TG THERAPEUTICS, INC.
Form 10-Q
November 09, 2016

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

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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, 2016

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

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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, or a smaller reporting company. See definition of “large accelerated filer,” “accelerated filer” and “smaller reporting company” in Rule 12b-2 of the Exchange Act.

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

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

There were 54,731,109 shares of the registrant’s common stock, $0.001 par value, outstanding as of November 1, 2016.

TG THERAPEUTICS, INC.
FORM 10-Q
FOR THE QUARTER ENDED SEPTEMBER 30, 2016

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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, 2016 | December 31, 2015 |
|---|---|---|
| | (Unaudited) | (Note 1) |
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | $29,156,521 | $55,061,329 |
| Short-term investment securities | 31,445,616 | 22,166,512 |
| Interest receivable | 108,458 | 186,021 |
| Prepaid research and development | 10,121,215 | 9,151,142 |
| Other current assets | 500,564 | 308,327 |
| Total current assets | 71,332,374 | 86,873,331 |
| Restricted cash | 582,184 | 579,143 |
| Long-term investment securities | -- | 25,003,032 |
| Leasehold interest | 2,517,771 | -- |
| Equipment, net | 327,674 | 47,122 |
| Goodwill | 799,391 | 799,391 |
| Other assets | 127,700 | 171,182 |
| Total assets | $75,687,094 | $113,473,201 |
| Liabilities and stockholders' equity | | |
| Current liabilities: | | |
| Accounts payable and accrued expenses | $15,550,129 | $9,346,068 |
| Accrued compensation | 1,061,626 | 818,472 |
| Current portion of deferred revenue | 152,381 | 152,381 |
| Notes payable | 117,126 | 211,549 |
| Total current liabilities | 16,881,262 | 10,528,470 |
| Deferred rent | 793,968 | -- |
| Deferred revenue, net of current portion | 1,257,143 | 1,371,429 |
| Total liabilities | 18,932,373 | 11,899,899 |
| 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, 2016 and December 31, 2015) | -- | -- |
| | 54,766 | 54,095 |

| | | |
|---|---|---|
| Common stock, $0.001 par value per share (150,000,000 shares authorized, 54,765,890 and 54,095,110 shares issued, 54,724,581 and 54,053,801 shares outstanding at September 30, 2016 and December 31, 2015, respectively) | | |
| Contingently issuable shares | 6 | 6 |
| Additional paid-in capital | 269,646,963 | 259,887,464 |
| Treasury stock, at cost, 41,309 shares at September 30, 2016 and December 31, 2015 | (234,337) | (234,337) |
| Accumulated deficit | (212,712,677) | (158,133,926) |
| Total stockholders' equity | 56,754,721 | 101,573,302 |
| Total liabilities and stockholders' equity | $75,687,094 | $113,473,201 |

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, | |
|---|---|---|---|---|
| | 2016 | 2015 | 2016 | 2015 |
| License revenue | $38,096 | $38,096 | $114,286 | $114,286 |
| Costs and expenses: | | | | |
| Research and development: | | | | |
| Noncash compensation | 919,648 | 35,756 | 1,873,730 | 2,733,110 |
| Other research and development | 20,878,108 | 11,538,246 | 45,075,097 | 29,719,891 |
| Total research and development | 21,797,756 | 11,574,002 | 46,948,827 | 32,453,001 |
| General and administrative: | | | | |
| Noncash compensation | 1,914,390 | 1,204,278 | 4,307,670 | 10,106,938 |
| Other general and administrative | 1,251,421 | 1,085,400 | 3,798,859 | 3,094,362 |
| Total general and administrative | 3,165,811 | 2,289,678 | 8,106,529 | 13,201,300 |
| Total costs and expenses | 24,963,567 | 13,863,680 | 55,055,356 | 45,654,301 |
| Operating loss | (24,925,471) | (13,825,584) | (54,941,070) | (45,540,015) |
| Other (income) expense: | | | | |
| Interest income | (87,965) | (55,977) | (265,456) | (109,660) |
| Other income | (33,042) | -- | (33,042) | -- |
| Interest expense | 211,538 | 246,527 | 674,699 | 730,710 |
| Change in fair value of notes payable | (184,975) | (360,218) | (738,520) | (824,231) |
| Total other income | (94,444) | (169,668) | (362,319) | (203,181) |
| Net loss | $(24,831,027) | $(13,655,916) | $(54,578,751) | $(45,336,834) |
| Basic and diluted net loss per common share | $(0.50) | $(0.28) | $(1.11) | $(1.01) |
| Weighted average shares used in computing basic and diluted net loss per common share | 49,203,277 | 47,946,309 | 48,961,582 | 44,810,352 |

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

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

| | Common Stock | | | | Treasury Stock | | | |
|---|---|---|---|---|---|---|---|---|
| | Shares | Amount | Contingently issuable shares | Additional paid-in capital | Shares | Amount | Accumulated Deficit | Total |
| Balance at January 1, 2016 | 54,095,110 | $54,095 | $6 | $259,887,464 | 41,309 | $(234,337) | $(158,133,926) | $101,573,302 |
| Issuance of common stock in connection with exercise of warrants | 44,541 | 45 | | 100,851 | | | | 100,896 |
| Issuance of common stock in connection with conversion of notes payable | 3,201 | 3 | | 30,598 | | | | 30,601 |
| Issuance of restricted stock | 261,000 | 261 | | (261) | | | | -- |
| Forfeiture of restricted stock | (34,773) | (35) | | 35 | | | | -- |
| Issuance of common stock in At-the-Market offering (net of offering costs of $122,497) | 396,811 | 397 | | 3,446,876 | | | | 3,447,273 |
| Compensation in respect of restricted stock granted to employees, directors and consultants | | | | 6,181,400 | | | | 6,181,400 |
| Net loss | | | | | | | (54,578,751) | (54,578,751) |
| Balance at September 30, | 54,765,890 | $54,766 | $6 | $269,646,963 | 41,309 | $(234,337) | $(212,712,677) | $56,754,721 |

2016

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, | |
|---|---|---|
| | 2016 | 2015 |
| CASH FLOWS FROM OPERATING ACTIVITIES: | | |
| Net loss | $(54,578,751) | $(45,336,834) |
| 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 | 6,181,400 | 12,840,048 |
| Depreciation | 42,464 | 10,326 |
| Amortization of premium on investment securities | 367,673 | 377,770 |
| Change in fair value of notes payable and accrued interest | (63,822) | (93,522) |
| Changes in assets and liabilities: | | |
| Increase in restricted cash | (3,041) | (3,114) |
| Increase in prepaid research and development and other current assets | (1,162,310) | (4,055,116) |
| Increase in leasehold interest | (2,517,771) | -- |
| Decrease (increase) in accrued interest receivable | 77,563 | (73,011) |
| Increase in other assets | (3,523) | -- |
| Increase in accounts payable and accrued expenses | 6,447,215 | 4,658,128 |
| Increase in deferred rent | 793,968 | -- |
| Decrease in deferred revenue | (114,286) | (114,286) |
| Net cash used in operating activities | (44,566,263) | (31,789,611) |
| CASH FLOWS FROM INVESTING ACTIVITIES: | | |
| Purchases of equipment | (323,015) | (59,194) |
| Investment in held-to-maturity securities | (15,199,922) | (40,955,137) |
| Proceeds from maturity of short-term securities | 18,000,000 | 13,850,000 |
| Proceeds from the sale of long-term securities | 12,589,219 | -- |
| Net cash provided by (used in) investing activities | 15,066,282 | (27,164,331) |
| CASH FLOWS FROM FINANCING ACTIVITIES: | | |
| Proceeds from the exercise of warrants | 100,896 | 1,009,985 |
| Proceeds from sale of common stock, net | 3,504,261 | 67,760,517 |
| Financing costs | (9,984) | (68,404) |
| Net cash provided by financing activities | 3,595,173 | 68,702,098 |
| NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS | (25,904,808) | 9,748,156 |
| CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD | 55,061,329 | 55,713,784 |

| | | |
|---|---|---|
| CASH AND CASH EQUIVALENTS AT END OF PERIOD | $29,156,521 | $65,461,940 |
| | | |
| NONCASH TRANSACTIONS | | |
| Reclassification of deferred financing costs to additional paid-in capital | $(56,988) | $(63,788) |
| Conversion of convertible notes payable to common stock | $30,601 | $-- |

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

TG Therapeutics, Inc.
Notes to Condensed Consolidated Financial Statements (unaudited)

Unless the context requires otherwise, references in this report to "TG," the "Company," "we," "us" and "our" refer to TG Therapeutics, Inc. and our subsidiaries.

NOTE 1 – ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Description of Business

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

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

The accompanying unaudited condensed consolidated financial statements were prepared in accordance with U.S. generally accepted accounting principles, or GAAP, for interim financial information and with the instructions to Quarterly Report on Form 10-Q and Article 10 of Regulation S-X of the Exchange Act. Accordingly, they may not include all of the information and footnotes required by GAAP for complete financial statements. All adjustments that are, in the opinion of management, of a normal recurring nature and are necessary for a fair presentation of the condensed consolidated financial statements have been included. Nevertheless, these condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements contained in our Annual Report on Form 10-K for the year ended December 31, 2015. The accompanying condensed December 31, 2015 balance sheet has been derived from these statements. The results of operations for the three and nine months ended September 30, 2016 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, expect to continue to incur operating losses for the foreseeable future, and may never attain profitable operations. As of September 30, 2016, we have an accumulated deficit of approximately $212.7 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 with one or more partners. We may continue to incur substantial operating losses even if we begin to generate revenues from our drug candidates.

As of September 30, 2016, we had approximately $60.7 million in cash, cash equivalents, investment securities, and interest receivable, which we believe will be sufficient to fund the company's planned operations into the first half of 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 provide the cash necessary to execute our current strategic plan, including the commercialization of any of our drug candidates.

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

Recently Issued Accounting Standards

In August 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update (“ASU”) No. 2016-15, “Classification of Certain Cash Receipts and Cash Payments” (“ASU 2016-15”). ASU 2016-15 amends the guidance in Accounting Standards Codification (“ASC” or “Codification”) 230 on the classification of certain cash receipts and payments in the statement of cash flows. The primary purpose of ASU 2016-15 is to reduce the diversity in practice that has resulted from the lack of consistent principles on this topic. The amendments in ASU 2016-15 add or clarify guidance on eight cash flow issues:

Debt prepayment or debt extinguishment costs.

Settlement of zero-coupon debt instruments or other debt instruments with coupon interest rates that are insignificant in relation to the effective interest rate of the borrowing.

Contingent consideration payments made after a business combination.

Proceeds from the settlement of insurance claims.

Proceeds from the settlement of corporate-owned life insurance policies, including bank-owned life insurance policies.

Distributions received from equity method investees.

Beneficial interests in securitization transactions.

Separately identifiable cash flows and application of the predominance principle.

ASU 2016-15 is effective for annual and interim periods beginning after December 15, 2017, and early adoption is permitted for all entities. Entities must apply the guidance retrospectively to all periods presented but may apply it prospectively from the earliest date practicable if retrospective application would be impracticable. The provisions of this standard are not expected to significantly impact the Company.

In May 2016, the FASB issued ASU No. 2016-11, “Rescission of SEC Guidance Because of Accounting Standards Update 2014-09 and 2014-16 Pursuant to Staff Announcements at the March 3, 2016 EITF Meeting” (“ASU 2016-11”). ASU 2016-11 rescinds certain SEC guidance from the FASB Codification in response to announcements made by the SEC staff at the Emerging Issues Task Force’s March 3, 2016 meeting. Specifically, ASU 2016-11 supersedes SEC observer comments on the following topics:

Upon the adoption of ASU 2014-09:

- Revenue and expense recognition for freight services in process (ASC 605-20-S99-2)
- Accounting for shipping and handling fees and costs (ASC 605-45-S99-1)
- Accounting for consideration given by a vendor to a customer (ASC 605-50-S99-1)
- Accounting for gas-balancing arrangements (ASC 932-10-S99-5).

Upon the adoption of ASU 2014-16:

- Determining the nature of a host contract related to a hybrid financial instrument issued in the form of a share under ASC 815 (ASC 815-10-S99-3).

ASU 2016-11 is effective upon the adoption of ASU 2014-09 and ASU 2014-16. The adoption of ASU 2016-11 is not expected to have a material impact on the Company's condensed consolidated financial statements.

In March 2016, the FASB issued ASU No. 2016-09, "Simplifying the Accounting for Share-Based Payments" ("ASU 2016-09"). ASU 2016-09 simplifies several aspects of the accounting for employee share-based payment transactions for both public and nonpublic entities, including the accounting for income taxes, forfeitures, and statutory tax withholding requirements, as well as classification in the statement of cash flows. ASU 2016-09 is effective for annual reporting periods beginning after December 15, 2016, including interim periods within those annual reporting periods. The provisions of this standard are not expected to significantly impact the Company.

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

Use of Estimates

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

Cash and Cash Equivalents

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

Restricted Cash

We record cash pledged or held in trust as restricted cash. As of September 30, 2016 and December 31, 2015, 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 September 30, 2016 and December 31, 2015 consist of short-term and long-term government securities. We classify these securities as held-to-maturity. Held-to-maturity securities are those securities in which we have the ability and intent to hold the security until maturity. Held-to-maturity securities are recorded at amortized cost, adjusted for the amortization or accretion of premiums or discounts. Premiums and discounts are amortized or accreted over the life of the related held-to-maturity security as an adjustment to yield using the effective interest method.

A decline in the market value of any investment security below cost, that is deemed to be other than temporary, results in a reduction in the carrying amount to fair value. The impairment is charged to operations and a new cost basis for the security is established. Other-than-temporary impairment charges 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, short-term investments and long-term investments. The Company maintains its cash and cash equivalents, short-term investments and long-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 FASB 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, certain costs related to development and manufacturing services. These development and manufacturing agreements often require payments in advance of services performed or goods received. Accordingly, as of September 30, 2016 and December 31, 2015, we recorded approximately $10.1 million and $9.2 million of prepaid development and manufacturing services, 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.

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 options, restricted stock and warrants 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 6,664,591 and 5,634,005 for the three and nine months ended September 30, 2016 and 2015, respectively. The following outstanding shares of potentially dilutive securities 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, |
|---|---|

| | 2016 | 2015 |
|---|---|---|
| Unvested restricted stock | 5,507,250 | 4,404,805 |
| Warrants | 1,142,208 | 1,211,177 |
| Shares issuable upon note conversion | 15,133 | 18,023 |
| Total | 6,664,591 | 5,634,005 |

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.

NOTE 2 – CASH AND CASH EQUIVALENTS

The following tables summarize our cash and cash equivalents at September 30, 2016 and December 31, 2015:

| | September 30, 2016 | December 31, 2015 |
|---|---|---|
| Money market funds | $24,316,496 | $8,265,583 |
| Checking and bank deposits | 4,840,025 | 46,795,746 |
| Total | $29,156,521 | $55,061,329 |

NOTE 3 – INVESTMENT SECURITIES

Our investments as of September 30, 2016 and December 31, 2015 are classified as held-to-maturity. Held-to-maturity investments are recorded at amortized cost. During the three months ended September 30, 2016, we liquidated our long-term investment securities with a net carrying amount of approximately $12.6 million, realizing a gain of approximately $33,000 on the sale. The decision to sell our long-term securities was made due to market rate conditions on long-term securities coupled with the recognized gain we were able to yield on the sale of the securities.

The following tables summarize our investment securities at September 30, 2016 and December 31, 2015:

| | September 30, 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 October 2016 and September 2017) (held-to-maturity) | $31,445,616 | $19,363 | $-- | $31,464,979 |
| Total short-term investment securities | $31,445,616 | $19,363 | $-- | $31,464,979 |

| | December 31, 2015 | | | |
|---|---|---|---|---|
| | Amortized cost, as adjusted | Gross unrealized holding gains | Gross unrealized holding losses | Estimated fair value |
| Short-term investments: | | | | |

| | | | | |
|---|---|---|---|---|
| Obligations of domestic governmental agencies (maturing between January 2016 and December 2016) (held-to-maturity) | $22,166,512 | $-- | $22,822 | $22,143,690 |
| Long-term investments: | | | | |
| Obligations of domestic governmental agencies (maturing between January 2017 and December 2017) (held-to-maturity) | 25,003,032 | -- | 85,846 | 24,917,186 |
| Total short-term and long-term investment securities | $47,169,544 | $-- | $108,668 | $47,060,876 |

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, 2016 and December 31, 2015, the fair values of cash and cash equivalents, restricted cash, and notes and interest payable, approximate their carrying value.

At the time of our merger (we were then known as Manhattan Pharmaceuticals, Inc.) 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 to the Ariston subsidiary including accrued and unpaid interest of the 5% Notes was approximately $17.0 million at September 30, 2016 and $19.9 million at December 31, 2015. No payments have been made on the 5% Notes as of September 30, 2016.

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, 2016 and December 31, 2015. 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, 2016 and December 31, 2015:

| | Financial liabilities at fair value as of September 30, 2016 | | | |
|---|---|---|---|---|
| | Level 1 | Level 2 | Level 3 | Total |
| 5% Notes | $-- | $-- | $117,126 | $117,126 |
| Total | $-- | $-- | $117,126 | $117,126 |

| | Financial liabilities at fair value as of December 31, 2015 | | | |
|---|---|---|---|---|

| | Level 1 | Level 2 | Level 3 | Total |
|---|---|---|---|---|
| 5% Notes | $-- | $-- | $211,549 | $211,549 |
| Total | $-- | $-- | $211,549 | $211,549 |

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

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The following table summarizes the changes in Level 3 instruments during the nine months ended September 30, 2016:

| | |
|---|---|
| Fair value at December 31, 2015 | $211,549 |
| Interest accrued on face value of 5% Notes | 674,699 |
| Conversion of 5% notes | (30,601) |
| Change in fair value of Level 3 liabilities | (738,521) |
| Fair value at September 30, 2016 | $117,126 |

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.

In April and May of 2016, we sold a total of 396,811 shares of common stock under the 2015 ATM for aggregate total gross proceeds of approximately $3.6 million at an average selling price of $9.00 per share, resulting in net proceeds of approximately $3.5 million after deducting commissions and other transaction costs.

The 2015 S-3 is currently our only active shelf registration statement. After deducting shares already sold, including under the 2015 ATM, there is approximately $178 million of common stock that remains available for sale under the

2015 S-3. We may offer the securities under the 2015 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 2015 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, 2016, no options were outstanding and up to an additional 3,938,403 shares may be issued under the 2012 Incentive Plan.

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, 2016:

| | Number of Shares | Weighted Average Grant Date Fair Value |
|---|---|---|
| Outstanding at December 31, 2015 | 7,359,915 | $7.83 |
| Granted | 261,000 | 7.13 |
| Vested | (578,892) | 7.13 |
| Forfeited | (34,773) | 11.83 |
| Outstanding at September 30, 2016 | 7,007,250 | $7.82 |

Total expense associated with restricted stock grants was approximately $2.8 million and $1.2 million during the three months ended September 30, 2016 and 2015, respectively, and $6.2 million and $12.8 million during the nine months ended September 30, 2016 and 2015, respectively. As of September 30, 2016, there was approximately $15.8 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 1.64 years. This amount does not include, as of September 30, 2016, 411,172 shares of restricted stock outstanding which are milestone-based and vest upon certain corporate milestones; and 2,306,958 shares of restricted stock outstanding issued to non-employees, the expense for which is determined each reporting period at the measurement date. The expense is recognized over the vesting period of the award. Until the measurement date is reached for milestone awards, 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, 2016:

| | Warrants | Weighted average exercise price | Aggregate Intrinsic Value |
|---|---|---|---|
| Outstanding at December 31, 2015 | 1,186,749 | $2.37 | $11,341,452 |
| Issued | -- | -- | |
| Exercised | (44,541) | 2.26 | |
| Expired | -- | -- | |
| Outstanding at September 30, 2016 | 1,142,208 | $2.38 | $6,125,109 |

Stock-Based Compensation

We did not grant any stock options during the nine months ended September 30, 2016 and 2015.

The following table summarizes stock-based compensation expense information about restricted stock and stock options for the three and nine months ended September 30, 2016 and 2015:

| | Three months ended September 30, | | Nine months ended September 30, | |
|---|---|---|---|---|
| | 2016 | 2015 | 2016 | 2015 |
| Stock-based compensation expense associated with restricted stock | $2,834,038 | $1,240,034 | $6,181,400 | $12,840,048 |
| | $2,834,038 | $1,240,034 | $6,181,400 | $12,840,048 |

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NOTE 6 – NOTES PAYABLE

The following is a summary of notes payable:

| | September 30, 2016 | | | December 31, 2015 | | |
|---|---|---|---|---|---|---|
| | Current portion, net | Non-current portion, net | Total | Current portion, net | Non-current portion, net | Total |
| Convertible 5% Notes Payable | $117,126 | $- | $117,126 | $211,549 | $- | $211,549 |
| Total | $117,126 | $- | $117,126 | $211,549 | $- | $211,549 |

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 $17.0 million at September 30, 2016 and $19.9 million at December 31, 2015. No payments have been made on the 5% Notes as of September 30, 2016.

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 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 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, 2016 and 2015, and approximately $0.1 million for each of the nine months ended September 30, 2016 and 2015 and, at September 30, 2016 and December 31, 2015, have deferred revenue of approximately $1.4 million and $1.5 million, respectively, associated with this $2.0 million payment (approximately $0.2 million of which has been classified in current liabilities at September 30, 2016 and December 31, 2015).

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

NOTE 8 – RELATED PARTY TRANSACTIONS

LFB Biotechnologies

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

Under the terms of the LFB License Agreement, we utilize LFB Group for certain development and manufacturing services. We incurred expenses of $1.9 million and $2.5 million during the three months ended September 30, 2016 and 2015, respectively, and $4.3 million and $4.9 million during the nine months ended September 30, 2016 and 2015, respectively, which have been included in other research and development expenses in the accompanying condensed consolidated statements of operations. As of September 30, 2016 and December 31, 2015, we had approximately $0.3 million and $2.1 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, 2016 and December 31, 2015, we recorded approximately $3.1 million and $3.0 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 Interim Chief Executive Officer is a Managing Member of Opus. During the three and nine months ended September 30, 2016, we incurred expenses of approximately $0 and $0.1 million, respectively, principally for rent, related to this agreement. The Opus Shared Services Agreement is no longer in effect as we began occupying new 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, 2016, we recorded rent expense of approximately $1.0 million and at September 30, 2016, have deferred rent of approximately $0.8 million. Mr. Weiss, our Executive Chairman and Interim CEO, is also Executive Vice Chairman of Fortress.

During the nine months ended September 30, 2016, we agreed to pay Fortress $2.7 million for 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 period 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, 2016, we had approximately $0.4 million recorded in accounts payable related mostly to the upfront leasehold interest. Also in connection with this lease, in October 2014 we pledged $0.6 million to secure a line of credit as a security deposit for the Office Agreement, which has been recorded as restricted cash in the accompanying condensed consolidated balance sheets.

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 $0.5 million for shared services for the nine months ended September 30, 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 as part of the JBET Agreement. As of September 30, 2016, we had approximately $0.3 million recorded in accounts payable, related to the JBET Agreement. Mr. Weiss is also the Executive Chairman of Checkpoint.

## 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, 2015.

### OVERVIEW

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

and anti-PD-L1 and anti-GITR antibodies.

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

TG-1101 (ublituximab)

Overview

TG-1101 (ublituximab) is a chimeric, glycoengineered monoclonal antibody that targets a unique epitope on the CD20 antigen found on the surface of B-lymphocytes developed to aid in the depletion of circulating B-cells. We hold exclusive worldwide rights to develop and commercialize TG-1101 for all indications, except for the territories of France and Belgium which have been retained by LFB Biotechnologies, and South Korea and Southeast Asia which were licensed 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 2015 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 patients at doses as high as 450mg per infusion. Subsequently, a single-agent Phase I study was undertaken in the US enrolling patients with both NHL and CLL, dosing patients up to 1200mg per infusion. In both studies, single agent therapy with TG-1101 was deemed well tolerated by treating investigators and displayed promising clinical activity in relapsed and refractory patients.

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

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-DLBCL Trial – 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 Diffuse Large B-Cell Lymphoma (DLBCL); and

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

In addition, we have announced our intent of evaluating TG-1101 for the treatment of certain autoimmune diseases. Currently, 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. Preliminary data from this Phase 1 study in NMO was presented at the 32nd Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS), in London, UK in September 2016. Data from the poster presentation demonstrated that TG-1101 was

well tolerated with minimal adverse events (AEs) observed and rapid and robust B-cell depletion observed following a single 450 mg infusion of TG-1101. In August 2016, it was also announced that TG-1101 received orphan drug designation for the Treatment of Neuromyelitis Optica and Neuromyelitis Optica Spectrum Disorder.

Further details on our priority ongoing combination 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 now enroll approximately 120 patients, with the PFS analysis component removed. The sole primary endpoint of the study is now ORR, and the SPA is no longer in effect. We expect to complete enrollment in the revised trial by year end 2016, and will have topline data available in the first half of 2017. If the results of the study are positive, we plan to request a pre-BLA meeting to discuss the data and a filing strategy with the FDA. We have communicated with the FDA regarding our intention to file a Biologics Licensing Application (BLA) for accelerated approval if the results of the amended study are positive and the FDA has agreed that a pre-BLA meeting can be requested based on ORR data from the GENUINE study.

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 an 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.

TG-1101 in Combination with TGR-1202 Phase 2b Registration-Directed Program – The UNITY-DLBCL 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.

The study, entitled "A Phase 2b Randomized Study to Assess the Efficacy and Safety of the Combination of Ublituximab + TGR-1202 and TGR-1202 alone in Patients with Previously Treated Diffuse Large B-Cell Lymphoma," 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. The primary objective of the study is to assess the efficacy of TGR-1202 alone and in combination with TG-1101 in patients with previously treated DLBCL 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. In addition to monitoring for safety and efficacy this study will analyze the impact of cell of origin (GCB vs. non-GCB), mutational status and select biomarkers of efficacy.

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.

Updates for TGR-1202

In August 2016, we announced that TGR-1202 had received orphan drug designation for the treatment of CLL.

In October 2016, a manuscript titled, "Silencing c-Myc Translation as a Therapeutic Strategy through Targeting PI3K Delta and CK1 Epsilon in Hematological Malignancies," was published online in the First Edition section of Blood, the Journal of the American Society of Hematology. The publication presents preclinical data describing the synergy of TGR-1202 with the proteasome inhibitor carfilzomib and the unique effects of the combination to silence c-Myc in various preclinical lymphoma and myeloma models. In addition, the manuscript for the first time reports on TGR-1202's unique complimentary mechanism of inhibiting the protein kinase casein kinase-1 (CK1) epsilon, which may contribute to the silencing of c-Myc and explain TGR-1202's clinical activity in aggressive lymphoma, including Diffuse Large B-cell Lymphoma (DLBCL).

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 studies in combination with TG-1101, our current combination clinical trials that are ongoing or have been completed for TGR-1202 are:

TGR-1202 in combination with the anti-CD20 antibody, obinutuzumab (GAZYVA®) and chlorambucil in patients with CLL;

TGR-1202 in combination with the anti-CD30 antibody drug conjugate, brentuximab vedotin (ADCETRIS®), in patients with relapsed or refractory Hodgkin’s lymphoma;

TGR-1202 in combination with the BTK inhibitor, ibrutinib, in patients with previously treated CLL and MCL; and

TGR-1202 in combination with the JAK inhibitor, ruxolitinib (JAKAFI®), in patients with previously treated Myelofibrosis or Polycythemia Vera

In addition, given the favorable safety profile demonstrated to date, a trial of TGR-1202 monotherapy in patients with CLL who were previously intolerant to prior BTK or PI3K inhibitor therapy is also underway.

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 most recently 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 in Combination with obinutuzumab and chlorambucil in patients with CLL

In March 2014, the Company initiated a Phase I/Ib, open label, multi-center, clinical trial of TGR-1202 in combination with obinutuzumab and chlorambucil in patients with CLL, both treatment naïve and relapsed. The study

entitled TGR-GA-106, "A Multi-center Phase I/Ib Study Evaluating the Efficacy and Safety of TGR-1202, a Novel PI3K Delta Inhibitor, in Combination with Obinutuzumab and Chlorambucil in Patients with Chronic Lymphocytic Leukemia (CLL)," is being led by Dr. Daruka Mahadevan of the West Clinic in Memphis, TN. As of February 2016, this study has completed enrollment.

Data from the study was presented at the 57th Annual American Society of Hematology (ASH) meeting held in December 2015.

TGR-1202 Combination Trials

TGR-1202 is being 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 BTK inhibitor, ibrutinib, in patients with CLL and MCL; and in combination with the JAK inhibitor, ruxolitinib, in patients with Myelofibrosis or Polycythemia Vera. It is anticipated that preliminary results from these studies will be presented at future medical conferences.

TGR-1202 in Solid Tumors

In addition to the exploration of TGR-1202 in various hematologic malignancies, a study was opened in October 2015 to evaluate TGR-1202 as a single agent as well as in combination with various chemotherapies for the treatment of select solid tumors. The study, entitled TGR-1202-102, “A Phase I Study Evaluating the Safety and Efficacy of TGR-1202 Alone and in Combination with either nab-paclitaxel + Gemcitabine or with FOLFOX in Patients with Select Relapsed or Refractory Solid Tumors” is being run in collaboration with the Sarah Cannon Research Institute in Nashville, TN with Johanna Bendell, MD, Director of GI Oncology Research as the acting study chair.

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 and anti-GITR programs are currently in pre-clinical development.

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 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 continue to fund in-licensing and development of new drug candidates. As we continue our development efforts, we may enter into additional third-party collaborative agreements and may incur additional expenses, such as licensing fees and milestone payments. In addition, we may need to establish the commercial infrastructure required to manufacture, market and sell our drug candidates following approval, if any, by the FDA, which would result in us incurring additional expenses. As a result, our quarterly results may fluctuate and a quarter-by-quarter comparison of our operating results may not be a meaningful indication of our future performance.

RESULTS OF OPERATIONS

Three months ended September 30, 2016 and 2015

License Revenue. License revenue was $38,096 for each of the three months ended September 30, 2016 and 2015. 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 $919,648 for the three months ended September 30, 2016, as compared to $35,756 during the comparable period in 2015. The increase in noncash compensation expense was primarily related to restricted stock grants to personnel in 2016 and a decrease in the measurement date fair value of certain consultant restricted stock during the period ended September 30, 2015.

Other Research and Development Expenses. Other research and development expenses increased by $9,339,862 to $20,878,108 for the three months ended September 30, 2016, as compared to $11,538,246 for the three months ended September 30, 2015. The increase was mainly due to the ongoing clinical development programs and related manufacturing costs for TG-1101 and TGR-1202 during the three months ended September 30, 2016. We expect our other research and development costs to increase for the remainder of 2016 as the enrollment of additional patients in our Phase 3 clinical trials increases and we prepare for launch.

Noncash Compensation Expense (General and Administrative). Noncash compensation expense (general and administrative) related to equity incentive grants increased by $710,112 to $1,914,390 for the three months ended September 30, 2016, as compared to $1,204,278 for the three months ended September 30, 2015. The increase in

noncash compensation expense was primarily related to restricted stock granted to executive personnel and a decrease in the measurement date fair value of certain consultant restricted stock during the three months ended September 30, 2015.

Other General and Administrative Expenses. Other general and administrative expenses increased by $166,021 to $1,251,421 for the three months ended September 30, 2016, as compared to $1,085,400 for the three months ended September 30, 2015. The increase was due primarily to the straight-line rent expense of our new office space, as well as increased personnel and other general and administrative costs. We expect our other general and administrative expenses to remain at a comparable level for the remainder of 2016.

Other (Income) Expense. Other income decreased by $75,224 to $94,444 for the three months ended September 30, 2016, as compared to $169,668 for the three months ended September 30, 2015. The decrease is mainly due to a decrease in the change in fair value of notes payable for the three months ended September 30, 2016.

Nine months ended September 30, 2016 and 2015

License Revenue. License revenue was $114,286 for each of the nine months ended September 30, 2016 and 2015. License revenue for the nine months ended September 30, 2016 and 2015 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 $1,873,730 for the nine months ended September 30, 2016, as compared to $2,733,110 during the comparable period in 2015. The decrease in noncash compensation expense was primarily related to milestone-based vesting of restricted stock grants to non-executive personnel in the nine months ended September 30, 2015, and a decrease in the measurement date fair value of certain consultant restricted stock during the period ended September 30, 2016.

Other Research and Development Expenses. Other research and development expenses increased by $15,355,206 to $45,075,097 for the nine months ended September 30, 2016, as compared to $29,719,891 for the nine months ended September 30, 2015. The increase in other research and development expenses was due primarily to a $1.0 million licensing fee for the Jubilant sub-license agreement, as well as the ongoing clinical development programs and related manufacturing costs for TG-1101 and TGR-1202 during the nine months ended September 30, 2016. We expect our other research and development costs to increase for the remainder of 2016 as enrollment of additional patients in our Phase 3 clinical trials increases and we prepare for launch.

Noncash Compensation Expense (General and Administrative). Noncash compensation expense (general and administrative) related to equity incentive grants decreased by $5,799,268 to $4,307,670 for the nine months ended September 30, 2016, as compared to $10,106,938 for the nine months ended September 30, 2015. The decrease in noncash compensation expense was primarily related to greater measurement date fair values of certain consultant restricted stock during the nine months ended September 30, 2015.

Other General and Administrative Expenses. Other general and administrative expenses increased by $704,497 to $3,798,859 for the nine months ended September 30, 2016, as compared to $3,094,362 for the nine months ended September 30, 2015. The increase was due primarily to the straight-line rent expense of our new office space, as well as increased personnel and other general and administrative costs. We expect our other general and administrative expenses to remain at a comparable level for the remainder of 2016.

Other (Income) Expense. Other income increased by $159,138 to $362,319 for the nine months ended September 30, 2016, as compared to $203,181 for the nine months ended September 30, 2015. The increase is mainly due to an increase in interest income for the nine months ended September 30, 2016.

LIQUIDITY AND CAPITAL RESOURCES

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

As of September 30, 2016, we had approximately $60.7 million in cash and cash equivalents, investment securities, and interest receivable.

As of September 30, 2016 we anticipate that our cash and cash equivalents and investments will be sufficient to fund the company's planned operations into the first half of 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, 2016 was $44,566,263 as compared to $31,789,611 for the nine months ended September 30, 2015. 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, 2016, net cash provided by investing activities was $15,066,282 as compared to net cash used in investing activities of $27,164,331 for the nine months ended September 30, 2015. The increase in net cash provided by investing activities was primarily due to the maturity and sale of treasury securities during the nine months ended September 30, 2016.

For the nine months ended September 30, 2016 and 2015, net cash provided by financing activities of $3,595,173 and $68,702,098 related to our ATM program, as well as proceeds from the exercise of warrants.