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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-Q**

(Mark One)

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

For the quarterly period ended September 30, 2015

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: 000-50549

**GTx, Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**62-1715807**  
(I.R.S. Employer Identification No.)

**175 Toyota Plaza**  
**7<sup>th</sup> Floor**  
**Memphis, Tennessee**  
(Address of principal executive offices)

**38103**  
(Zip Code)

**(901) 523-9700**  
(Registrant's telephone number, including area code)

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

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

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

Large accelerated filer <input type="checkbox"/>	Accelerated filer <input checked="" type="checkbox"/>
Non-accelerated filer <input type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company <input type="checkbox"/>

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

As of November 3, 2015, 140,374,112 shares of the registrant's Common Stock were outstanding.

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**GTx, INC.**  
**FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2015**  
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**PART I: FINANCIAL INFORMATION****ITEM 1. FINANCIAL STATEMENTS**

**GTx, Inc.**  
**CONDENSED BALANCE SHEETS**  
**(in thousands, except share data)**

	<u>September 30,</u> <u>2015</u>	<u>December 31,</u> <u>2014</u>
	<u>(unaudited)</u>	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 11,797	\$ 17,880
Short-term investments	22,663	31,415
Prepaid expenses and other current assets	2,458	856
Total current assets	36,918	50,151
Property and equipment, net	8	29
Intangible and other assets, net	852	471
Total assets	<u>\$ 37,778</u>	<u>\$ 50,651</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 184	\$ 512
Warrant liability	30,078	30,430
Accrued expenses and other current liabilities	3,204	1,850
Total current liabilities	33,466	32,792
Other long-term liabilities	—	30
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.001 par value: 400,000,000 shares and 200,000,000 shares authorized at September 30, 2015 and December 31, 2014, respectively; 140,374,112 and 140,325,643 shares issued and outstanding at September 30, 2015 and December 31, 2014, respectively	140	140
Additional paid-in capital	514,413	512,460
Accumulated deficit	(510,241)	(494,771)
Total stockholders' equity	4,312	17,829
Total liabilities and stockholders' equity	<u>\$ 37,778</u>	<u>\$ 50,651</u>

The accompanying notes are an integral part of these financial statements.

**GTx, Inc.**  
**CONDENSED STATEMENTS OF OPERATIONS**  
**(in thousands, except share and per share data)**  
**(unaudited)**

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
<b>Expenses:</b>				
Research and development expenses	\$ 3,824	\$ 3,362	\$ 9,728	\$ 17,616
General and administrative expenses	2,039	1,594	6,155	7,275
Total expenses	<u>5,863</u>	<u>4,956</u>	<u>15,883</u>	<u>24,891</u>
Loss from operations	(5,863)	(4,956)	(15,883)	(24,891)
Other income, net	9	21	61	25
Gain on change in fair value of warrant liability	40,720	—	352	—
Net income (loss)	<u>\$ 34,866</u>	<u>\$ (4,935)</u>	<u>\$ (15,470)</u>	<u>\$ (24,866)</u>
<b>Net income (loss) per share:</b>				
Basic	<u>\$ 0.25</u>	<u>\$ (0.06)</u>	<u>\$ (0.11)</u>	<u>\$ (0.34)</u>
Diluted	<u>\$ (0.04)</u>	<u>\$ (0.06)</u>	<u>\$ (0.11)</u>	<u>\$ (0.34)</u>
<b>Weighted average shares outstanding:</b>				
Basic	<u>140,374,112</u>	<u>76,014,531</u>	<u>140,361,507</u>	<u>72,688,108</u>
Diluted	<u>154,852,127</u>	<u>76,014,531</u>	<u>140,361,507</u>	<u>72,688,108</u>

The accompanying notes are an integral part of these financial statements.

**GTx, Inc.**  
**CONDENSED STATEMENTS OF CASH FLOWS**  
**(in thousands)**  
**(unaudited)**

	Nine Months Ended September 30,	
	2015	2014
<b>Cash flows from operating activities:</b>		
Net loss	\$ (15,470)	\$ (24,866)
Adjustments to reconcile net loss to net cash used in operating activities:		
Gain on change in fair value of warrant liability	(352)	—
Depreciation and amortization	36	86
Share-based compensation	1,868	4,186
Directors' deferred compensation	85	94
Changes in assets and liabilities:		
Prepaid expenses and other assets	(1,994)	(679)
Accounts payable	(328)	(629)
Accrued expenses and other liabilities	1,324	(1,890)
Net cash used in operating activities	<u>(14,831)</u>	<u>(23,698)</u>
<b>Cash flows from investing activities:</b>		
Purchase of property and equipment	(4)	(5)
Purchase of short-term investments, held to maturity	(40,219)	(10,490)
Proceeds from maturities of short-term investments, held to maturity	48,971	8,775
Net cash provided by (used in) investing activities	<u>8,748</u>	<u>(1,720)</u>
<b>Cash flows from financing activities:</b>		
Net proceeds from the issuance of common stock and warrants	—	21,135
Tax payments related to shares withheld for vested restricted stock units	—	(617)
Payments on capital lease and financed equipment obligations	—	(2)
Net cash provided by financing activities	<u>—</u>	<u>20,516</u>
Net decrease in cash and cash equivalents	<u>(6,083)</u>	<u>(4,902)</u>
Cash and cash equivalents, beginning of period	17,880	14,529
Cash and cash equivalents, end of period	<u>\$ 11,797</u>	<u>\$ 9,627</u>

The accompanying notes are an integral part of these financial statements.

**GTx, Inc.**  
**NOTES TO THE CONDENSED FINANCIAL STATEMENTS**  
**(in thousands, except share and per share data)**  
**(unaudited)**

**1. Business and Basis of Presentation**

***Business***

GTx, Inc. (“GTx” or the “Company”), a Delaware corporation incorporated on September 24, 1997 and headquartered in Memphis, Tennessee, is a biopharmaceutical company dedicated to the discovery, development and commercialization of small molecules for the treatment of cancer, including treatments for breast and prostate cancer, and other serious medical conditions.

The Company is developing selective androgen receptor modulators (“SARMs”), including its lead product candidate, enobosarm (GTx-024). SARMs are a new class of drugs that the Company believes have the potential to be used as a novel hormonal therapy for the treatment of advanced breast cancer, as well as the potential to treat other serious medical conditions where increasing muscle mass is important. The Company announced during the second quarter of 2014 positive results from an ongoing Phase 2 proof-of-concept, open-label clinical trial evaluating a 9 mg oral daily dose of enobosarm for the treatment of patients with estrogen receptor (“ER”) positive and androgen receptor (“AR”) positive metastatic breast cancer who have previously responded to hormonal therapy. The Company recently commenced enrollment in a Phase 2 proof-of-concept clinical trial designed to evaluate the efficacy and safety of enobosarm in patients with advanced AR positive triple-negative breast cancer. The Company also commenced enrollment during the third quarter of 2015 in a Phase 2 clinical trial evaluating enobosarm in patients with ER positive and AR positive advanced breast cancer. Additionally, the Company is evaluating enobosarm and other compounds in its SARM portfolio for indications outside of oncology where unmet medical needs in muscle-related diseases may benefit from increasing muscle mass, such as stress urinary incontinence and Duchenne muscular dystrophy.

In March 2015, the Company entered into an exclusive license agreement with the University of Tennessee Research Foundation (“UTRF”) to develop UTRF’s proprietary selective androgen receptor degrader, or SARD, technology which has the potential to provide compounds that can degrade multiple forms of AR for those patients who do not respond or are resistant to current therapies to inhibit tumor growth in patients with progressive castration-resistant prostate cancer (“CRPC”). The Company’s evaluation of the licensed SARD technology is at a very early stage and any future preclinical or clinical development of the SARD technology, beyond identifying potential lead clinical compounds, will require us to obtain additional funding.

The Company is also developing GTx-758 (Capesaris<sup>®</sup>), an oral nonsteroidal selective ER alpha agonist, for the treatment of advanced prostate cancer. The Company is presently conducting a Phase 2 clinical trial evaluating GTx-758 as a secondary hormonal therapy in men with metastatic and high risk non-metastatic CRPC. The Company does not plan to dedicate further resources to this program after the conclusion of this Phase 2 clinical trial and is discussing this data with potential strategic partners to determine their interest in partnering or acquiring this asset, as well as the Company’s library of ER alpha agonist compounds.

The Company estimates that its current cash, cash equivalents and short-term investments, together with interest thereon, will be sufficient to meet its projected operating requirements through the end of 2016, during which time it expects to obtain results from the patients enrolled in the first stage of each of its ongoing open-label Phase 2 clinical trials of enobosarm in patients with AR positive advanced breast cancer and from its planned Phase 2 proof-of-concept clinical trial evaluating enobosarm to treat postmenopausal women with stress urinary incontinence.

***Basis of Presentation***

The accompanying unaudited condensed financial statements reflect, in the opinion of management, all adjustments (consisting of normal recurring adjustments) necessary for a fair presentation of GTx’s financial position, results of operations and cash flows for each period presented in accordance with accounting principles generally accepted in the United States for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, information and footnote disclosures normally included in financial

**GTx, Inc.**  
**NOTES TO THE CONDENSED FINANCIAL STATEMENTS**  
**(in thousands, except share and per share data)**  
**(unaudited)**

statements prepared in accordance with accounting principles generally accepted in the United States have been condensed or omitted from the accompanying condensed financial statements. These interim condensed financial statements should be read in conjunction with the audited financial statements and related notes thereto, which are included in the Company's Annual Report on Form 10-K for the year ended December 31, 2014. Operating results for the three and nine months ended September 30, 2015 are not necessarily indicative of the results that may be expected for the entire fiscal year ending December 31, 2015.

***Use of Estimates***

The preparation of condensed financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the condensed financial statements, and the reported amounts of revenues and expenses during the reporting period. Actual amounts and results could differ from those estimates.

***Warrant Liability***

In November 2014, the Company issued warrants to purchase 64,311,112 shares of its common stock. The Company classifies the warrants as a liability on its balance sheet since the warrants contain certain terms that could require the Company (or its successor) to purchase the warrants for cash in an amount equal to the value (as calculated utilizing a contractually-agreed Black-Scholes-Merton option pricing valuation model ("Black-Scholes Model")) of the unexercised portion of the warrants in connection with certain change of control transactions occurring on or prior to December 31, 2016, with such cash payment capped at an amount equal to \$0.125 per unexercised share underlying each warrant. In addition, each warrant was subject to net cash settlement if, at the time of any exercise, there was then an insufficient number of authorized and reserved shares of common stock to effect a share settlement of the warrant. Under the terms of the warrants, as of May 6, 2015, the net cash settlement feature of the warrants automatically became inoperative; accordingly, the warrants are exercisable only for shares of the Company's common stock.

As a result of the provision of the warrant requiring cash settlement upon certain change of control transactions, the Company is required to account for these warrants as a liability at fair value and the estimated warrant liability is required to be revalued at each balance sheet date until the earlier of the exercise of the warrants or the expiration of the provision on December 31, 2016 that could require cash settlement upon certain change of control transactions. Upon the exercise of the warrants or the expiration of the provision on December 31, 2016 that could require cash settlement upon certain change of control transactions, the fair value of the warrants will be reclassified from a liability to stockholders' equity on the Company's balance sheet and no further adjustment to the fair value would be made in subsequent periods. See Note 4, *Stockholders' Equity*, for further information regarding these warrants and the Company's valuation of the warrant liability.

***Fair Value of Financial Instruments and Warrant Liability***

The carrying amounts of the Company's financial instruments (which include cash, cash equivalents, short-term investments, and accounts payable) and its warrant liability approximate their fair values. The fair value of the warrant liability is estimated using the Black-Scholes Model. See Note 4, *Stockholders' Equity*, for additional disclosure on the valuation methodology and significant assumptions. The Company's financial assets and liabilities are classified within a three-level fair value hierarchy that prioritizes the inputs used to measure fair value, which is defined as follows:

**GTx, Inc.**  
**NOTES TO THE CONDENSED FINANCIAL STATEMENTS**  
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Level 1 — Quoted prices in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date

Level 2 — Inputs other than quoted prices in active markets that are observable for the asset or liability, either directly or indirectly

Level 3 — Inputs that are unobservable for the asset or liability

Asset and liabilities measured at fair value on a recurring basis as of September 30, 2015 and December 31, 2014 included only the Company's warrant liability of \$30,078 and \$30,430, respectively, which was classified within Level 3 of the hierarchy. A gain of \$40,720 and \$352 related to the change in the fair value of the warrant liability was recognized during the three and nine months ended September 30, 2015, respectively, as a non-cash gain in the Company's condensed statement of operations.

As the Company has the positive intent and ability to hold its certificates of deposit classified as short-term investments until maturity, these investments have been classified as held to maturity investments and are stated at cost, which approximates fair value. The Company considers these to be Level 2 investments as the fair values of these investments are determined using third-party pricing sources, which generally utilize observable inputs, such as interest rates and maturities of similar assets.

***Research and Development Expenses***

Research and development expenses include, but are not limited to, the Company's expenses for personnel, supplies, and facilities associated with research activities, screening and identification of product candidates, formulation and synthesis activities, manufacturing, preclinical studies, toxicology studies, clinical trials, regulatory and medical affairs activities, quality assurance activities and license fees. The Company expenses these costs in the period in which they are incurred. The Company estimates its liabilities for research and development expenses in order to match the recognition of expenses to the period in which the actual services are received. As such, accrued liabilities related to third party research and development activities are recognized based upon the Company's estimate of services received and degree of completion of the services in accordance with the specific third party contract.

***Cash, Cash Equivalents and Short-term Investments***

The Company considers highly liquid investments with initial maturities of three months or less to be cash equivalents.

At September 30, 2015 and December 31, 2014, short-term investments consisted of Federal Deposit Insurance Corporation insured certificates of deposit with original maturities of greater than three months and less than one year.

***Income Taxes***

The Company accounts for deferred taxes by recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. A valuation allowance is provided when it is more likely than not that some portion or all of the deferred tax assets will not be realized. Accordingly, at September 30, 2015 and December 31, 2014, net of the valuation allowance, the net deferred tax assets were reduced to zero. Income taxes are described more fully in Note 9 to the Company's financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2014.

**GTx, Inc.**  
**NOTES TO THE CONDENSED FINANCIAL STATEMENTS**  
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**Other Income, net**

Other income, net consists of foreign currency transaction gains and losses associated with conducting clinical trials in foreign countries, interest earned on the Company's cash, cash equivalents and short-term investments, interest expense, and other non-operating income or expense.

**Recent Accounting Pronouncements**

In August 2014, the Financial Accounting Standards Board issued Accounting Standard Update 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*. The new guidance is intended to define management's responsibility to evaluate whether there is substantial doubt about an organization's ability to continue as a going concern within one year of the date the financial statements are issued and to provide related footnote disclosure. This new guidance is effective for the first annual period ending after December 15, 2016 and interim periods thereafter.

**Subsequent Events**

The Company has evaluated all events or transactions that occurred after September 30, 2015 up through the date the condensed financial statements were issued. There were no material recognizable or nonrecognizable subsequent events during the period evaluated.

**2. Share-Based Compensation**

Share-based payments include stock option grants and restricted stock units ("RSUs") under the Company's stock option and equity incentive plans and deferred compensation arrangements for the Company's non-employee directors. The Company recognizes compensation expense for its share-based payments based on the fair value of the awards over the period during which an employee or non-employee director is required to provide service in exchange for the award. The Company's share-based compensation plans are described more fully in Note 3 to the Company's financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2014.

The following table summarizes share-based compensation expense included within the condensed statements of operations for the three and nine months ended September 30, 2015 and 2014:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Research and development expenses	\$ 331	\$ 89	\$ 857	\$ 2,419
General and administrative expenses	423	177	1,096	1,861
Total share-based compensation	<u>\$ 754</u>	<u>\$ 266</u>	<u>\$ 1,953</u>	<u>\$ 4,280</u>

Share-based compensation expense recorded as general and administrative expense for the three months ended September 30, 2015 and 2014 included share-based compensation expense related to deferred compensation arrangements for the Company's non-employee directors of \$27 and \$31, respectively. Share-based compensation expense recorded as general and administrative expense for the nine months ended September 30, 2015 and 2014 included share-based compensation expense related to deferred compensation arrangements for the Company's non-employee directors of \$85 and \$94, respectively. As a result of the modification of the Company's former chief executive officer's options upon his resignation in April 2014, the Company recognized a one-time, noncash net compensation expense of \$215, which was included in general and administrative expenses for the nine months ended September 30, 2014. This amount reflects the net of the aggregate incremental fair value associated with the

**GTx, Inc.**  
**NOTES TO THE CONDENSED FINANCIAL STATEMENTS**  
(in thousands, except share and per share data)  
**(unaudited)**

modifications of \$359, partially offset by the reversal of \$144 of previously recognized share-based compensation expense for the Company's former chief executive officer's unvested options.

The Company uses the Black-Scholes Model to value stock options. The expected life of options is determined by calculating the average of the vesting term and the contractual term of the options. The expected price volatility is based on the Company's historical stock price volatility. The risk-free interest rate is determined using U.S. Treasury rates where the term is consistent with the expected life of the stock options. Expected dividend yield is not considered as the Company has not made any dividend payments and has no plans of doing so in the foreseeable future. The amount of share-based compensation expense recognized is reduced ratably over the vesting period by an estimate of the percentage of options granted that are expected to be forfeited or canceled before becoming fully vested.

The fair value of options granted was estimated using the following assumptions for the periods presented:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Expected price volatility	88.1%	86.6%	89.6%	86.5%
Risk-free interest rate	2.1%	2.1%	1.6%	2.3%
Weighted average expected life in years	7.0 years	7.0 years	6.0 years	6.9 years

The following is a summary of stock option transactions for all of the Company's stock option and equity incentive plans since the Company's most recent fiscal year end:

	Number of Shares	Weighted Average Exercise Price Per Share
Options outstanding at December 31, 2014	8,104,434	\$ 4.24
Options granted	365,000	0.77
Options expired	(202,100)	7.29
Options exercised	—	—
Options outstanding at September 30, 2015	8,267,334	4.01

During the nine months ended September 30, 2015, the Company granted 8,200,000 RSUs to employees of which a portion of each award vests annually over a three year period from the date of grant. The Company estimates the fair value of RSUs using the closing price of its stock on the grant date. The fair value of RSUs is amortized on a straight-line basis over the requisite service period of the awards. The amount of share-based compensation expense recognized is reduced ratably over the vesting period by an estimate of the percentage of RSUs granted that are expected to be forfeited or canceled before becoming fully vested. The non-vested RSUs had a weighted average grant date fair value per share of \$0.72.

### 3. Basic and Diluted Net Income (Loss) Per Share

Basic and diluted net income (loss) per share attributable to common stockholders is calculated based on the weighted average number of common shares outstanding during the period. Diluted net income (loss) per share gives effect to the dilutive potential of common stock consisting of stock options, unvested RSUs and common stock warrants. The calculation of diluted income (loss) per share also requires that, to the extent the average market price of the underlying shares for the reporting period exceeds the exercise price of the warrants and the presumed exercise of such warrants are dilutive to income (loss) per share for the period, adjustments to net income or net loss used in the calculation are required to remove the change in fair value of the warrant liability for the period.

**GTx, Inc.**  
**NOTES TO THE CONDENSED FINANCIAL STATEMENTS**  
(in thousands, except share and per share data)  
**(unaudited)**

The following table sets forth the computation of the Company's net income (loss) per share is as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
<b>Basic and diluted net income (loss) per share</b>				
Numerator:				
Net income (loss) — basic	\$ 34,866	\$ (4,935)	\$ (15,470)	\$ (24,866)
Adjustments for the gain on change in fair value of the warrant liability	(40,720)	—	—	—
Net income (loss) — diluted	<u>(5,854)</u>	<u>(4,935)</u>	<u>(15,470)</u>	<u>(24,866)</u>
Denominator:				
Weighted average shares outstanding — basic	140,374,112	76,014,531	140,361,507	72,688,108
Dilutive warrants	11,955,547	—	—	—
Dilutive restricted stock units	2,499,629	—	—	—
Dilutive stock options	22,839	—	—	—
Weighted average shares outstanding — diluted	<u>154,852,127</u>	<u>76,014,531</u>	<u>140,361,507</u>	<u>72,688,108</u>
Net income (loss) per share:				
Basic	<u>\$ 0.25</u>	<u>\$ (0.06)</u>	<u>\$ (0.11)</u>	<u>\$ (0.34)</u>
Diluted	<u>\$ (0.04)</u>	<u>\$ (0.06)</u>	<u>\$ (0.11)</u>	<u>\$ (0.34)</u>
Weighted average shares outstanding:				
Basic	<u>140,374,112</u>	<u>76,014,531</u>	<u>140,361,507</u>	<u>72,688,108</u>
Diluted	<u>154,852,127</u>	<u>76,014,531</u>	<u>140,361,507</u>	<u>72,688,108</u>

Weighted average potential shares of common stock of 8,609,193 and 18,395,096 for the three months ended September 30, 2015 and 2014, respectively, and 81,364,457 and 15,658,766 for the nine months ended September 30, 2015 and 2014, respectively, were excluded from the calculations of diluted income (loss) per share as inclusion of the potential shares would have had an anti-dilutive effect on the net income (loss) per share for these periods. The number of weighted average potential shares of common stock excluded from the calculation of diluted net income (loss) per share for the nine months ended September 30, 2015 increased from the prior year due to the issuance of warrants under two Company financing transactions that occurred during the year ended December 31, 2014 and due to the issuance of RSUs during the first quarter of 2015.

**4. Stockholders' Equity**

*Common Stock and Associated Warrant Liability*

On November 14, 2014, the Company completed a private placement of units consisting of an aggregate of 64,311,112 shares of common stock and warrants to purchase an aggregate of 64,311,112 shares of its common stock for net proceeds of \$42,814, after deducting offering expenses. The purchasers in the private placement included certain existing GTx stockholders and certain members of the GTx management team and board of directors. The net proceeds from the private placement were allocated to the common stock and warrants based

**GTx, Inc.**  
**NOTES TO THE CONDENSED FINANCIAL STATEMENTS**  
**(in thousands, except share and per share data)**  
**(unaudited)**

upon the fair value method. Similarly, the offering expenses were allocated between the common stock and warrants with the portion allocated to common stock offset against the proceeds allocated to stockholders' equity, whereas the portion allocated to the warrants was expensed immediately. The warrants have a per share exercise price of \$0.85, became exercisable on May 6, 2015 and will continue to be exercisable for four years thereafter. Prior to May 6, 2015, each warrant was subject to net cash settlement if, at the time of any exercise, there was then an insufficient number of authorized and reserved shares of common stock to effect a share settlement of the warrant. Under the terms of the warrants, as May 6, 2015, the net cash settlement feature of the warrants automatically became inoperative; accordingly, the warrants are exercisable only for shares of the Company's common stock. The warrants, however, contain certain terms that could require the Company (or its successor) to purchase the warrants for cash in an amount equal to the value (as calculated utilizing a contractually-agreed Black-Scholes Model) of the unexercised portion of the warrants in connection with certain change of control transactions occurring on or prior to December 31, 2016, with the cash payment capped at an amount equal to \$0.125 per unexercised share underlying each warrant. Due to the provision of the warrants that could require cash settlement upon certain change of control transactions, the Company is required to account for these warrants as a liability at fair value using the Black-Scholes Model and the estimated warrant liability is required to be revalued at each balance sheet date until the earlier of the exercise of the warrants or the expiration of the provision on December 31, 2016 that could require cash settlement upon certain change of control transactions.

The fair value of the warrants at September 30, 2015 of \$30,078 was estimated using the Black-Scholes Model with the following assumptions: expected volatility of 94%, risk-free interest rate of 1.0%, expected life of approximately 3.6 years and no dividends. The fair value of the warrants at December 31, 2014 of \$30,430 was estimated using the Black-Scholes Model with the following assumptions: expected volatility of 91%, risk-free interest rate of 1.5%, expected life of approximately 4.5 years and no dividends. The decrease in fair value from December 31, 2014 of \$352 was recorded as a non-cash gain on the change in fair value of warrant liability in the Company's condensed statement of operations. Significant changes to the Company's market price for its common stock will impact the implied and/or historical volatility used to fair value the warrants. Any significant increases in the Company's stock price will likely create an increase to the fair value of the warrant liability. Similarly, any significant decreases in the Company's stock price will likely create a decrease to the fair value of the warrant liability.

On March 6, 2014, the Company completed a private placement of units consisting of an aggregate of 11,976,048 shares of common stock and warrants to purchase an aggregate of 10,179,642 shares of its common stock for net proceeds of \$21,135, after deducting offering expenses. The net proceeds from the private placement were allocated to the common stock and warrants based upon their relative fair values. The warrants, which had a one year term, expired unexercised on March 6, 2015.

#### **5. University of Tennessee Research Foundation License Agreements**

The Company and the University of Tennessee Research Foundation ("UTRF") are parties to a consolidated, amended and restated license agreement (the "SARM License Agreement") pursuant to which the Company was granted exclusive worldwide rights in all existing SARM technologies owned or controlled by UTRF, including all improvements thereto, and exclusive rights to future SARM technology that may be developed by certain scientists at the University of Tennessee or subsequently licensed to UTRF under certain existing inter-institutional agreements with The Ohio State University. Under the SARM License Agreement, the Company is obligated to pay UTRF annual license maintenance fees, low single-digit royalties on net sales of products and mid-single-digit royalties on sublicense revenues.

The Company and UTRF also entered into a license agreement (the "SARD License Agreement") in March 2015 pursuant to which the Company was granted exclusive worldwide rights in all existing SARD technologies owned or controlled by UTRF, including all improvements thereto. Under the SARD License Agreement, the Company is obligated to employ active, diligent efforts to conduct preclinical research and development activities for the SARD program to advance one or more lead compounds into clinical development. The Company is also

**GTx, Inc.**  
**NOTES TO THE CONDENSED FINANCIAL STATEMENTS**  
**(in thousands, except share and per share data)**  
**(unaudited)**

obligated to pay UTRF annual license maintenance fees, low single-digit royalties on net sales of products and additional royalties on sublicense revenues, depending on the state of development of a clinical product candidate at the time it is sublicensed.

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

The following discussion should be read in conjunction with the condensed financial statements and the notes thereto included in Part 1, Item 1 of this Quarterly Report on Form 10-Q.

**Forward-Looking Information**

This Quarterly Report on Form 10-Q contains forward-looking statements. The forward-looking statements are contained principally in the sections entitled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Risk Factors.” These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. Forward-looking statements include statements about:

- the implementation of our business strategies, including our ability to preserve or realize any significant value from our enobosarm (GTx-024) and GTx-758 (Capesaris®) programs;
- the therapeutic and commercial potential of, and our ability to advance the development of, enobosarm and our SARD development program;
- the timing of regulatory discussions and submissions, and the anticipated timing, scope and outcome of related regulatory actions or guidance;
- our ability to establish and maintain potential new collaborative, partnering or other strategic arrangements for the development and commercialization of our product candidates;
- the anticipated progress of our preclinical and clinical programs, including whether our ongoing and planned clinical trials will achieve clinically relevant results;
- the timing, scope and anticipated initiation, enrollment and completion of our ongoing and planned clinical trials and any other future clinical trials that we may conduct;
- our ability to obtain and maintain regulatory approvals of our product candidates and any related restrictions, limitations, and/or warnings in the label of an approved product candidate;
- our ability to market, commercialize and achieve market acceptance for our product candidates;
- our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others; and
- our estimates regarding the sufficiency of our cash resources, expenses, capital requirements and needs for additional financing, and our ability to obtain additional financing.

In some cases, you can identify forward-looking statements by terms such as “anticipates,” “believes,” “could,” “estimates,” “expects,” “intends,” “may,” “plans,” “potential,” “predicts,” “projects,” “should,” “will,” “would” and similar expressions intended to identify forward-looking statements. Forward-looking statements reflect our current views with respect to future events, are based on assumptions and are subject to risks, uncertainties and other important factors. We discuss many of these risks in this Quarterly Report on Form 10-Q in greater detail in the section entitled “Risk Factors” under Part II, Item 1A below. Given these risks, uncertainties and other important factors, you should not place undue reliance on these forward-looking statements. Also, forward-looking statements represent our estimates and assumptions only as of the date of this Quarterly Report on Form 10-Q. You should read this Quarterly Report on Form 10-Q and the documents that we incorporate by reference in and have filed as exhibits to this Quarterly Report on Form 10-Q, completely and with the understanding that our actual future results may be materially different from what we expect. Except as required by law, we assume no obligation to update any forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in any forward-looking statements, even if new information becomes available in the future.

## Overview

### ***Business Overview***

We are a biopharmaceutical company dedicated to the discovery, development and commercialization of small molecules for the treatment of cancer, including treatments for breast and prostate cancer, and other serious medical conditions. Our current strategy is focused on the further development of selective androgen receptor modulators, or SARMs, a new class of drugs that we believe have the potential to be used as a hormonal therapy for the treatment of advanced breast cancer, as well as the potential to treat other serious medical conditions where unmet medical needs in muscle-related diseases may benefit from increasing muscle mass, such as stress urinary incontinence, or SUI, and Duchenne muscular dystrophy, or DMD. In March 2015, we entered into an exclusive worldwide license agreement with the University of Tennessee Research Foundation, or UTRF, to develop its proprietary selective androgen receptor degrader, or SARD, technology, which has the potential to provide compounds that can degrade multiple forms of androgen receptor, or AR, to inhibit tumor growth in patients with progressive castration-resistant prostate cancer, or CRPC, including those patients who do not respond or are resistant to current therapies. We are also currently developing GTX-758, an oral nonsteroidal selective estrogen receptor alpha agonist, for the treatment of advanced prostate cancer.

### ***Business Highlights***

Our lead SARM candidate, enobosarm (GTX-024), has to date been evaluated in 23 completed or ongoing clinical trials, including in five Phase 2 and two Phase 3 clinical trials, enrolling over 1,500 subjects, of which approximately 1,000 subjects were treated with enobosarm. Enobosarm is the generic name given to the compound by the USAN Council and the World Health Organization and is the first compound to receive the SARM stem in its name, recognizing enobosarm as the first in this new class of compounds. We announced during the second quarter of 2014 positive results from an ongoing Phase 2 proof-of-concept, open-label clinical trial evaluating enobosarm 9 mg oral daily for the treatment of patients with estrogen receptor, or ER, positive and AR positive metastatic breast cancer who have previously responded to hormonal therapy. Based on the positive results of the Phase 2 proof-of-concept clinical trial in patients with ER positive and AR positive metastatic breast cancer, as well as positive data reported in medical literature regarding the use of androgens for the treatment of breast cancer and our preclinical data demonstrating tumor growth inhibition with enobosarm in animal models of disease, we believe enobosarm has the potential to be an effective treatment alternative with a favorable side effect profile for women with ER positive and AR positive advanced breast cancer, as well as for women with advanced AR positive triple-negative breast cancer, or TNBC.

During the fourth quarter of 2015, we commenced enrollment in a Phase 2 proof-of-concept clinical trial of enobosarm designed to evaluate the efficacy and safety of enobosarm in patients with advanced AR positive TNBC. This open-label, multinational clinical trial, which utilizes a Simon's two-stage clinical trial design, is designed to enroll up to approximately 55 patients to obtain 41 evaluable patients, who will be administered an 18 mg oral daily dose of enobosarm, and clinical benefit will be assessed at 16 weeks of treatment. There will be two stages of evaluation in the clinical trial, with the first stage assessment occurring following 16 weeks of treatment for the first 21 evaluable patients. If at least 2 of the 21 patients achieve clinical benefit, the trial will continue to enroll the second stage of the study. During the third quarter of 2015, we commenced enrollment in a Phase 2 clinical trial evaluating enobosarm in patients with metastatic or locally advanced ER positive and AR positive breast cancer. This open-label, multinational clinical trial, which is enrolling patients whose cancer treatment has shown prior response to hormonal therapy but has subsequently progressed, will also utilize a Simon's two-stage clinical trial design. The trial is designed to enroll up to approximately 118 patients to obtain 44 evaluable patients in each of two cohorts. One cohort will receive a daily dose of 9 mg of enobosarm and the other cohort a daily dose of 18 mg of enobosarm. There will be two stages of evaluation in the clinical trial, with the first stage assessment occurring following 24 weeks of treatment for the first 18 evaluable patients in each of the two cohorts. If at least 3 of the 18 patients achieve clinical benefit in one or both cohorts, the trial will continue through the second stage for that cohort. For each of these two Phase 2 clinical trials, clinical benefit is defined as a complete response, partial response or stable disease as measured by standardized response evaluation criteria. We currently estimate we have sufficient funding through the end of 2016 to allow us to obtain the results from the patients enrolled in the first stage of each clinical trial, but our ability to enroll patients to the second stage and complete both of these clinical trials will require us to seek sufficient additional funding.

We are also evaluating enobosarm and other compounds in our SARM portfolio for indications outside of oncology where unmet medical needs in muscle-related diseases may benefit from increasing muscle mass. We plan to conduct, using our current resources, a Phase 2 proof-of-concept clinical trial of enobosarm to treat

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postmenopausal women with SUI. This will be the first clinical trial to evaluate a SARM for the treatment of SUI. SUI refers to the unintentional leakage of urine during activities that increase abdominal pressure such as coughing, sneezing or physical exercise and is the most common type of incontinence suffered by women, affecting up to 35 percent of adult women. The rationale for evaluating enobosarm as a treatment for SUI in the proof-of-concept trial is supported by preclinical *in vivo* data demonstrating increases in pelvic floor muscle mass following treatment with our SARM compounds, including enobosarm, as well as safety data from enobosarm clinical trials involving more than 1,000 subjects treated with enobosarm. In October 2015, we announced the U.S. Food and Drug Administration, or FDA, has accepted our investigational new drug application for a Phase 2 proof-of-concept clinical trial of enobosarm to treat postmenopausal women with SUI. We plan to initiate this clinical trial in the first quarter of 2016 and anticipate top-line data by the end of 2016. We are also currently evaluating several SARM compounds in preclinical models of DMD where a SARM's ability to increase muscle mass may prove beneficial to patients suffering from DMD, which is a rare genetic disorder characterized by progressive muscle degeneration and weakness. Based on the extensive SARM data from our preclinical and clinical development efforts, we are undertaking preclinical studies and have initiated discussions with experts to better understand the potential of SARMs as a treatment for DMD. Our evaluation of SARMs as a potential treatment for DMD is at a very early stage, and our ability to meaningfully advance preclinical development of SARMs as a potential treatment for DMD is subject to our ability to obtain additional funding.

In March 2015, we entered into an exclusive worldwide license agreement with the UTRF to develop SARD compounds that may be capable of degrading multiple forms of AR. We envision initially developing SARDs as a potentially novel treatment for men with CRPC, including those who do not respond or are resistant to currently approved therapies. Although current therapies have improved overall survival in men with CRPC, approximately one-third of the CRPC patients do not respond to these therapies, due in part to the presence of splice variants, including AR-V7. Splice variants of the androgen receptor have been identified in which the ligand binding domain, the binding site for androgens and necessary for the action of many of the current therapies, is lost. In addition, most patients who initially respond to available treatments eventually progress due to the emergence of resistance to these therapies. It is believed that CRPC growth remains highly dependent on androgen receptor activity, although the mechanisms which underlie this resistance are not fully understood. We believe a therapeutic agent that would safely degrade multiple forms of the androgen receptor, including those without the ligand binding domain, would be uniquely positioned to address this patient population. Our evaluation of the licensed SARD program is at a very early stage. We are currently preparing an appropriate development program for SARDs and are conducting research in collaboration with the University of Tennessee Health Science Center to select and optimize appropriate drug development candidates to move into the preclinical studies required to support initial clinical trials. However, to advance preclinical development of our SARD program through the requisite preclinical studies to support initial human studies, we will require additional funding, which we may seek to obtain through the licensing, partnering or sale of certain other assets, including GTx-758 and its ER alpha agonist family of compounds, or through a strategic partnership or collaboration for the development and commercialization of SARDs.

We are also currently developing GTx-758, an oral nonsteroidal selective estrogen receptor alpha agonist, for the treatment of advanced prostate cancer. We believe GTx-758 has the potential to reduce free testosterone to levels lower than those attainable with androgen deprivation therapy, or ADT, alone while ameliorating estrogen deficiency side effects, such as bone loss and hot flashes, which are common with current androgen deprivation therapies for prostate cancer.

We are currently conducting a Phase 2 open-label clinical trial in men who have developed metastatic or high risk non-metastatic CRPC while on ADT. GTx-758 has previously demonstrated the ability to increase the production of a protein called sex hormone binding globulin, or SHBG, that binds testosterone and thereby reduces free testosterone. By reducing free testosterone, we believe serum prostate specific antigen, or PSA, will be reduced in men with CRPC. The primary endpoint of the current Phase 2 clinical trial is the proportion of subjects with a greater than or equal to 50% decline from baseline in serum PSA by day 90. Other key endpoints include serum SHBG and total and free testosterone levels in the study subjects. In addition, the clinical trial is evaluating the ability of GTx-758 to treat certain estrogen deficiency side effects associated with luteinizing hormone releasing hormone agonists such as hot flashes and bone loss. The Phase 2 clinical trial is designed to allow us to assess the safety and tolerability of GTx-758 in these subjects, including monitoring for venous thromboembolic events (blood clots), or VTEs. We have completed enrollment of the clinical trial and all of the subjects have reached the primary endpoint assessment. Both the 125 mg and 250 mg doses have demonstrated dose dependent increases from baseline in SHBG, reductions in free testosterone, and reductions in PSA, confirming the mechanism of action of the compound. In the cohort receiving the 125 mg dose, 11% of the patients met the primary endpoint, whereas in the cohort receiving the 250 mg dose, 26% of the patients met the primary endpoint. Improvements in bone turnover

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and hot flashes have likewise been observed. To date, there has been one reported incidence of a VTE and one reported incidence of a myocardial infarction in patients enrolled in the 250 mg arm. The final meeting of the independent Data Safety Monitoring Board occurred in June 2015 and did not identify any addressable safety issues with either dose. The final efficacy and safety data will be presented at an appropriate scientific meeting and submitted for publication. While we do not plan to dedicate any further resources to this program after the conclusion of our Phase 2 clinical trial, we are discussing this data with potential strategic partners to determine their interest in partnering or acquiring this asset, as well as our library of ER alpha agonist compounds.

***Financial Highlights***

Our net income for the three months ended September 30, 2015 was \$34.9 million. The net income for the three months ended September 30, 2015 resulted from a non-cash gain of \$40.7 million due to the revaluation of our warrant liability at September 30, 2015, which warrant liability resulted from the issuance of common stock and warrants in our November 2014 private placement discussed below. Our operating loss for the three months ended September 30, 2015 was \$5.8 million. We expect to incur significant operating losses for the foreseeable future as we continue our clinical development activities and potentially seek regulatory approval of our product candidates. We have funded our operations primarily through the sale of equity securities, collaboration and license agreements, and prior to September 2012, product revenue from sales of FARESTON<sup>®</sup>, the rights to which we sold to a third party in the third quarter of 2012. We currently have no ongoing collaborations for the development and commercialization of our product candidates and no source of revenue, nor do we expect to generate revenue for the foreseeable future. We do not expect to obtain any regulatory approvals to market any of our product candidates, including enobosarm, for the foreseeable future, and it is possible that none of our product candidates will ever receive any regulatory approvals.

At September 30, 2015, we had cash, cash equivalents and short-term investments of \$34.5 million compared to \$49.3 million at December 31, 2014. On March 6, 2014, we completed a private placement of units consisting of 12.0 million shares of common stock and warrants to purchase 10.2 million shares of our common stock for net proceeds to us of approximately \$21.1 million, after deducting offering expenses. These warrants expired on March 6, 2015. On November 14, 2014, we completed a separate private placement of units consisting of an aggregate of 64.3 million shares of our common stock and warrants to purchase an aggregate of 64.3 million shares of our common stock for net proceeds to us of \$42.8 million, after deducting offering expenses.

We estimate that our current cash, cash equivalents and short-term investments, together with interest thereon, will be sufficient to meet our projected operating requirements through the end of 2016, during which time we expect to obtain results from the patients enrolled in the first stage of each of our ongoing open-label Phase 2 clinical trials of enobosarm in patients with AR positive advanced breast cancer, using a Simon's two-stage clinical trial design, as well as the results from our planned Phase 2 proof-of-concept clinical trial evaluating enobosarm to treat postmenopausal women with SUI. While we estimate that our current cash, cash equivalents and short-term investments are sufficient to fund our operations through 2016, we will need to obtain substantial additional funding to initiate and complete the second stage of both of our ongoing open-label Phase 2 clinical trials of enobosarm in patients with AR positive advanced breast cancer and to otherwise conduct additional studies required of us to seek regulatory approval for enobosarm in patients with AR positive advanced breast cancer. In addition, if we decide to undertake any further development of our SARMs beyond our ongoing and currently-planned clinical trials and preclinical development and/or to meaningfully advance the preclinical development of the licensed SARD program, beyond identifying potential lead clinical compounds, we would need to obtain additional funding for such development, either through a financing, a strategic sale or licensing of assets, or by entering into collaborative arrangements or partnerships with third parties for such further development.

While we have been able to fund our operations to date, we currently have no ongoing collaborations for the development and commercialization of our product candidates and no source of revenue, nor do we expect to generate revenue for the foreseeable future. We also do not have any commitments for future external funding. Until we can generate a sufficient amount of product revenue, which we may never do, we expect to finance future cash needs through potential collaboration, partnering or other strategic arrangements, as well as through public or private equity offerings or debt financings, or a combination of the foregoing. Our ability to raise additional funds and the terms upon which we are able to raise such funds have been severely harmed by the failure of our POWER 1 and POWER 2 Phase 3 clinical trials of enobosarm for the prevention and treatment of muscle wasting in patients with advanced non-small cell lung cancer, or NSCLC, to meet the primary statistical criterion for the co-primary endpoints agreed upon with the FDA, and may in the future be adversely impacted by the uncertainty

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regarding the prospects of our development of enobosarm for the treatment of patients with AR positive advanced breast cancer, our ability to realize any return on our investment in GTx-758 and our ability to advance the development of enobosarm or SARDs, if at all. Our ability to raise additional funds and the terms upon which we are able to raise such funds may also be adversely affected by the uncertainties regarding our financial condition, the sufficiency of our capital resources, our ability to maintain the listing of our common stock on the NASDAQ Capital Market and recent and potential future management turnover. As a result of these and other factors, we cannot be certain that additional funding will be available on acceptable terms, or at all. If adequate funds are not available when we need them, we may be required to delay, reduce the scope of or eliminate one or more of our research or development programs, including our SARMs, GTx-758, or SARD programs, or conduct additional workforce or other expense reductions, any of which could have a material adverse effect on our business and our prospects.

**Research and Development**

Since our inception in 1997, we have been focused on drug discovery and development programs. Research and development expenses include, but are not limited to, our expenses for personnel and supplies associated with our research activities, screening and identification of product candidates, formulation and synthesis activities, manufacturing, preclinical studies, toxicology studies, clinical trials, regulatory and medical affairs activities, quality assurance activities and license fees.

We expect that our research and development expenses for fiscal year 2015 will decrease as compared to fiscal year 2014 as the prior year included employee retention expenses designed to retain essential employees continuing with us following our October 2013 workforce reduction.

There is a risk that any drug discovery and development program may not produce revenue. Moreover, because of the uncertainties inherent in drug discovery and development, including those factors described in Part II, Item 1A “Risk Factors” of this Quarterly Report on Form 10-Q, we may not be able to successfully develop and commercialize any of our product candidates.

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**Product Candidates**

The following table identifies the development phase and status for each of our clinical product candidates:

<b>Product Candidate/ Proposed Indication</b>	<b>Program</b>	<b>Clinical Development Phase</b>	<b>Status</b>
<b>Enobosarm</b> Treatment of women with advanced AR positive TNBC (18 mg)	SARM	Phase 2	Commenced enrollment of a Phase 2 open-label proof-of-concept clinical trial evaluating enobosarm in patients with advanced AR positive TNBC.
<b>Enobosarm</b> Treatment of women with ER positive and AR positive advanced breast cancer (9 mg and 18 mg)	SARM	Phase 2	Commenced enrollment of a Phase 2 open-label clinical trial evaluating enobosarm in patients with ER positive and AR positive advanced breast cancer.
<b>Enobosarm</b> Treatment of postmenopausal women with SUI (3mg)	SARM	Phase 2	Plan to initiate a Phase 2 proof-of-concept clinical trial evaluating enobosarm in postmenopausal women with SUI in the first quarter of 2016.
<b>GTx-758</b> Secondary hormonal therapy in men with metastatic and non-metastatic CRPC	Selective ER alpha agonist	Phase 2	All subjects have reached the primary endpoint assessment. Final efficacy and safety data to be presented at an appropriate scientific meeting and submitted for publication. No further development planned.

**General and Administrative Expenses**

Our general and administrative expenses consist primarily of salaries and other related costs for personnel serving executive, finance, legal, human resources, information technology, and investor relations functions. General and administrative expenses also include facility costs, insurance costs, and professional fees for legal, accounting, and public relation services.

**Critical Accounting Policies and Significant Judgments and Estimates**

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate our estimates and judgments related to revenue recognition, valuation of warrants, income taxes, intangible assets, long-term service contracts, share-based compensation, and other contingencies. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 2 to our financial statements appearing in our Annual Report on Form 10-K for the year ended December 31, 2014 as filed with the SEC, we

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believe that the following accounting policies are most critical to aid you in fully understanding and evaluating our reported financial results.

***Warrant Liability***

In November 2014, we issued warrants to purchase 64.3 million shares of our common stock in a private placement to certain investors. We classify the warrants as a liability on our balance sheet since these warrants contain certain terms that could require us (or our successor) to purchase the warrants for cash in an amount equal to the value (as calculated utilizing a contractually-agreed Black-Scholes option pricing formula) of the unexercised portion of the warrants in connection with certain change of control transactions occurring on or prior to December 31, 2016, with such cash payment capped at an amount equal to \$0.125 per unexercised share underlying each warrant. As a result of the provision of the warrants that could require cash settlement upon certain change of control transactions, we are required to account for these warrants as a liability at fair value, which is calculated using the Black-Scholes-Merton pricing valuation model. The Black-Scholes-Merton pricing valuation model requires that we use significant assumptions and judgment to determine appropriate inputs to the model. Some of the assumptions that we rely on include the volatility of our common stock over the life of the warrant and risk-free interest rate. Our warrant liability is influenced by these assumptions and the price of our common stock as of the balance sheet date. The estimated warrant liability is required to be revalued at each balance sheet date until the earlier of the exercise of the warrants or the expiration of the provision on December 31, 2016 that could require cash settlement upon certain change of control transactions. Upon the exercise of the warrants or the expiration of the provision on December 31, 2016 that could require cash settlement upon certain change of control transactions, the fair value of the warrants will be reclassified from a liability to stockholders' equity on our balance sheets and no further adjustment to the fair value would be made in subsequent periods.

***Research and Development Expenses***

Research and development expenses include, but are not limited to, our expenses for personnel, supplies, and facilities associated with research activities, screening and identification of product candidates, formulation and synthesis activities, manufacturing, preclinical studies, toxicology studies, clinical trials, regulatory and medical affairs activities, quality assurance activities and license fees. We expense these costs in the period in which they are incurred. We estimate our liabilities for research and development expenses in order to match the recognition of expenses to the period in which the actual services are received. As such, accrued liabilities related to third party research and development activities are recognized based upon our estimate of services received and degree of completion of the services in accordance with the specific third party contract.

***Share-Based Compensation***

We have stock option and equity incentive plans that provide for the purchase or acquisition of our common stock by certain of our employees and non-employees. We measure compensation expense for our share-based payments based on the fair value of the awards on the grant date and recognize the expense over the period during which an employee or non-employee director is required to provide service in exchange for the award.

The determination of the fair value of stock options on the date of grant include the expected life of the award, the expected stock price volatility over the expected life of the awards, and risk-free interest rate. We estimate the expected life of options by calculating the average of the vesting term and contractual term of the options. We estimate the expected stock price volatility based on the historical volatility of our common stock. The risk-free interest rate is determined using U.S. Treasury rates where the term is consistent with the expected life of the stock options. Expected dividend yield is not considered as we have not made any dividend payments and have no plans of doing so in the foreseeable future. The amount of share-based compensation expense recognized is reduced ratably over the vesting period by an estimate of the percentage of options granted that are expected to be forfeited or canceled before becoming fully vested. This estimate is adjusted periodically based on the extent to which actual forfeitures differ, or are expected to differ, from the previous estimate.

Share-based compensation also includes restricted stock units, or RSUs, granted to employees. We estimate the fair value of RSUs using the closing price of our stock on the grant date. The fair value of RSUs is amortized on a straight-line basis over the requisite service period of the awards. The amount of share-based compensation expense recognized is reduced ratably over the vesting period by an estimate of the percentage of RSUs that are expected to be forfeited or canceled before becoming fully vested.

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The following table summarizes share-based compensation expense included within the condensed statements of operations for the three and nine months ended September 30, 2015 and 2014:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
	(in thousands)		(in thousands)	
Research and development expenses	\$ 331	\$ 89	\$ 857	\$ 2,419
General and administrative expenses	423	177	1,096	1,861
Total share-based compensation	<u>\$ 754</u>	<u>\$ 266</u>	<u>\$ 1,953</u>	<u>\$ 4,280</u>

Share-based compensation expense recorded in the condensed statement of operations as general and administrative expense for the three months ended September 30, 2015 and 2014 included share-based compensation expense related to deferred compensation arrangements for our non-employee directors of \$27,000 and \$31,000, respectively. Share-based compensation expense recorded in the condensed statement of operations as general and administrative expense for the nine months ended September 30, 2015 and 2014 included share-based compensation expense related to deferred compensation arrangements for our non-employee directors of \$85,000 and \$94,000, respectively. At September 30, 2015, the total compensation cost related to non-vested stock options not yet recognized was approximately \$3.6 million with a weighted average expense recognition period of 3.17 years. At September 30, 2015, the total compensation cost related to non-vested RSUs not yet recognized was approximately \$4.6 million with a weighted average expense recognition period of 2.3 years.

**Recent Accounting Pronouncements**

In August 2014, the Financial Accounting Standards Board issued Accounting Standard Update 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*. The new guidance is intended to define management's responsibility to evaluate whether there is substantial doubt about an organization's ability to continue as a going concern within one year of the date the financial statements are issued and to provide related footnote disclosure. This new guidance is effective for the first annual period ending after December 15, 2016 and interim periods thereafter.

## Results of Operations

### Three and Nine Months Ended September 30, 2015 and 2014

#### Research and Development Expenses

The following table identifies the research and development expenses for each of our clinical product candidates, as well as research and development expenses pertaining to our other research and development efforts, for each of the periods presented. Research and development spending for past periods is not indicative of spending in future periods.

Proposed Candidate / Proposed Indication	Program	Three Months Ended September 30,		Nine Months Ended September 30,	
		2015	2014	2015	2014
(in thousands)					
<b>Enobosarm</b>					
Treatment of women with AR positive TNBC (18 mg)	<b>SARM</b>	\$ 1,312	\$ —	\$ 3,544	\$ —
<b>Enobosarm</b>					
Treatment of women with ER positive and AR positive advanced breast cancer (9 mg and 18 mg)	<b>SARM</b>	1,578	635	3,327	2,262
<b>Enobosarm</b>					
Prevention and treatment of muscle wasting in patients with advanced non-small cell lung cancer (3 mg)	<b>SARM</b>	—	1,909	—	11,686
<b>GTx-758</b>					
Secondary hormonal therapy in men with metastatic and non-metastatic CRPC	<b>Selective ER alpha agonist</b>	358	782	1,371	3,471
<b>Other research and development</b>		<u>576</u>	<u>36</u>	<u>1,486</u>	<u>197</u>
<b>Total research and development expenses</b>		<u>\$ 3,824</u>	<u>\$ 3,362</u>	<u>\$ 9,728</u>	<u>\$ 17,616</u>

Research and development expenses increased to \$3.8 million for the three months ended September 30, 2015 from \$3.4 million for the three months ended September 30, 2014. Research and development expenses decreased to \$9.7 million for the nine months ended September 30, 2015 from \$17.6 million for the nine months ended September 30, 2014.

Research and development expenses for enobosarm for the treatment of women with AR positive TNBC increased for both the three and nine months ended September 30, 2015 from the prior year comparable periods due to preparatory activities related to, and the initiation of, our Phase 2 proof-of-concept clinical trial of enobosarm for the treatment of women with AR positive TNBC, which preparatory activities began in the fourth quarter of 2014.

Research and development expenses for enobosarm for the prevention and treatment of AR positive and ER positive metastatic breast cancer during the three and nine months ended September 30, 2015 consisted of expenses for preparatory activities related to, and the initiation of, the Phase 2 clinical trial evaluating enobosarm 9 mg and 18 mg for the treatment of women with ER positive and AR positive advanced breast cancer, which preparatory activities began in the fourth quarter of 2014, as well as expenses related to our ongoing Phase 2 proof-of-concept

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clinical trial evaluating enobosarm 9 mg for the treatment of AR positive and ER positive metastatic breast cancer in women who have previously responded to hormonal therapy for the treatment of their metastatic breast cancer. The prior year period consisted only of expenses related to our ongoing Phase 2 proof-of-concept clinical trial evaluating enobosarm 9 mg that began in the second quarter of 2013.

Research and development expenses for enobosarm for the prevention and treatment of muscle wasting in patients with advanced NSCLC decreased for both the three and nine months ended September 30, 2015 from the prior year comparable periods. As we previously announced in August 2013, data from our two POWER Phase 3 clinical trials evaluating enobosarm 3 mg daily for the prevention and treatment of muscle wasting in patients with advanced NSCLC failed to meet the primary statistical criterion pre-specified for the co-primary endpoints of lean body mass and physical function, and the FDA will not accept a new drug application for enobosarm for this indication. Additionally, we subsequently determined that data from the POWER trials is not sufficient to support the filing and approval of a marketing authorization application, or MAA, by the European Medicines Agency without confirmatory data from another Phase 3 clinical trial of enobosarm 3 mg and we do not intend to submit a MAA in the absence of such confirmatory data. Accordingly, in 2015 we ceased spending on this indication. The three and nine months ended September 30, 2014 included expenses for activities related to satisfying the prerequisites necessary for our then-planned regulatory submission in Europe for enobosarm 3 mg, including conducting seven Phase 1 clinical trials.

Research and development expenses related to our ongoing Phase 2 clinical trial to evaluate GTX-758 as secondary hormonal therapy in men with metastatic CRPC decreased for the three and nine months ended September 30, 2015 from the prior year comparable periods due to the timing of patient activities and related management expenses as this trial was initiated in the third quarter of 2012 and enrollment was completed during the first quarter of 2015.

Additionally, research and development expenses for each product candidate in the nine months ended September 30, 2014 included expenses related to cash bonuses and stock option and RSU grants made to employees as part of our efforts to retain essential employees continuing with us following our October 2013 workforce reduction.

“Other research and development” expenses for both the three and nine months ended September 30, 2015 primarily include costs for research to identify one or more potential lead SARD compounds that could potentially be advanced into preclinical and clinical development and activities related to evaluating enobosarm and other compounds in our SARM portfolio for indications outside of oncology.

### ***General and Administrative Expenses***

General and administrative expenses increased 28% to \$2.0 million for the three months ended September 30, 2015 from \$1.6 million for the three months ended September 30, 2014. General and administrative expenses decreased 15% to \$6.2 million for the nine months ended September 30, 2015 from \$7.3 million for the nine months ended September 30, 2014. The increase for the three months ended September 30, 2015 from the prior year period was due primarily to RSU grants made to employees in February 2015. The decrease from the nine months ended September 30, 2015 was due primarily to expenses in the prior year period related to cash bonuses and stock option and RSU grants made to the employees as part of our efforts to retain essential employees continuing with us following our October 2013 workforce reduction. Additionally, insurance and legal fees have decreased for both periods from the prior year periods.

### ***Gain on Change in Fair Value of Warrant Liability***

We recognized a warrant liability due to certain provisions of the warrants we issued as part of the November 2014 private placement of common stock and warrants. The warrants are required to be accounted for as a liability at fair value and the fair value must be revalued at each balance sheet date until the earlier of the exercise of the warrants or the expiration of the provision on December 31, 2016 that could require cash settlement upon certain change of control transactions. The resulting non-cash gain or loss on the fair value revaluation at each balance sheet date is recorded as non-operating income in our condensed statement of operations.

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These warrants were revalued at fair value as of September 30, 2015 and the decrease in fair value of \$40.7 million and \$352,000 for the three and nine months ended September 30, 2015, respectively, was recorded as a non-cash gain on the change in fair value of warrant liability in the Company's condensed statement of operations.

### **Liquidity and Capital Resources**

At September 30, 2015, we had cash, cash equivalents and short-term investments of \$34.5 million compared to \$49.3 million at December 31, 2014. Net cash used in operating activities was \$14.8 million and \$23.7 million for the nine months ended September 30, 2015 and 2014, respectively, and resulted primarily from funding our operations.

Net cash provided by investing activities was \$8.7 million for the nine months ended September 30, 2015 and resulted from the maturities of short-term investments of \$49.0 million offset by the purchase of short-term investments of \$40.2 million. Net cash used in investing activities was \$1.7 million for the nine months ended September 30, 2014 and resulted primarily from the purchase of short-term investments of \$10.5 million offset by the maturities of short-term investments of \$8.8 million.

Net cash provided by financing activities was \$0 and \$20.5 million for the nine months ended September 30, 2015 and 2014, respectively. Net cash provided by financing activities for the nine months ended September 30, 2014 reflects proceeds from the issuance of common stock and warrants of \$21.1 million, partially offset by \$617,000 of tax payments related to shares withheld in order to satisfy minimum tax withholding requirements in connection with the vesting of RSUs and payments of \$2,000 on capital lease obligations.

We estimate that our current cash, cash equivalents and short-term investments, together with interest thereon, will be sufficient to meet our projected operating requirements through the end of 2016, during which time we expect to obtain results from the patients enrolled in the first stage of each of our ongoing open-label Phase 2 clinical trials of enobosarm in patients with AR positive advanced breast cancer, using a Simon's two-stage clinical trial design, as well as the results from our planned Phase 2 proof-of-concept clinical trial evaluating enobosarm to treat postmenopausal women with SUI. While we estimate that our current cash, cash equivalents and short-term investments are sufficient to fund our operations through 2016, we will need to obtain substantial additional funding to initiate and complete the second stage of both of our ongoing open-label Phase 2 clinical trials of enobosarm in patients with AR positive advanced breast cancer and to otherwise conduct additional studies required of us to seek regulatory approval for enobosarm in patients with AR positive advanced breast cancer. In addition, if we decide to undertake any further development of our SARMs beyond our ongoing and currently-planned clinical trials and preclinical development and/or to meaningfully advance the preclinical development of the licensed SARD program, beyond identifying potential lead clinical compounds, we would need to obtain additional funding for such development, either through a financing, a strategic sale or licensing of assets, or by entering into collaborative arrangements or partnerships with third parties for such further development.

Our estimate of the period of time or events through which our financial resources will be adequate to support our projected operating requirements is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed under Part II, Item 1A "Risk Factors" section of this Quarterly Report on Form 10-Q. Because of the numerous risks and uncertainties associated with the development and potential commercialization of our product candidates and other research and development activities, including risks and uncertainties that could impact the rate of progress of our development activities, we are unable to estimate with certainty the amounts of increased capital outlays and operating expenditures associated with the future development of our product candidates, if any. Our future funding requirements will depend on many factors, including:

- the scope, rate of progress and cost of our preclinical and clinical development programs, including our ongoing, planned and any future clinical trials of our product candidates;
- the terms and timing of any potential collaborative, licensing and other strategic arrangements that we may establish;
- the amount and timing of any licensing fees, milestone payments and royalty payments from potential collaborators, if any;

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- future clinical trial results;
- the cost and timing of regulatory filings and/or approvals to commercialize our product candidates and any related restrictions, limitations, and/or warnings in the label of an approved product candidate;
- the effect of competing technological and market developments; and
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights, and the cost of defending any other litigation claims.

We do not currently have any commitments for future external funding nor do we currently have any sources of revenue. Until we can generate a sufficient amount of product revenue, which we may never do, we expect to finance future cash needs through potential collaboration, partnering or other strategic arrangements, as well as through public or private equity offerings or debt financings, or a combination of the foregoing. In October 2013, following our announcement that our POWER 1 and POWER 2 Phase 3 clinical trials for the prevention and treatment of muscle wasting in patients with advanced NSCLC failed to achieve the results required by the FDA for us to submit a new drug application for enobosam, we announced and implemented a workforce reduction of approximately 60%. If we are unable to raise additional funds when needed, we may need to further reduce our expenditures, perhaps significantly, to preserve our cash. Cost-cutting measures that we may take in the future may not be sufficient to enable us to meet our cash requirements, and they may negatively affect our business and growth prospects.

To the extent that we raise additional funds through potential collaboration, partnering or other strategic arrangements, it may be necessary to relinquish rights to some of our technologies or product candidates, or grant licenses on terms that are not favorable to us, any of which could result in the stockholders of GTx having little or no continuing interest in our SARMs, GTx-758 and/or SARDs programs as stockholders or otherwise. To the extent we raise additional funds by issuing equity securities, our stockholders may experience significant dilution, particularly given our currently depressed stock price, and debt financing, if available, may involve restrictive covenants. For example, we completed a private placement of common stock and warrants in March 2014, which was substantially dilutive, and completed a subsequent private placement in November 2014 that represented even greater dilution, and our stockholders may experience additional, perhaps substantial, dilution should we again raise additional funds by issuing equity securities. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. Our ability to raise additional funds and the terms upon which we are able to raise such funds have been severely harmed by the failure of our two enobosam POWER trials to meet the primary statistical criterion for the co-primary endpoints agreed upon with the FDA, and may in the future be adversely impacted by the uncertainty regarding the prospects of our development of enobosam for the treatment of patients with AR positive advanced breast cancer, our ability to realize any return on our investment in GTx-758 and our ability to advance the development of enobosam or SARDs, if at all. Our ability to raise additional funds and the terms upon which we are able to raise such funds may also be adversely affected by the uncertainties regarding our financial condition, the sufficiency of our capital resources, our ability to maintain the listing of our common stock on the NASDAQ Capital Market and recent and potential future management turnover. As a result of these and other factors, we cannot be certain that additional funding will be available on acceptable terms, or at all. If adequate funds are not available when we need them, we may be required to delay, reduce the scope of or eliminate one or more of our research or development programs, including our SARMs, GTx-758, or SARD programs, or conduct additional workforce or other expense reductions, any of which could have a material adverse effect on our business and our prospects.

### ***Contractual Obligations***

Our future minimum contractual obligations were reported in our Annual Report on Form 10-K for the year ended December 31, 2014, as filed with the SEC. On April 13, 2015, we entered into a new office lease with respect to our current office space. The new office lease term commenced on May 1, 2015 with a three year term ending on April 30, 2018. Operating lease obligations under the new office lease include aggregate future minimum payments of approximately \$1.4 million. There were no material changes during the third quarter of 2015 from the contractual obligations previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2014.

### ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

During the nine months ended September 30, 2015, there were no material changes to our market risk disclosures as set forth in Part II, Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2014.

### ITEM 4. CONTROLS AND PROCEDURES

We maintain disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities and Exchange Act of 1934, as amended (the "Exchange Act")) that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including our Principal Executive Officer and Principal Financial Officer, as appropriate, to allow for timely decisions regarding required disclosures.

We have carried out an evaluation, under the supervision and with the participation of our management, including our Principal Executive Officer and Principal 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) under the Exchange Act) as of the end of the period covered by this report. Based on the evaluation of these disclosure controls and procedures, our Principal Executive Officer and Principal Financial Officer have concluded that our disclosure controls and procedures were effective.

There were no changes in our internal control over financial reporting during the third quarter of 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## PART II: OTHER INFORMATION

### ITEM 1A. RISK FACTORS

We have identified the following additional risks and uncertainties that may have a material adverse effect on our business, financial condition or results of operations. Investors should carefully consider the risks described below before making an investment decision. Our business faces significant risks, and the risks described below may not be the only risks we face. Additional risks not presently known to us or that we currently believe are immaterial may also significantly impair our business operations. If any of these risks occur, our business, results of operations or financial condition could suffer, the market price of our common stock could decline and you could lose all or part of your investment in our common stock.

We have marked with an asterisk (\*) those risks described below that reflect substantive changes from the risks described under Part I, Item 1A "Risk Factors" included in our Annual Report on Form 10-K for the year ended December 31, 2014 filed with the Securities and Exchange Commission on March 16, 2015.

#### **Risks Related to Our Financial Condition and Need for Additional Financing**

*We have incurred losses since inception, and we anticipate that we will incur continued losses for the foreseeable future.\**

As of September 30, 2015, we had an accumulated deficit of \$510.2 million. Our net loss for the nine months ended September 30, 2015 was \$15.5 million. We expect to incur significant operating losses for the foreseeable future as we continue our clinical development activities and potentially seek regulatory approval of our product candidates. These losses, among other things, have had and will continue to have an adverse effect on our stockholders' equity and working capital.

Our current product candidates, enobosarm (GTx-024) and GTx-758 (Capesaris®), will require significant additional clinical development, financial resources and personnel in order to obtain necessary regulatory approvals for these product candidates and to develop them into commercially viable products. A substantial portion of our

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efforts and expenditures have been devoted to enobosarm 3 mg, which was the subject of our POWER 1 and POWER 2 Phase 3 clinical trials for the prevention and treatment of muscle wasting in patients with advanced non-small cell lung cancer, or NSCLC. The failure of the POWER trials to meet the primary statistical criterion for the co-primary endpoints agreed upon with the U.S. Food and Drug Administration, or FDA, significantly depressed our stock price and has harmed our future prospects. Although we evaluated the potential submission of a marketing authorization application, or MAA, to the European Medicines Agency, or EMA, seeking marketing approval of enobosarm 3 mg in the European Union, or EU, for the prevention and treatment of muscle wasting in patients with advanced NSCLC, based on input from the Medicines and Healthcare Products Regulatory Agency, or MHRA, we believe that the data from the POWER trials is not sufficient to support the filing and approval of a MAA without confirmatory data from another Phase 3 clinical trial of enobosarm 3 mg. As a result of this input, we do not intend to submit a MAA in the absence of such confirmatory data. In addition, since data from the two POWER trials failed to meet the primary statistical criterion pre-specified for the co-primary endpoints of lean body mass and physical function, the FDA will not accept a new drug application, or NDA, for enobosarm 3 mg for the prevention and treatment of muscle wasting in patients with advanced NSCLC. Accordingly, our strategy does not currently include further development of enobosarm for this indication in the U.S. or in Europe unless such development is part of a collaborative arrangement or strategic partnership. Moreover, our current strategy is focused on the further development of enobosarm for the treatment of patients with androgen receptor, or AR, positive advanced breast cancer. However, the development of enobosarm for the treatment of patients with AR positive advanced breast cancer is at an early stage and is subject to the substantial risk of failure inherent in the development of early-stage product candidates. While we do not intend to commit additional internal resources for the development of GTX-758 once we have completed the efficacy and safety analysis of our ongoing Phase 2 clinical trial, our preclinical evaluation of our newly in-licensed selective androgen receptor degrader, or SARD, technology, our preclinical evaluation of SARMS as a potential treatment of Duchenne muscular dystrophy, or DMD, and our planned clinical evaluation of enobosarm for the treatment of postmenopausal women with stress urinary incontinence, or SUI, will in each case require significant additional financial resources and personnel to continue our development of these programs. Because of the numerous risks and uncertainties associated with developing and commercializing small molecule drugs, we are unable to predict the extent of any future losses or when we will become profitable, if at all. In addition, we do not expect to obtain any regulatory approvals to market any of our product candidates, including enobosarm, for the foreseeable future, and it is possible that none of our product candidates will ever receive any regulatory approvals.

We have funded our operations primarily through public offerings and private placements of our securities, as well as payments from our former collaborators. We also previously recognized product revenue from the sale of FARESTON<sup>®</sup>, the rights to which we sold to a third party in the third quarter of 2012. Currently, we have no ongoing collaborations for the development and commercialization of our product candidates, and as a result of the sale of our rights and certain assets related to FARESTON<sup>®</sup>, we also currently have no sources of revenue.

If we and/or any potential collaborators are unable to develop and commercialize SARMS, GTX-758, or SARD technology, if development is further delayed or is eliminated, or if sales revenue from SARMS, GTX-758, or SARD technology upon receiving marketing approval, if ever, is insufficient, we may never become profitable and we will not be successful.

***We will need to raise substantial additional capital and may be unable to raise capital when needed, which would force us to delay, reduce or eliminate our product development programs and could cause us to discontinue our operations.\****

We will need to raise substantial additional capital to:

- fund our operations and conduct clinical trials;
- continue our research and development;
- seek regulatory approval for our product candidates; and
- commercialize our product candidates, if any such product candidates receive regulatory approval for commercial sale.

We estimate that our current cash, cash equivalents and short-term investments, together with interest thereon,

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will be sufficient to meet our projected operating requirements through the end of 2016, during which time we expect to obtain results from the patients enrolled in the first stage of each of our ongoing open-label Phase 2 clinical trials of enobosarm in patients with AR positive advanced breast cancer, using a Simon's two-stage clinical trial design, as well as the results from our planned Phase 2 proof-of-concept clinical trial evaluating enobosarm to treat postmenopausal women with SUI. While we estimate that our current cash, cash equivalents and short-term investments are sufficient to fund our operations through 2016, we will need to obtain substantial additional funding to initiate and complete the second stage of both of our ongoing open-label Phase 2 clinical trials of enobosarm in patients with AR positive advanced breast cancer and to otherwise conduct additional studies required of us to seek regulatory approval for enobosarm in patients with AR positive advanced breast cancer. In addition, if we decide to undertake any further development of our SARMs beyond our ongoing and currently-planned clinical trials and preclinical development and/or to meaningfully advance the preclinical development of the licensed SARD program, beyond identifying potential lead clinical compounds, we would need to obtain additional funding for such development, either through a financing, a strategic sale or licensing of assets, or by entering into collaborative arrangements or partnerships with third parties for such further development.

Our future funding requirements will depend on many factors, including:

- the scope, rate of progress and cost of our preclinical and clinical development programs, including our ongoing, planned and any future clinical trials of our product candidates;
- the terms and timing of any potential collaborative, licensing and other strategic arrangements that we may establish;
- the amount and timing of any licensing fees, milestone payments and royalty payments from potential collaborators, if any;
- future clinical trial results;
- the cost and timing of regulatory filings and/or approvals to commercialize our product candidates and any related restrictions, limitations, and/or warnings in the label of an approved product candidate;
- the effect of competing technological and market developments; and
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights, and the cost of defending any other litigation claims.

While we have been able to fund our operations to date, we currently have no ongoing collaborations for the development and commercialization of our product candidates and no source of revenue, nor do we expect to generate revenue for the foreseeable future. We also do not have any commitments for future external funding. Until we can generate a sufficient amount of product revenue, which we may never do, we expect to finance future cash needs through potential collaboration, partnering or other strategic arrangements, as well as through public or private equity offerings or debt financings, or a combination of the foregoing. In October 2013, following our announcement that the POWER trials failed to achieve the results required by the FDA for us to submit a NDA for enobosarm, we announced and implemented a workforce reduction of approximately 60%. If we are unable to raise additional funds when needed, we may need to further reduce our expenditures, perhaps significantly, to preserve our cash. Cost-cutting measures that we may take in the future may not be sufficient to enable us to meet our cash requirements, and they may negatively affect our business and growth prospects.

To the extent that we raise additional funds through potential collaboration, partnering or other strategic arrangements, it may be necessary to relinquish rights to some of our technologies or product candidates, or grant licenses on terms that are not favorable to us, any of which could result in the stockholders of GTx having little or no continuing interest in our SARMs, GTx-758 and/or SARDs programs as stockholders or otherwise. To the extent we raise additional funds by issuing equity securities, our stockholders may experience significant dilution, particularly given our currently depressed stock price, and debt financing, if available, may involve restrictive covenants. For example, we completed a private placement of common stock and warrants in March 2014, which was substantially dilutive, and completed a subsequent private placement in November 2014 that represented even greater dilution, and our stockholders may experience additional, perhaps substantial, dilution should we again raise additional funds by issuing equity securities. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. Our ability to raise additional funds and the terms upon which we are able to raise such funds have been severely harmed by the failure of our two prior enobosarm POWER trials to meet the primary statistical criterion for the co-primary endpoints agreed upon with the FDA, and may in the

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future be adversely impacted by the uncertainty regarding the prospects of our development of enobosarm for the treatment of patients with AR positive advanced breast cancer, our ability to realize any return on our investment in GTx-758 and our ability to advance the development of enobosarm or SARs, if at all. Our ability to raise additional funds and the terms upon which we are able to raise such funds may also be adversely affected by the uncertainties regarding our financial condition, the sufficiency of our capital resources, our ability to maintain the listing of our common stock on the NASDAQ Capital Market and recent and potential future management turnover. As a result of these and other factors, we cannot be certain that additional funding will be available on acceptable terms, or at all. If adequate funds are not available when we need them, we may be required to delay, reduce the scope of or eliminate one or more of our research or development programs, including our SARs, GTx-758, or SARD programs, or conduct additional workforce or other expense reductions, any of which could have a material adverse effect on our business and our prospects.

**Risks Related to Development of Product Candidates**

*We are substantially dependent on the success of enobosarm and our failure to advance the development of enobosarm or to obtain regulatory approval of enobosarm would significantly harm our prospects.\**

Our current strategy is focused on the further development of SARs. However, the development of enobosarm for the treatment of patients with AR positive advanced breast cancer is at an early stage and is subject to the significant risk of failure inherent in the development of early-stage product candidates. Moreover, we still have only limited data from our preclinical models of breast cancer and our ongoing Phase 2 proof-of-concept clinical trial evaluating enobosarm 9mg in women with ER positive and AR positive metastatic breast cancer. As a result, we will need to conduct costly and time-consuming additional clinical trials of enobosarm for the treatment of patients with AR positive advanced breast cancer to determine whether enobosarm is an effective treatment for patients with advanced AR positive TNBC and ER positive and AR positive advanced breast cancer.

Preclinical studies, including studies of SARs in animal models of disease, may not accurately predict the results of subsequent human clinical trials of enobosarm, including the results of our ongoing Phase 2 clinical trials of enobosarm in patients with AR positive advanced breast cancer. Furthermore, the positive results from our ongoing Phase 2 proof-of-concept clinical trial evaluating enobosarm 9mg in women with ER positive and AR positive metastatic breast cancer does not ensure that our ongoing Phase 2 clinical trials of enobosarm in patients with AR positive advanced breast cancer will be successful or that any later trials will be successful. A number of companies in the pharmaceutical industry, including us and those with greater resources and experience than we have, have suffered significant setbacks in Phase 3 and later-stage clinical trials, even after receiving encouraging results in earlier clinical trials. Due to the uncertain and time-consuming clinical development and regulatory approval process, we may not be successful in developing enobosarm for the treatment of patients with AR positive advanced breast cancer, or in developing any of our product candidates, and it is possible that none of our current product candidates will ever become commercial products.

A substantial portion of our efforts and expenditures have been devoted to enobosarm 3 mg, which was the subject of our POWER 1 and POWER 2 Phase 3 clinical trials evaluating enobosarm 3 mg for the prevention and treatment of muscle wasting in patients with advanced NSCLC. We announced in August 2013 that these two Phase 3 clinical trials failed to meet the co-primary endpoints of lean body mass and physical function that were assessed statistically using responder analyses as required by the FDA. The failure of the POWER trials to meet the primary statistical criterion for the co-primary endpoints agreed upon with the FDA significantly depressed our stock price and has harmed our future prospects. Although we evaluated the potential submission of a MAA to the EMA seeking marketing approval of enobosarm 3 mg in the EU for the prevention and treatment of muscle wasting in patients with advanced NSCLC, based on recent input from the MHRA, we believe that the data from the POWER trials is not sufficient to support the filing and approval of a MAA without confirmatory data from another Phase 3 clinical trial of enobosarm 3 mg. As a result of this input, we do not intend to submit a MAA in the absence of such confirmatory data. In addition, since data from the two POWER trials failed to meet the primary statistical criterion pre-specified for the co-primary endpoints of lean body mass and physical function, the FDA will not accept a NDA for enobosarm 3 mg for the prevention and treatment of muscle wasting in patients with advanced NSCLC. Accordingly, our strategy does not currently include further development of enobosarm for this indication in the U.S. or in Europe unless such development is part of a collaborative arrangement or strategic partnership.

In addition, we do not currently have any further clinical development plans for GTx-758 and we do not in any event have sufficient funds to enable further clinical development of GTx-758. Likewise, our evaluation of the

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recently-licensed SARD program is at a very early stage and any meaningful preclinical and clinical development of our SARD program, beyond identifying potential lead clinical compounds, will require us to obtain additional funding. In addition, our evaluation of SARMs as a potential treatment for SUI and DMD is at a very early stage, and our ability to meaningfully advance development of SARMs as a potential treatment for SUI or DMD is subject to our ability to obtain additional funding. Accordingly, our current strategy and near-term prospects are substantially dependent on the successful development of enobosarm for the treatment of patients with AR positive advanced breast cancer.

***We and any potential collaborators will not be able to commercialize our product candidates if our preclinical studies do not produce successful results or if our clinical trials do not adequately demonstrate safety and efficacy in humans.\****

Significant additional clinical development and financial resources will be required to obtain necessary regulatory approvals for our product candidates and to develop them into commercially viable products. Preclinical and clinical testing is expensive, can take many years to complete and has an uncertain outcome. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and interim results of a clinical trial do not necessarily predict final results. Typically, the failure rate for development candidates is high. If a product candidate fails at any stage of development, we will not have the anticipated revenues from that product candidate to fund our operations, and we will not receive any return on our investment in that product candidate. For example, we announced in August 2013 that our POWER 1 and POWER 2 Phase 3 clinical trials evaluating enobosarm for the prevention and treatment of muscle wasting in patients with advanced NSCLC failed to meet the co-primary endpoints of lean body mass and physical function that were assessed statistically using responder analyses as agreed upon with the FDA. Although we evaluated the potential submission of a MAA to the EMA seeking marketing approval of enobosarm 3 mg in the EU for the prevention and treatment of muscle wasting in patients with advanced NSCLC, based on recent input from the MHRA, we believe that the data from the POWER trials is not sufficient to support the filing and approval of a MAA without confirmatory data from another Phase 3 clinical trial of enobosarm 3 mg. As a result of this input, we do not intend to submit a MAA in the absence of such confirmatory data. In addition, since data from the two POWER trials failed to meet the primary statistical criterion pre-specified for the co-primary endpoints of lean body mass and physical function, the FDA will not accept a NDA for enobosarm 3 mg for the prevention and treatment of muscle wasting in patients with advanced NSCLC. Accordingly, our strategy does not currently include further development of enobosarm for this indication in the U.S. or in Europe unless such development is part of a collaborative arrangement or strategic partnership.

In addition, in the first quarter of 2015, we entered into an exclusive worldwide license agreement with the University of Tennessee Research Foundation, or UTRF, to develop its proprietary SARD technology. However, our evaluation of the licensed SARD program is at a very early stage and it is possible that we may determine not to move forward with any meaningful preclinical development of our SARD program, beyond identifying potential lead clinical compounds. Even if we do determine to move forward with any meaningful preclinical development of our SARD program, to advance preclinical development of our SARD program through the requisite preclinical studies to support initial human studies, we will require additional funding. Accordingly, as a result of our unsuccessful research and preclinical development and/or our inability to obtain sufficient funding to meaningfully advance preclinical development of our SARD program, we may fail to realize the anticipated benefits of our licensing of this program.

Significant delays in clinical testing could materially impact our product development costs. We do not know whether planned clinical trials will begin on time, or whether ongoing clinical trials will need to be modified or will be completed on schedule, if at all. For example, our ongoing Phase 2 clinical trials of enobosarm in patients with AR positive advanced breast cancer are designed to be conducted using a Simon's two-stage design, pursuant to which we plan to enroll approximately half of the patients in the first stage, and, upon achievement of a pre-specified minimal response rate, we plan to proceed with enrollment of the second stage. However, even if we achieve the pre-specified minimal response rate, our ability to proceed with enrollment of and to complete the second stage in both trials is subject to our ability to obtain additional funding, which we may be unable to do. In any event, we or any potential collaborators may experience numerous unforeseen and/or adverse events during, or as a result of, preclinical testing and the clinical trial process that could delay or prevent our or our potential collaborators' ability to commercialize our product candidates, including:

- regulators or institutional review boards may not authorize us or any potential collaborators to commence a clinical trial or conduct a clinical trial at a prospective trial site, or we may experience

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substantial delays in obtaining these authorizations;

- preclinical or clinical trials may produce negative or inconclusive results, which may require us or any potential collaborators to conduct additional preclinical or clinical testing or to abandon projects that we expect to be promising;
- even if preclinical or clinical trial results are positive, the FDA or foreign regulatory authorities could nonetheless require us to conduct unanticipated additional clinical trials;
- registration or enrollment in clinical trials may be slower than we anticipate, resulting in significant delays or study terminations;
- we or any potential collaborators may suspend or terminate clinical trials if the participating patients are being exposed to unacceptable health risks;
- regulators or institutional review boards may suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements; and
- our product candidates may not have the desired effects or may include undesirable side effects.

If any of these events were to occur and, as a result, we or any potential collaborators have significant delays in or termination of clinical trials, our costs could increase and our ability to generate revenue could be impaired, which would materially and adversely impact our business, financial condition and growth prospects.

***If we or any potential collaborators observe serious or other adverse events during the time our product candidates are in development or after our products are approved and on the market, we or any potential collaborators may be required to perform lengthy additional clinical trials, may be required to cease further development of such product candidates, may be denied regulatory approval of such products, may be forced to change the labeling of such products or may be required to withdraw any such products from the market, any of which would hinder or preclude our ability to generate revenues.***

In three Phase 2 clinical trials of GTX-758, which we discontinued in February 2012, we observed venous thromboembolic events, or blood clots, in subjects treated with GTX-758 at the doses then being studied in these clinical trials (1000 mg and higher per day) and reported those events to the FDA. There were two deaths in subjects treated with GTX-758 and two deaths in subjects treated with Lupron Depot<sup>®</sup>. In February 2012, the FDA placed all of our then ongoing clinical studies of GTX-758 on full clinical hold, and we suspended further enrollment into these studies and notified clinical sites to discontinue treatment of subjects with GTX-758. In May 2012, the FDA notified us that it had removed the full clinical hold on GTX-758. In the third quarter of 2012, we initiated a Phase 2 clinical trial to evaluate GTX-758, at doses lower than those which were previously being tested in our discontinued Phase 2 clinical trials, as secondary hormonal therapy in men with metastatic castration-resistant prostate cancer, or CRPC. Although our current Phase 2 clinical trial is evaluating GTX-758 at doses lower than those which were previously being tested in our discontinued Phase 2 clinical trials, we cannot be confident that we will not observe an unacceptable incidence of venous thromboembolic events or other serious adverse events, or SAEs, in the current Phase 2 clinical trial. In this regard, there has been one reported incidence of a VTE and one reported incidence of a myocardial infarction, or MI, in patients enrolled in the 250 mg arm of our ongoing Phase 2 clinical trial of GTX-758, resulting in the discontinuation of both patients from active treatment, and we cannot assure you that we will not observe additional SAEs in this trial. If an unacceptable incidence of VTEs, MIs, or other SAEs are observed in our current Phase 2 clinical trial of GTX-758, we may be required to abandon our development of GTX-758, in which case, we would not receive any return on our investment in that product candidate.

In our Phase 2 clinical trials for enobosarm for the treatment of muscle wasting in patients with cancer and healthy older males and postmenopausal females, we observed mild elevations of hepatic enzymes, which in certain circumstances may lead to liver failure, in a few patients in both the placebo and enobosarm treated groups. Reductions in high-density lipoproteins, or HDL, have also been observed in subjects treated with enobosarm. Lower levels of HDL could lead to increased risk of adverse cardiovascular events. In addition, in our ongoing Phase 2 proof-of-concept clinical trial evaluating enobosarm in a 9 mg daily dose for the treatment of patients with ER positive and AR positive metastatic breast cancer, bone pain of the chest cage was assessed as possibly related to enobosarm. Although doses up to 30 mg have been evaluated in short duration studies, doses of 9 mg and 18 mg currently being tested in our ongoing Phase 2 clinical trials may increase the risk or incidence of known potential side effects of SARMS including elevations in hepatic enzymes and further reductions in HDL, in addition to the emergence of side effects that have not been seen to date. Although no evidence of virilization has been seen to date with any dose of enobosarm, higher doses for longer duration may increase the risk of hair growth and

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masculinization in some women.

If the incidence of serious or other adverse events related to our product candidates increases in number or severity, if a regulatory authority believes that these or other events constitute an adverse effect caused by the drug, or if other effects are identified during clinical trials that we or any potential collaborators may conduct in the future or after any of our product candidates are approved and marketed:

- we or any potential collaborators may be required to conduct additional preclinical or clinical trials, make changes in the labeling of any such approved products, reformulate any such products, or implement changes to or obtain new approvals of our contractors' manufacturing facilities;
- regulatory authorities may be unwilling to approve our product candidates or may withdraw approval of our products;
- we may experience a significant drop in the sales of the affected products;
- our reputation in the marketplace may suffer; and
- we may become the target of lawsuits, including class action suits.

Any of these events could prevent approval or harm sales of the affected product candidates or products, or could substantially increase the costs and expenses of commercializing and marketing any such products.

**Risks Related to Our Dependence on Third Parties**

*If we do not establish collaborations for our product candidates or otherwise raise substantial additional capital, we will likely need to alter, delay or abandon our development and any commercialization plans.\**

Our strategy includes selectively partnering or collaborating with leading pharmaceutical and biotechnology companies to assist us in furthering development and potential commercialization of our product candidates. We face significant competition in seeking appropriate collaborators, and collaborations are complex and time consuming to negotiate and document. We may not be successful in entering into new collaborations with third parties on acceptable terms, or at all. In addition, we are unable to predict when, if ever, we will enter into any additional collaborative arrangements because of the numerous risks and uncertainties associated with establishing such arrangements. If we are unable to negotiate new collaborations, we may have to curtail the development of a particular product candidate, reduce, delay, or terminate its development or one or more of our other development programs, delay its potential commercialization or reduce the scope of our sales or marketing activities or increase our expenditures and undertake development or commercialization activities at our own expense. For example, we may have to cease further development of our enobosarm program if we are unable to raise sufficient funding for any additional clinical development of enobosarm through new collaborative arrangements with third parties or other financing alternatives. In this regard, if we decide to undertake any further development of our SARMs beyond our ongoing and currently-planned clinical trials and preclinical development, we would need to obtain additional funding for such development, either through financing or by entering into collaborative arrangements or partnerships with third parties for any such further development. Moreover, the ongoing Phase 2 clinical trials of enobosarm in patients with AR positive advanced breast cancer are designed to be conducted using a Simon's two-stage design, pursuant to which we plan to enroll approximately half of the patients in the first stage, and, upon achievement of a pre-specified minimal response rate, we plan to proceed with enrollment of the second stage. However, even if we achieve the pre-specified minimal response rate, our ability to proceed with enrollment of and to complete the second stage in both trials is subject to our ability to obtain additional funding, which we may be unable to do. In addition, we do not plan to dedicate further resources to GTx-758 after the conclusion of our ongoing Phase 2 clinical trial of GTx-758 and while we are currently determining third party interest in partnering or acquiring this asset and other preclinical ER alpha agonist compounds, we may be unable to partner or divest these assets in a timely manner, or at all, and therefore may not receive any return on our investment in GTx-758. Likewise, any meaningful preclinical development, beyond identifying potential lead clinical compounds, of our SARD program will require us to obtain additional funding. In addition, our evaluation of SARMs as a potential treatment for SUI and DMD is at a very early stage, and our ability to meaningfully advance development of SARMs as a potential treatment for SUI or DMD is subject to our ability to obtain additional funding. If we do not have sufficient funds, we will not be able to advance the development of our product candidates or otherwise bring our product candidates to market and generate product revenues.

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***Any collaborative arrangements that we establish in the future may not be successful or we may otherwise not realize the anticipated benefits from these collaborations. In addition, any future collaborative arrangements may place the development and commercialization of our product candidates outside our control, may require us to relinquish important rights or may otherwise be on terms unfavorable to us.***

We have in the past established and intend to continue to establish collaborations with third parties to develop and commercialize some of our current and future product candidates, and these collaborations may not be successful or we may otherwise not realize the anticipated benefits from these collaborations. For example, in March 2011, we and Ipsen Biopharm Limited, or Ipsen, mutually agreed to terminate our collaboration for the development and commercialization of our toremifene-based product candidate, and, as a result, we will not receive any additional milestone payments from Ipsen on account of our collaboration with Ipsen. As of the date of this report, we have no ongoing collaborations for the development and commercialization of our product candidates. We may not be able to locate third-party collaborators to develop and market our product candidates, and we lack the capital and resources necessary to develop our product candidates alone.

Dependence on collaborative arrangements subjects us to a number of risks, including:

- we may not be able to control the amount and timing of resources that our potential collaborators may devote to our product candidates;
- potential collaborations may experience financial difficulties or changes in business focus;
- we may be required to relinquish important rights such as marketing and distribution rights;
- should a collaborator fail to develop or commercialize one of our compounds or product candidates, we may not receive any future milestone payments and will not receive any royalties for the compound or product candidate;
- business combinations or significant changes in a collaborator's business strategy may also adversely affect a collaborator's willingness or ability to complete its obligations under any arrangement;
- under certain circumstances, a collaborator could move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors; and
- collaborative arrangements are often terminated or allowed to expire, which could delay the development and may increase the cost of developing our product candidates.

***If third parties do not manufacture our product candidates in sufficient quantities, in the required timeframe, at an acceptable cost, and with appropriate quality control, clinical development and commercialization of our product candidates would be delayed.***

We do not currently own or operate manufacturing facilities, and we rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our product candidates. Our current and anticipated future dependence upon others for the manufacture of our product candidates may adversely affect our future profit margins, if any, and our ability to develop product candidates and commercialize any product candidates on a timely and competitive basis.

We rely on third-party vendors for the manufacture of enobosarm drug substance. If the contract manufacturers that we are currently utilizing to meet our supply needs for enobosarm or any future SARM product candidates prove incapable or unwilling to continue to meet our supply needs, we could experience a delay in conducting any additional clinical trials of enobosarm or any future SARM product candidates. In addition, we rely on third-party contractors for the manufacture of GTx-758 drug substance. We may not be able to maintain or renew our existing or any other third-party manufacturing arrangements on acceptable terms, if at all. If our suppliers fail to meet our requirements for GTx-758, enobosarm or any future product candidates for any reason, we would be required to obtain alternate suppliers. Any inability to obtain alternate suppliers, including an inability to obtain approval from the FDA of an alternate supplier, would delay or prevent the clinical development and commercialization of these product candidates.

***Use of third-party manufacturers may increase the risk that we will not have adequate supplies of our product candidates or products.***

Reliance on third-party manufacturers entails risks, to which we would not be subject if we manufactured product candidates or products ourselves, including:

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- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party because of factors beyond our control;
- the possible termination or non-renewal of the agreement by the third party, based on its own business priorities, at a time that is costly or inconvenient for us; and
- drug product supplies not meeting the requisite requirements for clinical trial use.

If we are not able to obtain adequate supplies of our product candidates, it will be more difficult for us to develop our product candidates and compete effectively. Our product candidates and any products that we and/or our potential collaborators may develop may compete with other product candidates and products for access to manufacturing facilities.

Our present or future manufacturing partners may not be able to comply with FDA-mandated current Good Manufacturing Practice regulations, other FDA regulatory requirements or similar regulatory requirements outside the United States. Failure of our third-party manufacturers or us to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates.

***If third parties on whom we rely do not perform as contractually required or expected, we may not be able to obtain regulatory approval for or successfully commercialize our product candidates.***

We do not have the ability to independently conduct clinical trials for our product candidates, and we must rely on third parties, such as contract research organizations, or CROs, medical institutions, clinical investigators and contract laboratories to conduct our clinical trials. In addition, we rely on third parties to assist with our preclinical development of product candidates. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if the third parties need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our preclinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates.

### **Risks Related to Our Intellectual Property**

***If we lose our licenses from UTRF, we may be unable to continue a substantial part of our business.\****

We have licensed intellectual property rights and technology from UTRF used in a substantial part of our business. Our license agreements with UTRF, under which we were granted rights to SARM compounds and technologies, including enobosarm, and more recently, to SARD compounds and technology, may be terminated by UTRF if we are in breach of our obligations under, or fail to perform any terms of, the relevant agreement and fail to cure that breach. If one or both of these agreements are terminated, then we may lose our rights to utilize the SARM and/or SARD technology and intellectual property covered by those agreements to market, distribute and sell licensed products, which may prevent us from continuing a substantial part of our business and may result in a material and serious adverse effect on our financial condition, results of operations and any prospects for growth.

***If some or all of our or our licensor's patents expire or are invalidated or are found to be unenforceable, or if some or all of our patent applications do not result in issued patents or result in patents with narrow, overbroad, or unenforceable claims, or claims that are not supported in regard to written description or enablement by the specification, or if we are prevented from asserting that the claims of an issued patent cover a product of a third party, we may be subject to competition from third parties with products in the same class of products as our product candidates or products with the same active pharmaceutical ingredients as our product candidates, including in those jurisdictions in which we have no patent protection.\****

Our commercial success will depend in part on obtaining and maintaining patent and trade secret protection for our product candidates, as well as the methods for treating patients in the product indications using these product candidates. We will be able to protect our product candidates and the methods for treating patients in the product indications using these product candidates from unauthorized use by third parties only to the extent that we or our exclusive licensor owns or controls such valid and enforceable patents or trade secrets.

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Our rights to certain patents and patent applications relating to SARM compounds that we have licensed from UTRF are subject to the terms of UTRF's inter-institutional agreements with The Ohio State University, or OSU, and our rights to future related improvements in some instances are subject to UTRF's exercise of exclusive options under its agreements with OSU for such improvements.

Even if our product candidates and the methods for treating patients for prescribed indications using these product candidates are covered by valid and enforceable patents and have claims with sufficient scope, disclosure and support in the specification, the patents will provide protection only for a limited amount of time. Our and our licensor's ability to obtain patents can be highly uncertain and involve complex and in some cases unsettled legal issues and factual questions. Furthermore, different countries have different procedures for obtaining patents, and patents issued in different countries provide different degrees of protection against the use of a patented invention by others. Therefore, if the issuance to us or our licensor, in a given country, of a patent covering an invention is not followed by the issuance, in other countries, of patents covering the same invention, or if any judicial interpretation of the validity, enforceability, or scope of the claims in, or the written description or enablement in, a patent issued in one country is not similar to the interpretation given to the corresponding patent issued in another country, our ability to protect our intellectual property in those countries may be limited. Changes in either patent laws or in interpretations of patent laws in the United States and other countries may materially diminish the value of our intellectual property or narrow the scope of our patent protection.

We may be subject to competition from third parties with products in the same class of products as our product candidates or products with the same active pharmaceutical ingredients as our product candidates in those jurisdictions in which we have no patent protection. Even if patents are issued to us or our licensor regarding our product candidates or methods of using them, those patents can be challenged by our competitors who can argue such patents are invalid or unenforceable, lack of utility, lack sufficient written description or enablement, or that the claims of the issued patents should be limited or narrowly construed. Patents also will not protect our product candidates if competitors devise ways of making or using these product candidates without legally infringing our patents. The Federal Food, Drug, and Cosmetic Act and FDA regulations and policies create a regulatory environment that encourages companies to challenge branded drug patents or to create non-infringing versions of a patented product in order to facilitate the approval of abbreviated new drug applications for generic substitutes. These same types of incentives encourage competitors to submit new drug applications that rely on literature and clinical data not prepared for or by the drug sponsor, providing another less burdensome pathway to approval.

We also rely on trade secrets to protect our technology, especially where we do not believe that patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. Our employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our confidential information to competitors, and confidentiality agreements may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. Enforcing a claim that a third party illegally obtained and is using our trade secrets is expensive and time-consuming, and the outcome is unpredictable. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how. Failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

***If we infringe intellectual property rights of third parties, it may increase our costs or prevent us from being able to commercialize our product candidates.***

There is a risk that we are infringing the proprietary rights of third parties because numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields that are the focus of our development and manufacturing efforts. Others might have been the first to make the inventions covered by each of our or our licensor's pending patent applications and issued patents and/or might have been the first to file patent applications for these inventions. In addition, because patent applications take many months to publish and patent applications can take many years to issue, there may be currently pending applications, unknown to us or our licensor, which may later result in issued patents that cover the production, manufacture, synthesis, commercialization, formulation or use of our product candidates. In addition, the production, manufacture, synthesis, commercialization, formulation or use of our product candidates may infringe existing patents of which we are not aware. Defending ourselves against third-party claims, including litigation in particular, would be costly and time consuming and would divert management's attention from our business, which could lead to delays in our development or commercialization efforts. If third parties are successful in their claims, we might have to pay substantial damages or take other actions that are adverse to our business.

As a result of intellectual property infringement claims, or to avoid potential claims, we might:

- be prohibited from selling or licensing any product that we and/or any potential collaborators may

develop unless the patent holder licenses the patent to us, which the patent holder is not required to do;

- be required to pay substantial royalties or other amounts, or grant a cross license to our patents to another patent holder; or
- be required to redesign the formulation of a product candidate so that it does not infringe, which may not be possible or could require substantial funds and time.

#### **Risks Related to Regulatory Approval of Our Product Candidates**

***If we or any potential collaborators are not able to obtain required regulatory approvals, we or such collaborators will not be able to commercialize our product candidates, and our ability to generate revenue will be materially impaired.***

Our product candidates and the activities associated with their development and commercialization are subject to comprehensive regulation by the FDA, other regulatory agencies in the United States and by comparable authorities in other countries, including the EMA. Failure to obtain regulatory approval for a product candidate will prevent us or any potential collaborator from commercializing the product candidate. We have not received regulatory approval to market any of our product candidates in any jurisdiction, and we do not expect to obtain FDA, EMA or any other regulatory approvals to market any of our product candidates for the foreseeable future, if at all. The process of obtaining regulatory approvals is expensive, often takes many years, if approval is obtained at all, and can vary substantially based upon the type, complexity and novelty of the product candidates involved.

Changes in the regulatory approval policy during the development period, changes in or the enactment of additional regulations or statutes, or changes in regulatory review for each submitted product application may cause delays in the approval or rejection of an application. Even if the FDA or the EMA approves a product candidate, the approval may impose significant restrictions on the indicated uses, conditions for use, labeling, advertising, promotion, marketing and/or production of such product, and may impose ongoing requirements for post-approval studies, including additional research and development and clinical trials. Any FDA approval may also impose risk evaluation mitigation strategies, or REMS, on a product if the FDA believes there is a reason to monitor the safety of the drug in the market place. REMS may include requirements for additional training for health care professionals, safety communication efforts and limits on channels of distribution, among other things. The sponsor would be required to evaluate and monitor the various REMS activities and adjust them if need be. The FDA and EMA also may impose various civil or criminal sanctions for failure to comply with regulatory requirements, including withdrawal of product approval.

Furthermore, the approval procedure and the time required to obtain approval varies among countries and can involve additional testing beyond that required by the FDA. Approval by one regulatory authority does not ensure approval by regulatory authorities in other jurisdictions.

The FDA, the EMA and other foreign regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. For example, in October 2009, we received a Complete Response Letter from the FDA regarding our NDA for toremifene 80 mg to reduce fractures in men with prostate cancer on ADT notifying us that the FDA would not approve our NDA as a result of certain clinical deficiencies identified in the Complete Response Letter. We have since discontinued our toremifene 80 mg development program, as well as our other toremifene-based products and terminated our license and supply agreement with Orion for toremifene products. Although we evaluated the potential submission of a MAA to the EMA seeking marketing approval of enobosarm 3 mg in the EU for the prevention and treatment of muscle wasting in patients with advanced NSCLC, based on recent input from the MHRA, we believe that the data from the POWER trials is not sufficient to support the filing and approval of a MAA without confirmatory data from another Phase 3 clinical trial of enobosarm 3 mg. As a result of this input, we do not intend to submit a MAA in the absence of such confirmatory data. In addition, since data from the two POWER trials failed to meet the primary statistical criterion pre-specified for the co-primary endpoints of lean body mass and physical function, the FDA will not accept a NDA for enobosarm 3 mg for the prevention and treatment of muscle wasting in patients with advanced NSCLC. Accordingly, our strategy does not currently include further development of enobosarm for this indication in the U.S. or in Europe unless such development is part of a collaborative arrangement or strategic partnership.

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Additionally, there can be no assurance that the FDA will determine that the data from our ongoing, planned or potential future clinical trials of enobosarm for the treatment of patients with AR positive advanced breast cancer or GTX-758 will be sufficient for approval of these product candidates in any indications. For example, we may observe an unacceptable incidence of adverse events in our ongoing, planned or potential clinical trials of enobosarm or GTX-758, which could require us to abandon the development of the affected product candidate.

In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit, or prevent regulatory approval of a product candidate. Even if we submit an application to the FDA, the EMA and other foreign regulatory authorities for marketing approval of a product candidate, it may not result in any marketing approvals.

We do not expect to receive regulatory approval for the commercial sale of any of our product candidates that are in development for the foreseeable future, if at all. The inability to obtain approval from the FDA, the EMA and other foreign regulatory authorities for our product candidates would prevent us or any potential collaborators from commercializing these product candidates in the United States, the EU, or other countries. See the section entitled "Business — Government Regulation" under Part 1, Item 1 of this Annual Report on Form 10-K for the year ended December 31, 2014 for additional information regarding risks associated with marketing approval, as well as risks related to potential post-approval requirements.

### **Risks Related to Commercialization**

***The commercial success of any products that we and/or any potential collaborators may develop will depend upon the market and the degree of market acceptance among physicians, patients, health care payors and the medical community.***

Any products that we and/or any potential collaborators may develop, including enobosarm, may not gain market acceptance for its stated indication among physicians, patients, health care payors and the medical community. If these products do not achieve an adequate level of acceptance, we may not generate material product revenues or receive royalties to the extent we currently anticipate, and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- efficacy and safety results in clinical trials;
- the prevalence and severity of any side effects;
- potential advantages over alternative treatments;
- whether the products we commercialize remain a preferred course of treatment;
- the ability to offer our product candidates for sale at competitive prices;
- relative convenience and ease of administration;
- the strength of marketing and distribution support; and
- sufficient third-party coverage or reimbursement.

For example, if we are able to raise sufficient funding for any additional clinical development of enobosarm 3 mg through new collaborative arrangements with third parties or other financing alternatives and a MAA is submitted to the EMA for the marketing approval of enobosarm 3 mg in the EU for the more narrow indication of the prevention and treatment of muscle wasting in patients with advanced NSCLC treated with platinum plus taxane chemotherapy and marketing approval is obtained, we anticipate that the commercial prospects for enobosarm 3 mg could be diminished as a result of this more limited product indication.

***If we are unable to establish sales and marketing capabilities or establish and maintain agreements with third parties to market and sell our product candidates, we may be unable to generate product revenue from such candidates.***

We have limited experience as a company in the sales, marketing and distribution of pharmaceutical products. In the event one of our product candidates is approved, we will need to establish sales and marketing capabilities or establish and maintain agreements with third parties to market and sell our product candidates. We may be unable to build our own sales and marketing capabilities, and there are risks involved with entering into arrangements with third parties to perform these services, which could delay the commercialization of any of our product candidates if

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approved for commercial sale. In addition, to the extent that we enter into arrangements with third parties to perform sales, marketing and distribution services, our product revenues are likely to be lower than if we market and sell any products that we develop ourselves.

***If we and/or any potential collaborators are unable to obtain reimbursement or experience a reduction in reimbursement from third-party payors for products we sell, our revenues and prospects for profitability will suffer.***

Sales of products developed by us and/or any potential collaborators are dependent on the availability and extent of reimbursement from third-party payors. Changes in the reimbursement policies of these third-party payors that reduce reimbursements for any products that we and/or any potential collaborators may develop and sell could negatively impact our future operating and financial results.

Medicare coverage and reimbursement of prescription drugs exists under Medicare Part D for oral drug products capable of self-administration by patients. Our oral drug product candidates would likely be covered by Medicare Part D (if covered by Medicare at all). In March 2010, the United States Congress enacted the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act. This health care reform legislation will increase the number of individuals who receive health insurance coverage and will close a gap in drug coverage under Medicare Part D. The legislation, however, also implemented cost containment and other measures that could adversely affect revenues from sales of product candidates, including an increase in drug rebates manufacturers must pay under Medicaid for brand name prescription drugs and extension of these rebates to Medicaid managed care.

Pharmaceutical manufacturers and importers of brand name prescription drugs are assessed a fee based on our proportionate share of sales of brand name prescription drugs to certain government programs, including Medicare and Medicaid, made in the preceding year if such sales exceed a defined threshold. Since 2011, manufacturers have been required to provide a 50% discount on brand name prescription drugs sold to beneficiaries who fall within a gap that exists in the Medicare Part D prescription drug program (commonly known as the “donut hole”).

The health care reform legislation has been subject to political and judicial challenge. In 2012, the Supreme Court considered the constitutionality of certain provisions of the law. The court upheld as constitutional the mandate for individuals to obtain health insurance but held that the provision allowing the federal government to withhold certain Medicaid funds to states that do not expand state Medicaid programs was unconstitutional. In 2015, the Court considered whether the health care reform legislation provided for tax credits to low income individuals purchasing health insurance through health insurance exchanges (essentially entities established for the comparison and purchase of health insurance) only if the health insurance exchange had been established by a state (rather than the federal government). The Court held that the law should be interpreted to allow for tax credits regardless of whether the health insurance was purchased through an exchange operated by a state or the federal government. There may be additional judicial challenges to the law in the future and the success and impact of those challenges remains uncertain. Regardless of the various judicial rulings, political challenges to the law and its application may continue and it is not possible to predict the impact of such challenges.

Economic pressure on state budgets may result in states increasingly seeking to achieve budget savings through mechanisms that limit coverage or payment for drugs. State Medicaid programs are increasingly requesting manufacturers to pay supplemental rebates and requiring prior authorization for use of drugs where supplemental rebates are not provided. Private health insurers and managed care plans are likely to continue challenging the prices charged for medical products and services, and many of these third-party payors may limit reimbursement for newly-approved health care products. In particular, third-party payors may limit the indications for which they will reimburse patients who use any products that we and/or any potential collaborators may develop or sell. These cost-control initiatives could decrease the price we might establish for products that we or any potential collaborators may develop or sell, which would result in lower product revenues or royalties payable to us.

Similar cost containment initiatives exist in countries outside of the United States, particularly in the countries of the EU, where the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can extend well beyond the receipt of regulatory marketing approval for a product and may require us or any potential collaborators to conduct a clinical trial that compares the cost effectiveness of our product candidates or products to other available therapies. The conduct of such a clinical trial could be expensive and result in delays in our or a potential collaborators’ commercialization efforts. Third-party payors are challenging the prices charged for medical products and services, and many third-party payors limit reimbursement for newly-approved health care products. Recently budgetary pressures in many EU countries are also causing governments to consider or implement various cost-containment measures, such as price freezes, increased price cuts and rebates. If budget pressures continue, governments may implement additional cost

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containment measures. Cost-control initiatives could decrease the price we might establish for products that we or any potential collaborators may develop or sell, which would result in lower product revenues or royalties payable to us.

Another development that could affect the pricing of drugs would be if the Secretary of Health and Human Services allowed drug reimportation into the United States. The Medicare Prescription Drug, Improvement and Modernization Act of 2003 gives discretion to the Secretary of Health and Human Services to allow drug reimportation into the United States under some circumstances from foreign countries, including from countries where the drugs are sold at a lower price than in the United States. If the circumstances were met and the Secretary exercised the discretion to allow for the direct reimportation of drugs, it could decrease the price we or any potential collaborators receive for any products that we and/or any potential collaborators may develop, negatively affecting our revenues and prospects for profitability.

***Health care reform measures could hinder or prevent our product candidates' commercial success.***

Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting health care reform, as evidenced by the enactment in the United States of the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act in 2010. Federal and state legislatures within the United States and foreign governments will likely continue to consider changes to existing health care legislation. These changes adopted by governments may adversely impact our business by lowering the price of health care products in the United States and elsewhere.

We operate in a highly regulated industry and new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to health care availability, method of delivery or payment for health care products and services, or sales, marketing and pricing practices could negatively impact our business, operations and financial condition.

***If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of any products that we may develop.***

We face an inherent risk of product liability exposure related to our prior commercial sales of FARESTON® and the testing of our product candidates in human clinical trials, and we will face an even greater risk if we commercially sell any product that we may develop. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue; and
- the inability to commercialize any products for which we obtain or hold marketing approvals.

We have product liability insurance that covers our clinical trials and any commercial products up to a \$25 million annual aggregate limit. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost, and we may not be able to obtain insurance coverage that will be adequate to satisfy any liability that may arise.

***If our competitors are better able to develop and market products than any products that we and/or any potential collaborators may develop, our commercial opportunity will be reduced or eliminated.\****

We face competition from commercial pharmaceutical and biotechnology enterprises, as well as from academic institutions, government agencies and private and public research institutions. Our commercial opportunities will be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer side effects or are less expensive than any products that we and/or any potential collaborators may develop. Competition could result in reduced sales and pricing pressure on our product candidates, if approved, which in turn

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would reduce our ability to generate meaningful revenue and have a negative impact on our results of operations. In addition, significant delays in the development of our product candidates could allow our competitors to bring products to market before us and impair any ability to commercialize our product candidates.

Various products are currently marketed or used off-label for some of the diseases and conditions that we are targeting in our pipeline, and a number of companies are or may be developing new treatments. These product uses, as well as promotional efforts by competitors and/or clinical trial results of competitive products, could significantly diminish any ability to market and sell any products that we and/or any potential collaborators may develop.

With respect to our SARM program, there are other SARM product candidates in development that may compete with enobosarm and any future SARM product candidates, if approved for commercial sale. We plan to advance the development of enobosarm for the treatment of patients with AR positive advanced breast cancer. To our knowledge, no other SARMS are currently in development for this indication; although SARMS in development for muscle wasting and cachexia could enter into a breast cancer program in the future. For example, Radius Health, Inc. has stated that it may test its SARM compound, RAD140, in a breast cancer indication in the future. A number of other compounds targeting the androgen axis in breast cancer could compete with enobosarm if one or more are approved for commercial sale in the indications for which enobosarm is being developed. These compounds fall into two categories, androgen synthesis inhibitors, or ASIs, and androgen receptor antagonists, or ARAs. ASIs in development include orteronel being developed by Takeda Pharmaceuticals. ARAs in development include XTANDI® (enzalutamide) being developed by Medivation and Astellas Pharma, and generic bicalutamide. Agents targeting pathways outside of the androgen axis also may compete with enobosarm in breast cancer as they are directed towards similar patient populations that may benefit from enobosarm. Additionally, we initiated a proof of concept study in advanced AR positive TNBC patients for which there are no currently approved therapies, beyond chemotherapy. However, a number of approaches for the treatment of TNBC are currently under investigation. Agents also targeting the androgen axis include XTANDI® (enzalutamide) being developed by Medivation and Astellas Pharma, orteronel (TAK-700) being developed by Takeda, and CR-1447 being developed by Curadis. Only a subset of the total TNBC population is AR positive; therefore, agents targeting TNBC as a whole may also compete with enobosarm if approved for commercial sale. These agents include: PI3K/AKT inhibitors (BKM120 being developed by Novartis), IL6/JAK/Stat inhibitors (ruxolitinib being developed by Incyte), mTOR inhibitors (Neratinib being developed by Puma), and PARP inhibitors (Velaparib being developed by AbbVie), PD-1 inhibitors (pembrolizumab) being developed by Merck & Co. and MPDL3280A being developed by Roche.

We recently announced plans to initiate a Phase 2 proof-of-concept clinical trial of enobosarm to treat postmenopausal women with SUI. There are a variety of treatments that may be used for SUI in women; however, currently, there are no available oral agents approved for the treatment of SUI. Behavioral modification and pelvic floor physical therapy are common initial treatment approaches. Bulking agents, including carbon coated beads (Durasphere® marketed by Coloplast Corp), calcium hydroxylapatite (Coaptite® marketed by BioForm Medical, Inc) and silicon (Macroplastique® marketed by Cogentix Medical), can be injected into or around the urethra for treating intrinsic sphincter deficiency, a cause of SUI symptoms. Biologic bulking agents including patient-derived adipose stem cells and autologous muscle-derived stem cells (Cook Myosite) are being developed. Recently, an over-the-counter vaginal pessary (Impressa® marketed Kimberly-Clark) has been approved for the temporary management of urine leakage in women with SUI. Finally, surgical procedures (e.g. sling; bladder neck suspension) have been demonstrated to be effective in some women.

We also plan to explore the potential of SARMS to treat DMD. DMD is a rare genetic disorder which currently has no cure and leads to a progressive weakening of all the muscles in the body. A number of drugs are in various stages of development by pharmaceutical companies to meet the unmet medical need in DMD. These drugs may compete for patient enrollment during the clinical trial phase, should we be able to advance the development of SARMS as a potential treatment of DMD, or commercially should any of them be approved. The most advanced development is by those companies who are targeting the genetic mutation with exon skipping or codon blocking therapies including drisapersen by Biomarin Pharmaceutical Inc., eteplirsen by Sarepta Therapeutics Inc., and PTC 124 by PTC Therapeutics Inc., who have all filed new drug applications with the FDA. Santhera Pharmaceuticals has completed a Phase 3 trial with a synthetic analog of coenzyme Q<sub>10</sub>, idebenone, and has received fast track designation by FDA. Marathon Pharmaceuticals LLC has completed a Phase 3 trial with a glucocorticoid, deflazacort, which has fast track designation. Pfizer Inc. is developing its anti-myostatin monoclonal antibody, PF-06252616, and is currently in a Phase 2 trial. In addition, Akashi Therapeutics is developing two compounds for DMD, including a SARM which will be entering a Phase 2 study in healthy volunteers. Tarix Orphan is developing TXA127, an angiotensin 1-7 peptide, and plans to start a Phase 2 study in DMD patients in 2016. Fibrogen is developing FG-3019, a monoclonal antibody which inhibits connective tissue growth factor, and plans to start a

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Phase 2 study this year. Other companies may advance compounds into clinical development for DMD.

We are developing GTX-758 for secondary hormonal therapy in men with CRPC. There are various products approved or under clinical development to treat men with advanced prostate cancer who have metastatic CRPC which may compete with GTX-758. Provenge<sup>®</sup>, which was recently acquired by Valeant Pharmaceuticals, is an autologous cellular immunotherapy for the treatment of asymptomatic or minimally symptomatic metastatic castrate resistant prostate cancer. Medivation and Astellas Pharma market XTANDI<sup>®</sup> (enzalutamide), an oral androgen receptor antagonist, for the treatment of metastatic castration-resistant prostate cancer in men previously treated with docetaxel as well as those that have not yet received chemotherapy. Zytiga<sup>®</sup>, sold by Johnson & Johnson, has been approved for the treatment of metastatic CRPC in patients who have received prior chemotherapy and recently received approval for the treatment of metastatic castrate resistant prostate cancer prior to chemotherapy. Johnson & Johnson acquired Aragon Pharmaceuticals, Inc., which developed a second generation anti-androgen (ARN-509) that is currently being evaluated in Phase 2 studies in men with progressive, advanced prostate cancer. Bayer HealthCare and Orion Corporation are currently performing a Phase 3 study of ODM-201 in men with CRPC without metastases and with a rising PSA examining safety and efficacy by measuring metastatic free survival. Millennium: The Takeda Oncology Company is developing TAK-700 for the treatment of men with metastatic CRPC prior to chemotherapy.

We recently announced that we have entered into an exclusive worldwide license agreement with UTRF to develop its proprietary SARD technology which has the potential to provide compounds that can degrade multiple forms of AR for patients who do not respond or are resistant to current therapies to inhibit tumor growth in patients with progressive CRPC. We anticipate evaluating SARDs as a potentially novel treatment for men with CRPC, including those who do not respond or are resistant to currently approved therapies. Drugs in commercial development having potentially similar approaches to removing the AR by degradation include Arvinas Inc.'s ARV-330, a chimera with an AR binding moiety on one end and an E3 ligase recruiting element on the other, in preclinical development for application to advanced prostate cancer and Androscience Corporation's androgen receptor degrader enhancer, or ARD, currently in development for acne and alopecia with the potential for development in prostate cancer. In addition to this specific potential mechanistic competition, there are various products approved or under clinical development in the broader space of treating men with advanced prostate cancer who have metastatic CRPC which may compete with our proposed initial clinical objective for our SARD compounds, as set forth above in the paragraph relating to GTX-758. Additionally, it has been reported that two other companies are developing drugs to treat men with CRPC who are resistant to current therapies: Tokai Pharmaceuticals is developing TOK-001 (Galeterone) with a principal mechanism of action as a CYP17 lyase inhibitor and AR antagonist and Essa Pharma Inc. is beginning early studies with EPI-506, an AR antagonist that targets the N-terminal domain of the AR.

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies and technology licenses complementary to our programs or advantageous to our business.

#### **Risks Related to Employees, Growth and Other Aspects of Operations**

##### ***Management transition creates uncertainties and could harm our business.\****

We have recently had significant changes in executive leadership, and more could occur. Effective December 31, 2013, Mark Mosteller resigned as our Chief Financial Officer. In connection with Mr. Mosteller's resignation, Marc S. Hanover, who was then serving as our President and Chief Operating Officer, was appointed as our acting principal financial officer and Jason T. Shackelford, who was then serving as our Corporate Controller and Director of Accounting, was appointed as our principal accounting officer. On April 3, 2014, Mitchell S. Steiner resigned as our Vice Chairman and Chief Executive Officer. On April 3, 2014, Mr. Hanover was appointed as our interim Chief Executive Officer and on February 12, 2015, Mr. Hanover was appointed as our permanent Chief Executive Officer. Upon the appointment of Mr. Hanover as interim Chief Executive Officer, Mr. Hanover ceased to perform the duties of our principal financial officer, which duties were assigned to Mr. Shackelford. Additionally, James T. Dalton, our former Chief Scientific Officer, resigned effective August 31, 2014. Finally, on March 2, 2015, Robert J. Wills

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was appointed as our Executive Chairman and effective July 13, 2015, Diane C. Young joined us as our Vice President, Chief Medical Officer.

As a result of the recent changes in our management team, Messrs. Hanover and Shackelford have taken on substantially more responsibility for the management of our business and of our financial reporting which has resulted in greater workload demands and could divert their attention away from certain key areas of our business. For instance, Mr. Hanover has taken on the role of our Chief Executive Officer in addition to the role he served when functioning as our President and Chief Operating Officer, positions that were previously occupied by two persons. In addition, while Dr. Wills' role as our Executive Chairman is, in part, to support Mr. Hanover in his role as our permanent Chief Executive Officer, the position of Executive Chairman is relatively new to us and it may be some time before we can assess how much assistance he will provide to Mr. Hanover. Also, while we have retained Dr. Dalton as a consultant to GTx following his employment end date, we no longer have regular access to Dr. Dalton's key scientific expertise, which could materially and adversely impact our product candidate development efforts. Changes in our organization as a result of executive management transition may have a disruptive impact on our ability to implement our strategy and could have a material adverse effect on our business, financial condition and results of operations.

Changes to company strategy, which can often times occur with the appointment of new executives, can create uncertainty, may negatively impact our ability to execute quickly and effectively, and may ultimately be unsuccessful. In addition, executive leadership transition periods are often difficult as the new executives gain detailed knowledge of our operations, and friction can result from changes in strategy and management style. Management transition inherently causes some loss of institutional knowledge, which can negatively affect strategy and execution. Until we integrate new personnel, and unless they are able to succeed in their positions, we may be unable to successfully manage and grow our business, and our results of operations and financial condition could suffer as a result.

***Our internal computer and information technology systems, or those of our CROs or other contractors or consultants, may fail or suffer security breaches, or could otherwise face serious disruptions, which could result in a material disruption of our product development efforts.***

Despite the implementation of security measures, our internal computer systems and those of our CROs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, and telecommunication and electrical failures. Such events could cause interruptions of our operations. For instance, the loss of preclinical data or data from our ongoing, planned and potential future clinical trials involving our product candidates could result in delays in our development and regulatory filing efforts and significantly increase our costs. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data, or inappropriate disclosure of confidential, proprietary or protected health information, we could incur liability and the development of our product candidates could be delayed. In addition, our information technology and other internal infrastructure systems, including corporate firewalls, servers, leased lines and connection to the Internet, face the risk of systemic failure that could disrupt our operations. A significant disruption in the availability of our information technology and other internal infrastructure systems could cause delays in our research and development work and could otherwise adversely affect our business.

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

Our success depends on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel and on our ability to develop and maintain important relationships with leading academic institutions, clinicians and scientists. If we are not able to attract and keep senior management and key scientific personnel, we may not be able to successfully develop or commercialize our product candidates. All of our employees are at-will employees and can terminate their employment at any time.

In October 2013, we announced a reduction of approximately 60% of our workforce following our announcement that our POWER trials failed to achieve the results required by the FDA to file a NDA for enobosarm 3 mg for the prevention and treatment of muscle wasting in patients with advanced NSCLC. In addition, since our October 2013 workforce reduction, our former Chief Executive Officer, former Chief Financial Officer and former Chief Scientific Officer have resigned. Primarily as a result of our October 2013 workforce reduction, only 29 employees remained as employees of GTx as of September 30, 2015. Accordingly, we have been and are operating with a shortage of resources and may not be able to effectively conduct our operations with this limited number of employees. In addition, we announced past workforce reductions in each of December 2009 and June 2011, and our history of implementing workforce reductions, along with the potential for future workforce reductions, may negatively affect our ability to retain or attract talented employees. Further, to the extent we experience additional

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management transition, competition for top management is high and it may take many months to find a candidate that meets our requirements. If we are unable to attract and retain qualified management personnel, our business could suffer.

***We will need to hire additional employees in order to grow our business. Any inability to manage future growth could harm our ability to develop and commercialize our product candidates, increase our costs and adversely impact our ability to compete effectively.***

As of September 30, 2015, we had only 29 employees, and we will need to hire experienced personnel to develop and commercialize our product candidates and to otherwise grow our business, and we will need to expand the number of our managerial, operational, financial and other employees to support that growth. Competition exists for qualified personnel in the biotechnology field.

Future growth, if any, will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees. Our future financial performance and our ability to develop and commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively.

### **Risks Related to Our Common Stock**

***The market price of our common stock has been volatile and may continue to be volatile in the future. This volatility may cause our stock price and the value of your investment to decline.\****

The market prices for securities of biotechnology companies, including ours, have been highly volatile and may continue to be so in the future. In this regard, the market price for our common stock has varied between a high of \$1.59 on July 2, 2015 and a low of \$0.41 on October 14, 2014 in the twelve-month period ended September 30, 2015. The market price of our common stock is likely to continue to be volatile and subject to significant price and volume fluctuations. The following factors, in addition to other risk factors described in this section, may have a significant impact on the market price of our common stock:

- delays in the initiation, enrollment and/or completion of our ongoing, planned and any future clinical trials of enobosarm and GTx-758, or negative, inconclusive or mixed results reported in any of our ongoing, planned and any future clinical trials of enobosarm and GTx-758;
- our ability to raise additional capital in the future to carry through with our preclinical and clinical development plans, including to initiate and complete the second stage of our ongoing and planned Phase 2 clinical trials of enobosarm, as well as our current and future operations, and the terms of any related financing arrangements;
- reports of unacceptable incidences of adverse events observed in any of our ongoing and planned clinical trials of enobosarm and GTx-758;
- announcements regarding further cost-cutting initiatives or restructurings;
- uncertainties created by our past and potential future management turnover;
- our ability to enter into new collaborative, licensing or other strategic arrangements with respect to our product candidates;
- the terms and timing of any future collaborative, licensing or other arrangements that we may establish;
- the timing of achievement of, or failure to achieve, our and any potential collaborators' clinical, regulatory and other milestones, such as the commencement of clinical development, the completion of a clinical trial or the receipt of regulatory approval;
- announcement of FDA approval or non-approval of our product candidates or delays in or adverse events during the FDA review process;
- actions taken by regulatory agencies with respect to our product candidates or our clinical trials, including regulatory actions requiring or leading to a delay or stoppage of our ongoing or planned clinical trials;
- the commercial success of any product approved by the FDA or its foreign counterparts;

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- introductions or announcements of technological innovations or new products by us, our potential collaborators, or our competitors, and the timing of these introductions or announcements;
- market conditions for equity investments in general, or the biotechnology or pharmaceutical industries in particular;
- regulatory developments in the United States and foreign countries;
- changes in the structure or reimbursement policies of health care payment systems;
- any intellectual property infringement lawsuit involving us;
- actual or anticipated fluctuations in our results of operations;
- changes in financial estimates or recommendations by securities analysts;
- hedging or arbitrage trading activity that may develop regarding our common stock;
- sales of large blocks of our common stock;
- sales of our common stock by our executive officers, directors and significant stockholders;
- the trading volume of our common stock;
- changes in accounting principles; and
- additional losses of any of our key scientific or management personnel.

In addition, the stock markets in general, and the markets for biotechnology stocks in particular, have experienced significant volatility that has often been unrelated to the operating performance of particular companies. These broad market fluctuations may adversely affect the trading price of our common stock.

In the past, class action litigation has often been instituted against companies whose securities have experienced periods of volatility in market price. Any such litigation brought against us could result in substantial costs, which would hurt our financial condition and results of operations and divert management's attention and resources, which could result in delays of our clinical trials or commercialization efforts.

***Our executive officers, directors and largest stockholders have the ability to control all matters submitted to stockholders for approval.\****

As of September 30, 2015, our executive officers, directors and holders of 5% or more of our outstanding common stock, including their affiliated or associated entities, held approximately 75.6% of our outstanding common stock, and our executive officers and directors alone, including their affiliated or associated entities, held approximately 35.9% of our outstanding common stock as well as warrants to purchase up to an additional 24.8 million shares of common stock. As a result, these stockholders, acting together, have the ability to control all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combination transactions. The interests of this group of stockholders may not always coincide with our interests or the interests of other stockholders.

***If we fail to meet continued listing standards of The NASDAQ Stock Market LLC, our common stock may be delisted. Delisting could adversely affect the liquidity of our common stock and the market price of our common stock could decrease, and our ability to obtain sufficient additional capital to fund our operations and to continue as a going concern would be substantially impaired.\****

Our common stock is currently listed on The NASDAQ Capital Market. The NASDAQ Stock Market LLC, or NASDAQ, has minimum requirements that a company must meet in order to remain listed on The NASDAQ Capital Market. These requirements include maintaining a minimum closing bid price of \$1.00 per share, or the Bid Price Requirement, and the closing bid price of our common stock has in the past been well below \$1.00 per share. In this regard, on October 2, 2014, we received a letter from NASDAQ notifying us that we were out of compliance with the Bid Price Requirement. In connection with this notification, we requested and, on March 16, 2015 received approval from NASDAQ, to transfer our listing from The NASDAQ Global Market to The NASDAQ Capital Market. On April 1, 2015, we were afforded an additional 180-day grace period, or through September 28, 2015, to comply with the Bid Price Requirement. While the bid price of our common stock exceeded \$1.00 for at least ten consecutive business days during this additional grace period and we are therefore currently in compliance with the Bid Price Requirement, if the closing bid price of our common stock were again to fall below \$1.00 per share for 30 consecutive trading days, or we do not meet other applicable listing requirements, including maintaining minimum

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levels of stockholders' equity or market values of our common stock, we would again fail to be in compliance with NASDAQ's listing standards. In this regard, during the third quarter of 2015, the closing bid price of our common stock was below \$1.00 per share for 29 consecutive trading days. Likewise, during the period from August 1, 2015 through October 31, 2015, the closing bid price of our common stock was below \$1.00 per share on 43 of the 64 trading days during that period. Accordingly, there can be no assurance that we will continue to meet the Bid Price Requirement, or any other NASDAQ continued listing requirement, in the future. If we fail to meet these requirements, including the Bid Price Requirement, NASDAQ may notify us that we have failed to meet the minimum listing requirements and initiate the delisting process. If our common stock is delisted, the liquidity of our common stock would be adversely affected and the market price of our common stock could decrease, and our ability to obtain sufficient additional capital to fund our operations and to continue as a going concern would be substantially impaired.

***Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.***

Under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change," generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes (such as research tax credits) to offset its post-change taxable income or taxes may be limited. Although we completed a study in 2014 to determine whether any Section 382 limitations exist and we do not believe that any Section 382 limitations exist at this time, Section 382 of the Internal Revenue Code is an extremely complex provision with respect to which there are many uncertainties and we have not established whether the IRS agrees with our determination. In any event, changes in our stock ownership, some of which are outside of our control, could in the future result in an ownership change and an accompanying Section 382 limitation. If a limitation were to apply, utilization of a portion of our domestic net operating loss and tax credit carryforwards could be limited in future periods and a portion of the carryforwards could expire before being available to reduce future income tax liabilities.

***Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.***

Provisions in our certificate of incorporation and our bylaws may delay or prevent an acquisition of us or a change in our management. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our Board of Directors. Because our Board of Directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt by our stockholders to replace current members of our management team. These provisions include:

- a classified Board of Directors;
- a prohibition on actions by our stockholders by written consent;
- the ability of our Board of Directors to issue preferred stock without stockholder approval, which could be used to institute a "poison pill" that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our Board of Directors; and
- limitations on the removal of directors.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. Finally, these provisions establish advance notice requirements for nominations for election to our Board of Directors or for proposing matters that can be acted upon at stockholder meetings. These provisions would apply even if the offer may be considered beneficial by some stockholders.

***If there are substantial sales of our common stock, the market price of our common stock could drop substantially, even if our business is doing well.\****

For the 12-month period ended September 30, 2015, the average daily trading volume of our common stock on The NASDAQ Global Market was 166,402 shares. As a result, future sales of a substantial number of shares of our common stock in the public market, or the perception that such sales may occur, could adversely affect the then-

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prevailing market price of our common stock. As of September 30, 2015, we had 140,374,112 shares of common stock outstanding. In addition, as a result of the relatively low trading volume of our common stock, the trading of relatively small quantities of shares by our stockholders may disproportionately influence the market price of our common stock in either direction. The price for our shares could, for example, decline significantly in the event that a large number of our common shares are sold on the market without commensurate demand, as compared to an issuer with a higher trading volume that could better absorb those sales without an adverse impact on its stock price. In November 2014, we completed a private placement 64.3 million shares of our common stock and warrants to purchase 64.3 million shares of our common stock. Similarly, in March 2014 we completed a private placement of 12.0 million shares of our common stock and warrants to purchase 10.2 million shares of our common stock. Pursuant to the terms of a registration rights agreement we entered into in connection with the March 2014 private placement, we filed a registration statement under the Securities Act registering the resale of the 12.0 million shares of common stock we issued to the investors in the March 2014 private placement, which include J.R. Hyde, III, our largest stockholder, as well as the 10.2 million shares of common stock underlying the warrants we issued to those investors. Likewise, pursuant to the terms of the securities purchase agreement we entered into in connection with the November 2014 private placement, we filed registration statements under the Securities Act registering the resale of the 64.3 million shares of common stock we issued to the investors in the November 2014 private placement, which included J.R. Hyde, III, as well as the additional 64.3 million shares of common stock subject to the warrants we issued to the investors in the November 2014 private placement. Moreover, J.R. Hyde, III and certain of his affiliates, have rights under a separate registration rights agreement with us to require us to file resale registration statements covering an additional 7.9 million shares of common stock held in the aggregate or to include these shares in registration statements that we may file for ourselves or other stockholders. If Mr. Hyde or his affiliates or any of our other significant stockholders, including the other investors in our 2014 private placements, were to sell large blocks of shares in a short period of time, the market price of our common stock could drop substantially.

**ITEM 6. EXHIBITS**

The exhibits listed on the accompanying Exhibit Index are filed or incorporated by reference (as stated therein) as part of this Quarterly Report on Form 10-Q.

**SIGNATURES**

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

**GTx, Inc.**

Date: November 9, 2015

By: /s/ Marc S. Hanover  
Marc S. Hanover, President,  
Chief Executive Officer  
*(Principal Executive Officer)*

Date: November 9, 2015

By: /s/ Jason T. Shackelford  
Jason T. Shackelford, Senior Director of Accounting and Corporate  
Controller and Principal Financial and Accounting Officer  
*(Principal Financial and Accounting Officer)*

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EXHIBIT INDEX

Exhibit Number	Exhibit Description	Incorporation By Reference			
		Form	SEC File No.	Exhibit	Filing Date
2.1	Asset Purchase Agreement dated as of September 28, 2012 between the Registrant and Strakan International S.à r.l.	8-K	000-50549	2.1	10/03/2012
3.1	Restated Certificate of Incorporation of GTx, Inc.	S-3	333-127175	4.1	08/04/2005
3.2	Certificate of Amendment of Restated Certificate of Incorporation of GTx, Inc.	8-K	000-50549	3.2	05/06/2011
3.3	Certificate of Amendment of Restated Certificate of Incorporation of GTx, Inc.	8-K	000-50549	3.3	05/09/2014
3.4	Certificate of Amendment of Restated Certificate of Incorporation of GTx, Inc.	10-Q	000-50549	3.4	05/11/2015
3.5	Amended and Restated Bylaws of GTx, Inc.	8-K	000-50549	3.2	07/26/2007
4.1	Reference is made to Exhibits 3.1, 3.2, 3.3, 3.4 and 3.5	—	—	—	—
4.2	Specimen of Common Stock Certificate	S-1	333-109700	4.2	12/22/2003
4.3	Amended and Restated Registration Rights Agreement between Registrant and J. R. Hyde, III dated August 7, 2003	S-1	333-109700	4.4	10/15/2003
4.4	Consent, Waiver and Amendment between Registrant and J. R. Hyde, III and Pittco Associates, L.P. dated December 3, 2007	S-3	333-148321	4.6	12/26/2007
4.5	Waiver and Amendment Agreement among Registrant, J.R. Hyde, III and Pittco Associates, L.P. dated March 6, 2014	10-K	000-50549	4.5	03/12/2014
4.6	Amended and Restated Registration Rights Agreement among Registrant, J.R. Hyde, III and The Pyramid Peak Foundation, dated August 4, 2014	10-Q	000-50549	4.6	08/05/2014
4.7	Consent, Waiver and Amendment Agreement between Registrant and J.R. Hyde, III and Pittco Associates, L.P., dated August 4, 2014	10-Q	000-50549	4.8	08/05/2014
4.8	Form of Common Stock Warrant, issued by Registrant pursuant to the Purchase Agreement, dated November 9, 2014, between Registrant and the purchasers identified in Exhibit A therein	10-K	000-50549	4.9	03/16/2015
10.1+	Employment Agreement dated July 13, 2015, between Registrant and Diane C. Young	—	—	—	—
31.1+	Certification of Principal Executive Officer, as required by Rule 13a-14(a) or Rule 15d-14(a)	—	—	—	—
31.2+	Certification of Principal Financial Officer, as required by Rule 13a-14(a) or Rule 15d-14(a)	—	—	—	—
32.1+	Certification of Principal Executive Officer, as required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350)(1)	—	—	—	—
32.2+	Certification of Principal Financial Officer, as required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350)(1)	—	—	—	—
101.INS+	XBRL Instance Document	—	—	—	—
101.SCH+	XBRL Taxonomy Extension Schema Document	—	—	—	—
101.CAL+	XBRL Taxonomy Extension Calculation Linkbase Document	—	—	—	—
101.DEF+	XBRL Taxonomy Extension Definition Linkbase Document	—	—	—	—



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101.PRE+ XBRL Taxonomy Extension Presentation Linkbase Document — — — —

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+ Filed herewith

(1) This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.

EMPLOYMENT AGREEMENT

This Employment Agreement (this "Agreement") is made and entered into as of July 13, 2015 (the "Effective Date"), by and between **GTx, Inc.**, located at 175 Toyota Plaza, 7<sup>th</sup> Floor, Memphis, Tennessee 38103 (the "Employer"), and **Diane C. Young** (the "Employee"), residing at 12 Carriage Hill Drive, Far Hills, New Jersey 07931.

WHEREAS, the Employee is being retained to provide services to the Employer as Vice President, Chief Medical Officer of Employer; and

WHEREAS, during the course of the Employee's employment with the Employer, the Employer will train and continue to train the Employee and to impart to the Employee proprietary, confidential, and/or trade secret information, data and/or materials of the Employer; and

WHEREAS, the Employer has a vital interest in maintaining its confidential information and trade secrets, as well as rights to inventions, since doing so allows the Employer to compete fairly and enhances the value of the Employer to shareholders and job security for employees; and

WHEREAS, the Employer desires to retain the services of the Employee and the Employee is willing to be employed and continue to be employed with the Employer upon the terms and subject to the conditions set forth in this Agreement;

NOW, THEREFORE, in consideration of the mutual covenants and agreements contained in this Agreement, the employment and continued employment of the Employee in accordance with the terms and conditions of this Agreement, and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties, intending to be legally bound, agree and covenant as follows:

1. DEFINITIONS

For the purposes of this Agreement, the following terms have the meanings specified or referred to in this Section 1.

**"Agreement"** has the meaning set forth in first paragraph of this Agreement.

**"Basic Compensation"** means Salary and Benefits.

**"Benefits"** has the meaning stated in Section 3.1(b) of this Agreement.

**"Board of Directors"** means the Board of Directors of the Employer.

**"CEO"** has the meaning set forth in Section 2.2.

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**“Change of Control”** means any of the following events: (a) the sale or other disposition of all or substantially all of the assets of the Employer in a single transaction or in a series of transactions (including, without limitation, any liquidation or dissolution of the Employer); (b) any Person or group becomes the beneficial owner, directly, or indirectly, of securities of the Employer representing more than fifty percent (50%) of the combined voting power of the Employer’s then outstanding securities other than by virtue of a merger, consolidation or similar transaction (for such purposes, “voting stock” shall mean the capital stock of the Employer of any class or classes, the holders of which are ordinarily, in the absence of contingencies, entitled to vote for the election of members of the Board of Directors (or Persons performing similar functions) of the Employer); (c) a merger or consolidation of the Employer with or into any other entity, if immediately after giving effect to such transaction more than fifty percent (50%) of the issued and outstanding voting stock of the surviving entity of such transaction is held by Persons who were not holders (taking into account their individual and affiliated holdings) as of the Effective Date of at least fifty percent (50%) of the voting stock of the Employer; or (d) individuals who, on the Effective Date, are members of the Board of Directors (the “Incumbent Board”) cease for any reason to constitute at least a majority of the members of the Board of Directors; *provided, however*, that if the appointment or election (or nomination for election) of any new member of the Board of Directors was approved or recommended by a majority vote of the members of the Incumbent Board then still in office, such new member will, for purposes of this Agreement, be considered as a member of the Incumbent Board. A Change of Control shall not include: (1) any transfer or issuance of stock of the Employer to one or more of the Employer’s lenders (or to any agents or representatives thereof) in exchange for debt of the Employer owed to any such lenders; (2) any transfer of stock of the Employer to or by any Person or entity, including but not limited to one or more of the Employer’s lenders (or to any agents or representatives thereof), pursuant to the terms of any pledge of said stock as collateral for any loans or financial accommodations to the Employer and/or its subsidiaries; (3) any transfer or issuance to any Person or entity, including but not limited to one or more of the Employer’s lenders (or to any agents or representatives thereof), in connection with the workout or restructuring of the Employer’s debts to any one of the Employer’s lenders, including but not limited to the issuance of new stock in exchange for any equity contribution to the Employer in connection with the workout or restructuring of such debt; (4) any transfer of stock by a stockholder of the Employer which is a partnership or corporation to the partners or stockholders in such stockholder or any transfer of stock by a stockholder of the Employer to an entity affiliated with such stockholder or the immediate family of such stockholder or a trust or similar entity for the benefit of such family members; or (5) any transfer or issuance of stock in connection with an offering of the Employer’s stock in a registered public transaction not involving a transaction described in Rule 145, promulgated under the Securities Act of 1933, as amended, provided that the Employer’s officers and Board of Directors shall not materially change as a result thereof.

**“Change of Control Termination”** means (i) a Termination Without Cause of the Employee’s employment by the Employer (other than for death or disability) within twelve (12) months after a Change of Control or (ii) the Employee’s resignation for Good Reason within twelve (12) months after a Change of Control.

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**“Competing Business”** means any individual or entity, other than the Employer, that is engaging in, or proposes to engage in, the development, manufacture, distribution or sale of a Competing Product in North America, South America, Europe and Eastern Europe, and in the countries of Russia, Australia, Japan, China, Taiwan, South Korea and India; *provided, however*, that an entity that develops, manufactures, distributes or sells a Competing Product in a separate business unit than the business unit in which the Employee is then employed shall not be deemed a Competing Business unless the Employee provides Confidential Information and/or Proprietary Information to the business unit that is engaging in or proposes to engage in the development, manufacture, distribution or sale of a Competing Product.

**“Competing Product”** means any pharmaceutical or other compound, composition, formulation, method, process, product or material that is competitive with any product of the Employer under development, manufacture, distribution or commercialization at any time from and after the Effective Date through the date of termination of the Employee’s employment, including, without limitation, small molecules that target androgen, estrogen, glucocorticoid, and/or other hormone receptors for purposes of treating, diagnosing, or imaging humans in health and disease, including treating cancer, osteoporosis and bone loss and muscle loss.

**“Confidential Information and/or Proprietary Information”** means any and all:

- (a) information disclosed to the Employee or known by the Employee as a consequence of, or through, her discussions with Employer to potentially become employed by Employer from and after January 1, 2015, including all proprietary and confidential information of Employer, not generally known in the relevant trade or industry, about the Employer’s business, products, processes, and services; and trade secrets concerning the business and affairs of the Employer, product specifications, data, know-how, formulae, compositions, research, processes, designs, sketches, photographs, graphs, drawings, samples, inventions and ideas, past, current, and planned research and development, current and planned manufacturing or distribution methods and processes, customer lists, current and anticipated customer requirements, price lists, market studies, business plans, computer software and programs (including object code and source code), computer software and database technologies, systems, structures, and architectures (and related formulae, compositions, processes, improvements, devices, know-how, inventions, discoveries, concepts, ideas, designs, methods and information); and any other information, however documented, that is a trade secret within the meaning of Tenn. Code §39-14-138 or any other applicable law; and
  - (b) information concerning the business and affairs of the Employer (which includes historical financial statements, financial projections and budgets, historical and projected sales, capital spending budgets and plans, the names and backgrounds of key personnel, personnel training and techniques and materials), however documented; and
  - (c) intellectual property, inventions, methods, processes, techniques, computer programs, devices, products, services, compounds, gene therapy products, pharmaceuticals, substances, vectors, enzymes, genes, concepts, discoveries, improvements, and designs, whether or not patentable in the United States or foreign countries, any trade secrets, information,
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procedures, technologies, data, results, conclusions, know-how or show-how and business information; and

(d) notes, analysis, compilations, studies, summaries, and other material prepared by or for the Employer containing or based, in whole or in part, on any information included in the foregoing.

**“Delayed Initial Payment Date”** has the meaning stated in Section 9.2 of this Agreement.

**“Effective Date”** means the date stated in the first paragraph of this Agreement.

**“Employee”** has the meaning stated in the first paragraph of this Agreement.

**“Employee Invention”** means any idea, invention, technique, modification, process, improvement (whether patentable or not), industrial design (whether registerable or not), work of authorship (whether or not copyright protection may be obtained for it), design, copyrightable work, discovery, trademark, copyright, trade secret, formula, device, method, compound, gene, prodrug, pharmaceutical, structure, product concept, marketing plan, strategy, customer list, technique, blueprint, sketch, record, note, drawing, know-how, data, patent application, continuation application, continuation-in-part application, file wrapper continuation application or divisional application, created, conceived, or developed by the Employee from and after the Effective Date, either solely or in conjunction with others, during the Employee’s employment, or a period that includes a portion of the Employee’s employment, that relates in any way to, or is useful in any manner in, the business then being conducted or proposed to be conducted by the Employer, and any such item created by the Employee, either solely or in conjunction with others, following termination of the Employee’s employment with the Employer, that is based upon or uses Confidential Information and/or Proprietary Information.

**“Employer”** means GTX, Inc., its successors and assigns, and any of its current or future subsidiaries, or organizations controlled by, controlling, or under common control with it. Throughout the course of the Agreement, whenever the term “Employer” is used in a context requiring action or consent for, or approval of, action it is agreed that such action, consent or approval shall come from the Board of Directors or its designee.

**“Expenses”** has the meaning stated in Section 4.1 of this Agreement.

**“Good Reason”** for termination means that the Employee voluntarily resigns from all positions she then holds with the Employer if and only if:

(a) one of the following actions have been taken without the Employee’s express written consent:

(i) an adverse change in the Employee’s authority, duties or responsibilities (including reporting responsibilities) which, without the Employee’s consent, represents a material reduction in or a material demotion of the Employee’s authority, duties or responsibilities as in effect on the Effective Date with respect to the Employee’s position as Vice

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President, Chief Medical Officer or the assignment to the Employee of any duties or responsibilities which are materially inconsistent with and materially adverse to such authority, duties or responsibilities;

(ii) a material reduction in the then current Salary of the Employee;

(iii) following a Change of Control, the Employer requires that the Employee relocate to a location that is outside of New Jersey to perform her services for the Employer;

(iv) the failure of the Employer to obtain an agreement reasonably satisfactory to the Employee from any successor or assign of the Employer upon a Change of Control to assume and agree to perform this Agreement in all material respects following the Change of Control; or

(v) the Employer materially breaches its obligations under this Agreement or any other then-effective agreement with the Employee (including any agreement or arrangement providing for incentive compensation or employee benefits, including the Benefits provided in this Agreement).

(b) the Employee provides written notice to the Board of Directors within the thirty (30) day period immediately following such action; and

(c) such action is not remedied by the Employer within thirty (30) days following the Employer's receipt of such written notice; and

(d) the Employee's resignation is effective not later than sixty (60) days after the expiration of such thirty (30)-day cure period.

**"Person"** means any individual, corporation (including any non-profit corporation), general or limited partnership, limited liability company, joint venture, estate, trust, association, organization, or governmental body.

**"Proprietary Items"** means any Proprietary and/or Confidential Information embodied in any document, record, recording, electronic media, formulae, notebook, plan, model, component, device, or computer software or code, whether embodied in a disk or in any other form.

**"Release"** means a general release of claims in favor of the Employer, in a form determined by the Employer in its sole discretion, provided that such form is reasonably acceptable to the Employee, which shall specifically relate to all of the Employee's rights and claims in existence at the time of such execution and shall confirm the Employee's continuing obligations to the Employer (including but not limited to obligations under Section 7 and Section 8 of this Agreement, the Agreement on Condition of Employment and any other confidentiality and/or non-competition agreement with the Employer).

**"Salary"** has the meaning stated in Section 3.1(a) of this Agreement.

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**“Section 409A”** has the meaning stated in Section 9.2 of this Agreement.

**“Termination Date”** has the meaning stated in Section 6.1 of this Agreement.

**“Termination With Cause”** means the termination of the Employee’s employment by act of the Board of Directors for any of the following reasons, any of which shall constitute “Cause” for purposes of this Agreement:

- (a) the Employee’s conviction of a felony;
- (b) the Employee’s intentional theft, embezzlement, misappropriation of or infliction of material damage to the Employer’s property or business opportunities;
- (c) the Employee’s breach of the provisions contained in Section 7 or Section 8 of this Agreement or the provisions in the Agreement on Condition of Employment regarding confidentiality, non-competition or non-solicitation; or
- (d) the Employee’s ongoing willful neglect of or failure to perform her duties hereunder or her ongoing willful failure or refusal to follow any reasonable, unambiguous duly adopted written direction of the CEO, if such willful neglect or failure is materially damaging or materially detrimental to the business and operations of the Employer; provided that, if curable, the Employee shall have received written notice of such neglect or failure and shall have continued to engage in such neglect or failure after 30 days following receipt of such notice from Employer, which notice specifically identifies the manner in which the Employer believes that the Employee has engaged in such neglect or failure. For purposes of this subsection, no act, or failure to act, shall be deemed “willful” unless done, or omitted to be done, by the Employee not in good faith, and without reasonable belief that such action or omission was in the best interest of the Employer.

**“Termination Without Cause”** means the termination of the Employee’s employment by the Employer for any reason other than (i) Termination With Cause, or (ii) a termination by the Employer due to the Employee’s death or disability.

## 2. EMPLOYMENT TERMS AND DUTIES

### 2.1 Employment

The Employer hereby employs the Employee, and the Employee hereby accepts employment by the Employer, upon the terms and conditions set forth in this Agreement.

### 2.2 Term

Either the Employee or the Employer may terminate this Agreement and the Employee’s employment and compensation with or without Cause or notice, at any time, at either the Employer’s or the Employee’s option. No officer or manager of the Employer has the authority to enter into any other agreement for employment for a specified period of time, or to

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modify or to make any agreement contrary to the foregoing, except by written amendment to this Agreement, dated and signed by the Chief Executive Officer (“CEO”) of the Employer.

### 2.3 Duties

The Employee will have such duties as are assigned or delegated to the Employee by the CEO and will initially serve as Vice President, Chief Medical Officer for the Employer.

Such duties will include, but may not be limited to, working with other employees of Employer, including Employer’s other vice presidents, to oversee and direct the clinical development of Employer’s clinical product candidates, including making such medical decisions and providing such medical input as is appropriate and necessary to ensure the safety of patients participating in any Employer sponsored clinical study. To the extent requested by the CEO, Employee also will participate in investor and business development meetings important to the Employer and attend significant scientific and industry conferences with other Employer personnel. The Employee will devote such time, attention, skill and energy to the business of the Employer as is reasonably necessary to fulfill the requirements of her duties, but in any event, will agree to make herself available as needed to the CEO and other senior officers and employees of the Employer as necessary to provide executive leadership and direction to the business of the Employer.

The Employee agrees to use her best efforts to promote the success of the Employer’s business, and to cooperate fully with the CEO in the advancement of the best interest of the Employer. The Employee agrees to abide by all bylaws, policies, practices, procedures or rules of the Employer, as determined by the Board of Directors.

The Employer agrees that the Employee shall be permitted to remain a resident of New Jersey and shall be based, for purposes of her employment with the Employer, in New Jersey. The Employee agrees that periodic travel to Tennessee and elsewhere will be necessary, but the Employee shall not be required to relocate. The Employer agrees to make all reasonable and necessary accommodations to effectuate this arrangement.

### 2.4 Workweek

Notwithstanding the provisions of Section 2.3, the Employer agrees that the Salary to be paid to the Employee contemplates the Employee working on average approximately two and one-half (2.5) days per week. The Employee’s salary and benefits, as outlined in this Agreement, are based upon this agreed-upon two and one-half (2.5)-day workweek. If the Employee determines that she is working more than two and one-half (2.5) days per week, the Employee may request that the CEO seek approval of the Board of Directors (or its Compensation Committee) to amend this Agreement to adjust her Salary to reflect the increased workweek.

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3. COMPENSATION

3.1 Basic Compensation

(a) Salary. As of the Effective Date, the Employee will be paid for each of the twenty-six pay periods during the calendar year approximately \$6,730.77, which is the equivalent of \$175,000 per calendar year (the "Salary"), subject to review and adjustment from time to time by the Compensation Committee of the Board.

(i) Annual Salary Increase. The Employee shall be eligible for salary increases at least once annually as determined by the Compensation Committee of the Board. Such salary increase shall be based a review of the overall performance of the Employer as well as the performance of the Employee during the preceding twelve (12)-month period, as determined by the Compensation Committee of the Board, with input from the CEO.

(ii) Salary Increase Upon Increase In Workweek. Pursuant to Section 2.4, in the event that the Employee and the Compensation Committee of the Board agree to amend this Agreement to reflect an increase in the Employee's workweek, the Employer and the Employee will agree on a revised Salary that more accurately compensates her for the work she is doing for the Employer.

(b) Benefits. The Employee will, during her employment with the Employer, be permitted to participate in such life insurance, hospitalization, major medical, short term disability, long term disability, 401(k) plan and other employee benefit or additional compensation plans of the Employer that may be in effect from time to time, to the extent the Employee is eligible under the terms of those plans (collectively, the "Benefits"). All matters of eligibility for coverage or benefits under any such plan shall be determined in accordance with the provisions of such plan. The Employer reserves the right to change, alter, or terminate any such plan, in its sole discretion, subject to the terms of such plan.

(c) Annual Bonus. If and to the extent that the CEO and other vice presidents of Employer are eligible for an annual performance bonus, the Employee also shall be similarly eligible for an annual performance bonus (the "Annual Bonus"). Such bonus shall be subject to the same terms and calculated utilizing the same metrics as that provided for the other vice presidents of Employer.

(d) RSU Award. The Employee shall be granted a restricted stock unit award as of the Effective Date of her employment (the "RSU Award"). In the event of a Change of Control, the RSU Award shall become fully vested, as set forth in the grant documents executed in connection with the RSU Award.

(e) The Employer may withhold from the Salary or Benefits payable to the Employee all federal, state, local, and other taxes and other amounts as permitted or required pursuant to law, rules or regulations.

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#### 4. FACILITIES AND EXPENSES

##### 4.1 General

The Employer will furnish the Employee office space, equipment, supplies, and such other facilities and personnel as the Employee deems necessary or appropriate for the performance of the Employee's duties under this Agreement. The Employer will pay the Employee's dues in such professional societies and organizations as are reasonably related to the Employee's employment, and will pay on behalf of the Employee (or reimburse the Employee for) reasonable expenses incurred by the Employee at the request of, or on behalf of, the Employer in the performance of the Employee's duties pursuant to this Agreement, and in accordance with the Employer's employment policies, including reasonable expenses incurred by the Employee in attending conventions, seminars, and other business meetings, in appropriate business entertainment activities, and for promotional expenses (the "Expenses"). In the event that the Employee is required to or deems it appropriate to travel to Memphis, all reasonable travel and lodging-related expenses shall be paid by or reimbursed by the Employer. To the extent that any reimbursements payable or in-kind benefits provided pursuant to this Agreement are subject to the provisions of Section 409A of the Internal Revenue Code of 1986, as amended (the "Code"), any such reimbursements payable pursuant to this Agreement shall be paid no later than December 31 of the year following the year in which the expense was incurred, the amount of expenses reimbursed or in-kind benefits provided in one year shall not affect the amount eligible for reimbursement or in-kind benefits to be provided in any subsequent year, and the right to reimbursement or in-kind benefits under this Agreement will not be subject to liquidation or exchange for another benefit. The Employee must file expense reports with respect to such expenses in accordance with the Employer's policies.

#### 5. VACATIONS AND HOLIDAYS

The Employee will be eligible to accrue paid vacation each calendar year in accordance with the vacation policies of the Employer in effect from time to time. Under such policies of the Employer as of the Effective Date, the Employee is eligible to accrue up to four (4) weeks of paid vacation each calendar year. Additionally, the Employee will be entitled to the paid holidays set forth in the Employer's policies.

Any accrued vacation days and holidays that are not used by the Employee by the end of the calendar year in which they were accrued will be lost and may not be used in any subsequent calendar year; *provided, however*, that upon termination of the Employee's employment, the Employee will be paid the equivalent compensation attributable to any accrued vacation days which were accrued during the calendar year in which such termination occurs and are not otherwise used by the Employer as of the date of such termination.

#### 6. TERMINATION

6.1 At-Will Employment. The Employee's employment is at-will, which means that either the Employee or the Employer may terminate this Employment Agreement (with the exception of the provisions of Sections 7 and 8 which shall survive termination of this

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Agreement and the Employee's employment) with or without Cause or notice, at any time at either the Employee's or the Employer's option. Except as otherwise specifically set forth herein, or as provided in any plan documents governing any compensatory equity awards that have been or may be granted to the Employee from time to time in the sole discretion of the Employer or an affiliate, upon termination of the Employee's employment the Employer shall be released from any and all further obligations under this Agreement, except the Employer shall be obligated to pay the Employee (i) her accrued but unpaid Basic Compensation and Expenses owing to the Employee through the day on which the Employee's employment is terminated (the "Termination Date") and (ii) any earned but unpaid Annual Bonus with respect to any completed calendar year immediately preceding the Termination Date (the "Unpaid Annual Bonus"), which shall be paid on the otherwise applicable payment date (but in no event later than the 15<sup>th</sup> day of the third month following the end of such year) except to the extent payment is otherwise deferred pursuant to any applicable deferred compensation arrangement. The Employee's obligations under Sections 7 and 8 shall continue pursuant to the terms and conditions of this Agreement.

6.2 Termination Upon Death. The employment of the Employee shall terminate on the date of the Employee's death, in which event the Employee's accrued but unpaid Basic Compensation and Expenses and any Unpaid Annual Bonus, owing to the Employee through the date of the Employee's death, shall be paid to her estate in accordance with Section 6.1. The Employee's estate will not be entitled to any other compensation under this Agreement.

6.3 Termination Under Certain Circumstances. As additional consideration for the covenants in Section 7 and Section 8, in the event of a Change of Control Termination and provided that the Employee signs and allows to become effective a Release within the time period provided therein (but not later than the 60<sup>th</sup> day following the Termination Date, such latest permitted effective date is the "Release Deadline" for purposes of this Agreement), then subject to Section 9.2:

(a) The Employee shall receive as severance one (1) year of her Salary, payable in accordance with the Employer's then current payroll schedule over the one (1) year period following the Termination Date, less deductions required by law; *provided, however*, that if the Employee terminates her employment on account of a material reduction in her Salary, as provided in paragraph (a)(ii) of the definition of Good Reason, the amount of such severance shall be based on the Employee's Salary immediately prior to such reduction. Notwithstanding the foregoing payment schedule, no severance will be paid prior to the effective date of the Release. Subject to Section 9.2, on the first regular payroll pay day following the effective date of the Release, the Employer will pay the Employee the severance that the Employee would otherwise have received on or prior to such date but for the delay in payment related to the effectiveness of the Release, with the balance of the severance being paid as originally scheduled.

(b) If the Employee timely elects group health insurance coverage under the Consolidated Omnibus Budget Reconciliation Act of 1985 ("COBRA"), the Employer will pay the Employee's monthly COBRA premiums (including the cost of eligible

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dependent coverage, if any) through the earliest of the following (the “COBRA Payment Period”): (i) for twelve (12) months following the Termination Date; (ii) the date that the Employee becomes eligible for group health insurance coverage through a new employer; or (iii) the date that the Employee is no longer eligible for COBRA coverage. Notwithstanding the foregoing, if at any time the Employer determines, in its sole discretion, that its payment of the Employee’s COBRA premiums would result in a violation of applicable law (including, without limitation, Section 105(h)(2) of the Code and Section 2716 of the Public Health Service Act), then in lieu of paying such COBRA premiums, the Employer will pay the Employee on the last day of each remaining month of the COBRA Payment Period a fully taxable cash payment equal to the COBRA premium for that month, subject to applicable tax withholding (such amount, the “Special Severance Payment”); *provided, however*, that any such Special Severance Payment will be made without regard to the Employee’s payment of COBRA premiums and for purposes of any such Special Severance Payment, the “COBRA Payment Period” will be determined without regard to the expiration of the Employee’s eligibility for continued coverage under COBRA.

(c) If the Employee’s employment is terminated due to a termination with Good Reason or a Termination Without Cause, in each case prior to a Change of Control, then any unvested portion of the RSU Award that is scheduled to vest on the next scheduled vesting date will become fully vested upon such termination and any other unvested portion of the RSU Award will be forfeited to the Company upon such termination.

## 7. NON-DISCLOSURE COVENANT; EMPLOYEE INVENTIONS

### 7.1 Acknowledgements by the Employee

The Employee acknowledges and agrees that (a) during the course of her employment and as a part of her employment, the Employee will be afforded access to Confidential Information and/or Proprietary Information; (b) public disclosure of such Confidential Information and/or Proprietary Information could have an adverse effect on the Employer and its business; (c) because the Employee possesses substantial technical expertise and skill with respect to the Employer’s business, the Employer desires to obtain exclusive ownership of each Employee Invention, and the Employer will be at a substantial competitive disadvantage if it fails to acquire exclusive ownership of each Employee Invention; and (d) the provisions of this Section 7 are reasonable and necessary to prevent the improper use or disclosure of Confidential Information and/or Proprietary Information and to provide the Employer with exclusive ownership of all Employee Inventions.

### 7.2 Agreements of the Employee

In consideration of the compensation and benefits to be paid or provided to the Employee by the Employer under this Agreement and otherwise, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Employee covenants and agrees as follows:

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(a) Confidentiality

(i) That all of such Confidential Information and/or Proprietary Information is a unique asset of the business of the Employer, the disclosure of which would be damaging to the Employer.

(ii) That the Employee will not at any time, whether during or after termination or cessation of the Employee's employment, except as authorized by the Employer and for its benefit, use, divulge or disclose (or enable anyone else to use, divulge or disclose) to any Person, association or entity any Confidential Information and/or Proprietary Information which the Employee presently possesses or which the Employee may obtain during the course of the Employee's employment with respect to the business, finances, customers or affairs of the Employer or trade secrets, developments, methods or other information and data pertaining to the Employer's business. The Employee shall keep strictly confidential all matters and information entrusted to the Employee and shall not use or attempt to use any such Confidential Information and/or Proprietary Information in any manner which may injure or cause loss or may be calculated to injure or cause loss, whether directly or indirectly, to the Employer.

(iii) That during the course of this Agreement or at any time after termination, the Employee will keep in strictest confidence and will not disclose or make accessible to any other Person without the prior written consent of the Employer, the Confidential Information and/or Proprietary Information; the Employee agrees: (a) not to use any such Confidential Information and/or Proprietary Information for himself or others; and (b) not to take any such material or reproductions thereof from the Employer's facilities at any time during his employment except, in each case, as required in connection with the Employee's duties to the Employer.

(iv) The Employee agrees to hold in confidence, and not to distribute or disseminate to any Person or entity for any reason, any Confidential Information and/or Proprietary Information of the Employer under this Agreement, or information relating to experiments or results obtained based on the duties of the Employee, except for information which: (a) is in or which becomes a part of the public domain not as a result of a breach of this Agreement, (b) is information lawfully received from a third party who had the right to disclose such information or (c) is required by legal process before a court of proper jurisdiction (by oral questions, deposition, interrogatories, requests for information or documents, subpoena, civil investigative domain or other similar process) to disclose all or any part of any Confidential Information and/or Proprietary Information, provided that the Employee will provide the Employer with prompt notice of such request or requirement, as well as notice of the terms and circumstances surrounding such request or requirements, so that the Employer may seek an appropriate protective order or waive compliance with the provisions of this Agreement. In such case, the parties will consult with each

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other on the advisability of pursuing any such order or other legal action or available step to resist or narrow such request or requirement. If, failing the entry of a protective order or the receipt of a waiver hereunder, the Employee is, in the opinion of counsel, legally compelled to disclose Confidential Information and/or Proprietary Information, the Employee may disclose that portion of such information which counsel advises is necessary to disclose. The Employee will not oppose any action by the Employer to prevent disclosure pursuant to an appropriate protective order or to request other reliable assurances that confidential treatment will be accorded to the disclosure of such information.

(v) Upon termination of this Agreement by either party or upon written notice by the Employer, the Employee shall promptly redeliver to the Employer, or, if requested by the Employer, promptly destroy all written Confidential Information and/or Proprietary Information and any other written material containing any information included in the Confidential Information and/or Proprietary Information (whether prepared by the Employer, the Employee, or a third party), and will not retain any copies, extracts or other reproductions in whole or in part of such written Confidential Information and/or Proprietary Information (and upon request certify such redelivery or destruction to the Employer in a written instrument reasonably acceptable to the Employer and its counsel).

(vi) This Agreement and the terms and conditions recited herein are confidential and non-public, except as may be expressly permitted by the Employer. The Employee agrees not to disclose the contents of this Agreement to any Person or entity, including, but not limited to the press, other media, any public body, or any competitor of the Employer, except to the Employee's legal counsel, financial advisors, immediate family, or as may be required by law. The Employee shall also be permitted to disclose Sections 7 and 8 to any potential employer.

(vii) Any trade secrets of the Employer will be entitled to all of the protections and benefits of State of Tennessee law and any other applicable law. If any information that the Employer deems to be a trade secret is found by a court of competent jurisdiction not be to a trade secret for purposes of this Agreement, such information will, nevertheless, be considered Confidential Information and/or Proprietary Information for purposes of this Agreement. The Employee hereby waives any requirement that the Employer submits proof of the economic value of any trade secret or posts a bond or other security.

(viii) None of the foregoing obligations and restrictions applies to any part of the Confidential Information and/or Proprietary Information that the Employee demonstrates was or became generally available to the public other than as a result of a disclosure by the Employee.

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(ix) The Employee will not remove from the Employer's premises (except to the extent such removal is for purposes of the performance of the Employee's duties at home or while traveling, or except as otherwise specifically authorized by the Employer) any Proprietary Items. The Employee recognizes that, as between the Employer and the Employee, all of the Proprietary Items, whether or not developed by the Employee, are the exclusive property of the Employer. Upon termination of this Agreement by either party, or upon the request of the Employer during the employment of the Employee, the Employee will return to the Employer all of the Proprietary Items in the Employee's possession or subject to the Employee's control, and the Employee shall not retain any copies, abstracts, sketches, or other physical or electronic embodiment of any of the Proprietary Items.

(x) During the Employee's employment with the Employer, the Employee will not improperly use or disclose any confidential information or trade secrets, if any, of any former employer or any other Person to whom the Employee has an obligation of confidentiality, and the Employee will not bring onto the premises of the Employer any unpublished documents or any property belonging to any former employer or any other Person to whom the Employee has an obligation of confidentiality unless consented to in writing by that former employer or Person.

(b) Employee Inventions

(i) Each Employee Invention will belong exclusively to the Employer. The Employee agrees that the Employer shall have sole and exclusive ownership rights in any conception, invention, trade secrets, information, ideas, improvement, substance, know-how, whether or not patentable, arising out of, resulting from, or derivative of: (1) the work or services of the Employee, or (2) within the scope of the duties of the Employee, or (3) using any materials, compounds, devices, or monies of the Employer. Any resulting or derivative rights, including patent rights, shall become the exclusive property of the Employer and the Employer shall be entitled to the entire right, title and interest with respect hereto. The Employee agrees, without additional compensation, to convey, assign the entire right, title, and interest in and to any inventions for the United States and all foreign jurisdictions to the Employer arising out of, resulting from, or derivative of: (1) the work or services of the Employee, or (2) within the scope of the duties of the Employee, or (3) using any materials, compounds, devices, or monies.

(ii) The Employer shall retain the entire right, title and interest in and to any and all Confidential Information and/or Proprietary Information provided by the Employer to the Employee and to any methods, compounds, improvements, substances, and compositions using or incorporating such Confidential Information and/or Proprietary Information.

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(iii) The Employee agrees that Confidential Information and/or Proprietary Information provided to the Employee by the Employer shall be used for work purposes only and shall not be used for any other uses, studies, experiments or tests.

(iv) The Employee agrees that she will promptly disclose to the Employer, or any Persons designated by the Employer, all the Employee Inventions, made or conceived or reduced to practice or learned by her, either alone or jointly with others, during the employment of the Employee. The Employee further agrees to assist the Employer in every proper way (but at the Employer's expense) to obtain and from time to time enforce patents, copyrights or other rights on Employee Inventions in any and all countries, and to that end the Employee will execute all documents necessary: (a) to apply for, obtain and vest in the name of the Employer alone (unless the Employer otherwise directs) letters patent, copyrights or other analogues protection in any country throughout the world and when so obtained or vested to renew and restore the same; and (b) to defend (including the giving of testimony and rendering any other assistance) any opposition proceedings in respect of such applications and any opposition proceedings or petitions or applications for revocation of such letters patent, copyright or other analogous protection. The Employee's obligation to provide reasonable assistance to the Employer in obtaining and enforcing patents and copyrights for Employee Inventions in any and all countries shall continue beyond and after the termination of the Employee.

(v) Any copyrightable work whether published or unpublished created by the Employee in connection with or during the performance of services below shall be considered a work made for hire, to the fullest extent permitted by law and all right, title and interest therein, including the worldwide copyrights, shall be the property of the Employer as the employer and party specially commissioning such work. In the event that any such copyrightable work or portion thereof shall not be legally qualified as a work made for hire, or shall subsequently be so held, the Employee agrees to properly convey to the Employer, without additional compensation, the entire right, title and interest in and to such work or portion thereof, including but not limited to the worldwide copyrights, extensions of such copyrights, and renewal copyrights therein, and further including all rights to reproduce the copyrighted work in copies or phonorecords, to prepare derivative works based on the copyrighted work, to distribute copies of the copyrighted work, to perform the copyrighted work publicly, to display the copyrighted work publicly, and to register the claim of copyright therein and to execute any and all documents with respect hereto.

(vi) The Employee may not publish or disclose any Confidential Information and/or Proprietary Information relating to, arising from, derivative of, or as a result of her employment pursuant to this Agreement, including but not limited to: information, improvements, results, experiments, data, or methods that makes reference to any of the Confidential Information

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and/or Proprietary Information. Any work performed under, or arising from, or a result of her employment with the Employer shall not be published or disclosed in written, electronic, or oral form without the express written permission of the Employer.

### 7.3 Disputes or Controversies

The Employee recognizes that should a dispute or controversy arising from or relating to this Agreement be submitted for adjudication to any court, arbitration panel, or other third party, the preservation of the secrecy of Confidential Information and/or Proprietary Information may be jeopardized. All pleadings, documents, testimony, and records relating to any such adjudication will be maintained in secrecy and will be available for inspection by the Employer, the Employee, and their respective attorneys and experts, who will agree, in advance and in writing, to receive and maintain all such information in secrecy, except as may be limited by them in writing.

### 7.4 Agreement on Condition of Employment

As a condition of employment, the Employee agrees to execute and abide by the Employer's current form of Agreement on Condition of Employment, which may be amended by the parties from time to time without regard to this Agreement. The Agreement on Condition of Employment contains provisions that are intended by the parties to survive and do survive termination or expiration of this Agreement. In the event that the terms of this Agreement differ from or are in conflict with the Agreement on Condition of Employment, this Agreement shall control.

## 8. NON-COMPETITION

### 8.1 Acknowledgments by the Employee

The Employee understands and recognizes that the Employee's services provided to the Employer are special, unique, unusual, extraordinary and intellectual in character. Subject to Section 8.4 below, the Employee agrees that, during the employment of the Employee and for a period of two (2) years from the date of termination of the Employee's employment with the Employer, she will not in any manner, directly or indirectly, on behalf of himself or any Person, firm, partnership, joint venture, corporation or other business entity, engage or invest in, own, manage, operate, finance, control or participate in the ownership, management, operation, financing, or control of, be employed by, associated with, or in any manner connected with, lend the Employee's name or similar name to, lend the Employee's credit to or render services or advice to, enter into or engage in any Competing Business; *provided, however,* that the Employee may purchase or otherwise acquire up to (but not more than) five percent (5%) of any class of securities of any enterprise (but without otherwise participating in the activities of such enterprise) if such securities are listed on any national or regional securities exchange or have been registered under Section 12(g) of the Securities Exchange Act of 1934. The Employer and Employee specifically acknowledges that, upon her employment by Employer, the Employee shall not be permitted to engage in other employment endeavors on a part-time basis, including

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but not limited to serving as a pharmaceutical consultant or part-time pharmaceutical employee unless specifically approved in advance by the Executive Chairman of the Employer's Board of Directors, and then only so long as the Employee does not undertake any such consulting work or part-time employment work for a Competing Business.

8.2 In consideration of the acknowledgements by the Employee, and in consideration of the compensation and benefits to be paid or provided to the Employee by the Employer, the Employee covenants that, subject to Section 8.4 below, she will not, directly or indirectly, whether for the Employee's own account or the account of any other Person (i) at any time during the employment of the Employee and for a period of two (2) years from the termination of the Employee's employment with the Employer interfere with the Employer's relationship with any then-current employee by soliciting, employing, or otherwise engaging as an employee, independent contractor, or otherwise, any Person who is an employee of the Employer at the time of termination or in any manner induce or attempt to induce any employee of the Employer to terminate his employment with the Employer; or (ii) at any time during the employment of the Employee with the Employer and for two (2) years from the termination of the Employee's employment with the Employer, interfere with the Employer's relationship with any Person, including any Person who at any time during the Employee's employment with the Employer was an employee, contractor, supplier, or customer of the Employer.

8.3 In further consideration of these promises, the Employee agrees that she will not at any time during or after the Employee's employment with the Employer, disparage the Employer or any of its shareholders, directors, officers, employees, parents, subsidiaries, affiliates or agents in any manner likely to be harmful to the Employer; *provided, however*, that the Employee may respond accurately and fully to any question, inquiry or request for information when required by legal process. Likewise, the Employer agrees that it will not at any time during or after the Employee's employment with the Employer, disparage the Employee in any manner likely to be harmful to the Employee or her business or personal reputation. The Employer shall take reasonable steps to ensure that the Employer's employees comply with this provision.

8.4 Change of Control. In the event of a Change of Control Termination, the Employee's obligations under Sections 8.1 and 8.2 above and the non-competition and non-solicitation provisions in the Agreement on Condition of Employment shall expire one (1) year from the date of termination of her employment with the Employer (or any entity acquiring the Employer as a result of a Change of Control).

8.5 If any covenant in Section 8 is held to be unreasonable, arbitrary, or against public policy, such covenant will be considered to be divisible with respect to scope, time, and geographic area, and such lesser scope, time, or geographic area, or all of them, as a court of competent jurisdiction may determine to be reasonable, not arbitrary, and not against public policy, will be effective, binding, and enforceable against the Employee.

The period of time applicable to any covenant in Section 8 will be extended by the duration of any violation by the Employee of such covenant.

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The Employee will, while the covenants under Section 8 are in effect, give notice to the Employer, within ten days after accepting any other employment, of the identity of the Employee's employer. The Employer may notify such employer that the Employee is bound by this Agreement and, at the Employer's election, furnish such employer with a copy of this Agreement or relevant portions thereof.

## 9. TAX MATTERS

9.1 **Responsibility for Tax Obligations.** The Employee agrees that she is responsible for any applicable taxes of any nature (including any penalties or interest that may apply to such taxes) that the Employer reasonably determines apply to any payment or equity award made to the Employee hereunder (or any arrangement contemplated hereunder), that the Employee's receipt of any payment or benefit hereunder is conditioned on the Employee's satisfaction of any applicable withholding or similar obligations that apply to such payment or benefit, and that any cash payment owed to the Employee hereunder will be reduced to satisfy any such withholding or similar obligations that may apply thereto.

9.2 **Compliance with Section 409A.** Any payments or benefits provided under this Agreement that constitute "deferred compensation" within the meaning of Section 409A of the Code and the regulations and other guidance thereunder and any state law of similar effect (collectively "Section 409A") shall not commence in connection with the Employee's termination of employment unless the Employee has also incurred a "separation from service," as such term is defined in Treasury Regulation Section 1.409A-1(h) (without regard to any permissible alternative definition thereunder) ("Separation from Service"). It is intended that each installment of the payments and benefits provided for in this Agreement is a separate "payment" for purposes of Treasury Regulation Section 1.409A-2(b)(2)(i). For the avoidance of doubt, it is intended that payments of the amounts set forth in this Agreement satisfy, to the greatest extent possible, the exemptions from the application of Section 409A provided under Treasury Regulations 1.409A-1(b)(4), 1.409A-1(b)(5) and 1.409A-1(b)(9). However, if the Employer determines that the payments and benefits provided under this Agreement constitute "deferred compensation" under Section 409A and the Employee is, on the date of the Employee's Separation from Service, a "specified employee" of the Employer or any successor entity thereto, as such term is defined in Section 409A(a)(2)(B)(i) of the Code, then, solely to the extent necessary to avoid the incurrence of the adverse personal tax consequences under Section 409A, the timing of any such payments or benefits shall be delayed as follows: on the earlier to occur of (i) the date that is six (6) months and one (1) day after the Employee's Separation from Service or (ii) the date of the Employee's death (such earlier date, the "Delayed Initial Payment Date"), the Employer shall (A) pay to the Employee a lump sum amount equal to the sum of the payments that the Employee would otherwise have received through the Delayed Initial Payment Date if the commencement of the payment of the payments had not been so delayed pursuant to this Section 9.2 and (B) commence paying the balance of the payments in accordance with the applicable payment schedules set forth in this Agreement. If the Employer determines that any payments or benefits provided under this Agreement constitute "deferred compensation" under Section 409A and the Release could become effective in the calendar year following the calendar year in which the Employee's Separation from Service occurs, the Release will not be deemed

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effective any earlier than the Release Deadline for purposes of determining the timing of payment of any such payments or benefits.

### 9.3 Parachute Payments

(a) Notwithstanding anything in this Agreement to the contrary, if any payment or benefit the Employee will or may receive from the Employer or otherwise (a "280G Payment") would (i) constitute a "parachute payment" within the meaning of Section 280G of the Code, and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the "Excise Tax"), then any such 280G Payment pursuant to this Agreement (a "Payment") shall be equal to the Reduced Amount. The "Reduced Amount" shall be either (x) the largest portion of the Payment that would result in no portion of the Payment (after reduction) being subject to the Excise Tax or (y) the largest portion, up to and including the total, of the Payment, whichever amount (*i.e.*, the amount determined by clause (x) or by clause (y)), after taking into account all applicable federal, state and local employment taxes, income taxes, and the Excise Tax (all computed at the highest applicable marginal rate), results in the Employee's receipt, on an after-tax basis, of the greater economic benefit notwithstanding that all or some portion of the Payment may be subject to the Excise Tax. If a reduction in a Payment is required pursuant to the preceding sentence and the Reduced Amount is determined pursuant to clause (x) of the preceding sentence, the reduction shall occur in the manner (the "Reduction Method") that results in the greatest economic benefit for the Employee. If more than one method of reduction will result in the same economic benefit, the items so reduced will be reduced pro rata (the "Pro Rata Reduction Method").

(b) Notwithstanding any provision of Section 9.3(a) to the contrary, if the Reduction Method or the Pro Rata Reduction Method would result in any portion of the Payment being subject to taxes pursuant to Section 409A that would not otherwise be subject to taxes pursuant to Section 409A, then the Reduction Method and/or the Pro Rata Reduction Method, as the case may be, shall be modified so as to avoid the imposition of taxes pursuant to Section 409A as follows: (A) as a first priority, the modification shall preserve to the greatest extent possible, the greatest economic benefit for the Employee as determined on an after-tax basis; (B) as a second priority, Payments that are contingent on future events (*e.g.*, being terminated without Cause), shall be reduced (or eliminated) before Payments that are not contingent on future events; and (C) as a third priority, Payments that are "deferred compensation" within the meaning of Section 409A shall be reduced (or eliminated) before Payments that are not deferred compensation within the meaning of Section 409A.

(c) If the Employee receives a Payment for which the Reduced Amount was determined pursuant to clause (x) of Section 9.3(a) and the Internal Revenue Service determines thereafter that some portion of the Payment is subject to the Excise Tax, the Employee shall promptly return to the Employer a sufficient amount of the Payment (after reduction pursuant to clause (x) of Section 9.3(a)) so that no portion of the remaining Payment is subject to the Excise Tax. For the avoidance of doubt, if the Reduced Amount was determined pursuant to clause (y) of Section 9.3(a), the Employee

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shall have no obligation to return any portion of the Payment pursuant to the preceding sentence.

#### 10. CLAWBACK/RECOVERY

Any amounts paid to the Employee by the Employer, whether or not under this Agreement or any incentive plan of the Employer, will be subject to recoupment in accordance with The Sarbanes-Oxley Act of 2002, The Dodd-Frank Wall Street Reform and Consumer Protection Act and any implementing regulations under these acts, any clawback policy adopted by the Employer, or as otherwise required by applicable law. In addition, in consideration of the Employee's continued employment with the Employer and in recognition of the Employee's position of trust and authority with the Employer, the Employee agrees to promptly consent to any clawback policy adopted by the Employer.

#### 11. GENERAL PROVISIONS

##### 11.1 Injunctive Relief and Additional Remedy

The parties acknowledge that the injury that would be suffered by the other as a result of a breach of the provisions of this Agreement (including any provision of Sections 7 and 8) would be irreparable and that an award of monetary damages to the either for such a breach would be an inadequate remedy. Consequently, either party will have the right, in addition to any other rights it may have, to obtain injunctive relief to restrain any breach or threatened breach or otherwise to specifically enforce any provision of this Agreement, and will not be obligated to post bond or other security in seeking such relief. Without limiting the Employer's rights under this Section 11 or any other remedies of the Employer, if the Employee breaches any of the provisions of Section 7 or 8, the Employer will have the right to cease making any payments otherwise due to the Employee under this Agreement.

##### 11.2 Covenants of Sections 7 and 8 are Essential and Independent Covenants

The covenants by the Employee in Sections 7 and 8 are essential elements of this Agreement, and without the Employee's agreement to comply with such covenants, the Employer would not have entered into this Agreement or employed or continued the employment of the Employee. The Employer and the Employee have independently consulted their respective counsel and have been advised in all respects concerning the reasonableness and propriety of such covenants, with specific regard to the nature of the business conducted by the Employer. The Employee agrees that this Agreement does not prevent her from earning a living or pursuing her career and that she has the ability to secure other non-competitive employment using her marketable skills. The Employee agrees that the restrictions contained in this Agreement are reasonable, proper, and necessitated by the Employer's legitimate business interests, including without limitation, the Employer's Confidential and/or Proprietary Information and the goodwill of its customers.

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The Employee's covenants in Sections 7 and 8 are independent covenants and the existence of any claim by the Employee against the Employer under this Agreement or otherwise will not excuse the Employee's breach of any covenant in Section 7 or 8.

If the Employee's employment hereunder is terminated by either party, this Agreement will continue in full force and effect as is necessary or appropriate to enforce the covenants and agreements of the Employee in Sections 7 and 8.

#### 11.3 Representations and Warranties by the Employee

The Employee represents and warrants to the Employer that the execution and delivery by the Employee of this Agreement do not, and the performance by the Employee of the Employee's obligations hereunder will not, with or without the giving of notice or the passage of time, or both: (a) violate any judgment, writ, injunction, or order of any court, arbitrator, or governmental agency applicable to the Employee; or (b) conflict with, result in the breach of any provisions of or the termination of, or constitute a default under, any agreement to which the Employee is a party or by which the Employee is or may be bound.

#### 11.4 Waiver

The rights and remedies of the parties to this Agreement are cumulative and not alternative. Neither the failure nor any delay by either party in exercising any right, power, or privilege under this Agreement will operate as a waiver of such right, power, or privilege, and no single or partial exercise of any such right, power, or privilege will preclude any other or further exercise of such right, power, or privilege or the exercise of any other right, power, or privilege. To the maximum extent permitted by applicable law, (a) no claim or right arising out of this Agreement can be discharged by one party, in whole or in part, by a waiver or renunciation of the claim or right unless in writing signed by the other party; (b) no waiver that may be given by a party will be applicable except in the specific instance for which it is given; and (c) no notice to or demand on one party will be deemed to be a waiver of any obligation of such party or of the right of the party giving such notice or demand to take further action without notice or demand as provided in this Agreement.

#### 11.5 Binding Effect; Delegation of Duties Prohibited

This Agreement shall inure to the benefit of, and shall be binding upon, the parties hereto and their respective successors, assigns, heirs, and legal representatives, including any entity with which the Employer may merge or consolidate or to which all or substantially all of its assets may be transferred. The duties and covenants of the Employee under this Agreement, being personal, may not be delegated.

#### 11.6 Notices

All notices, consents, waivers, and other communications under this Agreement must be in writing and will be deemed to have been duly given when (a) delivered by hand (with written confirmation of receipt), (b) sent by facsimile (with written confirmation of receipt), provided that a copy is mailed by registered mail, return receipt requested, or (c) when received

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by the addressee, if sent by a nationally recognized overnight delivery service (receipt requested), in each case to the appropriate addresses and facsimile numbers set forth below (or to such other addresses and facsimile numbers as a party may designate by notice to the other parties):

If to the Employer:                   GTx, Inc.  
175 Toyota Plaza, 7<sup>th</sup> Floor  
Memphis, Tennessee 38103  
Attention: Vice President, Chief Legal Officer  
Facsimile No.: 901-844-8075

If to the Employee:                   Diane C. Young, M.D.  
12 Carriage Hill Drive  
Far Hills, New Jersey 07931

The Employee shall notify the Employer in writing of any change of her address. Otherwise, the Employer shall send all notices to the Employee's address herein.

11.7    Entire Agreement; Amendments

This Agreement, including the Agreement on Condition of Employment, contains the entire agreement between the parties with respect to the subject matter hereof and supersedes all prior agreements and understandings, oral or written, between the parties hereto with respect to the subject matter hereof. The Employer and the Employee further acknowledge and agree that the provisions of this Agreement amend and supersede the Prior Employment Agreement, which shall be of no further force and effect. This Agreement may not be amended orally, but only by an agreement in writing signed by the Employee and a duly authorized officer or director of the Employer.

11.8    Governing Law

This Agreement will be governed by the laws of the State of Tennessee without regard to conflicts of laws principles.

11.9    Jurisdiction

Any action or proceeding seeking to enforce any provision of, or based on any right arising out of, this Agreement shall be brought against either of the parties in the courts of the State of Tennessee, County of Shelby, or, if it has or can acquire jurisdiction, in the United States District Court for the Western District of Tennessee, and each of the parties consents to the jurisdiction of such courts (and of the appropriate appellate courts) in any such action or proceeding and waives any objection to venue laid therein. Process in any action or proceeding referred to in the preceding sentence may be served on either party anywhere in the world.

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11.10 Section Headings, Construction

The headings of Sections in this Agreement are provided for convenience only and will not affect its construction or interpretation. All references to “Section” or “Sections” refer to the corresponding Section or Sections of this Agreement unless otherwise specified. All words used in this Agreement will be construed to be of such gender or number as the circumstances require. Unless otherwise expressly provided, the word “including” does not limit the preceding words or terms.

11.11 Severability

If any provision of this Agreement is held invalid or unenforceable by any court of competent jurisdiction, the other provisions of this Agreement will remain in full force and effect. Any provision of this Agreement held invalid or unenforceable only in part or degree will remain in full force and effect to the extent not held invalid or unenforceable.

11.12 Counterparts

This Agreement may be executed in one or more counterparts, each of which will be deemed to be an original copy of this Agreement and all of which, when taken together, will be deemed to constitute one and the same agreement.

11.13 Waiver of Jury Trial

THE PARTIES HERETO HEREBY WAIVE A JURY TRIAL IN ANY LITIGATION WITH RESPECT TO THIS AGREEMENT, OR ARISING OUT OF OR CONCERNING THE EMPLOYEE’S EMPLOYMENT WITH THE EMPLOYER OR TERMINATION THEREOF.

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IN WITNESS WHEREOF, the parties have executed and delivered this Agreement as of the date above first written above.

**DIANE C. YOUNG**

/s/ Diane C. Young

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**GTx, Inc.**

By: /s/ Henry P. Doggrell

Title: VP, Chief Legal Officer

Date: July 13, 2015

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## PRINCIPAL EXECUTIVE OFFICER CERTIFICATION

I, Marc S. Hanover, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of GTx, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

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

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

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

Date: November 9, 2015

/s/ Marc S. Hanover

Marc S. Hanover

Chief Executive Officer

(Principal Executive Officer)

## PRINCIPAL FINANCIAL OFFICER CERTIFICATION

I, Jason T. Shackelford, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of GTx, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2015

/s/ Jason T. Shackelford

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Jason T. Shackelford  
Senior Director of Accounting and Corporate Controller,  
and Principal Financial and Accounting Officer  
(Principal Financial and Accounting Officer)

CERTIFICATION PURSUANT TO  
18 U. S. C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of GTx, Inc. (the "Company") on Form 10-Q for the three months ended September 30, 2015, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Marc S. Hanover, Chief Executive Officer of the Company certify, pursuant to Rule 13a-14(b) or Rule 15d-14(b) and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 9, 2015

/s/ Marc S. Hanover

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Marc S. Hanover

Chief Executive Officer

(Principal Executive Officer)

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934 (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.

CERTIFICATION PURSUANT TO  
18 U. S. C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of GTx, Inc. (the "Company") on Form 10-Q for the three months ended September 30, 2015, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Jason T. Shackelford, Principal Financial Officer of the Company certify, pursuant to Rule 13a-14(b) or Rule 15d-14(b) and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 9, 2015

/s/ Jason T. Shackelford

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Jason T. Shackelford

Senior Director of Accounting and Corporate Controller,  
and Principal Financial and Accounting Officer  
(Principal Financial and Accounting Officer)

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934 (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.

