drugs fail in the early stages of clinical development for safety and tolerability issues, accordingly if our pre-clinical assets advance into clinical development, no assurance can be made that a safe and efficacious dose can be found.

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

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

In September 2015 we announced a Phase 3 clinical trial for the combination of TG-1101 + TGR-1202 for patients with CLL, which is being conducted pursuant to an SPA with the FDA and in August 2017 we announced an SPA for our registration program for TG-1101 in relapsing forms of MS. Many companies which have been granted SPAs and/or the right to utilize the FDA's Fast Track or accelerated approval process have ultimately failed to obtain final approval to market their drugs. Since we are seeking approvals under SPAs for some of our product registration strategies, based on protocol designs negotiated with the FDA, we may be subject to enhanced scrutiny. Further, any changes or amendments to a protocol that is being conducted under SPA will have to be reviewed and approved by the FDA to verify that the SPA agreement is still valid. Even if the primary endpoint in a Phase 3 clinical trial is achieved, a SPA does not guarantee approval. The FDA may raise issues of safety, study conduct, bias, deviation from the protocol, statistical power, patient completion rates, changes in scientific or medical parameters or internal inconsistencies in the data prior to making its final decision. The FDA may also seek the guidance of an outside advisory committee prior to making its final decision.

The sufficiency of our GENUINE trial results for approval are subject to FDA's discretion.

In October 2017, we announced the outcome of a meeting with the U.S. Food and Drug Administration (FDA) regarding the use of the results from the GENUINE Phase 3 trial to support a Biologics License Application (BLA) filing for accelerated approval of TG-1101 in combination with ibrutinib. As part of the discussion, the FDA guided that if one or more agents obtained full approval before we could obtain accelerated approval, we would need to show meaningful benefit over those agents as well. No assurance can be given that other agents will not receive full approval prior to our potential receipt of accelerated approval. If that were to occur, no assurance can be given that we would be successful in proving meaningful benefit over those later approved drugs. If we were unable to prove meaningful benefit over any such agents, we would be effectively blocked from receiving accelerated approval.

While we wait to see if any drugs receive full approval and can evaluate the data associated with any such agents, we are continuing to make preparations for a BLA filing for accelerated approval. Whether or not we ultimately file such application will be subject to multiple factors and no assurance can be given that a filing will be made. If a filing is made, the FDA acceptance of such a filing will depend on the FDA's views on the adequacy of the filing, and further even if the filing is accepted, approval of such a filing is a question wholly within the FDA's discretion to determine. In addition, if we were to receive accelerated approval, we would be required to conduct a post-market confirmatory study, which we may not complete, or if completed, may prove unsuccessful. In such instance, the FDA can remove the product from the market.

The Company plans to have a follow-up meeting with the FDA to discuss the use of the Progression-Free Survival Endpoint (PFS) endpoint from the GENUINE study for possible full approval. There can be no assurance given that we will reach agreement with the FDA on an acceptable use of PFS data from GENUINE to support approval of TG-1101, or even if an agreement is reached, that the PFS results of TG-1101 will be positive and/or sufficient to support a regulatory approval of TG-1101.

Any product candidates we may advance through 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 or "fast track" or "priority review" status 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. Even with "fast track" or "priority review" status which we intend to seek for our product candidates, where possible, including with regard to TG-1101, such designations do not necessarily mean a faster development process or regulatory review process or necessarily confer any advantage with respect to approval compared to conventional FDA procedures. In addition, the FDA may require post-approval clinical trials or studies which also may be costly. The FDA approval for a limited indication or approval with required warning language, such as a boxed warning, could significantly impact our ability to successfully market our product candidates. Finally, the FDA may require adoption of a Risk Evaluation and Mitigation Strategy ("REMS") requiring prescriber training, post-market registries, or otherwise restricting the marketing and dissemination of these products. Despite the time and expense invested in clinical development of product candidates, regulatory approval is never guaranteed. Assuming successful clinical development, we intend to seek product approvals in countries outside the United States. As a result, we would be subject to regulation by the European Medicines Agency ("EMA"), as well as the other regulatory agencies in many of these countries, and other regulatory agencies around the world.

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

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

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

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

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

We have not completed testing of any of our product candidates for the treatment of the indications for which we intend to seek product approval in humans, and we currently do not know the extent that adverse events, if any, will be observed in patients who receive any of our product candidates. To date, clinical trials using TG-1101 and TGR-1202 have demonstrated a toxicity profile that was deemed acceptable by the investigators performing such studies. Such interpretation may not be shared by future investigators or by the FDA and in the case of TG-1101 and TGR-1202, even if deemed acceptable for oncology applications, it may not be acceptable for diseases outside the oncology setting, and likewise for any other product candidates we may develop. Additionally, the severity, duration and incidence of adverse events may increase in larger study populations. With respect to both TG-1101 and TGR-1202, the toxicity when manufactured under different conditions and in different formulations is not known, and it is possible that additional and/or different adverse events may appear upon the human use of those formulations and those adverse events may arise with greater frequency, intensity and duration than in the current formulation. Should the Company not be able to adequately demonstrate analytical comparability between drug product manufactured under different conditions, the introduction of such new drug product into ongoing trials also has the potential to confound the interpretation of the results or complicate the statistical analysis of such trial. Further, with respect to TGR-1202, although several hundred patients have been dosed amongst all ongoing TGR-1202 studies, the full adverse effect profile of TGR-1202 is not known. It is also unknown as additional patients are exposed for longer durations to TGR-1202, whether greater frequency and/or severity of adverse events are likely to occur. Common toxicities of other drugs in the same class as TGR-1202 include high levels of liver toxicity, infections and colitis, the latter of which notably has presented with later onset, with incidence increasing with duration of exposure. To date, the incidence of these events has been limited for TGR-1202, however no assurance can be given that this safety and tolerability profile will continue to be demonstrated in the future as higher doses, longer durations of exposure, and multiple drug combinations are explored. If any of our product candidates cause unacceptable adverse events in clinical trials, we may not be able to obtain marketing approval and generate revenues from its sale, or even if approved for sale may lack differentiation from competitive products, which could have a material adverse impact on our business and operations.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Our product candidates are in the initial stages of development and are currently manufactured in small batches for use in pre-clinical and clinical studies. Process improvements implemented to date have changed, and process improvements in the future may change, the activity profile of the product candidates, which may affect the safety and efficacy of the products. No assurance can be given that the material manufactured from any of the optimized processes will perform comparably to the product candidates as manufactured to date and used in currently available pre-clinical data and or in early clinical trials reported in this or any previous filing. Additionally, future clinical trial results will be subject to the same level of uncertainty if, following such trials, additional process improvements are made. In addition, we have engaged a secondary manufacturer for TG-1101 to meet our current clinical and future commercial needs and anticipate engaging additional manufacturing sources for TGR-1202 to meet expanded clinical trial and commercial needs. While material produced from this secondary manufacturer for TG-1101 has to date demonstrated acceptable comparability, no assurance can be given that any additional manufacturers will be successful or that material manufactured by the additional manufacturers will perform comparably to TG-1101 or TGR-1202 as manufactured to date and used in currently available pre-clinical data and or in early clinical trials reported in this or any previous filing, or that the relevant regulatory agencies will agree with our interpretation of comparability. If a secondary manufacturer is not successful in replicating the product or experiences delays, or if regulatory authorities impose unforeseen requirements with respect to product comparability from multiple manufacturing sources, we may experience delays in clinical development.

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

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

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

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

The cancer indications for which we are developing our products have a number of established therapies with which we will compete. Most major pharmaceutical companies and many biotechnology companies are aggressively pursuing new cancer development programs for the treatment of NHL, CLL, and other B-cell proliferative malignancies, including both therapies with traditional, as well as novel, mechanisms of action. Additionally, numerous established therapies exist for the autoimmune disorders for which we are developing TG-1101, including and in particular, multiple sclerosis (MS).

If approved, we expect TG-1101 to compete directly with Roche Group's Rituxan® (rituximab) and Gazyva® (obinutuzumab or GA-101), and Novartis' Arzerra® (ofatumumab) among others, each of which is currently approved for the treatment of various diseases including NHL and CLL. In addition, a number of pharmaceutical companies are developing antibodies targeting CD20, CD19, and other B-cell associated targets, chimeric antigen receptor T-cell (CAR-T) immunotherapy, and other B-cell ablative therapy which, if approved, would potentially compete with TG-1101 both in oncology settings as well as in autoimmune disorders. Earlier this year, the Roche Group's anti-CD20 antibody ocrelizumab was approved for the treatment of MS. Genmab and GSK's (ofatumumab) is also under clinical development for patients with MS. New developments, including the development of other pharmaceutical technologies and methods of treating disease, occur in the pharmaceutical and life sciences industries at a rapid pace.

With respect to TGR-1202, there are several PI3K delta targeted compounds both approved, such as Gilead's Zydelig™ (idelalisib) and Bayer's Aliqopa® (copanlisib), and in development, including, but not limited to, Verastem's duvelisib 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 both approved and in development, which could also compete with TGR-1202 in similar indications, such as the BTK inhibitor, ibrutinib (FDA approved for MCL, CLL, Marginal Zone Lymphoma and WM and marketed by AbbVie and Janssen), the BTK inhibitor acalabrutinib (FDA approved for MCL and marketed by AstraZeneca), or the BCL-2 inhibitor venetoclax (FDA approved for CLL and marketed by AbbVie and Roche).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Obtaining coverage and reimbursement approval for a product from a government or other third-party payor is a time consuming and costly process that could require that we provide supporting scientific, clinical and cost-effectiveness data for the use of our products to the payor. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. If reimbursement of our future products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability. Additionally, while we may seek approval of our products in combination with each other, there can be no guarantee that we will obtain coverage and reimbursement for any of our products together, or that such reimbursement will incentivize the use of our products in combination with each other as opposed to in combination with other agents which may be priced more favorably to the medical community.

In both the United States and certain foreign countries, there have been a number of legislative and regulatory changes to the healthcare system that could impact our ability to sell our products profitably. In particular, the Medicare Modernization Act of 2003 revised the payment methodology for many products reimbursed by Medicare, resulting in lower rates of reimbursement for many types of drugs, and added a prescription drug benefit to the Medicare program that involves commercial plans negotiating drug prices for their members. Since 2003, there have been a number of other legislative and regulatory changes to the coverage and reimbursement landscape for pharmaceuticals.

Most recently, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, collectively, the "ACA," was enacted. The ACA and any revisions or replacements of that Act, any substitute legislation, and other changes in the law or regulatory framework could have a material adverse effect on our business.

Among the provisions of the ACA of importance to our potential product candidates are:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;
- expansion of healthcare fraud and abuse laws, including the federal False Claims Act and the federal Anti-Kickback Statute, new government investigative powers and enhanced penalties for non-compliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for a manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 138% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- expansion of the entities eligible for discounts under the 340B Drug Pricing Program;
- the new requirements under the federal Open Payments program and its implementing regulations;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians;
- 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; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

The Supreme Court upheld the ACA in the main challenge to the constitutionality of the law in 2012. The Supreme Court also upheld federal subsidies for purchasers of insurance through federally facilitated exchanges in a decision released in June 2015. Any remaining legal challenges to the ACA are viewed generally as not significantly impacting the implementation of the law if the plaintiffs prevail.

President Trump ran for office on a platform that supported the repeal of the ACA, and one of his first actions after his inauguration was to sign an Executive Order instructing federal agencies to waive or delay requirements of the ACA that impose economic or regulatory burdens on states, families, the health-care industry and others. Modifications to or repeal of all or certain provisions of the ACA have been attempted in Congress as a result of the outcome of the recent presidential and congressional elections, consistent with statements made by the incoming administration and members of Congress during the presidential and congressional campaigns and following the election. In January 2017, Congress voted to adopt a budget resolution for fiscal year 2017, or the Budget Resolution, that authorizes the implementation of legislation that would repeal portions of the ACA. The Budget Resolution is not a law. However, it is widely viewed as the first step toward the passage of legislation that would repeal certain aspects of the ACA. In March 2017, following the passage of the budget resolution for fiscal year 2017, the U.S. House of Representatives passed legislation known as the American Health Care Act of 2017, which, if enacted, would amend or repeal significant portions of the ACA. Attempts in the Senate in 2017 to pass ACA repeal legislation, including the Better Care Reconciliation Act of 2017, so far have been unsuccessful.

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

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

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

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

As of November 1, 2017, we had 69 full and part time employees. Over time, we will need to expand our managerial, operational, financial and other resources in order to manage and fund our operations and clinical trials, continue research and development activities, and commercialize our product candidates. Our management and scientific personnel, systems and facilities currently in place may not be adequate to support our future growth. Our need to effectively manage our operations, growth, and various projects requires that we:

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

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

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

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

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

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

In addition to FDA restrictions on the marketing of pharmaceutical and biotechnology products, several other types of state and federal laws have been applied to restrict certain marketing practices in the pharmaceutical and medical device industries, as well as consulting or other service agreements with physicians or other potential referral sources and regulate the use and disclosure of identifiable patient information. 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, recommending 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. Finally, the Health Insurance Portability and Accountability Act (HIPAA), as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, their respective implementing regulations and similar state laws and regulations, impose obligations on covered healthcare providers, health plans, and healthcare clearinghouses, as well as their business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information. In the event our operations result in our receiving such information, we could become subject to the requirements of these laws and regulations, including potential civil and criminal penalties.

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

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

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

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

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

Risks Relating to Acquisitions

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

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

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

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

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

Risks Relating to Our Intellectual Property

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

Our commercial success depends on obtaining and maintaining patent protection and trade secret protection in the US and other countries with respect to our product candidates or any future product candidate that we may license or acquire, their formulations and uses and the methods we use to manufacture them, as well as successfully defending these patents against third-party challenges. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our novel technologies and product candidates, and by maintenance of our trade secrets through proper procedures. We will only be able to protect our technologies from unauthorized use by third parties to the extent that valid and enforceable patents or trade secrets cover them in the market they are being used or developed. If any of our licensors or partners fails to appropriately prosecute and maintain patent protection for these product candidates, our ability to develop and commercialize these product candidates may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products. This failure to properly protect the intellectual property rights relating to these product candidates could have a material adverse effect on our financial condition and results of operations.

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

These risks and uncertainties include the following:

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

If patents are not issued that protect our product candidates, it could have a material adverse effect on our financial condition and results of operations. The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify any patentable aspects of our research and development output and methodology, and, even if we do, an opportunity to obtain patent protection may have passed. Given the uncertain and time-consuming process of filing patent applications and prosecuting them, it is possible that our product(s) or process(es) originally covered by the scope of the patent application may have changed or been modified, leaving our product(s) or process(es) without patent protection. If our licensors or we fail to obtain or maintain patent protection or trade secret protection for one or more product candidates or any future product candidate we may license or acquire, third parties may be able to leverage our proprietary information and products without risk of infringement, which could impair our ability to compete in the market and adversely affect our ability to generate revenues and achieve profitability. Moreover, should we enter into other collaborations we may be required to consult with or cede control to collaborators regarding the prosecution, maintenance and enforcement of licensed patents. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has in recent years been the subject of much litigation. In addition, no consistent policy regarding the breadth of claims allowed in pharmaceutical or biotechnology patents has emerged to date in the US. The patent situation outside the US is even more uncertain. The laws of foreign countries may not protect our rights to the same extent as the laws of the US, and we may fail to seek or obtain patent protection in all major markets. For example, European patent law restricts the patentability of methods of treatment of the human body more than US law does. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the US and other countries may diminish the value of our patents or narrow the scope of our patent protection. For example, the federal courts of the US have taken an increasingly dim view of the patent eligibility of certain subject matter, such as naturally occurring nucleic acid sequences, amino acid sequences and certain methods of utilizing same, which include their detection in a biological sample and diagnostic conclusions arising from their detection. Such subject matter, which had long been a staple of the biotechnology and biopharmaceutical industry to protect their discoveries, is now considered, with few exceptions, ineligible in the first instance for protection under the patent laws of the US. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents or in those licensed from a third-party.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include changes to transition from a "first-to-invent" system to a "first-to-file" system and to the way issued patents are challenged. The formation of the Patent Trial and Appeal Board now provides a quicker and less expensive process for challenging issued patents. The PTO recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first inventor-to-file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

Moreover, we may be subject to a third-party pre-issuance submission of prior art to the PTO, or become involved in opposition, derivation, reexamination, inter partes review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. The costs of these proceedings could be substantial and it is possible that our efforts to establish priority of invention would be unsuccessful, resulting in a material adverse effect on our US patent position. An adverse determination in any such submission, patent office trial, proceeding or litigation could reduce the scope of, render unenforceable, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner.

The issuance of a patent does not foreclose challenges to its inventorship, scope, validity or enforceability. Therefore, our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

In addition to patents, we and our partners also rely on trade secrets and proprietary know-how, technology and other proprietary information, to maintain our competitive position, particularly where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. 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 and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Moreover, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

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

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

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

In addition, because patent applications can take many years to issue, there may be currently pending applications, unknown to us, which may later result in issued patents that our product candidates or proprietary technologies may infringe. Similarly, there may be issued patents relevant to our product candidates of which we are not aware. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the US and other jurisdictions are typically not published until 18 months after a first filing, or in some cases not at all. Therefore, we cannot know with certainty whether we or our licensors were the first to make the inventions claimed in patents or pending patent applications that we own or licensed, or that we or our licensors were the first to file for patent protection of such inventions.

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 need to license certain intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.

A third party may hold intellectual property, including patent rights that are important or necessary to the development and commercialization of our products. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our products, in which case we would be required to obtain a license from these third parties, whom may or may not be interested in granting such a license, on commercially reasonable terms, or our business could be harmed, possibly materially.

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. Any claims we assert against accused infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents; or provoke those parties to petition the PTO to institute inter parties review against the asserted patents, which may lead to a finding that all or some of the claims of the patent are invalid. 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. Furthermore, adverse results on US patents may affect related patents in our global portfolio. 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. The costs of these proceedings could be substantial. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States.

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

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

As is common in the biotechnology and pharmaceutical industry, we engage the services of consultants to assist us in the development of our product candidates. Many of these consultants were previously employed at, may have previously been, or are currently providing consulting services to, other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these consultants or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers or their former or current customers. Even if frivolous or unsubstantiated in nature, 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, day-to-day business operations, and the implicated employee(s).

Risks Relating to Our Finances and Capital Requirements

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

As of September 30, 2017, we had approximately $91.8 million in cash and cash equivalents, which we believe will be sufficient to fund the Company's planned operations through 2018. As a result, we will need additional capital to continue our operations beyond that time. Required additional sources of financing to continue our operations in the future might not be available on favorable terms, if at all. If we do not succeed in raising additional funds on acceptable terms, we might be unable to complete planned preclinical and clinical trials or obtain approval of any of our product candidates from the FDA or any foreign regulatory authorities. In addition, we could be forced to discontinue product development, reduce or forego sales and marketing efforts and forego attractive business opportunities. Any additional sources of financing will likely involve the issuance of our equity securities, which would have a dilutive effect to stockholders.

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

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

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

We have never been profitable and, as of September 30, 2017, we had an accumulated deficit of $324.0 million. We have generated operating losses in all periods since we were incorporated. We expect to make substantial expenditures resulting in increased operating costs in the future and our accumulated deficit will increase significantly as we expand development and clinical trial efforts for our product candidates. Our losses have had, and are expected to continue to have, an adverse impact on our working capital, total assets and stockholders' equity. Because of the risks and uncertainties associated with product development, we are unable to predict the extent of any future losses or when we will become profitable, if ever. Even if we achieve profitability, we may not be able to sustain or increase profitability on an ongoing basis.

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Our Common Stock

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

Our directors, executive officers, their affiliates, and our principal stockholders beneficially own approximately 43% of our outstanding voting stock, including shares underlying outstanding options and warrants. Our directors, officers and principal stockholders, taken as a whole, have the ability to exert substantial influence over the election of our Board of Directors and the outcome of issues submitted to our stockholders.

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

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

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

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

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

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

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

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

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

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

ITEM 6. EXHIBITS

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

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 9, 2017.
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 9, 2017.
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 9, 2017.
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 9, 2017.
101	The following financial information from the Company's Quarterly Report on Form 10-Q for the period ended September 30, 2017, formatted in Extensible Business Reporting Language (XBRL): (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Operations, (iii) the Condensed Consolidated Statement of Stockholders' Equity, (iv) the Condensed Consolidated Statements of Cash Flows, and (v) Notes to the Condensed Consolidated Financial Statements (filed herewith).

SIGNATURES

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

TG THERAPEUTICS, INC.

Date: November 9, 2017

By: /s/ Sean A. Power

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

Exhibit 31.1

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

I, Michael S. Weiss, certify that:

1.I have reviewed this quarterly report on Form 10-Q of TG Therapeutics, Inc.;

2.Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3.Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4.The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2017

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

Exhibit 31.2

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

I, Sean A. Power, certify that:

1.I have reviewed this quarterly report on Form 10-Q of TG Therapeutics, Inc.;

2.Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3.Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4.The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5.The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2017

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

Exhibit 32.1

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

In connection with the quarterly report of TG Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2017 as filed with the Securities and Exchange Commission (the "Report"), I, Michael S. Weiss, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, based on my knowledge:

1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 9, 2017

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

Exhibit 32.2

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

In connection with the quarterly report of TG Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2017 as filed with the Securities and Exchange Commission (the "Report"), I, Sean A. Power, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, based on my knowledge:

1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 9, 2017

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