TG THERAPEUTICS, INC.
Form 10-Q
November 14, 2014

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

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**FORM 10-Q**

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

**For the quarterly period ended September 30, 2014**

**OR**

**¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the transition period from _____ to _____**

**Commission File Number 000-30929**

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**TG THERAPEUTICS, INC.**

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

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

**3 Columbus Circle, 15th Floor**

**New York, New York 10019**

(Address including zip code of principal executive offices)

**(212) 554-4484**

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

x Yes ¨ No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definition of “large accelerated filer,” “accelerated filer” and “smaller reporting company” in Rule 12b-2 of the Exchange Act.

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

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

Yes £ No x

There were 43,964,350 shares of the registrant’s common stock, $0.001 par value, outstanding as of November 13, 2014.

**TG THERAPEUTICS, INC.**

**FORM 10-Q**

**FOR THE QUARTER ENDED SEPTEMBER 30, 2014**

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**SPECIAL CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS**

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

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

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

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

**PART I. FINANCIAL INFORMATION**

**ITEM 1. FINANCIAL STATEMENTS**

**TG Therapeutics, Inc.**
Condensed Consolidated Balance Sheets

| | September 30, 2014 (Unaudited) | December 31, 2013 |
|---|---|---|
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | $ 53,225,799 | $ 40,485,466 |
| Short-term investment securities | 14,009,644 | — |
| Interest receivable | 53,821 | 27,169 |
| Prepaid research and development | 9,117,863 | 1,742,824 |
| Other current assets | 258,721 | 47,804 |
| Total current assets | 76,665,848 | 42,303,263 |
| Long-term investment securities | — | 4,918,897 |
| Equipment, net | 7,763 | 5,718 |
| Goodwill | 799,391 | 799,391 |
| Other assets | 71,251 | 85,121 |
| Total assets | $ 77,544,253 | $ 48,112,390 |
| | | |
| Liabilities and equity | | |
| Current liabilities: | | |
| Notes payable, current portion | $ 183,144 | $ 677,778 |
| Accounts payable and accrued expenses | 7,967,548 | 4,764,502 |
| Accrued compensation | 599,083 | 532,500 |
| Current portion of deferred revenue | 152,381 | 152,381 |
| Interest payable | — | 190,017 |
| Total current liabilities | 8,902,156 | 6,317,178 |
| Deferred revenue, net of current portion | 1,561,905 | 1,676,191 |
| Notes payable, less current portion, at fair value | — | 64,529 |
| Total liabilities | 10,464,061 | 8,057,898 |
| Commitments and contingencies | | |
| Equity: | | |
| Preferred stock, $0.001 par value per share (10,000,000 shares authorized, 0 issued and outstanding as of September 30, 2014 and December 31, 2013) | — | — |
| Common stock, $0.001 par value per share (150,000,000 and 500,000,000 shares authorized, 41,481,047 and 34,336,235 shares issued, 41,439,738 | 41,481 | 34,336 |

| | | |
|---|---|---|
| and 34,294,926 shares outstanding at September 30, 2014 and December 31, 2013, respectively) | | |
| Contingently issuable shares | 6 | 6 |
| Additional paid-in capital | 143,661,893 | 79,658,490 |
| Treasury stock, at cost, 41,309 shares at September 30, 2014 and December 31, 2013 | (234,337) | (234,337) |
| Accumulated deficit | (76,388,851) | (39,404,003) |
| Total equity | 67,080,192 | 40,054,492 |
| Total liabilities and equity | $ 77,544,253 | $ 48,112,390 |

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

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

| | Three months ended September 30, | | Nine months ended September 30, | |
|---|---|---|---|---|
| | 2014 | 2013 | 2014 | 2013 |
| License revenue | $ 38,096 | $ 38,096 | $ 114,286 | $ 114,286 |
| Costs and expenses: | | | | |
| Research and development: | | | | |
| Noncash stock expense associated with in-licensing agreements | 4,138,844 | — | 5,350,094 | — |
| Noncash compensation | 1,200,575 | 171,442 | 6,402,296 | 892,313 |
| Other research and development | 8,352,154 | 3,138,119 | 13,197,183 | 9,014,776 |
| Total research and development | 13,691,573 | 3,309,561 | 24,949,573 | 9,907,089 |
| General and administrative: | | | | |
| Noncash compensation | 2,895,997 | 825,313 | 9,664,560 | 3,363,687 |
| Other general and administrative | 889,872 | 550,639 | 2,500,121 | 1,833,733 |
| Total general and administrative | 3,785,869 | 1,375,952 | 12,164,681 | 5,197,420 |
| Total costs and expenses | 17,477,442 | 4,685,513 | 37,114,254 | 15,104,509 |
| Operating loss | (17,439,346) | (4,647,417) | (36,999,968) | (14,990,223) |
| Other (income) expense: | | | | |
| Interest income | (12,107) | (12,375) | (38,308) | (15,054) |
| Other income | — | — | (95,427) | — |
| Interest expense | 234,787 | 240,530 | 695,914 | 712,016 |
| Change in fair value of notes payable | (210,857) | (319,377) | (577,299) | (872,827) |
| Total other expense (income) | 11,823 | (91,222) | (15,120) | (175,865) |
| Consolidated net loss | $ (17,451,169) | $ (4,556,195) | $ (36,984,848) | $ (14,814,358) |
| Basic and diluted net loss per common share | $ (0.51) | $ (0.16) | $ (1.14) | $ (0.62) |
| Weighted average shares used in computing basic and diluted net loss per common share | 34,188,108 | 27,684,802 | 32,436,420 | 24,057,200 |

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

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**TG Therapeutics, Inc.**
Condensed Consolidated Statement of Equity
for the nine months ended September 30, 2014 (Unaudited)

| | Preferred stock | | Common stock | | Contingently issuable shares | Additional paid-in capital | Treasury Stock | | Accumulated Deficit | Total |
|---|---|---|---|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | | | Shares | Amount | | |
| Balance at January 1, 2014 | — | $— | 34,336,235 | $34,336 | $6 | $79,658,490 | 41,309 | $(234,337) | $(39,404,003) | $40,054 |
| Issuance of common stock in connection with exercise of warrants | | | 1,272,340 | 1,272 | | 2,889,033 | | | | 2,890, |
| Issuance of common stock in connection with exercise of options | | | 33,000 | 33 | | 145,167 | | | | 145,20 |
| Issuance of restricted stock | | | 310,690 | 311 | | (311) | | | | — |
| Issuance of common stock in public offering (net of offering costs of $1,344,440) | | | 2,702,809 | 2,703 | | 16,788,705 | | | | 16,791 |
| Issuance of common stock in At the Market offering (net of offering costs of $565,191) | | | 2,329,443 | 2,329 | | 22,764,356 | | | | 22,766 |
| Compensation in respect of restricted stock and options | | | | | | 16,066,856 | | | | 16,066 |

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| granted to employees, directors and consultants | | | | | | | | | | |
| Common stock issued in connection with in-licensing agreements | | | 496,530 | 497 | | 5,349,597 | | | | 5,350, |
| Net loss | — | – | — | — | | — | — | — | (36,984,848) | (36,98 |
| Balance at September 30, 2014 | — | $— | 41,481,047 | $41,481 | $6 | $143,661,893 | 41,309 | $(234,337) | $(76,388,851) | $67,080 |

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

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

| | Nine months ended September 30, | |
|---|---|---|
| | 2014 | 2013 |
| CASH FLOWS FROM OPERATING ACTIVITIES: | | |
| Consolidated net loss | $ (36,984,848) | $ (14,814,358) |
| Adjustments to reconcile consolidated net loss to net cash used in operating activities: | | |
| Gain on settlement of notes payable | (95,427) | — |
| Noncash stock compensation expense | 16,066,856 | 4,256,000 |
| Noncash stock expense associated with in-licensing agreements | 5,350,094 | — |
| Depreciation | 2,454 | 634 |
| Amortization of premium on investment securities | 127,260 | — |
| Change in fair value of notes payable | 118,615 | (210,052) |
| Changes in assets and liabilities, net of effects of acquisition: | | |
| (Increase) decrease in other current assets | (7,585,956) | 1,589,950 |
| Increase in accrued interest receivable | (26,652) | — |
| Decrease (increase) in other assets | 13,870 | (85,121) |
| Increase in accounts payable and accrued expenses | 3,269,629 | 3,412,916 |
| (Decrease) increase in interest payable | (94,590) | 49,240 |
| Decrease in deferred revenue | (114,286) | (114,286) |
| Net cash used in operating activities | (19,952,981) | (5,915,077) |
| CASH FLOWS FROM INVESTING ACTIVITIES: | | |
| Purchases of equipment | (4,498) | (3,299) |
| Investment in held-to-maturity short-term securities | (9,218,008) | — |
| Net cash used in investing activities | (9,222,506) | (3,299) |
| CASH FLOWS FROM FINANCING ACTIVITIES: | | |
| Proceeds from the exercise of warrants | 2,890,305 | 1,997,498 |
| Proceeds from the exercise of options | 145,200 | — |
| Payment of notes payable | (677,778) | — |
| Proceeds from sale of common stock, net | 39,558,093 | 37,648,280 |
| Net cash provided by financing activities | 41,915,820 | 39,645,778 |
| NET INCREASE IN CASH AND CASH EQUIVALENTS | 12,740,333 | 33,727,402 |
| Cash and cash equivalents at beginning of period | 40,485,466 | 16,455,995 |
| CASH AND CASH EQUIVALENTS AT END OF PERIOD | $ 53,225,799 | $ 50,183,397 |

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

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

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

## NOTE 1 – ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

### *Description of Business*

We are a biopharmaceutical company focused on the acquisition, development and commercialization of novel treatments for cancer and autoimmune diseases. We acquire rights to these technologies by licensing or otherwise acquiring an ownership interest, funding their research and development, and eventually either out-licensing or bringing the technologies to market. Currently, we are developing two therapies targeting hematological malignancies:

- TG-1101 (ublituximab) a novel, glycoengineered monoclonal antibody that targets a specific and unique epitope on the CD20 antigen found on mature B-lymphocytes; and
- TGR-1202, an orally available PI3K delta inhibitor.

We are also developing a portfolio of inhibitors of IRAK-4 (interleukin-1 receptor-associated kinase 4), which is currently in pre-clinical development.

The accompanying unaudited condensed consolidated financial statements were prepared in accordance with U.S. generally accepted accounting principles, or GAAP, for interim financial information and with the instructions to Quarterly Report on Form 10-Q and Article 10 of Regulation S-X of the Exchange Act. Accordingly, they may not include all of the information and footnotes required by GAAP for complete financial statements. All adjustments that are, in the opinion of management, of a normal recurring nature and are necessary for a fair presentation of the consolidated financial statements have been included. Nevertheless, these consolidated financial statements should be read in conjunction with the audited consolidated financial statements contained in our Annual Report on Form 10-K for the year ended December 31, 2013. The December 31, 2013 balance sheet has been derived from these statements. The results of operations for the three and nine months ended September 30, 2014 are not necessarily indicative of the results that may be expected for the entire fiscal year or any other interim period.

***Liquidity and Capital Resources***

We have incurred operating losses since our inception and expect to continue to incur operating losses for the foreseeable future and may never become profitable. As of September 30, 2014, we have an accumulated deficit of $76,388,851.

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

As of September 30, 2014, we had $67,289,264 in cash, cash equivalents, investment securities, and interest receivable. We currently anticipate that our cash and cash equivalents and investments will be sufficient to fund our anticipated operating cash requirements for more than 24 months from September 30, 2014. The actual amount of cash that we will need to operate is subject to many factors, including, but not limited to, the timing, design and conduct of clinical trials for our drug candidates. We are dependent upon significant future financing to provide the cash necessary to execute our current strategic plan, including the commercialization of any of our drug candidates.

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

***Recently Issued Accounting Standards***

In May 2014, the FASB issued an update to ASC 606, Revenue from Contracts with Customers. This update to ASC 606 provides a five-step process to determine when and how revenue is recognized. The core principle of the guidance is that a Company should recognize revenue upon transfer of promised goods or services to customers in an amount that reflects the expected consideration to be received in exchange for those goods or services. This update to ASC 606 will also result in enhanced disclosures about revenue, providing guidance for transactions that were not previously addressed comprehensively, and improving guidance for multiple-element arrangements. This update to ASC 606 is effective for us beginning in fiscal 2017. We are currently evaluating the impact of this update on our consolidated financial statements.

On June 10, 2014, FASB issued Accounting Standards Update No. 2014-10, Development Stage Entities: Elimination of Certain Financial Reporting Requirements. The update removes the definition of a development stage entity from FASB ASC 915 and eliminates the requirement for development stage entities to present inception-to-date information on the statements of operations, cash flows and stockholders' deficit. We early adopted this standard for the period covered by this report.

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

***Cash and Cash Equivalents***

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

***Revenue Recognition***

We recognize license revenue in accordance with the revenue recognition guidance of the FASB Accounting Standards Codification, or Codification. We analyze each element of our licensing agreement to determine the appropriate revenue recognition. The terms of the license agreement may include payments to us of non-refundable up-front license fees, milestone payments if specified objectives are achieved, and/or royalties on product sales. We recognize revenue from upfront payments over the period of significant involvement under the related agreements unless the fee is in exchange for products delivered or services rendered that represent the culmination of a separate earnings process and no further performance obligation exists under the contract. We recognize milestone payments as

revenue upon the achievement of specified milestones only if (1) the milestone payment is non-refundable, (2) substantive effort is involved in achieving the milestone, (3) the amount of the milestone is reasonable in relation to the effort expended or the risk associated with achievement of the milestone, and (4) the milestone is at risk for both parties. If any of these conditions are not met, we defer the milestone payment and recognize it as revenue over the estimated period of performance under the contract.

***Research and Development Costs***

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

***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 non-employee directors (as compensation for service) 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 (including related 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 (including related parties) are then revalued, or the total compensation is recalculated based on the then current fair value, at each subsequent reporting date.

***Basic and Diluted Net Loss Per Share of Common Stock***

Basic net loss per share of our common stock is calculated by dividing net loss applicable to the common stock by the weighted-average number of our common stock outstanding for the period. Diluted net loss per share of common stock is the same as basic net loss per share of common stock since potentially dilutive securities from stock options, stock warrants and convertible preferred stock would have an antidilutive effect either because we incurred a net loss during the period presented or because such potentially dilutive securities were out of the money and the Company realized net income during the period presented. The amounts of potentially dilutive securities excluded from the calculation were 9,100,404 and 9,994,297 at September 30, 2014 and 2013, respectively. During the three and nine months ended September 30, 2014 and 2013, we incurred a net loss; therefore, all of the dilutive securities are excluded from the computation of diluted earnings per share.

***Long-Lived Assets and Goodwill***

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

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

**NOTE 2 – CASH AND CASH EQUIVALENTS**

The following tables summarize our cash and cash equivalents at September 30, 2014 and December 31, 2013:

| | September 30, 2014 | December 31, 2013 |
|---|---|---|
| Money market funds | $ 6,445,474 | $ 554,069 |
| Checking and bank deposits | 46,780,325 | 39,931,397 |
| Total | $ 53,225,799 | $ 40,485,466 |

**NOTE 3 – INVESTMENT SECURITIES**

We record our investments as either held-to-maturity or available-for-sale. Held-to-maturity investments are recorded at amortized cost.

The following tables summarize our investment securities at September 30, 2014 and December 31, 2013:

| | September 30, 2014 | | | |
|---|---|---|---|---|
| | **Amortized cost, as adjusted** | **Gross unrealized holding gains** | **Gross unrealized holding losses** | **Estimated fair value** |
| Short-term investments: | | | | |
| Obligations of domestic governmental agencies (maturing between January 2015 and September 2015) | $14,009,644 | $ 5,827 | $ — | $14,015,471 |

(held-to-maturity)

| | December 31, 2013 | | | |
|---|---|---|---|---|
| | **Amortized cost, as adjusted** | **Gross unrealized holding gains** | **Gross unrealized holding losses** | **Estimated fair value** |
| Long-term investments: | | | | |
| Obligations of domestic governmental agencies (maturing between January 2015 and April 2015) (held-to-maturity) | $4,918,897 | $ — | $ 650 | $ 4,918,247 |

**NOTE 4 – FAIR VALUE MEASUREMENTS**

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

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

As of September 30, 2014 and December 31, 2013, the fair values of cash and cash equivalents, accounts payable, accrued expenses, and notes and interest payable approximate their carrying value.

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

In connection with the exchange transaction with TG Biologics, Inc. ("TGBio") in December 2011, we performed a valuation of the assets and liabilities of Manhattan immediately prior to the transaction. The cumulative liability including accrued and unpaid interest of the 5% Notes was approximately $16,876,000 immediately prior to the transaction, and $18,614,000 at December 31, 2013 and $19,310,000 at September 30, 2014. As the 5% Notes are tied directly to net product cash flows derived from the preexisting products of Ariston, the 5% Notes and accrued interest were recorded at fair value of $3,287,700 as of the date of the transaction. No payments have been made on the 5% Notes as of September 30, 2014.

We elected the fair value option for valuing the 5% Notes upon the transaction with TGBio. We elected the fair value option in order to reflect in our financial statements the assumptions that market participants use in evaluating these financial instruments.

As of December 31, 2013, as a result of expiring intellectual property rights and other factors, it was determined that net product cash flows from AST-726 were unlikely. As we have no other obligations under the 5% Notes aside from the net product cash flows and the conversion feature, the conversion feature was used to estimate the 5% Notes' fair value as of September 30, 2014 and December 31, 2013. The assumptions, assessments and projections of future revenues are subject to uncertainties, difficult to predict, and require significant judgment. The use of different assumptions, applying different judgment to inherently subjective matters and changes in future market conditions could result in significantly different estimates of fair value and the differences could be material to our consolidated financial statements.

The following table provides the fair value measurements of applicable financial liabilities as of September 30, 2014 and December 31, 2013:

| | Financial liabilities at fair value as of September 30, 2014 | | | |
|---|---|---|---|---|
| | Level 1 | Level 2 | Level 3 | Total |
| 5% Notes | $ — | $ — | $ 183,144 | $ 183,144 |
| Totals | $ — | $ — | $ 183,144 | $ 183,144 |

| | Financial liabilities at fair value as of December 31, 2013 | | | |
|---|---|---|---|---|
| | Level 1 | Level 2 | Level 3 | Total |
| 5% Notes | $ — | $ — | $ 64,529 | $ 64,529 |
| Totals | $ — | $ — | $ 64,529 | $ 64,529 |

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

The following table summarizes the changes in Level 3 instruments during the nine months ended September 30, 2014:

| | |
|---|---|
| Fair value at December 31, 2013 | $64,529 |
| Interest accrued on face value of 5% Notes | 695,914 |
| Change in fair value of Level 3 liabilities | (577,299) |
| Fair value at September 30, 2014 | $183,144 |

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

**NOTE 5 - STOCKHOLDERS' EQUITY**

***Preferred Stock***

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

***Stockholder Rights Plan***

On July 18, 2014, we adopted a stockholder rights plan. The stockholder rights plan is embodied in the Stockholder Protection Rights Agreement dated as of July 18, 2014 (the “Rights Agreement”), between us and American Stock Transfer & Trust Company, LLC, as rights agent (the “Rights Agent”).

Accordingly, the Board of Directors declared a distribution of one right (a “Right”) for each outstanding share of common stock, to stockholders of record at the close of business on July 28, 2014, for each share of common stock issued (including shares distributed from treasury) by us thereafter and prior to the Separation Time (as defined in the Rights Agreement), and for certain shares of common stock issued after the Separation Time. Following the Separation Time, each Right entitles the registered holder to purchase from us one one-thousandth (1/1,000) of a share

of Series A Junior Participating Preferred Stock, par value $0.001 per share (the "Preferred Stock"), at a purchase price of $100.00 (the "Exercise Price"), subject to adjustment. The description and terms of the Rights are set forth in the Rights Agreement. Each one one-thousandth of a share of Preferred Stock has substantially the same rights as one share of common stock. Subject to the terms and conditions of the Rights Agreement, Rights become exercisable ten days after the public announcement that a “Person” has become an “Acquiring Person” (as each such term is defined in the Rights Agreement). Any Rights held by an Acquiring Person are void and may not be exercised.

If a Person becomes an Acquiring Person, all holders of Rights, except the Acquiring Person, may purchase at the Right’s then-current exercise price, common stock having a market value equal to twice the exercise price. Moreover, at any time after a Person becomes an Acquiring Person (unless such Person acquires 50 percent or more of our common stock then outstanding, as more fully described in the Rights Agreement), the Board of Directors may exchange all (but not less than all) of the then outstanding Rights (other than rights owned by such Person, which would have become void) for shares of common stock at an exchange ratio of one share of common stock per Right, appropriately adjusted in order to protect the interests of holders of Rights.

The Rights Agreement was approved by our Board of Directors on July 18, 2014. The Rights will expire at the close of business on its ten year anniversary, unless earlier exchanged or terminated by us.

***Common Stock***

Our amended and restated certificate of incorporation authorizes the issuance of up to 150,000,000 shares of $0.001 par value common stock. At the annual shareholder meeting on June 6, 2014, an amendment to the Company's Certificate of Incorporation to decrease its authorized share capital by 350,000,000 shares from 500,000,000 to 150,000,000 was approved.

On March 11, 2014, we announced the pricing of an underwritten sale of 2,702,809 shares of our common stock at a price of $6.71 per share for gross proceeds of approximately $18.1 million. Net proceeds from this offering were approximately $16.8 million, net of underwriting discounts and offering expenses of approximately $1.3 million. The shares were sold under a shelf registration statement on Form S-3 (File No. 333-189015) that was previously filed and declared effective by the SEC on June 17, 2013.

On June 21, 2013, we entered into an At-the-Market Issuance Sales Agreement (the "ATM") with MLV & Co. LLC ("MLV") under which we may issue and sell shares of our common stock, having an aggregate offering price of up to $50.0 million, from time to time through MLV, acting as the sales agent. Under the agreement we will pay MLV a commission rate of up to 3.0% of the gross proceeds from the sale of any shares of common stock sold through MLV.

In August and September 2014, we sold an aggregate of 2,329,443 shares of common stock pursuant to the ATM for an aggregate of approximately $23.4 million in gross proceeds at an average selling price of $10.03 per share. Net proceeds were approximately $22.8 million after deducting commissions and other transactions costs.

From October 1, 2014 through November 7, 2014, we sold an aggregate of 2,520,612 shares of common stock pursuant to the ATM for an aggregate of approximately $26.6 million in gross proceeds at an average selling price of $10.57 per share. Net proceeds were approximately $26.1 million after deducting commissions and other transactions costs.

During and subsequent to the quarter ended September 30, 2014, we sold a total of 4,850,055 shares of common stock for aggregate total gross proceeds of approximately $50.0 million at an average selling price of $10.31 per share. Net proceeds were approximately $48.9 million after deducting commissions and other transactions costs. We have fully utilized the capacity under the ATM and, accordingly, no further sales can or will be made under the ATM.

We currently have one shelf registration statement on Form S-3 filed and declared effective by the SEC (File No. 333-189015). Subsequent to the above, there remains available under this shelf registration statement up to approximately $67 million of common stock. We may offer the securities under our shelf registration statement from time to time in response to market conditions or other circumstances if we believe such a plan of financing is in the best interests of our stockholders. We believe that this shelf registration statement provides us with the flexibility to raise additional capital to finance our operations, as needed.

***Equity Incentive Plans***

Shares available for the issuance of stock options or other stock-based awards under our stock option and incentive plans were 797,103 shares at September 30, 2014.

Stock Options

The following table summarizes stock option activity for the nine months ended September 30, 2014:

| | **Number of shares** | **Weighted-average exercise price** | **Weighted-average Contractual Term** (in years) | **Aggregate Intrinsic Value** |
|---|---|---|---|---|
| Outstanding at December 31, 2013 | 46,591 | $ 46.37 | 8.50 | $ — |
| Granted | — | — | | |
| Exercised | (33,000) | 4.40 | | |
| Forfeited | — | — | | |
| Expired | (397) | 4,457.57 | | |
| Outstanding at September 30, 2014 | 13,194 | $ 18.62 | 7.78 | $ 81,510 |
| | | | | |
| Vested and expected to vest at September 30, 2014 | 4,194 | $ 49.14 | 7.65 | $ 25,080 |
| Exercisable at September 30, 2014 | 4,194 | $ 49.14 | 7.65 | $ 25,080 |

As of September 30, 2014, the total compensation cost related to unvested time-based option awards not yet recognized was $0. This amount does not include, as of September 30, 2014, 9,000 non-employee options outstanding which are milestone-based and vest upon certain corporate milestones. Stock-based compensation will be measured and recorded if and when a milestone occurs.

Restricted Stock

Certain employees, directors and consultants have been awarded restricted stock under the 2012 Incentive Plan. The restricted stock vesting consists of milestone and time-based vesting provisions. The following table summarizes restricted share activity for the nine months ended September 30, 2014:

| | Number of Shares | **Weighted Average Grant Date Fair Value** |
|---|---|---|
| Outstanding at December 31, 2013 | 7,034,957 | $ 4.60 |
| Granted | 310,690 | 8.28 |
| Vested | (903,416) | 7.34 |
| Forfeited | — | — |
| Outstanding at September 30, 2014 | 6,442,231 | $ 4.76 |

Total expense associated with restricted stock grants was $15,814,346 during the nine months ended September 30, 2014. As of September 30, 2014, there was approximately $10,213,000 of total unrecognized compensation cost related to unvested time based restricted stock, which is expected to be recognized over a weighted-average period of 1.1 years. This amount does not include, as of September 30, 2014, 2,017,250 shares of restricted stock outstanding issued to non-employees. The expense for these shares 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.

Warrants

The following table summarizes warrant activity for the nine months ended September 30, 2014:

| | Warrants | **Weighted-average exercise price** | **Aggregate Intrinsic Value** |
|---|---|---|---|
| Outstanding at December 31, 2013 | 5,718,947 | $ 1.34 | $14,809,030 |
| Issued | — | — | |
| Exercised | (1,272,340) | 2.27 | |
| Expired | (9,795) | 20.92 | |
| Outstanding at September 30, 2014 | 4,436,812 | $ 1.03 | $42,811,487 |

***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. We did not grant any stock options during the nine months ended September 30, 2014.

The following table summarizes stock-based compensation expense information about stock options and restricted stock for the three and nine months ended September 30, 2014:

| | **Three months ended September 30, 2014** | **Nine months ended September 30, 2014** |
|---|---|---|
| Stock-based compensation expense associated with restricted stock | $ 4,096,572 | $ 15,814,346 |
| Stock-based compensation expense associated with option grants | — | 252,510 |
| | $ 4,096,572 | $ 16,066,856 |

**NOTE 6 – NOTES PAYABLE**

The following is a summary of notes payable:

| | September 30, 2014 | | | December 31, 2013 | | |
|---|---|---|---|---|---|---|
| | Current portion, net | Non-current portion, net | Total | Current portion, net | Non-current portion, net | Total |
| Convertible 5% Notes Payable | $183,144 | $ - | $183,144 | $- | $64,529 | $64,529 |
| ICON Convertible Note | - | - | - | 677,778 | - | 677,778 |
| Total | $183,144 | | | | | |