

MANHATTAN PHARMACEUTICALS INC  
Form 10-K  
March 14, 2012

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**FORM 10-K**

**ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF  
<sup>x</sup>1934**

**For the fiscal year ended December 31, 2011.**

**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 1-32639**

**MANHATTAN PHARMACEUTICALS, INC.**

**(Exact name of registrant as specified in its charter)**

**Delaware** **36-3898269**  
(State or other jurisdiction of (I.R.S. Employer  
incorporation or organization) Identification No.)

**787 Seventh Avenue**  
**New York, New York** **10019**  
(Address of principal executive offices) (Zip Code)

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

**Securities registered pursuant to Section 12(b) of the Act:**

Common Stock, Par Value \$0.001 Per Share OTC Bulletin Board  
(Title of Class) (Name of Each Exchange on Which Registered)

**Securities registered pursuant to Section 12(g) of the Act:**

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.

Yes  No

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 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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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 definitions of "large accelerated filer," "accelerated filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act). (Check one):

Large accelerated filer  Accelerated filer   
Non-accelerated filer  Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes  No

The aggregate market value of voting common stock held by non-affiliates of the registrant (assuming, for purposes of this calculation, without conceding, that all executive officers and directors are "affiliates") was \$619,416 as of June 30, 2011, based on the closing sale price of such stock as reported on the OTC Bulletin Board.

There were 284,683,977 shares of the registrant's common stock outstanding as of March 1, 2012.

#### **DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the registrant's Proxy Statement for the 2012 Annual Meeting of Stockholders are incorporated by reference in Part III of this Annual Report on Form 10-K.

**MANHATTAN PHARMACEUTICALS, INC.**

**ANNUAL REPORT ON FORM 10-K**

**FOR THE FISCAL YEAR ENDED DECEMBER 31, 2011**

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This Annual Report on Form 10-K contains trademarks and trade names of Manhattan Pharmaceuticals, Inc., including our name and logo. All other trademarks, service marks, or trade names referenced in this Annual Report on Form 10-K are the property of their respective owners.

## SPECIAL CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS

Certain matters discussed in this report, including matters discussed under the caption “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” may constitute forward-looking statements for purposes of the Securities Act of 1933, as amended, or the Securities Act, and the Securities Exchange Act of 1934, as amended, or the Exchange Act, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from the future results, performance or achievements expressed or implied by such forward-looking statements. The words "anticipate," "believe," "estimate," "may," "expect" and similar expressions are generally intended to identify forward-looking statements. Our actual results may differ materially from the results anticipated in these forward-looking statements due to a variety of factors, including, without limitation, those discussed under the captions “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this report, as well as other factors which may be identified from time to time in our other filings with the Securities and Exchange Commission, or 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;

- our use of clinical research centers and other contractors;

- expectations for incurring capital expenditures to expand our research and development and manufacturing capabilities;

- expectations for generating revenue or becoming profitable on a sustained basis;

- expectations or ability to enter into marketing and other partnership agreements;

- expectations or ability to enter into product acquisition and in-licensing transactions;

- expectations or ability to build our own commercial infrastructure to manufacture, market and sell our drug candidates;

- acceptance of our products by doctors, patients or payors;

- our ability to compete against other companies and research institutions

- our ability to secure adequate protection for our intellectual property;

- our ability to attract and retain key personnel;

- availability of reimbursement for our products;

estimates of the sufficiency of our existing cash and cash equivalents and investments to finance our operating requirements, including expectations regarding the value and liquidity of our investments;

- the volatility of our stock price;

- expected losses; and

- expectations for future capital requirements.

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

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

## **PART I**

*Unless the context requires otherwise, references in this report to “Manhattan,” “Company,” “we,” “us” and “our” refer to Manhattan Pharmaceuticals, Inc. and our subsidiaries.*

### **ITEM 1. BUSINESS.**

#### **OVERVIEW**

We are a biopharmaceutical company focused on the acquisition, development and commercialization of innovative and medically important pharmaceutical products for the treatment of cancer and other underserved therapeutic needs. We aim to acquire rights to these technologies by licensing or otherwise acquiring an ownership interest, funding their research and development and eventually out-licensing or bringing the technologies to market. Currently we are developing ublituximab (TGTX-1101), a novel, third generation monoclonal antibody that targets a specific and unique epitope on the CD20 antigen found on mature B-lymphocytes.

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

TGTX-1101 has demonstrated both safety and preliminary clinical efficacy in a recently completed Phase I clinical trial in relapsed and refractory patients with Chronic Lymphocytic Leukemia (“CLL”).

Our portfolio of product candidates is summarized below:

- TGTX-1101 (ublituximab), an anti-CD20 monoclonal antibody for oncology and B-cell related disorders
- AST-726, a nasally delivered form of hydroxocobalamin for the treatment of vitamin B<sub>12</sub> deficiency

The Company has discontinued development of the topical GEL for the treatment of mild psoriasis.



We also actively engage in business development activities that include seeking strategic relationships for our product candidates, as well as evaluating compounds and companies for in-licensing or acquisition. 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.

## **CORPORATE INFORMATION**

We were incorporated in Delaware in 1993. Our executive offices are located at 787 Seventh Avenue, New York, New York 10019. Our telephone number is 212-554-4484, and our e-mail address is info@tgtxinc.com.

We file reports with the SEC on an annual basis using Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K. You may read and copy any such reports and amendments thereto at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549 on official business days during the hours of 10:00 a.m. to 3:00 p.m. Please call the SEC at 1-800-SEC-0330 for information on the Public Reference Room. Additionally, the SEC maintains a website that contains annual, quarterly, and current reports, proxy statements, and other information that issuers (including us) file electronically with the SEC. The SEC's website address is <http://www.sec.gov>.

## **RECENT DEVELOPMENTS**

### *Exchange Transaction with TG Therapeutics, Inc. and its majority shareholders*

On December 29, 2011, the Company entered into and consummated an Exchange Transaction Agreement with Opus Point Partners, LLC ("Opus") and TG Therapeutics, Inc. ("TG") (the "Agreement").

Under the Agreement, Opus exchanged (the "Exchange Transaction") its shares of common stock in TG ("TG Common Stock") for shares of Series A preferred stock in the Company ("Company Preferred Stock"). The exchange ratio was \$2.25, divided by \$.04, divided by 500. As a result Opus received 281,250 shares of Company Preferred Stock. Furthermore, the Agreement provides that each holder of restricted TG Common Stock outstanding on December 29, 2011 receive restricted shares of Company Preferred Stock using the same exchange ratio, and such shares will carry the same restrictions that existed prior to the execution of the Agreement.

As a result of the Agreement, TG Therapeutics, Inc. became a majority-owned subsidiary of the Company. Since the stockholders of TG received the majority of the voting shares of the Company, the merger was accounted for as a reverse acquisition whereby TG was the accounting acquirer (legal acquiree) and the Company was the accounting acquiree (legal acquirer) under the acquisition method of accounting.

***TGTX-1101 (ublituximab)***

In April 2011, TG acquired from LFB Biotechnologies, a fully owned subsidiary of France based LFB S.A., an option (the "License Option") for exclusive worldwide rights (except France/Belgium) to develop and market ublituximab ("LFB-R603"), a monoclonal antibody that targets a specific epitope on the B-cell lymphocyte CD20 antigen.

On January 30, 2012, TG Therapeutics exercised the License Option and entered into a license agreement with GTC Biotherapeutics, Inc., LFB Biotechnologies S.A.S. ("LFB"), and LFB/GTC LLC, all wholly-owned subsidiaries of LFB Group. In connection with the license agreement, TG Therapeutics issued 7,368,000 shares of its common stock to LFB, and the Company agreed to contribute \$15 million, less applicable fees and expenses associated with the financing, to TG Therapeutics to fund the development of ublituximab under the license agreement, in exchange for 7,500,000 shares of TG Therapeutics common stock.

In addition, in connection with the issuance of 7,368,000 TG Therapeutics shares, the Company and TG Therapeutics provided LFB Group, the option to, in its sole discretion, elect to convert all, and not less than all, of the TG Therapeutics' shares into 828,900 shares of Manhattan's Series A Preferred Stock, \$0.001 par value per share. Each share of Manhattan preferred stock shall be convertible into 500 shares of Manhattan's common stock, \$0.001 par value per share, in accordance with the terms of the Series A Preferred Stock Certificate of Designation filed with the Secretary of State of the State of Delaware on December 29, 2011. In addition, should Manhattan have sufficient common stock authorized and available for issuance at the time the Purchaser elects to convert, then Purchaser will receive such number of shares of Manhattan Common Stock into which the Manhattan Preferred Stock is then convertible. This option may be exercised by LFB Group at any time within 60 days of the filing of Manhattan's Annual Report on Form 10-K for the year ended December 31, 2011.

**PRODUCTS UNDER DEVELOPMENT**

***TGTX-1101 (ublituximab)***

*Overview*

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

Multiple preclinical studies both *in vitro* and *in vivo* produced data that support the activity and potency of ublrituximab as an efficient and selective B-cell targeting anti-CD20 antibody with the ability to effectively deplete B lymphocytes in both malignant laboratory cell models as well as NHL and CLL patient donor cell lines. B-cell depletion has been demonstrated to occur through three primary mechanisms: direct or programmed cell death (“DCD” or “PCD”), complement dependent cytotoxicity (“CDC”), and antibody dependent cell-mediated cytotoxicity (“ADCC”) - the primary mechanism for which ublrituximab has been bio-engineered for enhanced activity.

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

Manufacturing of ublituximab is currently performed by our partner, LFB Biotechnologies, using mammalian cells with plans to explore a second manufacturing method utilizing a transgenic animal vector developed by GTC Biotherapeutics, a wholly owned subsidiary of LFB S.A. To date, both LFB and GTC have invested in excess of a combined \$60 million in direct expenses related to the development of ublituximab.

#### *Pre-Clinical Data Overview*

The mechanism of action of anti-CD20 antibodies, including rituximab and ublituximab has been elucidated and detailed in numerous academic and clinical studies. Upon conjugation of the antibody to the CD20 surface antigen, rituximab has been found to deplete B-lymphocytes through three primary mechanisms: direct cell death (“DCD” or “programmed cell death” or “PCD”), complement dependent cytotoxicity (“CDC”), and antibody dependent cell-mediated cytotoxicity (“ADCC”).

In programmed cell death, the binding of the antibody ligand to the CD20 antigen leads to the activation of apoptotic signaling pathways which include caspase-3, caspase-9, and the bcl-2 family of proteins. The resulting signaling cascade induces apoptosis of the B-lymphocyte, and has been found to be enhanced by hyper-crosslinking of antibodies and the binding of the Fc region of the antibody to an Fc $\gamma$ R receptor on effector cells such as natural killer (“NK”) cells, macrophages, neutrophils or monocytes. Additionally anti-CD20 antibodies such as rituximab can induce non-apoptotic programmed cell death via vacuolar or lysosomal mechanisms.

Cell depletion via complement dependent cytotoxicity occurs when binding of the antibody to the CD20 epitope leads to activation of the complement immune system. The C1q component of the complement system binds to the Fc portions of the complexed anti-CD20 antibody, triggering a “complement cascade” of proteolytic events eventually leading to the formation of a membrane attack complex (“MAC”) which lyses the cell via osmotic influx. Alternatively, the complement cascade can trigger the opsonization of the B-cell by the C3b component which strongly targets the cell for phagocytosis by macrophages and neutrophils.

Antibody dependent cellular cytotoxicity is a mechanism that is dependent on interactions between the Fc region of the antibody and the Fc $\gamma$ R receptors on immune system effector cells, most notably the Fc $\gamma$ RIIIA (“CD16”) receptor found on NK cells. Fc-Fc $\gamma$ R interactions trigger cells to release pre-forming proteins and proteases resulting in B-cell death. Empirically, ADCC has been the most heavily described and studied mechanism of action, and the subsequent focal point in the research and development of improved CD20 targeted antibodies.

Ublituximab is a type I chimeric murine/human IgG1 monoclonal antibody with an engineered Fc region designed specifically to induce higher ADCC activity in comparison to rituximab. The antibody consists of 37% murine variable regions fused to 63% human constant regions.



*In vitro* preclinical testing has confirmed the superior ADCC induction ability of ublituximab over rituximab (see *Figure 1*). Tested on CLL patient donor B-cell samples at concentrations of 50 ng/mL, ublituximab produces ADCC activity of 35%, while rituximab was found to exhibit ADCC levels of only 5% at the same concentration.

**Figure 1:** ADCC activity of ublituximab (black) in comparison to rituximab (white) at equivalent concentrations. Cell lysis measured with calcein acetoxymethylester with  $\%ADCC = (\%lysis\ in\ presence\ of\ mAb) - (\%lysis\ without\ mAb)$

Ublituximab has also demonstrated significant CDC activity *in vitro*, competitive with rituximab when tested in an assay utilizing both Raji and Wi12S B-cell Lymphoma cell lines. Further *in vitro* studies have been conducted to evaluate the mechanism by which ublituximab affects apoptotic signaling pathways. Binding of ublituximab to the CD20 antigen was found to inhibit the NF- $\kappa$ B survival pathway which is often seen constitutively active in cancer cell lines, including NHL (see *Figure 2*). Deactivation of the NF- $\kappa$ B survival pathway causes inhibition of the Snail transcription factor which, when active, plays a role in repressing RKIP and PTEN, two pro-apoptotic genes. Once Snail is inactivated, RKIP and PTEN expression is unrepressed, leading to further inhibition of the NF- $\kappa$ B pathway by RKIP and inhibition of the PI3/Akt survival pathway by PTEN. The end result of these signaling alterations by ublituximab is the sensitization of the cell to apoptotic factors such as the TNF-related apoptosis inducing ligand (“TRAIL”) and chemotherapeutic agents. The Company believes these findings may suggest an enhanced synergistic ability of ublituximab when delivered in combination with chemotherapeutic agents in the treatment of B-cell proliferative diseases, leading to improved therapeutic outcomes.

**Figure 2:** Inhibition of the NF- $\kappa$ B pathway sensitizes cells to TRAIL induced apoptosis. R603 displays superior TRAIL sensitizing ability compared to RTX. Apoptosis measured by caspase 3 levels (an apoptotic signaling protein)

Ublituximab was also studied *in vivo* in severe combined immunodeficient (“SCID”) mice and cynomolgus monkeys. SCID mice with Mantle Cell Lymphoma (“MCL”) xenografts displayed markedly delayed tumor volume growth when treated with ublituximab compared with equivalent doses of rituximab. The inhibition of tumor growth by ublituximab is greater than rituximab at 4 dosage levels ranging from 3 mg/kg to 60 mg/kg (*see Figure 3*).

**Figure 3:** *Influence of ublituximab (LFB-R603) vs. rituximab on tumor volume in xenograft MCL SCID mice. At equivalent dosages, LFB-R603 displays a markedly superior influence on tumor growth in comparison to rituximab.*

In further *in vivo* studies, B-cell lymphocyte levels were observed in cynomolgus monkeys administered a single IV injection of ublituximab at varying concentrations. At the lowest dosage point of 0.3 mg/kg, depletion of B-cell lymphocytes was sustained for 77 days and recovered to only 16% of basal level at day 130 (*see Figure 4*).

**Figure 4:** *B-cell lymphocyte levels observed in cynomolgus monkeys following single IV injection of ublituximab at varying dosage levels.*

Additional pre-clinical studies of ublituximab, including *in vivo* assays in combination with chemotherapeutic agents, were presented in abstract and poster form at the 53<sup>rd</sup> Annual American Society of Hematology Meeting in San Diego, CA in December 2011. As a result of the elucidation of the mechanism of action of ublituximab, and observance of its performance in various *in vitro* and *in vivo* assays in comparison to the gold standard, rituximab, the Company believes ublituximab is an active and potent CD20 targeted antibody.

#### *Clinical Data Overview*

A multicenter, open-label Phase I clinical trial of ublituximab was recently completed which aimed to assess the safety, tolerability, and efficacy of ublituximab in patients with relapsed or refractory CLL. This two part, first-in-man, dose escalating trial was conducted in 9 centers in France with preliminary results from Parts 1 and 2 presented at the 52<sup>nd</sup> and 53<sup>rd</sup> Annual American Society of Hematology (“ASH”) meetings.

The study included patients who had relapsed or refractory CLL following at least one prior course of fludarabine and were between the ages of 18 and 80 years old. Patients were excluded if they had prior treatment with any anti-CD20 monoclonal antibody within the 6 months prior to enrollment, displayed a creatinine clearance level below 60 mL/mn, or had an ALT and/or AST level greater than 1.5N.

In Part 1 of this trial, 21 patients were enrolled with a median age of 62 years. Disease status included 20 CLL patients relapsed and 1 CLL patient refractory to treatment with 12 patients (57%) having had prior exposure to rituximab. All patients (100%) displayed lymph node enlargement with 8 patients (38%) considered “Bulky” (>5cm).



The study regimen in Part 1 involved 21 patients receiving infusions of ublituximab at a dose ranging from 5mg to 450mg once weekly over the course of 4 weeks. Premedication consisted of allopurinol, dexchlorpheniramine and paracetamol combined with methylprednisolone at 1 mg/kg prior to the first two infusions. Patients were assessed at week 16 with a follow up assessment at week 24 for those patients displaying a partial response (“PR”) at week 16.

The patients were divided into 5 dosing cohorts with dosages escalated based on safety in a 3+3 design. Total dosage over 4 weeks ranged from 75 mg in cohort A to 1650 mg in cohort E (*see Figure 5*).

**Figure 5:** *Dosage levels for each cohort in Part 1 of Phase I/II study of ublituximab*

Adverse events were consistent with those exhibited by other anti-CD20 antibodies and consisted mostly of infusion related reactions, infection, headache, neutropenia, thrombocytopenia and transient elevation of AST/ALT levels. Assessing patients according to the National Cancer Institute-Working Group (“NCI/WG”) CLL guidelines, 5 out of 18 (28%) of evaluable patients were in partial response (“PR”) at week 16 in Part 1, with three of these five having confirmed PR at week 24.

Part 2 of this study evaluated the safety and efficacy profile of ublituximab when administered in an 8-dose regimen (150mg initial dose, followed by 7 doses of 450mg). Inclusion criteria were the same as Part 1, with 12 patients enrolled, having a median age of 69.5 years, and a median of 3 prior therapies. Seven of these patients had received at least one prior rituximab containing regimen.

Adverse events were similar to Part 1 of this study, with the most frequent being infusion related reactions, neutropenia, pyrexia, and thrombocytopenia. All AEs were reversible spontaneously or with supportive care.

Rapid, near total blood lymphocyte depletion was observed in all patients except one and was sustained up to 10 months after the last infusion of ublituximab. With efficacy assessment at month 4 according to NCI-WG guidelines following treatment, ublituximab was found to produce a durable PR in 5/11 (45%) evaluable patients. The Company intends to pursue additional Phase I and II trials to explore the use of ublituximab in CLL and other B-cell proliferative diseases.

*Market Opportunity*

Anti-CD20 antibodies have been approved and studied in a variety of diseases falling into several therapeutic areas including oncology, autoimmune disorders, and neurologic disease, creating a market with worldwide sales of roughly \$7 Billion in 2010. NHL and CLL are the most common B-cell proliferative diseases for which rituximab, the first anti-CD20 antibody approved by the FDA, is the current gold standard treatment. While the addition of rituximab to chemotherapeutic treatment of NHL has dramatically improved patient outcomes, there are still many drawbacks to the current standard of care.

Rituximab's usage as a single agent for lymphoma has proved to be largely ineffective with half of patients refractory to treatment or relapsing shortly following therapy. Patients with CLL have been shown to be poor responders to rituximab treatment, an outcome attributed to weak expression of the CD20 cell surface antigen on B-CLL lymphocytes.

Rituximab resistance is becoming an increasing concern for clinicians as relapsing patients are exposed to multiple lines of rituximab containing regimens to treat recurrence of disease. Approximately half of patients initially responsive to their first exposure to rituximab do not respond upon retreatment.

We believe these factors contribute to an immediate and sustained need for anti-CD20 monoclonal antibody that is differentiated and therapeutically superior to the gold standard rituximab in order to extend and enhance CD20 therapy as it stands today.

### **AST-726**

AST-726 is a nasally delivered form of hydroxocobalamin for the treatment of Vitamin B<sub>12</sub> deficiency. The Company acquired global rights to AST-726 as part of the Ariston acquisition. AST-726 has demonstrated pharmacokinetic equivalence to a marketed intramuscular injection product for Vitamin B<sub>12</sub> remediation. The Company believes that AST-726 may enable both a single, once-monthly treatment for maintenance of normal Vitamin B<sub>12</sub> levels in deficient patients, and more frequent administration to restore normal levels in newly diagnosed B<sub>12</sub> deficiency. Further, we believe that AST-726 could offer a convenient, painless, safe and cost-effective treatment for Vitamin B<sub>12</sub> deficiency, eliminating the need for intramuscular injections.

The Company has reached an agreement with the U.S. Food and Drug Administration (FDA) on a special protocol assessment (SPA) for the design of a Phase 3 clinical trial of AST-726 in patients with a confirmed medical history of Vitamin B<sub>12</sub> deficiency. The Company has designed an open label, multicenter study for investigating the maintenance of trough serum cobalamin levels after monthly administration of AST-726, with a goal of enrolling approximately 75 subjects and a goal of having 53 evaluable subjects complete the study.

The Company is currently reviewing its development plans for AST-726, which may include: (1) ceasing further development and attempting to sell or license AST-726, (2) continuing development as originally contemplated under the SPA or (3) evaluating and implementing alternative development plans. No decision has been made as to which approach to execute. A final decision is expected to take 6-12 months, but may occur earlier or later.

The Company has a sponsored research arrangement for AST-915, an orally delivered treatment for essential tremor, which is currently ongoing and we expect to conclude in June 2012. It is unlikely that the Company will continue the development of AST-915 thereafter, but a final determination will be reserved until development activities have concluded.

The Company has discontinued development of the topical GEL for the treatment of mild psoriasis.

### **COSTS AND TIME TO COMPLETE PRODUCT DEVELOPMENT**

The information below provides estimates regarding the costs associated with the completion of the current development phase and our current estimated range of the time that will be necessary to complete that development phase for our key pipeline products. We also direct your attention to the risk factors which could significantly affect our ability to meet these cost and time estimates found in this report in Item 1A under the heading "Risks Related to

Manhattan's Business and Industry."

Product candidate	Target indication	Development status	Completion of phase	Estimated cost to complete phase
TGTX-1101 (ublituximab)	Multiple forms of cancer and various autoimmune diseases	Phase I/II	Mid-2014	Approximately \$4 million

Completion dates and costs in the above table are estimates due to the uncertainties associated with clinical trials and the related requirements of development. In the cases where the requirements for clinical trials and development programs have not been fully defined, or are dependent on the success of other trials, we cannot estimate trial completion or cost with any certainty. The actual spending on each trial during the year is also dependent on funding. We therefore direct your attention to Item 7 under the heading "Liquidity and Capital Resources."

## INTELLECTUAL PROPERTY AND PATENTS

### *General*

Our goal is to obtain, maintain and enforce patent protection for our products, formulations, processes, methods and other proprietary technologies, preserve our trade secrets, and operate without infringing on the proprietary rights of other parties, both in the United States and in other countries. Our policy is to actively seek to obtain, where appropriate, the broadest intellectual property protection possible for our product candidates, proprietary information and proprietary technology through a combination of contractual arrangements and patents, both in the U.S. and elsewhere in the world.

We also depend upon the skills, knowledge and experience of our scientific and technical personnel, as well as that of our advisors, consultants and other contractors. This knowledge and experience we call "know-how." To help protect our proprietary know-how which is not patentable, and for inventions for which patents may be difficult to enforce, we rely on trade secret protection and confidentiality agreements to protect our interests. To this end, we require all employees, consultants, advisors and other contractors to enter into confidentiality agreements which prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business.

Patents and other proprietary rights are crucial to the development of our business. We will be able to protect our proprietary technologies from unauthorized use by third parties only to the extent that our proprietary rights are covered by valid and enforceable patents, supported by regulatory exclusivity or are effectively maintained as trade secrets. We have a number of patents and patent applications related to our compounds and other technology, but we cannot guarantee the scope of protection of the issued patents, or that such patents will survive a validity or enforceability challenge, or that any of the pending patent applications will issue as patents.

Generally, patent applications in the U.S. are maintained in secrecy for a period of 18 months or more. Since publication of discoveries in the scientific or patent literature often lag behind actual discoveries, we are not certain that we were the first to make the inventions covered by each of our pending patent applications or that we were the first to file those patent applications. The patent positions of biotechnology and pharmaceutical companies are highly uncertain and involve complex legal and factual questions. Therefore, we cannot predict the breadth of claims allowed in biotechnology and pharmaceutical patents, or their enforceability. To date, there has been no consistent policy regarding the breadth of claims allowed in biotechnology patents. Third parties or competitors may challenge or circumvent our patents or patent applications, if issued. If our competitors prepare and file patent applications in the U.S. that claim technology also claimed by us, we may have to participate in interference proceedings declared by the U.S. Patent and Trademark Office to determine priority of invention, which could result in substantial cost, even if the eventual outcome is favorable to us. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that before we commercialize any of our products, any related patent may expire or remain in existence for only a short period following commercialization, thus reducing any advantage of the patent. However, the life of a patent covering a product that has been subject to regulatory approval may have the ability be extended through the patent restoration program, although any such extension could still be minimal.

If a patent is issued to a third party containing one or more preclusive or conflicting claims, and those claims are ultimately determined to be valid and enforceable, we may be required to obtain a license under such patent or to develop or obtain alternative technology. In the event of litigation involving a third party claim, an adverse outcome in the litigation could subject us to significant liabilities to such third party, require us to seek a license for the disputed rights from such third party, and/or require us to cease use of the technology. Further, our breach of an existing license or failure to obtain a license to technology required to commercialize our products may seriously harm our business. We also may need to commence litigation to enforce any patents issued to us or to determine the scope and validity of third-party proprietary rights. Litigation would involve substantial costs.

#### **TGTX-1101**

Pursuant to our license for TGTX-1101 (ublituximab) with LFB Biotechnologies, GTC Biotherapeutics, and LFB/GTC LLC, we have the exclusive commercial rights to a series of patents and patent applications in the U.S., and in multiple countries around the world. These patents and patent applications include composition of matter patents relating to the structure and mechanism of action for ublituximab as well as method of use patents which cover use of ublituximab in combination with various agents and for various therapeutic indications.

**AST-726**

The Company has patent rights and other intellectual property relating to AST-726:

U.S. Patent No. 5,801,161 entitled, "Pharmaceutical composition for the intranasal administration of hydroxocobalamin." Franciscus W.H.M. Merkus, Inventor. Application filed June 17, 1996. Patent issued September 1, 1998. This patent is scheduled to expire on September 1, 2015.

European Patent No. EP0735859B1 (granted July 30, 1997, national phase of PCT Publication No. WO9517164) entitled, "Pharmaceutical composition for the intranasal administration of hydroxocobalamin." Franciscus W.H.M. Merkus, Inventor. Application filed May 13, 1994. Patents validated in Great Britain, Austria, Belgium, Denmark, France, Ireland, Italy, the Netherlands, Switzerland, Germany, Spain, and Sweden are scheduled to expire on May, 13, 2014.

## **AST-915**

The Company has patent rights and other intellectual property relating to AST-915:

U.S. Patent Application No. PCT/US2009/000876 entitled “Octanoic acid formulations and methods of treatment using the same.” McLane, Nahab, and Hallet, Inventors. Application filed February 12, 2009. This application has not yet issued as a patent.

The patent rights that we own or have licensed relating to our product candidates are limited in ways that may affect our ability to exclude third parties from competing against us if we obtain regulatory approval to market these product candidates. See section “*Risks Related to the Company’s Intellectual Property.*”

Proof of direct infringement by a competitor for method of use patents can prove difficult because the competitors making and marketing a product typically do not engage in the patented use. Additionally, proof that a competitor contributes to or induces infringement of a patented method of use by another can also prove difficult because an off-label use of a product could prohibit a finding of contributory infringement and inducement of infringement requires proof of intent by the competitor.

Moreover, physicians may prescribe such a competitive identical product for indications other than the one for which the product has been approved, or off-label indications, that are covered by the applicable patents. Although such off-label prescriptions may directly infringe or contribute to or induce infringement of method of use patents, such infringement is difficult to prevent or prosecute.

In addition, the limited patent protection described above may adversely affect the value of our product candidates and may inhibit our ability to obtain a corporate partner at terms acceptable to us, if at all.

### ***Other Intellectual Property Rights***

We depend upon trademarks, trade secrets, know-how and continuing technological advances to develop and maintain our competitive position. To maintain the confidentiality of trade secrets and proprietary information, we require our employees, scientific advisors, consultants and collaborators, upon commencement of a relationship with us, to execute confidentiality agreements and, in the case of parties other than our research and development collaborators, to agree to assign their inventions to us. These agreements are designed to protect our proprietary information and to grant us ownership of technologies that are developed in connection with their relationship with us. These agreements may not, however, provide protection for our trade secrets in the event of unauthorized disclosure of such information.

In addition to patent protection, we may utilize orphan drug regulations or other provisions of the Food, Drug and Cosmetic Act of 1938, as amended, or FDCA, to provide market exclusivity for certain of our drug candidates. Orphan drug regulations provide incentives to pharmaceutical and biotechnology companies to develop and manufacture drugs for the treatment of rare diseases, currently defined as diseases that exist in fewer than 200,000 individuals in the U.S., or, diseases that affect more than 200,000 individuals in the U.S. but that the sponsor does not realistically anticipate will generate a net profit. Under these provisions, a manufacturer of a designated orphan-drug can seek tax benefits, and the holder of the first FDA approval of a designated orphan product will be granted a seven-year period of marketing exclusivity for such FDA-approved orphan product.

Pursuant to these regulations, TGTX-1101 (ublituximab) has received Orphan-Drug designation from the FDA for the treatment of CLL in August of 2010, and Orphan-Drug designation by the EMA for the treatment of CLL in November of 2009. We believe that TGTX-1101 may be eligible for additional orphan drug designations; however, we cannot assure that TGTX-1101, or any other drug candidates we may acquire or in-license, will obtain such orphan drug designations. Additionally, upon FDA approval, we believe that ublituximab would qualify as a New Chemical Entity, or NCE, which provides for five years of exclusivity following approval.

We cannot assure that any other drug candidates we may acquire or in-license, will obtain such orphan drug designation or that we will be the first to receive FDA approval for such drugs so as to be eligible for market exclusivity protection.

## **LICENSING AGREEMENTS AND COLLABORATIONS**

We have formed strategic alliances with a number of companies for the manufacture and commercialization of our products. Our current key strategic alliances are discussed below.



***LFB Biotechnologies S.A.S, GTC Biotherapeutics, LFB/GTC LLC.***

In January 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. Under the license agreement, we have acquired the exclusive worldwide rights (exclusive of France/Belgium) for the development and commercialization of TGTX-1101 (ublituximab). To date, we have made no payments to LFB Group and LFB Group is eligible to receive payments of up to an aggregate of approximately \$31.0 million upon our successful achievement of certain clinical development, regulatory and sales milestones, in addition to royalty payments on net sales of ublituximab. The license will terminate on a country by country basis upon the expiration of the last licensed patent right or 15 years after the first commercial sale of a product in such country, unless the agreement is earlier terminated.

## **COMPETITION**

Competition in the pharmaceutical and biotechnology industries is intense. Our competitors include pharmaceutical companies and biotechnology companies, as well as universities and public and private research institutions. In addition, companies that are active in different but related fields represent substantial competition for us. Many of our competitors have significantly greater capital resources, larger research and development staffs and facilities and greater experience in drug development, regulation, manufacturing and marketing than we do. These organizations also compete with us to recruit qualified personnel, attract partners for joint ventures or other collaborations, and license technologies that are competitive with ours. To compete successfully in this industry we must identify novel and unique drugs or methods of treatment and then complete the development of those drugs as treatments in advance of our competitors.

The drugs that we are attempting to develop will have to compete with existing therapies. In addition, a large number of companies are pursuing the development of pharmaceuticals that target the same diseases and conditions that we are targeting. Other companies have products or drug candidates in various stages of pre-clinical or clinical development to treat diseases for which we are also seeking to discover and develop drug candidates. Some of these potential competing drugs are further advanced in development than our drug candidates and may be commercialized earlier. Additional information can be found under Item 1A - Risk Factors – Other Risks Related to Our Business within this report.

## **SUPPLY AND MANUFACTURING**

We have limited experience in manufacturing products for clinical or commercial purposes. We currently do not have any manufacturing capabilities. We have established contract manufacturing relationships for the supply of

TGTX-1101 as part of our license agreement with LFB Biotechnologies, GTC Biotherapeutics, and LFB/GTC. As with any supply program, obtaining raw materials of the correct quality cannot be guaranteed and we cannot ensure that we will be successful in this endeavor.

At the time of commercial sale, to the extent possible and commercially practicable, we would seek to engage a back-up supplier for each of our product candidates. Until such time, we expect that we will rely on a single contract manufacturer to produce each of our product candidates under current Good Manufacturing Practice, or cGMP, regulations. Our third-party manufacturers have a limited number of facilities in which our product candidates can be produced and will have limited experience in manufacturing our product candidates in quantities sufficient for commercialization. Our third-party manufacturers will have other clients and may have other priorities that could affect their ability to perform the work satisfactorily and/or on a timely basis. Both of these occurrences would be beyond our control.

We expect to similarly rely on contract manufacturing relationships for any products that we may in-license or acquire in the future. However, there can be no assurance that we will be able to successfully contract with such manufacturers on terms acceptable to us, or at all.

Contract manufacturers are subject to ongoing periodic and unannounced inspections by the FDA, the Drug Enforcement Administration and corresponding state agencies to ensure strict compliance with cGMP and other state and federal regulations. Our contractors in Europe face similar challenges from the numerous European Union and member state regulatory agencies and authorized bodies. We do not have control over third-party manufacturers' compliance with these regulations and standards, other than through contractual obligations. If they are deemed out of compliance with cGMPs, product recalls could result, inventory could be destroyed, production could be stopped and supplies could be delayed or otherwise disrupted.

If we need to change manufacturers after commercialization, the FDA and corresponding foreign regulatory agencies must approve these new manufacturers in advance, which will involve testing and additional inspections to ensure compliance with FDA regulations and standards and may require significant lead times and delay. Furthermore, switching manufacturers may be difficult because the number of potential manufacturers is limited. It may be difficult or impossible for us to find a replacement manufacturer quickly or on terms acceptable to us, or at all.

## GOVERNMENT AND INDUSTRY REGULATION

Numerous governmental authorities, principally the FDA and corresponding state and foreign regulatory agencies, impose substantial regulations upon the clinical development, manufacture and marketing of our drug candidates, as well as our ongoing research and development activities. None of our drug candidates have been approved for sale in any market in which we have marketing rights. Before marketing in the U.S., any drug that we develop must undergo rigorous pre-clinical testing and clinical trials and an extensive regulatory approval process implemented by the FDA under the FDCA. The FDA regulates, among other things, the pre-clinical and clinical testing, safety, efficacy, approval, manufacturing, record keeping, adverse event reporting, packaging, labeling, storage, advertising, promotion, export, sale and distribution of biopharmaceutical products.

The regulatory review and approval process is lengthy, expensive and uncertain. We are required to submit extensive pre-clinical and clinical data and supporting information to the FDA for each indication or use to establish a drug candidate's safety and efficacy before we can secure FDA approval to market or sell a product in the U.S. The approval process takes many years, requires the expenditure of substantial resources and may involve ongoing requirements for post-marketing studies or surveillance. Before commencing clinical trials in humans, we must submit an IND to the FDA containing, among other things, pre-clinical data, chemistry, manufacturing and control information, and an investigative plan. Our submission of an IND may not result in FDA authorization to commence a clinical trial.

The FDA may permit expedited development, evaluation, and marketing of new therapies intended to treat persons with serious or life-threatening conditions for which there is an unmet medical need under its fast track drug development programs. A sponsor can apply for fast track designation at the time of submission of an IND, or at any time prior to receiving marketing approval of the new drug application, or NDA. To receive Fast Track designation, an applicant must demonstrate:

- that the drug is intended to treat a serious or life-threatening condition;

- that the drug is intended to treat a serious aspect of the condition; and

that the drug has the potential to address unmet medical needs, and this potential is being evaluated in the planned drug development program.

The FDA must respond to a request for fast track designation within 60 calendar days of receipt of the request. Over the course of drug development, a product in a fast track development program must continue to meet the criteria for fast track designation. Sponsors of products in fast track drug development programs must be in regular contact with the reviewing division of the FDA to ensure that the evidence necessary to support marketing approval will be developed and presented in a format conducive to an efficient review. Sponsors of products in fast track drug

development programs ordinarily are eligible for priority review of a completed application in six months or less and also may be permitted to submit portions of a NDA to the FDA for review before the complete application is submitted.

Sponsors of drugs designated as fast track also may seek approval under the FDA's accelerated approval regulations. Under this authority, the FDA may grant marketing approval for a new drug product on the basis of adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely, based on epidemiologic, therapeutic, pathophysiologic, or other evidence, to predict clinical benefit or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity. Approval will be subject to the requirement that the applicant study the drug further to verify and describe its clinical benefit where there is uncertainty as to the relation of the surrogate endpoint to clinical benefit or uncertainty as to the relation of the observed clinical benefit to ultimate outcome. Post-marketing studies are usually underway at the time an applicant files the NDA. When required to be conducted, such post-marketing studies must also be adequate and well-controlled. The applicant must carry out any such post-marketing studies with due diligence. Many companies who have been granted the right to utilize an accelerated approval approach have failed to obtain approval. Moreover, negative or inconclusive results from the clinical trials we hope to conduct or adverse medical events could cause us to have to repeat or terminate the clinical trials. Accordingly, we may not be able to complete the clinical trials within an acceptable time frame, if at all, and, therefore, could not submit the NDA to the FDA or foreign regulatory authorities for marketing approval.

Clinical testing must meet requirements for institutional review board oversight, informed consent and good clinical practices, and must be conducted pursuant to an IND, unless exempted.

For purposes of NDA approval, clinical trials are typically conducted in the following sequential phases:

*Phase 1:* The drug is administered to a small group of humans, either healthy volunteers or patients, to test for safety, dosage tolerance, absorption, metabolism, excretion, and clinical pharmacology.

*Phase 2:* Studies are conducted on a larger number of patients to assess the efficacy of the product, to ascertain dose tolerance and the optimal dose range, and to gather additional data relating to safety and potential adverse events.

*Phase 3:* Studies establish safety and efficacy in an expanded patient population.

*Phase 4:* The FDA may require Phase 4 post-marketing studies to find out more about the drug's long-term risks, benefits, and optimal use, or to test the drug in different populations.

The length of time necessary to complete clinical trials varies significantly and may be difficult to predict. Clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. Additional factors that can cause delay or termination of our clinical trials, or that may increase the costs of these trials, include:

slow patient enrollment due to the nature of the clinical trial plan, the proximity of patients to clinical sites, the eligibility criteria for participation in the study or other factors;

inadequately trained or insufficient personnel at the study site to assist in overseeing and monitoring clinical trials or delays in approvals from a study site's review board;

longer treatment time required to demonstrate efficacy or determine the appropriate product dose;

insufficient supply of the drug candidates;

adverse medical events or side effects in treated patients; and

ineffectiveness of the drug candidates.

In addition, the FDA, equivalent foreign regulatory authority, or a data safety monitoring committee for a trial may place a clinical trial on hold or terminate it if it concludes that subjects are being exposed to an unacceptable health

risk, or for futility. Any drug is likely to produce some toxicity or undesirable side effects in animals and in humans when administered at sufficiently high doses and/or for a sufficiently long period of time. Unacceptable toxicity or side effects may occur at any dose level at any time in the course of studies in animals designed to identify unacceptable effects of a drug candidate, known as toxicological studies, or clinical trials of drug candidates. The appearance of any unacceptable toxicity or side effect could cause us or regulatory authorities to interrupt, limit, delay or abort the development of any of our drug candidates and could ultimately prevent approval by the FDA or foreign regulatory authorities for any or all targeted indications.

Sponsors of drugs may apply for an SPA from the FDA. The SPA process is a procedure by which the FDA provides official evaluation and written guidance on the design and size of proposed protocols that are intended to form the basis for a new drug application. However, final marketing approval depends on the results of efficacy, the adverse event profile and an evaluation of the benefit/risk of treatment demonstrated in the Phase 3 trial. The SPA agreement may only be changed through a written agreement between the sponsor and the FDA, or if the FDA becomes aware of a substantial scientific issue essential to product safety or efficacy.

Before receiving FDA approval to market a product, we must demonstrate that the product is safe and effective for its intended use by submitting to the FDA an NDA containing the pre-clinical and clinical data that have been accumulated, together with chemistry and manufacturing and controls specifications and information, and proposed labeling, among other things. The FDA may refuse to accept an NDA for filing if certain content criteria are not met and, even after accepting an NDA, the FDA may often require additional information, including clinical data, before approval of marketing a product.

It is also becoming more common for the FDA to request a Risk Evaluation and Mitigation Strategy, or REMS, as part of a NDA. The REMS plan contains post-market obligations of the sponsor to train prescribing physicians, monitor off-label drug use, and conduct sufficient Phase 4 follow-up studies and registries to ensure the continued safe use of the drug.

As part of the approval process, the FDA must inspect and approve each manufacturing facility. Among the conditions of approval is the requirement that a manufacturer's quality control and manufacturing procedures conform to cGMP. Manufacturers must expend significant time, money and effort to ensure continued compliance, and the FDA conducts periodic inspections to certify compliance. It may be difficult for our manufacturers or us to comply with the applicable cGMP, as interpreted by the FDA, and other FDA regulatory requirements. If we, or our contract manufacturers, fail to comply, then the FDA may not allow us to market products that have been affected by the failure.

If the FDA grants approval, the approval will be limited to those disease states, conditions and patient populations for which the product is safe and effective, as demonstrated through clinical studies. Further, a product may be marketed only in those dosage forms and for those indications approved in the NDA. Certain changes to an approved NDA, including, with certain exceptions, any significant changes to labeling, require approval of a supplemental application before the drug may be marketed as changed. Any products that we manufacture or distribute pursuant to FDA approvals are subject to continuing monitoring and regulation by the FDA, including compliance with cGMP and the reporting of adverse experiences with the drugs. The nature of marketing claims that the FDA will permit us to make in the labeling and advertising of our products will generally be limited to those specified in FDA approved labeling, and the advertising of our products will be subject to comprehensive monitoring and regulation by the FDA. Drugs whose review was accelerated may carry additional restrictions on marketing activities, including the requirement that all promotional materials are pre-submitted to the FDA. Claims exceeding those contained in approved labeling will constitute a violation of the FDCA. Violations of the FDCA or regulatory requirements at any time during the product development process, approval process, or marketing and sale following approval may result in agency enforcement actions, including withdrawal of approval, recall, seizure of products, warning letters, injunctions, fines and/or civil or criminal penalties. Any agency enforcement action could have a material adverse effect on our business.

Should we wish to market our products outside the U.S., we must receive marketing authorization from the appropriate foreign regulatory authorities. The requirements governing the conduct of clinical trials, marketing authorization, pricing and reimbursement vary widely from country to country. At present, companies are typically required to apply for foreign marketing authorizations at a national level. However, within the European Union, registration procedures are available to companies wishing to market a product in more than one European Union member state. Typically, if the regulatory authority is satisfied that a company has presented adequate evidence of safety, quality and efficacy, then the regulatory authority will grant a marketing authorization. This foreign regulatory approval process, however, involves risks similar or identical to the risks associated with FDA approval discussed above, and therefore we cannot guarantee that we will be able to obtain the appropriate marketing authorization for any product in any particular country.

Failure to comply with applicable federal, state and foreign laws and regulations would likely have a material adverse effect on our business. In addition, federal, state and foreign laws and regulations regarding the manufacture and sale of new drugs are subject to future changes. We cannot predict the likelihood, nature, effect or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the U.S. or abroad.

**EMPLOYEES**

As of March 5, 2012, we had 5 full and part-time employees. None of our employees are represented by a collective bargaining agreement, and we have never experienced a work stoppage. We consider our relations with our employees to be good.



## **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. An investment in our securities is speculative in nature, involves a high degree of risk, and should not be made by an investor who cannot bear the economic risk of its investment for an indefinite period of time and who cannot afford the loss of its entire investment. You should carefully consider the following risk factors and the other information contained elsewhere in this Annual Report before making an investment in our securities.*

### **Risks Related to Manhattan’s Business and Industry**

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

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

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

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

In order to submit an Investigational New Drug application (“IND”) and Biologics License Application (“BLA”) to the FDA, it is necessary to submit all information on the clinical, non-clinical, chemistry, manufacturing, controls and

quality aspects of the product candidate. We rely on our licensing partners and, in some cases, third parties, to provide this data. If we are unable to obtain this data, or the data is not sufficient to meet the regulatory requirements, we may experience significant delays in our development programs. We currently do not have an active IND in the United States and no assurance can be given that we will be successful in obtaining an active IND. Without an active IND, we would be unable to conduct clinical trials in the United States, which would likely negatively impact the timelines discussed throughout this filing.

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

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

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

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

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

We plan on conducting additional Phase I and II clinical trials for ublituximab. If the results from these trials are different from those found in the completed Phase I clinical trial of ublituximab, we may need to terminate or revise our clinical development plan, which could extend the time for conducting our development program and could have a material adverse effect on our business.

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

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

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, EMA and any of the applicable European and other regulatory bodies 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 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 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 yet completed testing of any of our product candidates for the treatment of the indications for which we intend to seek product approval in humans, and we currently do not know the extent that adverse events, if any, will be observed in patients who receive any of its product candidates. To date, clinical trials using ublituximab and our other product candidates have demonstrated a toxicity profile that was deemed acceptable by the investigators performing such studies. Such interpretation may not be shared by future investigators or by the FDA and in the case of ublituximab, even if deemed acceptable for oncology applications, like the completed clinical trial, it may not be acceptable for diseases outside the oncology setting, and likewise for any other product candidates we may develop. Additionally, the severity, duration and incidence of adverse events may increase in larger study populations. With respect to TGTX-1101, the toxicity when manufactured under different conditions is not known, nor is the toxicity of transgenically derived ublituximab, and it is possible that additional and/or different adverse events may appear upon the human use of those formulations and those adverse events may arise with greater frequency, intensity and duration than in the current formulation. If any of our product candidates cause unacceptable adverse events in clinical trials, we may not be able to obtain marketing approval and generate revenues from its sale.

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

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

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

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

Delays in the commencement of clinical trials and delays in the receipt of data from preclinical or clinical trials conducted by third parties could significantly impact our product development costs. Before we can initiate clinical trials in the United States for our product candidates, we need to submit the results of preclinical testing, usually in

animals, to the FDA as part of an IND, along with other information including information about product chemistry, manufacturing and controls and its proposed clinical trial protocol for its product candidates.

We currently plan to rely on preclinical and clinical trial data from third parties for the IND submissions transgenically derived ublituximab. 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 TGTX-1101 or any other 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 animal studies to assess the potential safety and activity of the pharmaceutical product candidate. The conduct of the preclinical tests must comply with federal regulations and requirements including good laboratory practices (GLP).

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

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

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

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

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

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

Once a clinical trial has begun, patient recruitment and enrollment may be slower than we anticipate. Clinical trials may also be delayed as a result of ambiguous or negative interim results. Further, a clinical trial may be suspended or terminated by us, an IRB, an ethics committee or a Data 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 the product candidates for which we hold an exclusive license agreement, are still under development; manufacturing and process improvements implemented in the production of ublituximab, or any of our product candidates, may affect their ultimate activity or function.***

Ublituximab is in the initial stages of development and is currently manufactured in small batches for use in pre-clinical and clinical studies. Process improvements implemented to date have, and process improvements in the future may change the activity of the antibody, which may affect the safety and efficacy of the product. No assurance can be given that the material manufactured from any of the optimized processes will perform comparably to ublituximab as manufactured to date and used in currently available pre-clinical data and in early clinical trials reported in this or any previous filing. Additionally, future clinical trial results will be subject to the same level of uncertainty if, following such trials, additional process improvements are made, including without limitation, the introduction of transgenically derived ublituximab.

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

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

manage our operations in these subsidiaries and review equity investees effectively, or if we fail to manage our alliances, we may lose money in these countries and it may adversely affect our business and results of our operations.

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

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

The cancer indications for which we are developing our product, TGTX-1101, have a number of established therapies with which we will compete. Most major pharmaceutical companies and many biotechnology companies are aggressively pursuing new cancer development programs for the treatment of NHL, CLL, and other B-cell proliferative malignancies, including both therapies with traditional, as well as novel, mechanisms of action.

If approved, we expect TGTX-1101 to compete directly with Roche Group's Rituxan® (Rituximab), Spectrum Pharmaceutical's Zevalin® (<sup>90</sup>Y-Ibritumomab Tiuxetan), GlaxoSmithKline's Bexxar® (<sup>131</sup>I-Tositumomab), Dr. Reddy's Laboratories' Reditux®, and Genmab and GlaxoSmithKline's Arzerra® (Ofatumomab) among others, each of which is currently approved for the treatment of various diseases including NHL and CLL. New developments, including the development of other pharmaceutical technologies and methods of treating disease, occur in the pharmaceutical and life sciences industries at a rapid pace.

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

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

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

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

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

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

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

In most cases, our manufacturing partners are single source suppliers. It is expected that our manufacturing partners will be sole source suppliers from single site locations for the foreseeable future. Given this, any disruption of supply from these partners could have a material, long-term impact on our ability to supply products for clinical trials or commercial sale. Additionally, the proprietary transgenic technology that supports the manufacture of transgenically derived ublituximab is not easily transferrable, if at all, and it is expected that GTC will be the sole supplier of transgenically derived ublituximab at a single site for the foreseeable future. If the Company's suppliers do not deliver sufficient quantities of ublituximab on a timely basis, or at all, and in accordance with applicable specifications, there could be a significant interruption of our supply of ublituximab, which would adversely affect clinical development and commercialization of the product.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials, and will face an even greater risk if we sell our product candidates commercially. An individual may bring a liability claim against the Company if one of our product candidates causes, or merely appears to have caused, an injury. If we cannot successfully defend our self against product liability claims, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

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

We do not currently carry product liability insurance. However, we intend to obtain product liability insurance coverage for our clinical trials prior to the commencement of any such trials. Further, we intend to expand our insurance coverage to include the sale of commercial products if marketing approval is obtained for any of our product candidates. However, we may be unable to obtain this product liability insurance on commercially reasonable terms and with insurance coverage that will be adequate to satisfy any liability that may arise. On occasion, large judgments have been awarded in class action or individual lawsuits relating to marketed pharmaceuticals. A successful product liability claim or series of claims brought against the Company could cause its stock price to decline and, if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

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

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

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

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

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

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

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

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

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

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

As of March 1, 2012, the Company has 5 full and part time employees. We will need to expand our managerial, operational, financial and other resources in order to manage and fund our operations and clinical trials, continue research and development activities, and commercialize our product candidates. Our management and scientific personnel, systems and facilities currently in place may not be adequate to support our future growth. Our need to effectively manage our operations, growth, and various projects requires that we:

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

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

research, development and commercialization goals.

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

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

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

***If the Company fails to comply with healthcare regulations, it could face substantial penalties and its business, operations and financial condition could be adversely affected.***

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

***The Company uses biological and hazardous materials, and any claims relating to improper handling, storage or disposal of these materials could be time consuming or costly.***

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

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

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

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

## **Risks Relating to Acquisitions**

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

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

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

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

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

## **Risks Relating to the Company's Intellectual Property**

***The Company's success depends upon our ability to protect our intellectual property and proprietary technologies, and the intellectual property protection for our product candidates depends significantly on third parties.***

Our commercial success depends on obtaining and maintaining patent protection and trade secret protection for our product candidates and their formulations and uses, as well as successfully defending these patents against third-party challenges. If LFB Biotechnologies or any of our other licensors 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.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or our partners will be successful in protecting our product candidates by obtaining and defending patents. These risks and uncertainties include the following:

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



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

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

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

Our commercial success also depends upon our ability and the ability of any of our future collaborators to develop, manufacture, market and sell our product candidates without infringing the proprietary rights of third parties. Numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing products, some of which may be directed at claims that overlap with the subject matter of our intellectual property. For example, Roche has the Cabilly patents in the U.S. that block the commercialization of antibody products derived from a single cell line, like ublituximab. Also, Roche, Biogen Idec, and Genentech hold patents for the use of anti-CD20 antibodies utilized in the treatment of CLL in the U.S. Both of these patents are currently being challenged by third parties.

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

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

- obtain licenses, which may not be available on commercially reasonable terms, if at all;
- abandon an infringing product candidate or redesign its products or processes to avoid infringement;
- pay substantial damages, including treble damages and attorneys' fees, which we may have to pay if a court decides that the product or proprietary technology at issue infringes on or violates the third party's rights;
- pay substantial royalties, fees and/or grant cross licenses to our technology; and/or
- defend litigation or administrative proceedings which may be costly whether we win or lose, and which could result in a substantial diversion of our financial and management resources.

We have not conducted an extensive search of patents issued to third parties, and no assurance can be given that such patents do not exist, have not been filed, or could not be filed or issued, which contain claims covering its products, technology or methods. Because of the number of patents issued and patent applications filed in our technical areas or fields, we believe there is a significant risk that third parties may allege they have patent rights encompassing our products or methods.

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

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

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

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

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

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

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

### **Risks Relating to the Company’s Finances and Capital Requirements**

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

As of March 1, 2012, we had net cash on hand of approximately \$21,000,000. We believe that our cash on hand will sustain our operations for the next 24-30 months. As a result, we will need additional capital to continue our

operations beyond that time. We will need to seek additional sources of financing in the future, which might not be available on favorable terms, if at all, to continue our operations. If we do not succeed in raising additional funds on acceptable terms, we might be unable to complete planned preclinical and clinical trials or obtain approval of any of our product candidates from the FDA or any foreign regulatory authorities. In addition, we could be forced to discontinue product development, reduce or forego sales and marketing efforts and forego attractive business opportunities. Any additional sources of financing will likely involve the issuance of the Company's equity securities, which would have a dilutive effect on your holdings of our capital stock.

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

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

The Company was incorporated in December 1993. We have not yet demonstrated an ability to obtain regulatory approval for or commercialize a product candidate. Our short operating history makes it difficult to evaluate our business prospects and consequently, any predictions about our future performance may not be as accurate as they could be if we had a history of successfully developing and commercializing pharmaceutical or biotechnology products. The Company's prospects must be considered in light of the uncertainties, risks, expenses and difficulties frequently encountered by companies in their early stages of operations and the competitive environment in which we operate.

The Company has never been profitable, and, as of December 31, 2011, we had an accumulated deficit of approximately \$853,000. We have generated operating losses in all periods since the Company was incorporated. We expect to make substantial expenditures resulting in increasing operating costs in the future and our accumulated deficit may increase significantly as we expand development and clinical trial efforts for our product candidates. Our losses have had, and are expected to continue to have, an adverse impact on our working capital, total assets and stockholders' equity. Because of the risks and uncertainties associated with product development, we are unable to predict the extent of any future losses or when we will become profitable, if ever. Even if we achieve profitability, we may not be able to sustain or increase profitability on an ongoing basis.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Our directors, executive officers and principal stockholders beneficially own approximately 26% percent of our outstanding voting stock and, 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.*

During the last two fiscal years, our stock price has traded at a low of \$0.0175 in the fourth quarter of 2011 to a high of \$4.26 in the second quarter of 2010. The volatile price of our stock makes it difficult for investors to predict the value of their investment, to sell shares at a profit at any given time, or to plan purchases and sales in advance. A variety of factors may affect the market price of our common stock. These include, but are not limited to:

- The global economic crisis, which affected stock prices of many companies, and particularly many small pharmaceutical companies like ours;
- publicity regarding actual or potential clinical results relating to products under development by our competitors or us;
- delay or failure in initiating, completing or analyzing nonclinical or clinical trials or the unsatisfactory design or results of these trials;
- achievement or rejection of regulatory approvals by our competitors or us;

- announcements of technological innovations or new commercial products by our competitors or us;
- developments concerning proprietary rights, including patents;
- developments concerning our collaborations;
- regulatory developments in the United States and foreign countries;
- economic or other crises and other external factors;
- period-to-period fluctuations in our revenues and other results of operations;
- changes in financial estimates by securities analysts; and
- sales of our common stock.

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

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



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

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

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

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

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

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

*There is a risk of market fraud.*

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

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

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

- that a broker or dealer approve a person’s account for transactions in penny stocks; and
- the broker or dealer receives from the investor a written agreement to the transaction, setting forth the identity and quantity of the penny stock to be purchased.

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

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

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

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

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

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

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

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

## **ITEM 2. PROPERTIES.**

Our corporate and executive office is located in New York, New York. Our New York facilities consist of leased office space at 48 Wall Street, New York, New York 10005, and office space at 787 Seventh Avenue, 48<sup>th</sup> Floor, New York, New York 10019. The lease at 48 Wall Street expired on September 30, 2011 and we have continued to occupy the space on a month-to-month basis thereafter. In January 2012, the Company notified the landlord that March 2012 would be our final month in the space. We are not currently under a lease agreement at 787 Seventh Avenue. We believe that our existing facilities are adequate to meet our current requirements. We do not own any real property.

## **ITEM 3. 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 4. MINE SAFETY DISCLOSURES.**

This item is not applicable to the Company.

**PART II**

**ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.**

*Market Information*

Our common stock is listed on the Over the Counter Bulletin Board ("OTCBB") and during 2011 traded under the symbol "MHAN." Effective January 12, 2012 the Company began trading under the symbol "TGTX."

The following table sets forth the high and low closing sale prices of our common stock for the periods indicated.

<b>Fiscal Year Ended December 31, 2011</b>	<b>High</b>	<b>Low</b>
Fourth Quarter	\$0.20	\$0.02
Third Quarter	\$0.51	\$0.10
Second Quarter	\$0.85	\$0.28
First Quarter	\$1.65	\$0.63

*Holder*s

The number of record holders of our common stock as of March 1, 2012 was 327.

***Dividends***

We have never declared or paid any cash dividends on our common stock and do not anticipate paying any cash dividends in the foreseeable future. Any future determination to pay dividends will be at the discretion of our board of directors.

**Stock Repurchases**

We did not make any repurchases of our common stock during 2011.

***Securities Authorized for Issuance Under Equity Compensation Plans***

The following table provides information as of December 31, 2011, regarding the securities authorized for issuance under our equity compensation plans, consisting of the 1995 Stock Option Plan, and the 2003 Stock Option Plan.

**Equity Compensation Plan Information**

Plan Category	Number of securities to be issued upon exercise of outstanding options	Weighted-average exercise price of outstanding options	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
	(a)	(b)	(c)
Equity compensation plans approved by security holders	188,683	\$ 23.33	133,107
Equity compensation plans not approved by security holders	—	—	—
Total	188,683	\$ 23.33	133,107

For information about all of our equity compensation plans, see Note 4 to our Consolidated Financial Statements included in this report.

### **Recent Sales of Unregistered Securities**

On December 30, 2011, we completed an initial closing of the private placement of our securities, issuing 277,285,633 shares of Company Common Stock at a price per share of \$0.04 for total gross proceeds, before placement commissions and expenses, of \$11,091,425 (the “2011 Equity PIPE”). Investors also received warrants to purchase 69,321,424 shares of Company Common Stock. The warrants have an exercise price of \$0.04 per share and are exercisable for five years. The shares of Company Common Stock and warrants sold in the initial closing were offered and sold to accredited investors, including members of management, without registration under the Securities Act of 1933, as amended (the “Securities Act”), or state securities laws, in reliance on the exemptions provided by Section 4(2) of the Securities Act, and Regulation D promulgated thereunder and in reliance on similar exemptions under applicable state laws. Accordingly, the securities to be issued in the Offering have not been registered under the Securities Act, and until so registered, these securities may not be offered or sold in the United States absent registration or availability of an applicable exemption from registration. The placement agent received cash commissions equal to 10% of the gross proceeds of the Offering, five-year warrants to purchase shares of the Company’s stock equal to 10% of shares sold in the Offering, and a non-accountable expense allowance equal to two percent of the gross proceeds of the Offering for their expenses (not including up to \$80,000 of legal expenses and any blue sky fees, both of which were reimbursed by the Company).

In 2012, we completed two additional closings of the 2011 Equity PIPE. These closings were held on January 31, 2012, and February 24, 2012. In these closings, the Company issued 695,428 shares of our Series A Preferred Stock (“Preferred Stock”) at a price per share of \$20.00 for total gross proceeds, before placement commissions and expenses, of \$13,908,560. Each share of Series A Preferred Stock is convertible into 500 shares of the common stock of the Company (“Company Common Stock”) provided that such conversion rights are subject to sufficient available authorized shares of Company Common Stock, which the Company intends to accomplish through the amendment of its Certificate of Incorporation, or a reverse stock split, at the next meeting of stockholders. Investors also received warrants to purchase 86,928,500 shares of Company Common Stock. The warrants have an exercise price of \$0.04 per share and are exercisable for five years. The shares of Preferred Stock and warrants sold in these closings were offered and sold to accredited investors, including members of management, without registration under the Securities Act, or state securities laws, in reliance on the exemptions provided by Section 4(2) of the Securities Act, and Regulation D promulgated thereunder and in reliance on similar exemptions under applicable state laws. Accordingly, the securities to be issued in the Offering have not been registered under the Securities Act, and until so registered, these securities may not be offered or sold in the United States absent registration or availability of an applicable exemption from registration. The placement agent received cash commissions equal to 10% of the gross proceeds of the Offering, five-year warrants to purchase shares of the Company’s stock equal to 10% of shares sold in the Offering, and a non-accountable expense allowance equal to two percent of the gross proceeds of the Offering for their expenses.

#### **Activities Prior to the Exchange Transaction with TG Therapeutics, Inc.**

On February 3, 2009, we completed a private placement (the "2009 Private Placement") of 345 units, with each unit consisting of a 12% senior secured promissory note in the principal amount of \$5,000 and a warrant to purchase up to 166,667 shares of common stock at an exercise price of \$.09 per share which expires on December 31, 2013, for aggregate gross proceeds of \$1,725,000. The private placement was completed in three closings which occurred on November 19, 2008 with respect to 207 units, December 23, 2008 with respect to 56 units and February 3, 2009 with respect to 82 units.

All of the investors represented in the 2009 Private Placement represented that they were “accredited investors,” as that term is defined in Rule 501(a) of Regulation D under the Securities Act, and the sale of the units was made in reliance on exemptions provided by Regulation D and Section 4(2) of the Securities Act of 1933, as amended.

On February 9, 2011, the Company entered into a waiver and forbearance agreement (the “Extension Agreement”) with the requisite holders of the Secured 12% Notes whereby the holders of the notes (the “Noteholders”) agreed to forbear the exercise of their rights under the Notes and waive the default thereof until December 31, 2011. As part of the Extension Agreement, the Company agreed to take prompt steps to seek to reduce its outstanding indebtedness by permitting the Noteholders to convert the Secured 12% Notes into shares of the Company's common stock at a conversion price of \$0.50 per share and to amend the terms of the warrants issued with the Secured 12 % Notes to include a full-ratchet anti-dilution feature and an exercise price of \$0.50 per share. The Company obtained stockholder approval to, among other things, increase the number of its authorized common stock. The Secured 12% Notes became convertible into common stock at a conversion price of \$0.50, which triggered the antidilution rights of the

warrants issued with Secured 12% Notes, the warrants issued with the Convertible 12% Note and the warrants issued in the 2010 Equity Pipe. The Secured 12% Notes and interest thereon, amounting to \$676,072 at the time of conversion, converted into the right to receive 4,802,199 shares of the Company's common stock on September 15, 2011 (the "Secured Debt Conversion"). In connection with the Exchange Transaction with TG Therapeutics, Inc., the warrant holders of the 12% Notes agreed to waive their anti-dilution feature, in exchange for the exercise price being lowered to \$0.04, and the warrant life being adjusted to a five year term prior to the execution of the Exchange Transaction.

On March 2, 2010, we raised aggregate gross proceeds of approximately \$2,547,500 pursuant to a private placement of its securities (the "2010 Equity Financing"). The Company entered into subscription agreements (the "Subscription Agreements") with seventy-seven accredited investors (the "Investors") pursuant to which the Company sold an aggregate of 101.9 Units (as defined herein) for a purchase price of \$25,000 per Unit. Pursuant to the Subscription Agreements, the Company issued to each Investor units (the "Units") consisting of (i) 357,143 shares of common stock, \$0.001 par value per share (the "Common Stock" or "Shares") of the Company and (ii) 535,714 warrants (each a "Warrant" and collectively the "Warrants"), each of which will entitle the holder to purchase one additional share of Common Stock for a period of five years (each a "Warrant Share" and collectively the "Warrant Shares") at an exercise price of \$0.08 per share.

On April 8, 2010, we completed the final closing of the 2010 Equity Financing. In connection with the final closing, the Company sold an aggregate of 2.4 additional Units and received net proceeds of approximately \$51,700 after payment of an aggregate of \$8,300 of commissions and expense allowance to placement agent. In connection with the final closing, the Company also issued a warrant to purchase 12,857 shares of Common Stock at an exercise price of \$0.08 per share to the placement agent as additional compensation for its services.

Also in connection with the final closing on April 8, 2010, the holder of the Convertible 12% Note, exercised its option to convert its Convertible 12% Note (including all accrued interest thereon) into 16.88 Units. The conversion price was equal to the per Unit purchase price paid by the Investors in the 2010 Equity Financing.



All of the Investors represented that they were “accredited investors,” as that term is defined in Rule 501(a) of Regulation D under the Securities Act, and the sale of the Units was made in reliance on exemptions provided by Regulation D and Section 4(2) of the Securities Act of 1933, as amended.

The Company received net proceeds of approximately \$2.2 million after payment of an aggregate of \$300,000 of commissions and expense allowance to the Placement Agent, and approximately \$100,000 of other offering and related costs in connection with the private placement. In addition, the Company issued a warrant to purchase 3,652,146 shares of Common Stock at an exercise price of \$0.08 per share to the Placement Agent as additional compensation for its services.

The Company did not use any form of advertising or general solicitation in connection with the sale of the Units. The Shares, the Warrants and the Warrant Shares are non-transferable in the absence of an effective registration statement under the Act, or an available exemption therefrom, and all certificates are imprinted with a restrictive legend to that effect.

## **ITEM 7. 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 “Item 1A. 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 “Item 8. Financial Statements and Supplementary Data,” and our consolidated financial statements beginning on page F-1 of this report.

### **Overview**

We were incorporated in Delaware in 1993 under the name “Atlantic Pharmaceuticals, Inc.” and, in March 2000, we changed our name to “Atlantic Technology Ventures, Inc.” In 2003, we completed a “reverse acquisition” of privately held “Manhattan Research Development, Inc”. In connection with this transaction, we also changed our name to “Manhattan Pharmaceuticals, Inc.” From an accounting perspective, the accounting acquirer is considered to be Manhattan

Research Development, Inc. and accordingly, through December 29, 2011, the historical financial statements were those of Manhattan Research Development, Inc.

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

On December 29, 2011, we entered into and consummated an Exchange Transaction Agreement with Opus and TG. Under the Agreement, Opus exchanged its shares of TG Common Stock for shares of Series A Preferred Stock in the Company. The exchange ratio was \$2.25, divided by \$.04, divided by 500. As a result Opus received 281,250 shares of Company Preferred Stock. From an accounting perspective, the accounting acquirer is considered to be TG Therapeutics, Inc. and accordingly, the historical financial statements are those of TG Therapeutics, Inc. TG Therapeutics, Inc. was incorporated in Delaware in November 2010, but did not commence operations until April 2011, thus the historical financial statements of TG consists of only 2011.

We are a biopharmaceutical company focused on the development of a novel monoclonal antibody for the treatment of various B-cell proliferative disorders including lymphoma, leukemia, and auto-immune diseases. The Company may also pursue complementary technology and product acquisitions, in-licensing and investments.

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

Our research and development expenses consist primarily of expenses related to in-licensing of new product candidates, fees paid to consultants and outside service providers for clinical and laboratory development, facilities-related and other expenses relating to the design, development, manufacture, testing, and enhancement of our drug candidates and technologies. We expense our research and development costs as they are incurred. Research and development expenses for the year ended December 31, 2011 was \$327,283.

The following table sets forth the research and development expenses per project, for 2011.

	2011
Ublituximab	\$325,671
AST-726	—
AST-915	1,612
Total	\$327,283

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

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

For awards of options and restricted stock to consultants and other third-parties, compensation expense is determined at the “measurement date.” The expense is recognized over the vesting period of the award. Until the measurement date is reached, the total amount of compensation expense remains uncertain. We record compensation expense based on the fair value of the award at the reporting date. The awards to consultants and other third-parties are then revalued, or the total compensation is recalculated based on the then current fair value, at each subsequent reporting date. This results in a change to the amount previously recorded in respect of the equity award grant, and additional expense or a reversal of expense may be recorded in subsequent periods based on changes in the assumptions used to calculate fair value, such as changes in market price, until the measurement date is reached and the compensation expense is finalized. The Company did not grant any consultant options during the year ended December 31, 2011.

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****Year Ended December 31, 2011**

	Year ended December 31, 2011
Costs and expenses:	
Research and development:	
Non-cash compensation expense	\$-
Other research and development expenses	327,283
Total research and development expenses	327,283
General and administrative:	
Non-cash compensation expense	86,494
Other general and administrative expenses	468,197
Total general and administrative expenses	554,691
Other expense	
Interest and amortization on notes payable	(7,097 )
Total other expense	(7,097 )
Net loss	\$(889,071 )

*Non-Cash Compensation Expense (Research and Development).* No non-cash compensation expense (research and development) related to equity incentive grants was recorded during the year ended December 31, 2011. Non-cash compensation expense is related to grants of equity awards to research and development personnel and the recording of the related fair value of the awards over the respective vesting periods of the individual awards. We expect non-cash compensation expense (research and development) to increase in 2012 as we begin clinical trials with R-603 and hire personnel to manage those programs.

*Other Research and Development Expenses.* Other research and development expenses totaled \$327,283 for the year ended December 31, 2011. This expense was primarily related to a non-cash charge recorded associated with the stock issued to LFB Biotechnologies, for the license to TGTX-1101. We expect our other research and development costs to increase substantially in 2012 due to the commencement of our clinical development program for TGTX-1101.

*Non-Cash Compensation Expense (General and Administrative).* Non-cash compensation expense (general and administrative) related to equity incentive grants equaled \$86,494 for the year ended December 31, 2011. The non-cash compensation expense was primarily related to the period's expense for restricted stock grants to our chief

executive officer and chief financial officer. We expect non-cash compensation expense (general and administrative) to increase in 2012 as we hire additional personnel.

*Other General and Administrative Expenses.* Other general and administrative expenses totaled \$468,197 for the year ended December 31, 2011. This expense was primarily related to legal and financial advisory fees associated with the TG Therapeutics transaction. We expect our other general and administrative expenses in 2011 to increase substantially in 2012 as we hire additional staff, and build out our organization.

*Interest and amortization on notes payable.* Interest and amortization on notes payable totaled \$7,097 for the year ended December 31, 2011.

## **LIQUIDITY AND CAPITAL RESOURCES**

Our primary source of cash has been proceeds from the private placement of equity securities, and through debt financings. 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 December 31, 2011, we had \$9.7 million in cash, and cash equivalents. We currently anticipate that our cash and cash equivalents as of December 31, 2011, inclusive of our 2011 Equity PIPE closings subsequent to December 31, 2011, to be sufficient to fund our anticipated operating cash requirements for approximately 24-30 months from December 31, 2011. 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 year ended December 31, 2011 was \$86,577, which primarily related to general and administrative and research and development expenses associated with TG Therapeutics commencing operations and development of TGTX-1101.

For the year ended December 31, 2011, net cash provided by investing activities of \$10,386, which consisted of cash that was acquired in the Exchange Transaction between TG Therapeutics and the Company.

For the year ended December 31, 2011, net cash provided by financing activities of \$9,824,682, related to net proceeds from the issuance of the Company's common stock.

The Company did not use any form of advertising or general solicitation in connection with the sale of the Units. The Shares, the Warrants and the Warrant Shares are non-transferable in the absence of an effective registration statement under the Act, or an available exemption therefrom, and all certificates are imprinted with a restrictive legend to that effect.

### ***2011 Equity PIPE***

On December 30, 2011, we completed an initial closing of the private placement of our securities, issuing 277,285,633 shares of Company Common Stock at a price per share of \$0.04 for total gross proceeds, before placement commissions and expenses, of \$11,091,425 (the "2011 Equity PIPE"). Investors also received warrants to purchase 69,321,424 shares of Company Common Stock. The warrants have an exercise price of \$0.04 per share and are exercisable for five years. The shares of Company Common Stock and warrants sold in the initial closing were offered and sold to accredited investors, including members of management, without registration under the Securities Act, or state securities laws, in reliance on the exemptions provided by Section 4(2) of the Securities Act, and Regulation D promulgated thereunder and in reliance on similar exemptions under applicable state laws. Accordingly, the securities to be issued in the Offering have not been registered under the Securities Act, and until so registered,

these securities may not be offered or sold in the United States absent registration or availability of an applicable exemption from registration. The placement agent received cash commissions equal to 10% of the gross proceeds of the Offering, five-year warrants to purchase shares of the Company's stock equal to 10% of shares sold in the Offering, and a non-accountable expense allowance equal to two percent of the gross proceeds of the Offering for their expenses (not including up to \$80,000 of legal expenses and any blue sky fees, both of which were reimbursed by the Company).

In 2012, we completed two additional closings of the 2011 Equity PIPE. These closings were held on January 31, 2012, and February 24, 2012. In these closings, the Company issued 695,428 shares of our Series A Preferred Stock ("Preferred Stock") at a price per share of \$20.00 for total gross proceeds, before placement commissions and expenses, of \$13,908,560. Each share of Series A Preferred Stock is convertible into 500 shares of the common stock of the Company ("Company Common Stock") provided that such conversion rights are subject to sufficient available authorized shares of Company Common Stock, which the Company intends to accomplish through the amendment of its Certificate of Incorporation, or a reverse stock split, at the next meeting of stockholders. Investors also received warrants to purchase 86,928,500 shares of Company Common Stock. The warrants have an exercise price of \$0.04 per share and are exercisable for five years. The shares of Preferred Stock and warrants sold in these closings were offered and sold to accredited investors, including members of management, without registration under the Securities Act, or state securities laws, in reliance on the exemptions provided by Section 4(2) of the Securities Act, and Regulation D promulgated thereunder and in reliance on similar exemptions under applicable state laws. Accordingly, the securities to be issued in the Offering have not been registered under the Securities Act, and until so registered, these securities may not be offered or sold in the United States absent registration or availability of an applicable exemption from registration. The placement agent received cash commissions equal to 10% of the gross proceeds of the Offering, five-year warrants to purchase shares of the Company's stock equal to 10% of shares sold in the Offering, and a non-accountable expense allowance equal to two percent of the gross proceeds of the Offering for their expenses.

#### *Joint Venture Agreement*

On April 19, 2011, H Pharmaceuticals K/S (the "Hedrin JV"), of which the Company was a 15% limited partner at the time, filed a demand for arbitration against Thornton & Ross, LTD. ("T&R") with respect to alleged breaches by T&R of an Exclusive License Agreement (the "Hedrin License") dated June 28, 2007, which was originally entered into between the Company and T&R, and which the Company assigned in 2008 to the Hedrin JV, with T&R's consent. The Hedrin JV is seeking damages from T&R in the amount of approximately \$7,000,000. The Company was not a party to the initial arbitration demand.



On May 20, 2011, T&R filed an answer to the arbitration demand in which T&R asserted counterclaims against the Hedrin JV for alleged breaches by the Hedrin JV of the Hedrin License and for declaratory relief that the Hedrin License was properly terminated by T&R. In addition, T&R impleaded an individual (who is not associated with the Company), Nordic Biotech Venture Fund II K/S (an investment fund) and the Company, demanding arbitration against them based on alleged breaches of the Hedrin License and other related claims. The Company has recently been removed by the arbitrator as a party to the arbitration. T&R is seeking damages of approximately \$20,000,000.

The Hedrin JV and T&R held a mediation session in order to avoid the arbitration process. The mediation process did not produce a result. Nordic has recently made an additional capital contribution to the Hedrin JV in order to fund the arbitration. As a result of that capital contribution the Company now owns a 13% interest in the Hedrin JV. The arbitration process is ongoing.

#### ***SwissPharma Contract LLC Settlement***

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

#### **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.

#### **OBLIGATIONS AND COMMITMENTS**

##### *Leases*

Rent expense for the year ended December 31, 2011 was immaterial. The Company has no future minimum rental payments subsequent to December 31, 2011 under an operating lease for the Company's office facility, which expired on September 30, 2011.

## **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 financial statements requires us to make estimates and judgments that affect the reported amount of assets and liabilities and related disclosure of contingent assets and liabilities at the date of our financial statements and the reported amounts of revenues and expenses during the applicable period. Actual results may differ from these estimates under different assumptions or conditions.

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

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

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

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

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

based on our estimate of the degree of completion of the event or events specified in the specific clinical study or trial contract.

*Accounting Related to Goodwill.* As of December 31, 2011, there was approximately \$630,000 of goodwill on our consolidated balance sheet. Goodwill is reviewed for impairment annually, or when events arise that could indicate that an impairment exists. We test for goodwill impairment using a two-step process. The first step compares the fair value of the reporting unit with the unit's carrying value, including goodwill. When the carrying value of the reporting unit is greater than fair value, the unit's goodwill may be impaired, and the second step must be completed to measure the amount of the goodwill impairment charge, if any. In the second step, the implied fair value of the reporting unit's goodwill is compared with the carrying amount of the unit's goodwill. If the carrying amount is greater than the implied fair value, the carrying value of the goodwill must be written down to its implied fair value.

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

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

## **RECENTLY ISSUED ACCOUNTING STANDARDS**

In June 2011, the FASB issued ASU No. 2011-05, “Comprehensive Income (Topic 220): Presentation of Comprehensive Income” (ASU 2011-05). The new standard eliminated the current option to report other comprehensive income and its components in the statement of changes in equity. Under the new standard, companies can elect to present items of net income and other comprehensive income in one continuous statement or in two separate, but consecutive statements. The new standard is effective at the beginning of fiscal years beginning after December 15, 2011, and, if applicable, we will comply with this requirement in the first quarter 2012.

In September 2011, the FASB issued Accounting Standards Update No. 2011-08, *Testing Goodwill for Impairment* (the revised standard). The new standard allows companies an option to first assess qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount as a basis for determining if it is necessary to perform the two-step quantitative goodwill impairment test. Under the new standard, a company is no longer required to calculate the fair value of a reporting unit unless the company determines, based on the qualitative assessment, that it is more likely than not that its fair value is less than its carrying amount. The new standard is effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011.

## **ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURE 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 December 31, 2011, 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 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.**

Our consolidated financial statements and the notes thereto, included in Part IV, Item 15(a), part 1, are incorporated by reference into this Item 8.

## **ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.**

Not applicable.

## **ITEM 9A. CONTROLS AND PROCEDURES.**

*Evaluation of Disclosure Controls and Procedures.* As of December 31, 2011, we carried out an evaluation, under the supervision and with the participation of our Chief Executive Officer and our Chief Financial Officer, 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) of the Securities Exchange Act of 1934, as amended (the "Exchange Act")). Based upon that evaluation, our Chief Executive and Chief Financial Officers concluded that our disclosure controls and procedures were effective as of that date to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and to ensure that information required to be disclosed by us in such reports is accumulated and communicated to the our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure. There were no changes in our internal controls over financial reporting (as defined in Exchange Act Rules 13a – 15(f) and 15d – 15(f)) during the quarter ended December 31, 2011 that have materially affected, or is reasonably likely to materially affect, our internal controls over financial reporting.

Our disclosure controls or internal controls over financial reporting were designed to provide only reasonable assurance that such disclosure controls or internal control over financial reporting will prevent all errors or all instances of fraud, even as the same are improved to address any deficiencies. The design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be only reasonable, not absolute assurance that any design will succeed in achieving its stated goals under all potential future conditions. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs.

*Management's Report on Internal Control over Financial Reporting.* Our management is responsible for establishing and maintaining adequate internal control over financial reporting and for the assessment of the effectiveness of internal control over financial reporting. As defined by the SEC, internal control over financial reporting is a process designed by, or under the supervision of our principal executive and principal financial officers and effected by our Board of Directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of the financial statements in accordance with U.S. generally accepted accounting principles.

Our internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect our transactions and dispositions of our assets; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of the financial statements in accordance with U.S. generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In connection with the preparation of our annual financial statements, management has undertaken an assessment of the effectiveness of our internal control over financial reporting as of December 31, 2011, based on criteria established in Internal Control – Integrated framework issued by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO Framework. Management's assessment included an evaluation of the design of our internal control over financial reporting and testing of the operational effectiveness of those controls.

Based on this evaluation, management has concluded that our internal control over financial reporting is not effective as of December 31, 2011. This conclusion was reached because a lack of segregation of duties exists, as all financial and accounting duties are performed by the Chief Financial Officer. The Company intends to address this deficiency by hiring additional accounting personnel in 2012 to alleviate the segregation of duties issue.

This annual report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our independent registered public accounting firm pursuant to rules of the SEC that permit us to provide only management's report on internal control in this report.

*Limitations on the Effectiveness of Controls.* Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within our company have been detected.



**ITEM 9B. OTHER INFORMATION.**

Not Applicable.

**PART III**

**ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.**

The information required by this Item is incorporated herein by reference from our Proxy Statement for our 2012 Annual Meeting of Stockholders.

**ITEM 11. EXECUTIVE COMPENSATION.**

The information required by this Item is incorporated herein by reference from our Proxy Statement for our 2012 Annual Meeting of Stockholders.

**ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.**

The information required by this Item is incorporated herein by reference from our Proxy Statement for our 2012 Annual Meeting of Stockholders.

**ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE.**

The information required by this Item is incorporated herein by reference from our Proxy Statement for our 2012 Annual Meeting of Stockholders.

**ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES.**

The information required by this Item is incorporated herein by reference from our Proxy Statement for our 2012 Annual Meeting of Stockholders.

**PART IV**

**ITEM 15. EXHIBITS and FINANCIAL STATEMENT SCHEDULES.**

**(a)1. Consolidated Financial Statements**

The following consolidated financial statements of Manhattan Pharmaceuticals, Inc. are filed as part of this report.

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**2. Consolidated Financial Statement Schedules**

All schedules are omitted as the information required is inapplicable or the information is presented in the consolidated financial statements or the related notes.

**3. Exhibits**

**Exhibit  
Number Exhibit Description**

- 2.1 Agreement and Plan of Merger among the Registrant, Ariston Pharmaceuticals, Inc., and Ariston Merger Corp. dated March 8, 2010 (incorporated by reference to the Registrant's Current Report on Form 8-K filed

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March 12, 2010).

- 3.1 Certificate of Incorporation, as amended through September 25, 2003 (incorporated by reference to Exhibit 3.1 to the Registrant's Form 10-QSB for the quarter ended September 30, 2003).
- 3.2 Certificate of Designations of Series A Convertible Preferred Stock, dated October 31, 2003.
- 3.3 Certificate of Ownership Merging Tarpan Therapeutics, Inc. into the Registrant, dated December 28, 2006.
- 3.4 Certificate of Amendment to the Restated Certificate of Incorporation, dated November 30, 2009.
- 3.5 Certificate of Amendment to the Certificate of Incorporation, dated June 23, 2011 (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on June 29, 2011).
- 3.6 Certificate of Designations, Preferences and Other Rights of Series A Preferred Stock, dated December 29, 2011 (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on January 5, 2012).
- 3.7 Bylaws, as amended to date.
- 4.1 Specimen common stock certificate.
- 4.2 Form of Warrant issued to Noteholders on September 11, 2008 (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed on September 15, 2008).
- 4.3 Form of Warrant issued to Noteholders on November 19, 2008 (incorporated by reference to Exhibit 10.6 to the Registrant's Current Report on Form 8-K filed on November 25, 2008).

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- 10.1 1995 Stock Option Plan, as amended (incorporated by reference to Exhibit 10.18 to the Registrant's Form 10-QSB for the quarter ended September 30, 1996).
- Form of Notice of Stock Option Grant issued to employees of the Registrant from April 12, 2000 to February 21, 2003 (incorporated by reference to Exhibit 99.2 of the Registrant's Registration Statement on Form S-8 filed March 24, 1998 (File 333-48531)).
- 10.2
- Form of Stock Option Agreement issued to employees of the Registrant from April 12, 2000 to February 21, 2003 (incorporated by reference to Exhibit 99.3 to the Registrant's Registration Statement on Form S-8 filed March 24, 1998 (File 333-48531)).
- 10.3
- 10.4 2003 Stock Option Plan (incorporated by reference to Exhibit 4.1 to Registrant's Registration Statement on Form S-8 filed February 17, 2004).
- 10.5 Employment Agreement dated July 7, 2006 between the Registrant and Michael G. McGuinness (incorporated by reference to Exhibit 10.1 of the Registrant's Form 8-K filed July 12, 2006). †
- Amendment No. 1 to the Employment Agreement between the Registrant and Michael McGuinness, dated November 19, 2008 (incorporated by reference to Exhibit 10.8 to the Registrant's Current Report on Form 8-K filed on November 25, 2008). †
- 10.6
- Amendment No. 2 to the Employment Agreement between the Registrant and Michael McGuinness, dated December 15, 2011 (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on December 19, 2011). †
- 10.7
- 10.8 Summary terms of compensation plan for Registrant's non-employee directors (incorporated by reference to Exhibit 10.1 of Registrant's Current Report on Form 8-K filed February 5, 2007). †
- 10.9 Form of Stock Option Agreement issued under the Registrant's 2003 Stock Option Plan (incorporated by reference to Exhibit 10.15 to the Registrant's Form 10-KSB filed April 2, 2007).
- Exclusive License Agreement for "Altoderm" between Thornton & Ross Ltd. and Manhattan Pharmaceuticals, Inc. dated April 3, 2007 (incorporated by reference to Exhibit 10.3 of the registrant's form 10-Q for the quarter ended June 30, 2007 filed on August 14, 2007).
- 10.10
- Exclusive License Agreement for "Altolyn" between Thornton & Ross Ltd. and Manhattan Pharmaceuticals, Inc. dated April 3, 2007 (incorporated by reference to Exhibit 10.4 of the registrant's form 10-Q for the quarter ended June 30, 2007 filed on August 14, 2007).
- 10.11
- Exclusive License Agreement for "Hedrin" between Thornton & Ross Ltd. , Kerris, S.A. and Manhattan Pharmaceuticals, Inc. dated June 26, 2007 (incorporated by reference to Exhibit 10.5 of the registrant's form 10-Q for the quarter ended June 30, 2007 filed on August 14, 2007).
- 10.12
- Supply Agreement for "Hedrin" between Thornton & Ross Ltd. and Manhattan Pharmaceuticals, Inc. dated June 26, 2007 (incorporated by reference to Exhibit 10.6 of the Registrant's Form 10-Q for the quarter ended June 30, 2007 filed on August 14, 2007).
- 10.13

10.14

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Joint Venture Agreement between Nordic Biotech Fund II K/S and Manhattan Pharmaceuticals, Inc. to develop and commercialize “Hedrin” dated January 31, 2008 (incorporated by reference to Exhibit 10.19 of the Registrant’s Form 10-K filed March 31, 2008).

10.15 Amendment No. 1, dated February 25, 2008, to the Joint Venture Agreement between Nordic Biotech Fund II K/S and Manhattan Pharmaceuticals, Inc. to develop and commercialize “Hedrin” dated January 31, 2008 (incorporated by reference to Exhibit 10.20 to the Registrant's Form 10-K filed March 31, 2008).

10.16 Omnibus Amendment to Joint Venture Agreement and Additional Agreements, dated June 9, 2008, among Manhattan Pharmaceuticals, Inc., Hedrin Pharmaceuticals K/S, Hedrin Pharmaceuticals General Partner ApS and Nordic Biotech Venture Fund II K/S (incorporated by reference to Exhibit 10.1 to the Registrant’s Current Report on Form 8-K filed June 13, 2008).

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- Assignment and Contribution Agreement between Hedrin Pharmaceuticals K/S and Manhattan Pharmaceuticals, Inc. dated February 25, 2008 (incorporated by reference to Exhibit 10.21 to the Registrant's Form 10-K filed March 31, 2008).
- Registration Rights Agreement between Nordic Biotech Venture Fund II K/S and Manhattan Pharmaceuticals, Inc. dated February 25, 2008 (incorporated by reference to Exhibit 10.22 to the Registrant's Form 10-K filed March 31, 2008).
- Letter Agreement, dated September 17, 2008, between Nordic Biotech Venture Fund II K/S and Manhattan Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.24 to the Registrant's Amended Registration Statement on Form S-1/A filed on October 3, 2008).
- Form of Secured Promissory Note, dated September 11, 2008 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on September 15, 2008).
- Form of warrant issued to Note Holders, dated September 11, 2008 (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on September 15, 2008).
- Form of Placement Agent Warrant (incorporated by reference to Exhibit 10.9 to the Registrant's Current Report on Form 8-K filed on November 25, 2008).
- Warrant, dated October 28, 2009 (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K filed on November 3, 2009).
- Form of Placement Agent Warrant (incorporated by reference to Exhibit 10.4 to the Registrant's Current Report on Form 8-K filed on November 3, 2009).
- Settlement and Release Agreement, dated January 4, 2011, by and among the Registrant, Nordic Biotech Venture Fund II K/S and H Pharmaceuticals K/S (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on January 10, 2011).
- Waiver and Forbearance Agreement, dated January 10, 2011 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on February 14, 2011).
- Amended and Restated Convertible Promissory Note, dated March 1, 2011 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on March 7, 2011).
- Amendment to Settlement Agreement and Promissory Note between the Registrant and Swiss Pharma Contract Ltd., dated December 13, 2011 (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on December 19, 2011).
- Exchange Transaction Agreement dated December 29, 2011, by and among the Registrant, Opus Point Partners, LLC and TG Therapeutics, Inc. (incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on January 5, 2012).
- Employment Agreement, effective December 29, 2011, between the Registrant and Michael Weiss. †

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Restricted Stock Subscription Agreement, effective December 29, 2011, between the Registrant and Michael Weiss. †

10.32 Employment Agreement, effective December 29, 2011, between the Registrant and Sean Power. †

10.33 † Restricted Stock Subscription Agreement, effective December 29, 2011 between the Registrant and Sean Power.

10.34 Form of Warrant issued to stockholders on December 29, 2011, January 31, 2012 and February 24, 2012.



10.35 License Agreement, dated January 30, 2012, by and among the Registrant, GTC Biotherapeutics, Inc., LFB Biotechnologies S.A.S. and LFB/GTC LLC. \*

23.1 Consent of Independent Registered Public Accounting Firm

31.1 Certification of Principal Executive Officer

31.2 Certification of Principal Financial Officer

32.1 Certifications pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

† Indicates management contract or compensatory plan or arrangement.

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

Manhattan Pharmaceuticals, Inc.

**Consolidated Financial Statements as of December 31, 2011**

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**Report of Independent Registered Public Accounting Firm**

The Board of Directors and Stockholders

Manhattan Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheet of Manhattan Pharmaceuticals, Inc. and Subsidiaries (a development stage company) as of December 31, 2011, and the related consolidated statement of operations, equity and cash flows for the year and cumulative period then ended. Manhattan Pharmaceuticals, Inc.'s management is responsible for these financial statements. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Manhattan Pharmaceuticals, Inc. and Subsidiaries as of December 31, 2011, and their results of operations and cash flows for the year and cumulative period then ended, in conformity with accounting principles generally accepted in the United States of America.

/s/ J.H. Cohn LLP

Roseland, New Jersey

March 14, 2012

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**Manhattan Pharmaceuticals, Inc.**

(a development stage company)

**Consolidated Balance Sheet as of December 31, 2011**

Assets	
Current assets:	
Cash and cash equivalents	\$9,748,491
Other current assets	87,176
Total current assets	9,835,667
In-process research and development	5,441,839
Goodwill	629,752
Total assets	\$15,907,258
Liabilities and equity	
Current liabilities:	
Notes payable, current portion, net	\$877,778
Accounts payable and accrued expenses	666,640
Interest payable, current portion	61,941
Total current liabilities	1,606,359
Notes payable, noncurrent portion, net	4,006,666
Interest payable, noncurrent portion	658,031
Total liabilities	6,271,056
Commitments and contingencies	
Equity:	
Preferred stock, \$0.001 par value per share (10,000,000 shares authorized, 413,388 issued and outstanding, aggregate liquidation value of \$8,267,760 at December 31, 2011)	413
Common stock, \$0.001 par value per share (500,000,000 shares authorized, 284,683,977 shares issued and outstanding at December 31, 2011)	284,684
Contingently issuable shares	15,890
Additional paid-in capital	10,176,608
Deficit accumulated in development stage	(853,074 )
Total stockholder's equity	9,624,521
Non-controlling interest in subsidiary	11,681
Total equity	9,636,202
Total liabilities and equity	\$15,907,258

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

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**Manhattan Pharmaceuticals, Inc.**

(a development stage company)

**Consolidated Statement of Operations for the Year and Cumulative Period Ended December 31, 2011**

Costs and expenses		
Research and development		\$ 327,283
General and administrative:		
Non-cash compensation		86,494
Other general and administrative		468,197
Total general and administrative		554,691
Total operating expenses		881,974
Operating loss		(881,974 )
Interest expense		7,097
Consolidated net loss		(889,071 )
Net loss attributable to non-controlling interest		(35,997 )
Net loss attributable to Manhattan Pharmaceuticals, Inc. and subsidiaries		\$(853,074 )
Basic and diluted net loss per common share		\$(0.00 )*
Weighted average shares used in computing basic and diluted net loss per common share		108,348,538

\*Amount less than \$0.01.

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

**Manhattan Pharmaceuticals, Inc.**

(a development stage company)

**Consolidated Statement of Equity for the Year and Cumulative Period Ended December 31, 2011**

	Preferred Stock		Common stock		Additional paid-in capital	Contingently issuable shares	Non- controlling interest in subsidiary	Deficit Accumulated in the development stage	Total
	Shares	Amount	Shares	Amount					
Common stock issued to founders in exchange for seed capital in April 2011			140,625,000	\$ 140,625	\$(34,047 )				\$ 106,578
Stock issued at \$0.04 per share in exchange for license option			7,425,000	7,425	289,575				297,000
Issuance of restricted stock to employees			64,687,500	64,688	(63,538 )				1,150
Effect of reverse acquisition	281,250	\$ 281	(140,651,656)	(140,652)	399,767	\$ 15,890	\$ 47,678		322,964
Conversion of note payable to preferred stock	2,763	3			55,268				55,271
Issuance of replacement restricted preferred stock to employees	129,375	129	(64,687,500 )	(64,688 )	64,559				—
Common stock issued at \$0.04 per			277,285,633	277,286	9,378,530				9,655,816

share, net of expenses										
Compensation in respect of restricted preferred stock granted to employees					86,494					86,494
Net loss								(35,997)	\$(853,074)	(889,071 )
Balance at										
December 31, 2011	413,388	\$413	284,683,977	\$284,684	\$10,176,608	\$15,890	\$11,681	\$(853,074)	\$9,636,202	

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



**Manhattan Pharmaceuticals, Inc.**

(a development stage company)

**Consolidated Statement of Cash Flows for the Year and Cumulative Period Ended December 31, 2011****CASH FLOWS FROM OPERATING ACTIVITIES**

Consolidated net loss	\$(889,071 )
Adjustments to reconcile consolidated net loss to cash flows used in operating activities:	
Stock compensation expense	86,494
Stock issued in exchange for license option	297,000
Changes in assets and liabilities, net of effects of acquisition:	
Decrease in other current assets	3,593
Increase in accounts payable and accrued expenses	408,310
Increase in interest payable	7,097
Net cash used in operating activities	(86,577 )

**CASH FLOWS FROM INVESTING ACTIVITIES**

Cash acquired in connection with acquisition	10,386
Net cash provided by investing activities	10,386

**CASH FLOWS FROM FINANCING ACTIVITIES**

Proceeds from sale of common stock, net	9,824,682
Net cash provided by financing activities	9,824,682

**NET INCREASE IN CASH AND CASH EQUIVALENTS**

9,748,491

Cash and cash equivalents at beginning of year

—

**CASH AND CASH EQUIVALENTS AT END OF YEAR**

\$9,748,491

**NON-CASH TRANSACTIONS**

Conversion of notes payable to preferred stock	\$55,271
Accrued financing costs	\$61,138

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



**Manhattan Pharmaceuticals, Inc.**

**(a development stage company)**

**Notes to the Consolidated Financial Statements**

*Unless the context requires otherwise, references in this report to “Manhattan,” “Company,” “we,” “us” and “our” refer to Manhattan Pharmaceuticals, Inc. and our subsidiaries.*

**NOTE 1 - ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

**DESCRIPTION OF BUSINESS**

We are a biopharmaceutical company focused on the acquisition, development and commercialization of innovative and medically important pharmaceutical products for the treatment of cancer and other underserved therapeutic needs. We aim to acquire rights to these technologies by licensing or otherwise acquiring an ownership interest, funding their research and development and eventually out-licensing or bringing the technologies to market. Currently we are developing TGTX-1101 (ublituximab), a novel, third generation monoclonal antibody that targets a specific and unique epitope on the CD20 antigen found on mature B-lymphocytes. We also hold the development rights to AST-726 a nasally delivered product for the treatment of Vitamin B<sub>12</sub> deficiency, and AST-915 is an orally delivered treatment for essential tremor.

***Exchange Transaction with TG Therapeutics, Inc. and its majority shareholders***

On December 29, 2011, the Company entered into and consummated an Exchange Transaction Agreement with Opus Point Partners, LLC (“Opus”) and TG Therapeutics, Inc. (“TG”) (the “Agreement”). Under the Agreement, Opus exchanged (the “Exchange Transaction”) its shares of common stock in TG (“TG Common Stock”) for shares of Series A preferred stock in the Company (“Company Preferred Stock”). As a result Opus received 281,250 shares of Company Preferred Stock. Each share of Company Preferred Stock is convertible into 500 shares of the common stock of the Company (“Company Common Stock”) provided that such conversion rights are subject to sufficient available authorized shares of Company Common Stock. At the effective time of the Exchange Transaction, the Company Preferred Stock issued in the Exchange Transaction represented approximately 95 percent of the Company’s outstanding voting stock after giving effect to the merger. Since the stockholders of TG received the majority of the voting shares of the Company,

the merger was accounted for as a reverse acquisition whereby TG was the accounting acquirer (legal acquiree) and the Company was the accounting acquiree (legal acquirer) under the acquisition method of accounting. TG Therapeutics, Inc. was incorporated in Delaware in November 2010, but did not commence operations until April 2011, thus the accompanying historical financial statements of TG consists of only 2011. The results of the combined operations have been included in the Company's financial statements since December 29, 2011.

The filings with the Securities and Exchange Commission (the "SEC") include the historical financial results of TG Therapeutics, Inc. as of and for the period ending December 31, 2011 and Manhattan Pharmaceuticals, and its subsidiary only as of and for the period commencing December 29, 2011, the date of the reverse acquisition, and will hereafter collectively be referred to as the Company.

## **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 December 31, 2011, we have an accumulated deficit of \$853,074.

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

As of December 31, 2011, we had \$9.7 million in cash, and cash equivalents. We currently anticipate that our cash and cash equivalents as of December 31, 2011, inclusive of our 2011 Equity PIPE closings subsequent to December 31, 2011, to be sufficient to fund our anticipated operating cash requirements for approximately 24-30 months from December 31, 2011. 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.

On December 30, 2011, we completed the first closing of the private placement of our securities, issuing 277,285,633 shares of Company Common Stock at a price per share of \$0.04 for total gross proceeds, before placement commissions and expenses, of \$11,091,425 (the "2011 Equity PIPE"). Investors also received warrants to purchase 69,321,424 shares of Company Common Stock. The warrants have an exercise price of \$0.04 per share and are exercisable for five years. The shares of Company Common Stock and warrants sold in the initial closing were offered and sold to accredited investors, including members of management, without registration under the Securities Act of 1933, as amended (the "Securities Act"), or state securities laws, in reliance on the exemptions provided by Section 4(2) of the Securities Act, and Regulation D promulgated thereunder and in reliance on similar exemptions under applicable state laws. Accordingly, the securities to be issued in the Offering have not been registered under the Securities Act, and until so registered, these securities may not be offered or sold in the United States absent registration or availability of an applicable exemption from registration. The placement agent received cash commissions equal to 10% of the gross proceeds of the Offering, five-year warrants to purchase shares of the Company's stock equal to 10% of shares sold in the Offering, and a non-accountable expense allowance equal to two percent of the gross proceeds of the Offering for their expenses (not including up to \$80,000 of legal expenses and any blue sky fees, both of which were reimbursed by the Company).

In 2012, we completed two additional closings of the 2011 Equity PIPE. These closings were held on January 31, 2012, and February 24, 2012. In these closings, the Company issued 695,428 shares of our Series A Preferred Stock ("Preferred Stock") at a price per share of \$20.00 for total gross proceeds, before placement commissions and expenses, of \$13,908,560. Each share of Series A Preferred Stock is convertible into 500 shares of Company Common Stock provided that such conversion rights are subject to sufficient available authorized shares of Company Common Stock, which the Company intends to accomplish through the amendment of its Certificate of Incorporation, or a reverse stock split, at the next meeting of stockholders. Investors will also receive warrants to purchase 86,928,500 shares of Company Common Stock. The warrants have an exercise price of \$0.04 per share and are exercisable for five years. The shares of Preferred Stock and warrants sold in these closings were offered and sold to accredited investors, including members of management, without registration under the Securities Act, or state securities laws, in reliance on the exemptions provided by Section 4(2) of the Securities Act, and Regulation D promulgated thereunder and in reliance on similar exemptions under applicable state laws. Accordingly, the securities to be issued in the Offering have not been registered under the Securities Act, and until so registered, these securities may not be offered or sold in the United States absent registration or availability of an applicable exemption from registration. The placement agent received cash commissions equal to 10% of the gross proceeds of the Offering, five-year warrants to purchase shares of the Company's stock equal to 10% of shares sold in the Offering, and a non-accountable expense allowance equal to two percent of the gross proceeds of the Offering for their expenses.

Our common stock is quoted on the OTC Bulletin Board and trades under the symbol "TGTX.OB."

## **2011 MANAGEMENT CHANGES**

In connection with the Exchange Transaction with TG Therapeutics, Inc., effective December 29, 2011, Douglas Abel, David C. Shimko and Richard Steinhart resigned from their positions on the Board of Directors of the Company. Michael McGuinness resigned both his seat as a director and as an officer of the Company, effective December 29, 2011.

Effective December 29, 2011, Michael S. Weiss was appointed Executive Chairman, Interim Chief Executive Officer and President of the Company. In connection with the appointment, the Company assumed Mr. Weiss' employment agreement with TG, effective November 1, 2011, under which Mr. Weiss is to serve as the Company's Executive Chairman, Interim Chief Executive Officer and President until such employment is terminated pursuant to the terms of the agreement.

Under the terms of his employment agreement, Michael S. Weiss will receive an annual base salary of \$225,000 (which will automatically be reduced by 50% when Mr. Weiss resigns from his interim roles). Mr. Weiss will also be eligible to earn an annual cash performance bonus, based upon achievement of annual performance goals and objectives set by agreement between Mr. Weiss and the Board each year, with a target bonus of 100% of his base salary.

The Company will also grant Mr. Weiss a number of shares of restricted common stock equal to 1.25% of the shares of Common Stock outstanding on the date of grant on a fully-diluted basis. Each of these annual grants of restricted stock will vest and become non-forfeitable as to 25% of the shares on the first anniversary of the respective date of grant, as to 25% of the shares on the second anniversary of the respective date of grant and as to 50% of the shares on the date that the “market capitalization” (as defined in the employment agreement) is \$100 million greater than the market capitalization on the respective date of grant, provided that Mr. Weiss remains an employee, director and/or consultant of the Company through each vesting date.

In connection with the Exchange Transaction and the appointment of Mr. Weiss to his position, the Company issued replacement awards and granted 112,500 shares of Series A Preferred Stock, to Mr. Weiss on December 29, 2011. Each share of Series A Preferred Stock is convertible into 500 shares of the registrant’s Common Stock, provided that such conversion right is subject to sufficient available authorized shares of the registrant’s common stock. The shares vest as follows: 14,063 on each of November 15, 2012, November 15, 2013, November 15, 2014, and November 15, 2015; 28,125 upon the occurrence of the registrant achieving a particular market capitalization target; and 28,125 upon the occurrence of the registrant achieving a second particular market capitalization target.

Effective December 29, 2011, Sean A. Power was appointed Chief Financial Officer, Treasurer and Secretary of the Company. In connection with the appointment, the Company assumed Mr. Power’s employment agreement with TG, effective November 1, 2011, under which Mr. Power is to serve as the Company’s Chief Financial Officer, Treasurer and Secretary until such employment is terminated pursuant to the terms of the agreement.

Under the terms of his employment agreement, Sean A. Power will receive an annual base salary of \$135,000. Mr. Power will also be eligible to earn an annual cash performance bonus, based upon achievement of annual performance goals and objectives set by agreement between Mr. Power and the board each year, with a target bonus of 33% of his base salary.

The Company will grant Mr. Power a number of shares of restricted common stock of the Company as determined by the CEO and board. Each of these annual grants of restricted stock will be subject to vesting terms, which will be determined at the time of grant by the CEO and Board.

In connection with the Exchange Transaction and the appointment of Mr. Power to his position, the Company issued replacement awards and granted 16,875 shares of Series A Preferred Stock, to Mr. Power on December 29, 2011. Each share of Series A Preferred Stock is convertible into 500 shares of the registrant's Common Stock, provided that such conversion right is subject to sufficient available authorized shares of the registrant's common stock. The shares vest as follows: 2,812 on each of November 15, 2012, November 15, 2013, and November 15, 2014; 4,219 upon the occurrence of the registrant achieving a particular market capitalization target; and 4,220 upon the occurrence of the registrant achieving a second particular market capitalization target.

#### **RECENTLY ISSUED ACCOUNTING STANDARDS**

In June 2011, the FASB issued ASU No. 2011-05, "Comprehensive Income (Topic 220): Presentation of Comprehensive Income" (ASU 2011-05). The new standard eliminated the current option to report other comprehensive income and its components in the statement of changes in equity. Under the new standard, companies can elect to present items of net income and other comprehensive income in one continuous statement or in two separate, but consecutive statements. The new standard is effective at the beginning of fiscal years beginning after December 15, 2011, and, if applicable, we will comply with this requirement in the first quarter 2012.



In September 2011, the FASB issued Accounting Standards Update No. 2011-08, *Testing Goodwill for Impairment* (the revised standard). The new standard allows companies an option to first assess qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount as a basis for determining if it is necessary to perform the two-step quantitative goodwill impairment test. Under the new standard, a company is no longer required to calculate the fair value of a reporting unit unless the company determines, based on the qualitative assessment, that it is more likely than not that its fair value is less than its carrying amount. The new standard is effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011.

## **BASIS OF PRESENTATION**

The Company has not generated any revenue from its operations and, accordingly, the financial statements have been prepared in accordance with the provisions of accounting and reporting for Development Stage Enterprises.

## **USE OF ESTIMATES**

The preparation of financial statements in conformity with U.S. generally accepted accounting principles (“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 financial statements.

## **CASH AND CASH EQUIVALENTS**

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

## **RESEARCH AND DEVELOPMENT COSTS**

Research and development costs are expensed as incurred. Nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities are deferred and amortized over the period that the goods are delivered or the related services are performed, subject to an assessment of recoverability. We make

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

## **IN-PROCESS RESEARCH AND DEVELOPMENT**

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

## **INCOME TAXES**

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

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

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

## **STOCK - BASED COMPENSATION**

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

For share-based payments to consultants and other third-parties, compensation expense is determined at the “measurement date.” The expense is recognized over the vesting period of the award. Until the measurement date is reached, the total amount of compensation expense remains uncertain. We record compensation expense based on the fair value of the award at the reporting date. The awards to consultants and other third-parties are then revalued, or the total compensation is recalculated based on the then current fair value, at each subsequent reporting date. The Company did not grant any consultant options during the year ended December 31, 2011.

## **BASIC AND DILUTED NET (LOSS) INCOME PER COMMON SHARE**

Basic net income (loss) per common share is calculated by dividing net income (loss) applicable to common shares by the weighted-average number of common shares outstanding for the period. Diluted net loss per common share is the same as basic net income (loss) per common share, since potentially dilutive securities from stock options, stock warrants and convertible preferred stock would have an antidilutive effect either because the Company incurred a net loss during the period presented or because such potentially dilutive securities were out of the money and the Company realized net income during the period presented. The amounts of potentially dilutive securities excluded from the calculation were 326,981,188 at December 31, 2011. During the year ended December 31, 2011 the Company incurred a net loss, therefore all of the dilutive securities are excluded from the computation of diluted earnings per share.

## **IMPAIRMENT**

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

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

## NOTE 2 – CASH AND CASH EQUIVALENTS

	December 31, 2011
Money market funds	\$—
Checking and bank deposits	9,748,491
Total	\$9,748,491

## NOTE 3 – ACQUISITION

On December 29, 2011 the Company completed a reverse acquisition of privately held TG Therapeutics, Inc. (“TG”), a Delaware Corporation. The acquisition was effected pursuant to an Exchange Transaction Agreement (the “Agreement”) dated December 29, 2011 by and among the Company, TG Therapeutics, Inc. and Opus Point Partners, LLC, the largest shareholder of TG. In accordance with the terms of the Agreement, 95% of the holders of common shares of TG (one (1) minority shareholders of TG holding in aggregate 132,000 common shares of TG did not participate) surrendered their TG common shares. The Agreement caused the Company to issue to TG's shareholders 281,250 shares of the Company's Series A preferred stock, par value \$0.001 (the “Company Preferred Stock”). Each share of Company Preferred Stock is convertible into 500 shares of the common stock of the Company (“Company Common Stock”) provided that such conversion rights are subject to sufficient available authorized shares of Company Common Stock. The Company Preferred Stock has the same voting rights (on an as-converted basis), and other attributes as Company Common Stock. The Company Preferred Stock will automatically be exchanged for Company Common Stock when sufficient authorized shares are available to allow for such conversion. The Company Preferred Stock issued in connection with the Agreement, provided the former TG shareholders with direct and/or indirect ownership of approximately 95% of the Company's outstanding common stock immediately following the consummation of the transaction.

The Company Preferred Stock issued (and the underlying Company Common Stock once converted) are not registered for resale and, therefore, shall remain subject to the rights and restrictions of Rule 144. All Company Preferred Stock

received by the TG shareholders in exchange for their shares of TG common stock will not be registered for resale prior to six (6) months following December 29, 2011 and, therefore, shall remain subject to the rights and restrictions of Rule 144 prior to any such registration.

The Company Preferred Stock issued in connection with the agreement provided the former TG shareholders with direct and/or indirect ownership of approximately 95% of the Company's outstanding common stock as of December 29, 2011. Based on fair value of the Company's common stock of \$0.04 per share, the purchase price was \$295,933, plus the fair value of restricted stock assumed of \$82,305. In connection with the Exchange Transaction, the Company incurred \$231,580 of acquisition related costs.

A summary of the purchase price calculation is as follows:

Number of shares of Manhattan common stock outstanding at the time of the transaction	7,398,344	
Multiplied by Manhattan's fair value of the Common Stock	\$0.04	\$295,933
Fair value of restricted stock assumed		82,305
Total purchase price		\$378,238

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

Cash and cash equivalents	\$10,386
Other assets	90,769
In-process research and development acquired	5,441,840
Total identifiable assets	5,542,995
Accounts payable and accrued expenses	197,191
Notes payable (ICON and Swiss Pharma)	939,718
5% notes payable and accrued interest	4,657,600
Total identifiable liabilities	5,794,509
Net identifiable assets (liabilities)	(251,514 )
Goodwill	629,752
Total	\$378,238

A valuation using the guidance in ASC 805 was performed to determine the fair value of certain identifiable intangible assets of Manhattan.

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

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

The following supplemental pro forma information presents the financial results as if the transaction had occurred on January 1, 2011 for the year ended December 31, 2011. This supplemental pro forma information has been prepared for comparative purposes and does not purport to be indicative of what would have occurred had the acquisition been made on January 1, 2011, nor are they indicative of future results.

Revenue	\$—
Net loss	\$(818,279)
Basic and diluted loss per common share	\$(0.00 )*

\*Amount less than \$0.01

#### **NOTE 4 – STOCKHOLDERS’ EQUITY**

##### ***Preferred Stock***

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



There were 413,388 shares of preferred stock outstanding as of December 31, 2011. In connection with the Exchange Transaction with TG Therapeutics, Inc., on December 29, 2011, the Company filed a Certificate of Designation with respect to its Series A Preferred Stock with the Secretary of State of the State of Delaware. The Company Preferred Stock ranks senior to the Company Common Stock with regard to dividend rights, and has a liquidation preference of \$20 per share over the Company Common Stock and any other junior securities. The Company Preferred Stock is automatically convertible into 500 shares of Company Common Stock provided that prior to conversion, the Company has sufficient authorized Company Common Stock to effect such conversion. The Company Preferred Stock also automatically converts upon a change of control of the Company or the sale of substantially all of the assets of the Company. The Series A Preferred Stock votes on an as-converted basis with the Common Stock.

### *Common Stock*

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

On December 30, 2011, we completed the first closing of the private placement of our securities, issuing 277,285,633 shares of Company Common Stock at a price per share of \$0.04 for total gross proceeds, before placement commissions and expenses, of \$11,091,425 (the "2011 Equity PIPE"). Investors will also receive warrants to purchase 69,321,424 shares of Company Common Stock. The warrants have an exercise price of \$0.04 per share and are exercisable for five years. The shares of Company Common Stock and warrants sold in the initial closing were offered and sold to accredited investors, including members of management, without registration under the Securities Act, or state securities laws, in reliance on the exemptions provided by Section 4(2) of the Securities Act, and Regulation D promulgated thereunder and in reliance on similar exemptions under applicable state laws. Accordingly, the securities to be issued in the offering have not been registered under the Securities Act, and until so registered, these securities may not be offered or sold in the United States absent registration or availability of an applicable exemption from registration. The placement agent received cash commissions equal to 10% of the gross proceeds of the offering, five-year warrants to purchase shares of the Company's stock equal to 10% of shares sold in the offering, and a non-accountable expense allowance equal to two percent of the gross proceeds of the offering for their expenses (not including up to \$80,000 of legal expenses and any blue sky fees, both of which were reimbursed by the Company).

In 2012, we completed two additional closings of the 2011 Equity PIPE. These closings were held on January 31, 2012, and February 24, 2012. In these closings, the Company issued 695,428 shares of our Series A Preferred Stock ("Preferred Stock") at a price per share of \$20.00 for total gross proceeds, before placement commissions and expenses, of \$13,908,560. Each share of Series A Preferred Stock is convertible into 500 shares of Company Common Stock provided that such conversion rights are subject to sufficient available authorized shares of Company Common Stock, which the Company intends to accomplish through the amendment of its Certificate of Incorporation, or a reverse stock split, at the next meeting of stockholders. Investors also received warrants to purchase 86,928,500 shares of Company Common Stock. The warrants have an exercise price of \$0.04 per share and are exercisable for five years. The shares of Preferred Stock and warrants sold in these closings were offered and sold to accredited investors, including members of management, without registration under the Securities Act, or state securities laws, in reliance

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

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On December 19, 2011, Opus Point Partners, LLC loaned the Company \$55,271 in operating funds. Effective at the closing of the Exchange Transaction, the parties agreed to convert the loan into shares of Company Preferred Stock at the same exchange ratio used in the Exchange Transaction and Opus received 2,763 shares of Company Preferred Stock.

***Equity Incentive Plans***

We have in effect the following stock option and incentive plans.

a. The Company has shareholder-approved incentive stock option plans for employees under which it has granted non-qualified and incentive stock options. At December 31, 2011, 300,000 shares were authorized for issuance. The options have a maximum term of 10 years and vest over a period determined by the Company’s Board of Directors (generally 3 years) and are issued at an exercise price equal to or greater than the fair market value of the shares at the date of grant. At December 31, 2011 options to purchase 166,337 shares were outstanding, 556 shares of common stock were issued and there were 133,107 shares reserved for future grants under the Plan.

b. In July 1995, the Company established the 1995 Stock Option Plan (the “1995 Plan”), which provided for the granting of options to purchase up to 2,600 shares of the Company’s common stock to officers, directors, employees and consultants. The 1995 Plan was amended several times to increase the number of shares reserved for stock option grants. In June 2005, the 1995 Plan expired and no further options can be granted. At December 31, 2011 options to purchase 22,346 shares were outstanding and no shares were reserved for future stock option grants under the 1995 Plan.

A summary of the status of the Company’s stock options as of December 31, 2011 and changes during the period then ended is presented below:

Stock Options

The following table summarizes stock option activity for the year ended December 31, 2011:

<b>Number of shares</b>	<b>Weighted- average</b>	<b>Weighted- average</b>	<b>Aggregate Intrinsic</b>
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		<b>exercise price</b>	<b>Contractual Term</b> (in years)	<b>Value</b>
Outstanding at January 1, 2011	—	—		
Assumed in Exchange Transaction	231,499	\$ 24.37	5.60	
Granted	—	—		
Exercised	—	—		
Forfeited	(20,330 )	3.51		
Expired	(22,486 )	51.78		
Outstanding at December 31, 2011	188,683	\$ 23.33	6.39	\$ —
Vested and expected to vest at December 31, 2011	188,683	\$ 23.33	6.39	\$ —
Exercisable at December 31, 2011	188,017	\$ 23.40	6.39	\$ —

As of December 31, 2011, the total compensation cost related to unvested option awards not yet recognized is less than \$1,000. The weighted average period over which it is expected to be recognized is approximately 1 year.

Restricted Stock

Certain employees have been awarded restricted Series A preferred stock. The restricted stock vesting consists of milestone and time-based vesting. The following table summarizes restricted share activity for the year ended December 31, 2011:

	<b>Number of Shares Restricted Series A Preferred Stock<sup>(1)</sup></b>	<b>Weighted Average Grant Date Fair Value</b>	<b>Aggregate Intrinsic Value</b>
Outstanding at January 1, 2011	—	\$ —	
Granted	129,375	20.00	
Vested	—	—	
Forfeited	—	—	
Outstanding at December 31, 2011	129,375	\$ 20.00	\$ 1,306,688

<sup>(1)</sup> The restricted Series A preferred stock listed in the table above was granted in connection with the Exchange Transaction to certain executives as discussed above. Each share of Series A Preferred Stock is convertible into 500 shares of the registrant's Common Stock, provided that such conversion right is subject to sufficient available authorized shares of the registrant's common stock.

Total expense associated with restricted stock was \$86,494 during the year-ended December 31, 2011.

Warrants

The following table summarizes warrant activity for the year ended December 31, 2011:

	<b>Warrants</b>	<b>Weighted- Average exercise price</b>	<b>Aggregate Intrinsic Value</b>
Outstanding at January 1, 2011	—	\$ —	
Assumed in Exchange Transaction	22,130,436	0.26	\$ —
Issued	97,049,924	0.04	—
Exercised	—	—	
Expired	—	—	

Outstanding at December 31, 2011 119,180,360 \$ 0.08 \$ —

As discussed above, as part of the initial closing of the private placement of our securities completed on December 30, 2011, we issued warrants to purchase up to 69,321,424 shares of our common stock, none of which have been exercised as of December 31, 2011. The warrants have an exercise price of \$0.04 per warrant share. In addition, we issued to the placement agent in the transaction warrants to purchase up to 27,728,500 shares of our common stock at an exercise price of \$0.044 per warrant share, none of which have been exercised as of December 31, 2011.

***Stock-Based Compensation***

The fair value of stock options granted is estimated at the date of grant using the Black-Scholes pricing model. The expected term of options granted is derived from historical data and the expected vesting period. Expected volatility is based on the historical volatility of our common stock. The risk-free interest rate is based on the U.S. Treasury yield for a period consistent with the expected term of the option in effect at the time of the grant. We have assumed no expected dividend yield, as dividends have never been paid to stock or option holders and will not be paid for the foreseeable future. The Company did not grant any stock options during the year-ended December 31, 2011.

The following table summarizes stock-based compensation expense information about stock options and restricted stock for the years ended December 31, 2011:

	2011
Stock-based compensation expense associated with restricted stock	\$86,494
Stock-based compensation expense associated with option grants	—
	\$86,494

#### NOTE 5 – NOTES PAYABLE

The following is a summary of Notes payable:

	<b>December 31, 2011</b>		
	Current portion, net	Non-current portion, net	Total
Non-interest Bearing Note Payable, Net	\$200,000	\$ -	\$200,000
Convertible 5% Notes Payable	-	4,006,666	4,006,666
ICON Convertible Note	677,778		677,778
Total	\$877,778	\$ 4,006,666	\$4,884,444

We assumed the preceding notes payable as the result of the Exchange Transaction between the Company and TG Therapeutics, Inc. Accordingly, a valuation using the guidance in ASC 805 was performed and these notes have been presented at their fair value on the date of the transaction.

#### *Non-interest Bearing Note Payable*

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

*Convertible 5% Notes Payable*

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

The 5% Notes and accrued and unpaid interest thereon are convertible at the option of the holder into the Manhattan's common stock at the conversion price of \$20 per share. Ariston agreed to make quarterly payments on the 5% Notes equal to 50% of the net product cash flow received from the exploitation or commercialization of Ariston's product candidates, AST-726 and AST-915. The 5% Notes are solely the obligation of Ariston and have no recourse to Manhattan other than the conversion feature discussed above. Interest accrues monthly, is added to principal on an annual basis, every March 8, and is payable at maturity.

In connection with the Exchange Transaction between the Company and TG Therapeutics, Inc., the Company performed a valuation of the assets and liabilities of Manhattan immediately prior to the transaction. As these notes payable are tied directly to net product cash flows derived from the preexisting products of the Company, this note was recorded at fair value as of the date of the Exchange Transaction. The Company recorded approximately \$7,000 of interest expense on the 5% Notes, during the year ended December 31, 2011.



### ***ICON Convertible Note Payable***

In connection with the merger with Ariston as discussed above, Ariston satisfied an account payable of \$1,275,188 to ICON Clinical Research Limited (“ICON”) through the payment of \$275,188 in cash and the issuance of a three-year 5% note payable (the “ICON Note”). The principal was to be repaid in 36 monthly installments of \$27,778 commencing in April 2010. Interest was payable monthly in arrears. On March 1, 2011 Ariston entered into an amended and restated convertible promissory note (the “Amended ICON Note”) with ICON. The principal terms of the Amended ICON Note are that monthly payments of principal and interest will be waived for the thirteen month period ended December 31, 2011 (the “Waiver Period”) in exchange for a single payment of \$100,000 on March 31, 2011, an increase in the interest on the Amended ICON Note from 5% to 8% per annum during the Waiver Period and a balloon payment on January 31, 2012. The Amended ICON Note is convertible at the option of the holder into the Company’s common stock at the conversion price of \$10 per share. During the year ended December 31, 2011 (the period subsequent to the TG Therapeutics exchange transaction), the Company has immaterial interest expense on the Amended ICON Note. At December 31, 2011 the principal amount of the Amended ICON Note was \$677,778, of which the entire balance has been classified as current, and interest payable on the Amended ICON Note was \$61,941, and is reflected as components of notes payable, current portion, net, and interest payable, current portion, net respectively, in the accompanying balance sheet as of December 31, 2011. This note is currently in default as the Company did not make the balloon payment due on January 31, 2012.

### **NOTE 6 – INCOME TAXES**

We account for income taxes under the asset and liability method. Deferred tax assets and liabilities are determined based on differences between the financial reporting and tax basis of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. A valuation allowance is established when necessary to reduce deferred tax assets to the amount expected to be realized. In determining the need for a valuation allowance, management reviews both positive and negative evidence, including current and historical results of operations, future income projections and the overall prospects of our business. Based upon management's assessment of all available evidence, we believe that it is more-likely-than-not that the deferred tax assets will not be realizable; and therefore, a valuation allowance is established. The valuation allowance for deferred tax assets was \$29,408,000 as of December 31, 2011.

As of December 31, 2011, we have U.S. net operating loss carryforwards (“NOL’s”) of approximately \$69,382,000. For income tax purposes, these NOL’s will expire in various amounts through 2030. The Tax Reform Act of 1986 contains provisions which limit the ability to utilize net operating loss carryforwards in the case of certain events including significant changes in ownership interests. The recent exchange transaction with TG might have resulted in “change in ownership” as defined by IRC Section 382 of the Internal Revenue Code of 1986, as amended. Accordingly, a substantial portion of the Company’s net operating loss carryforwards above may be subject to annual limitations in reducing any future year’s taxable income.

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The tax effects of temporary differences that give rise to significant portions of the deferred tax assets and deferred tax liabilities at December 31, 2011 are presented below.

Deferred tax assets (liabilities):	
Net operating loss carryforwards	\$27,611,000
Research and development credit	1,858,000
Non-cash compensation	1,735,000
Acquired in-process research and development	(2,220,000 )
Other	424,000
Deferred tax asset, excluding valuation allowance	29,408,000
Less valuation allowance	(29,408,000)
Net deferred tax assets	\$—

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There was no current or deferred income tax expense for the year ended December 31, 2011. Income tax expense differed from amounts computed by applying the US federal income tax rate of 34% to pretax loss as follows:

(in thousands)	For the year ended December 31, 2011
Consolidated net loss, as reported in the consolidated statements of operations	\$ (889,071 )
Computed “expected” tax benefit	(302,284 )
Increase (decrease) in income taxes resulting from:	
Expected expense (benefit) from state & local taxes	(60,457 )
Research and development credits	(75,000 )
Other	(277 )
Change in the balance of the valuation allowance for deferred tax assets allocated to income tax expense	(438,018 )
	\$ —

We file income tax returns in the U.S. Federal and various state and local jurisdictions. With certain exceptions, the Company is no longer subject to U.S. Federal and state income tax examinations by tax authorities for years prior to 2008. However, net operating loss carryforwards and tax credits generated from those prior years could still be adjusted upon audit.

The Company recognizes interest and penalties to uncertain tax position in income tax expense in the statement of operations. There was no accrual for interest and penalties related to uncertain tax positions for 2011. We do not believe that there will be a material change in our unrecognized tax positions over the next twelve months. All of the unrecognized tax benefits, if recognized, would be offset by the valuation allowance.

#### NOTE 7 – LICENSE AGREEMENTS

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

On January 30, 2012, TG Therapeutics exercised the License Option and entered into an exclusive license agreement with LFB Biotechnologies, GTC Biotherapeutics, and LFB/GTC LLC, all wholly-owned subsidiaries of LFB Group, relating to the development of ublituximab. Under the license agreement, we have acquired the exclusive worldwide

rights (exclusive of France/Belgium) for the development and commercialization of TGTX-1101 (ublituximab). To date, we have made no payments to LFB Group and LFB Group is eligible to receive payments of up to an aggregate of approximately \$31.0 million upon our successful achievement of certain clinical development, regulatory and sales milestones, in addition to royalty payments on net sales of ublituximab. The license will terminate on a country by country basis upon the expiration of the last licensed patent right or 15 years after the first commercial sale of a product in such country, unless the agreement is earlier terminated.

In connection with the license agreement, TG Therapeutics issued 7,368,000 shares of its common stock to LFB, and the Company agreed to contribute \$15 million, less applicable fees and expenses associated with the financing, to TG Therapeutics to fund the development of ublituximab under the license agreement, in exchange for 7,500,000 shares of TG Therapeutics common stock.

#### NOTE 8 – JOINT VENTURE

On April 19, 2011, H Pharmaceuticals K/S (the “Hedrin JV”), of which the Company was a 15% limited partner at the time, filed a demand for arbitration against Thornton & Ross, LTD. (“T&R”) with respect to alleged breaches by T&R of an Exclusive License Agreement (the “Hedrin License”) dated June 28, 2007, which was originally entered into between the Company and T&R, and which the Company assigned in 2008 to the Hedrin JV, with T&R’s consent. The Hedrin JV is seeking damages from T&R in the amount of approximately \$7,000,000. The Company was not a party to the initial arbitration demand.

On May 20, 2011, T&R filed an answer to the arbitration demand in which T&R asserted counterclaims against the Hedrin JV for alleged breaches by the Hedrin JV of the Hedrin License and for declaratory relief that the Hedrin License was properly terminated by T&R. In addition, T&R impleaded an individual (who is not associated with the Company), Nordic Biotech Venture Fund II K/S (an investment fund) and the Company, demanding arbitration against them based on alleged breaches of the Hedrin License and other related claims. The Company has recently been removed by the arbitrator as a party to the arbitration. T&R is seeking damages of approximately \$20,000,000.

The Hedrin JV and T&R held a mediation session in order to avoid the arbitration process. The mediation process did not produce a result. Nordic has recently made an additional capital contribution to the Hedrin JV in order to fund the arbitration. As a result of that capital contribution the Company now owns a 13% interest in the Hedrin JV. The arbitration process is ongoing.

#### NOTE 9 – RELATED PARTY TRANSACTIONS

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

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

The Company completed the initial closing of the Offering on December 30, 2011, issuing 277,285,633 shares of Common Stock at a price per share of \$0.04 for total gross proceeds, before placement commissions and expenses, of \$11,091,425. Investors also received warrants to purchase 69,321,424 shares of Common Stock. The warrants have an exercise price of \$0.04 per share and are exercisable for five years. The Company completed the second closing of the Offering on January 31, 2012, issuing 489,199 shares of Series A Preferred Stock at a price per share of \$20.00 for gross proceeds, before placement commissions and expenses of \$9,783,980. Investors also received warrants to purchase 61,149,875 shares of Common Stock. The warrants have an exercise price of \$0.04 per share and are exercisable for five years. The Company completed the third and final closing of the Offering on February 24, 2012, issuing 206,229 shares of Series A Preferred Stock at a price per share of \$20.00 for gross proceeds, before placement commissions and expenses of 4,124,580. Investors also received warrants to purchase 25,778,625 shares of Common Stock. The warrants have an exercise price of \$0.04 per share and are exercisable for five years.

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

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## NOTE 10 – SUBSEQUENT EVENTS

As discussed above in Note 4, in 2012 we completed two additional closings of the 2011 Equity PIPE. These closings were held on January 31, 2012, and February 24, 2012. In these closings, the Company issued 695,428 shares of our Series A Preferred Stock (“Preferred Stock”) at a price per share of \$20.00 for total gross proceeds, before placement commissions and expenses, of \$13,908,560. Each share of Series A Preferred Stock is convertible into 500 shares of Company Common Stock provided that such conversion rights are subject to sufficient available authorized shares of Company Common Stock, which the Company intends to accomplish through the amendment of its Certificate of Incorporation, or a reverse stock split, at the next meeting of stockholders. Investors also received warrants to purchase 86,928,500 shares of Company Common Stock. The warrants have an exercise price of \$0.04 per share and are exercisable for five years.

As discussed above in Note 7, On January 30, 2012, TG Therapeutics exercised the License Option and entered into an exclusive license agreement with LFB Biotechnologies, GTC Biotherapeutics, and LFB/GTC LLC, all wholly-owned subsidiaries of LFB Group, relating to the development of ublituximab. Under the license agreement, we have acquired the exclusive worldwide rights (exclusive of France/Belgium) for the development and commercialization of TGTX-1101 (ublituximab). To date, we have made no payments to LFB Group and LFB Group is eligible to receive payments of up to an aggregate of approximately \$31.0 million upon our successful achievement of certain clinical development, regulatory and sales milestones, in addition to royalty payments on net sales of ublituximab. The license will terminate on a country by country basis upon the expiration of the last licensed patent right or 15 years after the first commercial sale of a product in such country, unless the agreement is earlier terminated.

In connection with the license agreement, TG Therapeutics issued 7,368,000 shares of its common stock to LFB, and the Company agreed to contribute \$15 million, less applicable fees and expenses associated with the financing, to TG Therapeutics to fund the development of ublituximab under the license agreement, in exchange for 7,500,000 shares of TG Therapeutics common stock.

In addition, in connection with the issuance of 7,368,000 TG Therapeutics shares, the Company and TG Therapeutics provided LFB Group, the option to, in its sole discretion, elect to convert all, and not less than all, of the TG Therapeutics’ shares into 828,900 shares of Manhattan’s Series A Preferred Stock, \$0.001 par value per share. Each share of Manhattan preferred stock shall be convertible into 500 shares of Manhattan’s common stock, \$0.001 par value per share, in accordance with the terms of the Series A Preferred Stock Certificate of Designation filed with the Secretary of State of the State of Delaware on December 29, 2011. In addition, should Manhattan have sufficient common stock authorized and available for issuance at the time the Purchaser elects to convert, then Purchaser will receive such number of shares of Manhattan Common Stock into which the Manhattan Preferred Stock is then convertible. This option may be exercised by LFB Group at any time within 60 days of the filing of Manhattan’s Annual Report on Form 10-K for the year ended December 31, 2011.

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

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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.

Date: March 14, 2012

**MANHATTAN PHARMACEUTICALS, INC.**

By: /s/ Michael S. Weiss

Michael S. Weiss

Executive Chairman, Interim Chief Executive  
Officer and President

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints each of Michael S. Weiss and Sean A. Power, his true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him and his name, place and stead, in any and all capacities, to sign any or all amendments to this annual report on Form 10-K, and to file the same, with all exhibits thereto and other documents in connection therewith, with the SEC, granting unto said attorney-in-fact and agent, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent or any of his substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Form 10-K has been signed by the following persons on behalf of the Registrant on March 14, 2012, and in the capacities indicated:

Signatures	Title
/s/ Michael S. Weiss	Executive Chairman, Interim Chief Executive Officer and President
Michael S. Weiss	(principal executive officer)
/s/ Sean A. Power	Chief Financial Officer
Sean A. Power	(principal financial and accounting officer)

/s/ Neil Herskowitz

Director

Neil Herskowitz

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## EXHIBIT INDEX

Exhibit Number	Exhibit Description
3.2	Certificate of Designations of Series A Convertible Preferred Stock, dated October 31, 2003.
3.3	Certificate of Ownership Merging Tarpan Therapeutics, Inc. into the Registrant, dated December 28, 2006.
3.4	Certificate of Amendment to the Restated Certificate of Incorporation, dated November 30, 2009.
3.7	Bylaws, as amended to date.
4.1	Specimen common stock certificate.
10.30	Employment Agreement, effective December 29, 2011, between the Registrant and Michael Weiss. †
10.31	Restricted Stock Subscription Agreement, effective December 29, 2011, between Registrant and Michael Weiss. †
10.32	Employment Agreement, effective December 29, 2011, between the Registrant and Sean Power. †
10.33	Restricted Stock Subscription Agreement, effective December 29, 2011 between the Registrant and Sean Power. †
10.34	Form of Warrant issued to stockholders on December 29, 2011, January 31, 2012 and February 24, 2012.
10.35	License Agreement, dated January 30, 2012, by and among the Registrant, GTC Biotherapeutics, Inc., LFB Biotechnologies S.A.S. and LFB/GTC LLC. *
23.1	Consent of Independent Registered Public Accounting Firm
31.1	Certification of Principal Executive Officer
31.2	Certification of Principal Financial Officer
32.1	Certifications pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
†	Indicates management contract or compensatory plan or arrangement.
*	Confidential treatment has been requested with respect to omitted portions of this exhibit.