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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2019

OR

o 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	**62-1715807**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
17 W Pontotoc Ave. Suite 100 Memphis, Tennessee	**38103**
(Address of principal executive offices)	(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 x No o

Indicate by check mark whether the registrant has submitted electronically pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes x No o

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

Large accelerated filer o	Accelerated filer x
Non-accelerated filer o	Smaller reporting company x
Emerging growth company o	

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

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	GTXI	The Nasdaq Stock Market, LLC

As of May 6, 2019, 24,051,844 shares of the registrant's Common Stock were outstanding.

GTx, INC.
FORM 10-Q FOR THE QUARTER ENDED MARCH 31, 2019
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PART I: FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	March 31, 2019 (unaudited)	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 21,012	$ 28,258
Short-term investments	175	200
Prepaid expenses and other current assets	1,347	2,750
Total current assets	22,534	31,208
Property and equipment, net	12	19
Intangible assets, net	90	94
Total assets	$ 22,636	$ 31,321
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 609	$ 3,279
Accrued expenses and other current liabilities	1,210	1,931
Total current liabilities	1,819	5,210
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.001 par value: 60,000,000 shares authorized at March 31, 2019 and December 31, 2018; 24,051,844 and 24,051,844 shares issued and outstanding at March 31, 2019 and December 31, 2018, respectively	24	24
Additional paid-in capital	626,650	626,142
Accumulated deficit	(605,857)	(600,055)
Total stockholders' equity	20,817	26,111
Total liabilities and stockholders' equity	$ 22,636	$ 31,321

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

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

	Three Months Ended March 31,	
	2019	2018
Expenses:		
Research and development expenses	$ 2,434	$ 11,000
General and administrative expenses	3,507	2,688
Total expenses	5,941	13,688
Loss from operations	(5,941)	(13,688)
Other income, net	139	131
Net loss	$ (5,802)	$ (13,557)
Net loss per share — basic and diluted	$ (0.24)	$ (0.62)
Weighted average shares outstanding — basic and diluted	24,051,844	21,967,805

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

GTx, Inc.
CONDENSED STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands, except share data)
(unaudited)

	Stockholders' Equity				
	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balances at January 1, 2019	24,051,844	$ 24	$ 626,142	$ (600,055)	$ 26,111
Directors' deferred compensation	—	—	28	—	28
Share-based compensation	—	—	480	—	480
Net loss	—	—	—	(5,802)	(5,802)
Balances at March 31, 2019	24,051,844	$ 24	$ 626,650	$ (605,857)	$ 20,817
Balances at January 1, 2018	21,541,909	$ 22	$ 599,876	$ (561,637)	$ 38,261
Issuance of common stock upon exercise of warrants	674,579	1	(1)	—	—
Vesting of restricted stock units, net of share withheld for tax payments	313,202	—	(643)	—	(643)
Directors' deferred compensation	—	—	42	—	42
Share-based compensation	—	—	646	—	646
Net loss	—	—	—	(13,557)	(13,557)
Balances at March 31, 2018	22,529,690	$ 23	$ 599,920	$ (575,194)	$ 24,749

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

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

	Three Months Ended March 31,	
	2019	**2018**
Cash flows from operating activities:		
Net loss	$ (5,802)	$ (13,557)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	11	11
Share-based compensation	480	646
Directors' deferred compensation	28	42
Changes in assets and liabilities:		
Prepaid expenses and other assets	1,403	111
Accounts payable	(2,670)	(865)
Accrued expenses and other liabilities	(721)	2,500
Net cash used in operating activities	(7,271)	(11,112)
Cash flows from investing activities:		
Purchase of short-term investments, held to maturity	(175)	(5,106)
Proceeds from maturities of short-term investments, held to maturity	200	16,003
Net cash provided by investing activities	25	10,897
Cash flows from financing activities:		
Tax payments related to shares withheld for vested restricted stock units	—	(643)
Net cash used in financing activities	—	(643)
Net decrease in cash and cash equivalents	(7,246)	(858)
Cash and cash equivalents, beginning of period	28,258	15,816
Cash and cash equivalents, end of period	$ 21,012	$ 14,958

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

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

1. Pending Merger with Oncternal Therapeutics, Inc.

Merger Agreement

On March 6, 2019, GTx, Inc. ("GTx" or the "Company") entered into an Agreement and Plan of Merger and Reorganization, as amended by Amendment No. 1 to Agreement and Plan of Merger and Reorganization dated April 30, 2019 (the "Merger Agreement"), with Oncternal Therapeutics, Inc., a Delaware corporation ("Oncternal"), and Grizzly Merger Sub, Inc., a Delaware corporation and wholly-owned subsidiary of GTx ("Merger Sub"). Upon the terms and subject to the satisfaction of the conditions described in the Merger Agreement, including approval of the transaction by the Company's stockholders and Oncternal's stockholders, Merger Sub will be merged with and into Oncternal (the "Merger"), with Oncternal surviving the Merger as a wholly-owned subsidiary of the Company.

Subject to the terms and conditions of the Merger Agreement, at the effective time of the Merger (the "Effective Time"): (i) each share of Oncternal common stock outstanding immediately prior to the Effective Time (excluding shares held by the Company, Merger Sub or Oncternal and dissenting shares) will be converted solely into the right to receive a number of shares of the Company's common stock equal to the exchange ratio described below, (ii) each outstanding Oncternal stock option will be assumed by the Company, and (iii) each outstanding Oncternal warrant will be assumed by the Company.

Under the exchange ratio formula in the Merger Agreement, the former Oncternal stockholders immediately before the Merger are expected to own approximately 77.5% of the outstanding capital stock of the Company, and the stockholders of the Company immediately before the Merger are expected to own approximately 22.5% of the outstanding capital stock of the Company, subject to certain assumptions. The exchange ratio formula excludes Oncternal's outstanding stock options and warrants and the Company's outstanding stock options and warrants.

Under certain circumstances further described in the Merger Agreement, the ownership percentages may be adjusted upward or downward based on cash levels of the respective companies at the closing of the Merger (the "Closing").

The Merger Agreement contains customary representations, warranties and covenants made by the Company and Oncternal, including covenants relating to obtaining the requisite approvals of the stockholders of the Company and Oncternal, indemnification of directors and officers, the Company's and Oncternal's conduct of their respective businesses between the date of signing of the Merger Agreement and the Closing. The Closing is subject to satisfaction or waiver of certain conditions included in the Merger Agreement.

Following the Closing, Oncternal's Chief Executive Officer, Chief Financial Officer, and Chief Operating Officer will serve in these positions for the Company. Additionally, following the Closing, the Company's board of directors will consist of nine directors, including two current GTx board members.

The Merger Agreement also includes termination provisions for both the Company and Oncternal. In connection with a termination of the Merger Agreement under specified circumstances, either party may be required to pay the other party a termination fee ranging between $500 to $2,000.

Contingent Value Rights Agreement

At the Effective Time, the Company will enter into a Contingent Value Rights Agreement (the "CVR Agreement"). Pursuant to the CVR Agreement, for each share of the Company's common stock held, the Company's stockholders of record as of immediately prior to the Effective Time will receive one contingent value right ("CVR") entitling such holders to receive in the aggregate 75% of any net proceeds received during the 15-year period after the Closing from the grant, sale or transfer of rights to the Company's selective androgen receptor degrader ("SARD") or selective androgen receptor modulator ("SARM") technology that occurs during the 10-year period after the Closing (or in the 11th year if based on a term sheet approved during the initial 10-year period) and, if applicable, to receive royalties on the sale of any SARD or SARM products by the combined company during the

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

15-year period after the Closing. The CVR Agreement will be effective prior to the Closing and will continue in effect until the payment of all amounts payable thereunder, unless terminated upon termination of the Merger Agreement.

2. Business and Basis of Presentation

GTx, 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 medicines to treat serious and/or significant unmet medical conditions.

In 2015, the Company entered into an exclusive license agreement with the University of Tennessee Research Foundation ("UTRF") to develop UTRF's proprietary SARD technology which the Company believes may have the potential to provide compounds that can degrade or antagonize multiple forms of androgen receptor to treat those patients who do not respond or are resistant to current androgen targeted therapies by inhibiting tumor growth in patients with progressive castration-resistant prostate cancer ("CRPC"). The Company has been conducting preclinical studies to determine if it can identify an appropriate SARD compound to move forward into additional preclinical studies required for the potential submission of an investigational new drug application ("IND") to enable the initiation of a first-in-human clinical trial, if any. However, the Company recently received and evaluated new preclinical data from an independent laboratory of an academic researcher engaged by the Company, which, among other things, showed that at higher dose concentrations, the SARD compounds tested by the independent laboratory demonstrated partial androgen receptor agonist activity. The academic researcher pointed out that if these results translate to the clinical setting where there is little or no dose separation between antagonist activity and agonist activity, the future of the SARD program as an effective treatment of men with CRPC would likely not be viable. This information (the "Recent SARD Information") was in conflict with other independent laboratory preclinical data previously received by GTx senior management and with internal preclinical data generated by the Company, that included: (1) conflicting *in vitro* data showing either partial agonist activity or no partial agonist activity, (2) *in vivo* data showing no evidence of agonist activity, and (3) data from another independent laboratory showing the dose-dependent suppression of enzalutamide-resistant prostate cancer tumors in a rat xenograft model. Considering this conflicting information, it was concluded that additional preclinical studies were required to better understand SARDs and their mechanism of action, and to reconcile the conflicting *in vitro* and *in vivo* findings. Accordingly, additional preclinical research would be required in order to determine whether an appropriate SARD compound can potentially be advanced into any IND-enabling preclinical studies.

The Company had been developing SARMs, including enobosarm (GTx-024). Most recently, enobosarm was evaluated in post-menopausal women with stress urinary incontinence ("SUI") compared to placebo. During the third quarter of 2018, the Company announced that the Phase 2 double-blind, placebo-controlled clinical trial of orally-administered enobosarm (3 mg or 1 mg) in post-menopausal women with SUI (the "ASTRID trial") did not achieve statistical significance on the primary endpoint for the trial. The Company has completed the ASTRID trial, including its review of the full data sets from the clinical trial, and has determined that there is not a sufficient path forward to warrant additional clinical development of enobosarm to treat SUI. The Company has therefore discontinued further development of enobosarm to treat SUI, including discontinuing the related durability and open-label safety extension studies the Company initiated before it received topline data from the ASTRID trial. The Company has also discontinued any further development of its SARM technology generally.

Following the announcement of the ASTRID trial results, the Company's board of directors commenced a process of evaluating strategic alternatives to maximize stockholder value. To assist with this process, the Company's board of directors engaged a financial advisory firm to help explore the Company's available strategic alternatives, including possible mergers and business combinations, a sale of part or all of the Company's assets, and collaboration and licensing arrangements. On March 6, 2019, the Company and Oncternal announced the signing of the Agreement and Plan of Merger and Reorganization, dated March 6, 2019, by and among the Company, Merger Sub and Oncternal (the "Original Merger Agreement"). See Note 1, Pending Merger with Oncternal Therapeutics, Inc., for further discussion regarding the Merger. On April 30, 2019, the Company entered into an Amendment No. 1

GTx, Inc.
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to the Original Merger Agreement (the "Merger Agreement Amendment") with Oncternal and Merger Sub, as described in more detail in Note 2, Business and Basis of Presentation — Subsequent Events.

At March 31, 2019, the Company had cash, cash equivalents and short-term investments of $21,187 compared to $28,458 at December 31, 2018. To conserve its cash resources, the Company has substantially reduced its workforce since November 2018 and has ceased its SARM development activities and all other operations except for day-to-day business operations, completing ongoing SARD preclinical studies and those activities necessary to complete the Merger.

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 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 filed with the Securities and Exchange Commission on March 18, 2019. Operating results for the three months ended March 31, 2019 are not necessarily indicative of the results that may be expected for the entire fiscal year ending December 31, 2019.

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.

Fair Value of Financial Instruments

The carrying amounts of the Company's financial instruments (which include cash, cash equivalents, short-term investments, and accounts payable) approximate their fair values. 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:

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

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.

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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 March 31, 2019 and December 31, 2018, 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 March 31, 2019 and December 31, 2018, net of the valuation allowance, the net deferred tax assets were reduced to zero. Income taxes are described more fully in Note 8 to the Company's financial statements included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 18, 2019.

Other Income, net

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

Accounting Pronouncements Recently Adopted

In February 2016, the Financial Accounting Standards Board issued Accounting Standard Update ("ASU") 2016-02, *Leases (Topic 842) ("ASU 2016-02").* This ASU requires that lessees recognize assets and liabilities on the balance sheet for the present value of the rights and obligations created by all leases with terms of more than 12 months. On January 1, 2019, the Company adopted the provisions of ASU 2016-02 under the transition method under which comparative financial information is not restated and continues to apply the provisions of the previous lease accounting standard in its financial disclosures for the comparative periods. The Company also elected the package of practical expedients permitted under the transition guidance, which among other things, allowed it to carry forward the historical lease classification. The Company leases office space under a lease that commenced on May 1, 2015 with a three year term ending on April 30, 2018, with an option to extend the lease for an additional three years, which was accounted for as an operating lease. In March 2018, the Company amended the lease to extend the term of the lease for an additional 12-month term expiring on April 30, 2019. For this operating lease, the Company recorded a right-of-use asset and corresponding lease liability of $41, which were included in other current assets and other current liabilities, respectively, in the condensed balance sheet for the three months ended

GTx, Inc.
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March 31, 2019. The adoption of ASU 2016-02 did not affect the Company's condensed statement of operations or condensed statement of cash flows. The Company recorded lease expense of $121 in general and administrative expenses and paid cash in the amount of $121 during the three months ended March 31, 2019.

Subsequent Events

The Company has evaluated all events or transactions that occurred after March 31, 2019 up through the date the condensed financial statements were issued. Other than as set forth below, there were no material recognizable or nonrecognizable subsequent events during the period evaluated.

Pending Merger with Oncternal

In connection with the Company's receipt of the Recent SARD Information and Oncternal's evaluation of the Recent SARD Information, on April 30, 2019, the Company entered into Merger Agreement Amendment with Oncternal and Merger Sub. The Merger Agreement Amendment amended certain of the terms of the Original Merger Agreement by, among other things: (i) amending the exchange ratio formula such that the former Oncternal stockholders immediately before the Merger are expected to own approximately 77.5% of the outstanding capital stock of GTx rather than 75% as set forth in the Original Merger Agreement; (ii) amending the exchange ratio formula such that the GTx stockholders immediately before the Merger are expected to own approximately 22.5% of the outstanding capital stock of GTx rather than 25% as set forth in the Original Merger Agreement; (iii) amending the calculation of GTx's cash balance at the Closing such that the cash balance will not be reduced by payments of GTx's transaction expenses or any other costs or payments by GTx triggered by the transactions contemplated by the Merger Agreement or pursuant to any of GTx's benefit plans; and (iv) amending GTx's and Oncternal's target cash amount used for purposes of determining whether there will be an adjustment to the ownership of GTx's stockholders in the calculation of the exchange ratio formula. Except as set forth above, the material terms of the Merger Agreement are substantially the same as the terms of the Original Merger Agreement.

On April 30, 2019, the form of the Contingent Value Rights Agreement to be entered into at the Effective Time was also amended in connection with the Merger Agreement Amendment (as such form has been amended, the "Amended Form CVR Agreement"). The original agreed upon form of the CVR Agreement (the "Original Form CVR Agreement") was amended to provide, among other things: (i) that for each share of GTx common stock held, GTx's stockholders of record as of immediately prior to the Effective Time will receive one contingent value right entitling such holders to receive in the aggregate 75% (rather than 50% as provided for in the Original Form CVR Agreement) of any net proceeds received during the 15-year period after the Closing from the grant, sale or transfer of rights to GTx's SARD or SARM technology that occurs during the 10-year period after the Closing (or in the 11th year if based on a term sheet approved during the initial 10-year period); and (ii) that instead of using commercially reasonable efforts to develop SARD products, as provided in the Original Form of CVR Agreement, Oncternal (as successor in interest to GTx) will use commercially reasonable efforts, in its sole discretion, either to develop SARD products or to divest SARD technology, subject to certain limitations. Except as set forth above, the material terms of the Amended Form CVR Agreement are substantially the same as the terms of the Original Form CVR Agreement.

Litigation Related to the Merger

Between April 10, 2019 and May 7, 2019, six purported stockholder class action lawsuits were filed, naming as defendants the Company and the Company's board of directors. Collectively, these lawsuits allege, among other things, violations of Sections 14(a) and 20(a) of the Exchange Act, as well as Rule 14a-9 promulgated thereunder, in connection with the filing of the registration statement on Form S-4 that the Company filed with the SEC in connection with the Merger. As relief, these lawsuits each separately seek an order, among other things, enjoining the defendants from closing the proposed transaction or taking any steps to consummate the Merger and/or awarding rescissory damages. The Company cannot predict the outcome of or estimate the possible loss or range of loss from any of these matters.

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

3. Share-Based Compensation

Share-based payments consist of stock option grants 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 filed with the Securities and Exchange Commission on March 18, 2019.

The following table summarizes share-based compensation expense included within the condensed statements of operations for the three months ended March 31, 2019 and 2018:

	Three Months Ended March 31,	
	2019	2018
Research and development expenses	$ 105	$ 281
General and administrative expenses	403	407
Total share-based compensation	$ 508	$ 688

Share-based compensation expense recorded as general and administrative expense for the three months ended March 31, 2019 and 2018 included share-based compensation expense related to deferred compensation arrangements for the Company's non-employee directors of $28 and $42, respectively.

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 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, 2018	2,335,447	$ 11.67
Options granted	—	—
Options forfeited or expired	(16,800)	25.30
Options outstanding at March 31, 2019	2,318,647	11.57

4. 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.

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Weighted average potential shares of common stock of 10,940,932 and 11,862,772 for the three months ended March 31, 2019 and 2018, 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 the periods.

5. Stockholders' Equity

On February 9, 2018, the Company entered into an At-the-Market Equity Offering℠ Sales Agreement (the "ATM Sales Agreement") with Stifel, Nicolaus & Company, Incorporated, as sales agent ("Stifel"), pursuant to which the Company may offer and sell, from time to time, through Stifel, shares of the Company's common stock, having an aggregate offering price of up to $50,000. In May 2018, the Company sold 1,501,501 shares of its common stock under the ATM Sales Agreement for net proceeds of $24,474. As of March 31, 2019, the Company had approximately $25,000 of common stock remaining available to be sold under the ATM Sales Agreement.

On September 29, 2017, the Company completed a private placement of units consisting of an aggregate of 5,483,320 shares of common stock and warrants to purchase an aggregate of 3,289,988 shares of its common stock for net proceeds of $45,648, after deducting placement agent fees and other offering expenses. The purchasers in the registered direct offering consisted solely of accredited investors that included certain institutional and existing stockholders, including a member of the Company's board of directors. The warrants, which have five year terms expiring on September 29, 2022, are immediately exercisable and have a per share exercise price of $9.02. The Company assessed whether the warrants require accounting as derivatives. The Company determined that the warrants were indexed to the Company's own stock. As such, the Company has concluded the warrants meet the scope exception for determining whether the instruments require accounting as derivatives and are classified in stockholders' equity. The fair value of the warrants was estimated at $21,069 using the Black-Scholes Model with the following assumptions: expected volatility of 97%, risk free interest rate of 1.92%, expected life of five years and no dividends. The net proceeds from the private placement were allocated to the common stock and warrants based upon their relative fair values.

On November 14, 2014, the Company completed a private placement of units consisting of an aggregate of 6,431,111 shares of common stock and warrants to purchase an aggregate of 6,430,948 shares of its common stock for net proceeds of $42,814, after deducting offering expenses. The net proceeds from the private placement were allocated to the common stock and warrants based 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. During the three months ended March 31, 2018, certain holders of warrants issued in November 2014 exercised 1,111,082 warrants in a cashless exercise for which the Company issued an aggregate of 674,579 shares of common stock upon exercise. The remaining unissued warrants, which had a four year term, expired unexercised on May 6, 2019.

6. University of Tennessee Research Foundation License Agreements

The Company and 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

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(in thousands, except share and per share data)
(unaudited)

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 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.

7. Workforce Reduction

In the first quarter of 2019, due to the entry into the Original Merger Agreement with Oncternal, the Company's board of directors committed to reducing its workforce by seven employees. All employees affected by the workforce reduction were eligible to receive, among other things, specified severance payments based on the applicable employee's level and years of service with the Company and the continuation of group health insurance coverage. In addition, the affected employees were eligible for full vesting acceleration of their outstanding stock options as well as an extension of the post-termination exercise period for their outstanding stock options.

As a result of the workforce reduction and prior termination of three employees earlier in the first quarter of 2019, the Company incurred severance-related cash expenses of $1,017, all of which was included in research and development expenses for the three months ended March 31, 2019. Additional cash severance of up to $500 in total for these employees is contingent upon the closing of the Merger. The Company did not record a non-cash charge related to the modification of outstanding stock options in connection with the workforce reduction.

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:

- our ability to satisfy the required conditions and otherwise complete our planned merger, or the Merger, with Oncternal Therapeutics, Inc., or Oncternal, pursuant to the Agreement and Plan of Merger and Reorganization, dated March 6, 2019, as amended by Amendment No. 1 to Agreement and Plan of Merger and Reorganization dated April 30, 2019, or the Merger Agreement, by and among GTx, Grizzly Merger Sub, Inc., a wholly-owned subsidiary of GTx, and Oncternal, on a timely basis or at all;
- the expected benefits and potential value created by the Merger for our stockholders, including the ownership percentage of our stockholders in the combined organization immediately following the consummation of the Merger and the potential value of the contingent value rights to be received by our stockholders in connection with the Merger if it is completed;
- the implementation of our business strategies, including our ability to preserve or realize any significant value from our selective androgen receptor degrader, or SARD, technology and our selective androgen receptor modulators, or SARMs;
- our expectations regarding any near-term development of our SARD technology, including our ability to reconcile the conflicting preclinical SARD data we have received to date and to determine whether an appropriate SARD compound can potentially be advanced into any preclinical studies required for the potential submission of an investigational new drug application, or IND, in a timely manner, if at all;
- the therapeutic and commercial potential of our SARD technology;
- our ability to establish and maintain potential new collaborative, partnering or other strategic arrangements for the development of our SARD technology;
- our ability to establish and maintain potential new collaborative, partnering or other strategic arrangements for our SARM assets, including a sale or other divestiture of our SARM assets;
- our ability to raise additional capital, whether through potential new collaborative, partnering or other strategic arrangements or otherwise;
- our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others;
- our projected operating and financial performance; and
- our estimates regarding the sufficiency of our cash resources, expenses, including those related to the consummation of the Merger, capital requirements and needs for additional financing, and our ability to obtain additional financing and to continue as a going concern if the Merger is not completed.

In some cases, you can identify forward-looking statements by terms such as "anticipates," "believes," "could," "estimates," "expects," "envisions," "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 and Highlights

We are a biopharmaceutical company dedicated to the discovery, development and commercialization of medicines to treat serious and/or significant unmet medical conditions. Under an exclusive worldwide license agreement with the University of Tennessee Research Foundation, or UTRF, we are developing UTRF's proprietary selective androgen receptor degrader, or SARD, technology, which we believe has the potential to provide compounds that can degrade or antagonize multiple forms of androgen receptor, or AR, thereby potentially inhibiting tumor growth in patients with progressive castration-resistant prostate cancer, or CRPC, including those patients who do not respond to or are resistant to current androgen targeted therapies. We have been conducting preclinical studies to determine if we can identify an appropriate SARD compound to move forward into additional preclinical studies required for the potential submission of an investigational new drug application, or IND, to enable the initiation of a first-in-human clinical trial, if any. However, we recently received and evaluated new preclinical data from an independent laboratory of an academic researcher engaged by us, which, among other things, showed that at higher dose concentrations, the SARD compounds tested by the independent laboratory demonstrated partial androgen receptor agonist activity. The academic researcher pointed out that if these results translate to the clinical setting where there is little or no dose separation between antagonist activity and agonist activity, the future of the SARD program as an effective treatment of men with CRPC would likely not be viable. This information, or the Recent SARD Information, was in conflict with other independent laboratory preclinical data previously received by our senior management and with internal preclinical data generated by us, that included: (1) conflicting *in vitro* data showing either partial agonist activity or no partial agonist activity, (2) *in vivo* data showing no evidence of agonist activity, and (3) data from another independent laboratory showing the dose-dependent suppression of enzalutamide-resistant prostate cancer tumors in a rat xenograft model. Considering this conflicting information, it was concluded that additional preclinical studies were required to better understand SARDs and their mechanism of action, and to reconcile the conflicting *in vitro* and *in vivo* findings. Accordingly, additional preclinical research would be required in order to determine whether an appropriate SARD compound can potentially be advanced into any IND-enabling preclinical studies.

We had been developing selective androgen receptor modulators, or SARMs. Our SARM product candidate, enobosarm (GTx-024), was most recently evaluated in post-menopausal women with stress urinary incontinence, or SUI. During the third quarter of 2018, we announced that our randomized, placebo-controlled Phase 2 clinical trial, or the ASTRID trial, evaluating the change in the mean number of daily SUI episodes following 12 weeks of enobosarm treatment failed to achieve statistical significance on the primary endpoint of the proportion of patients with a greater than 50% reduction in incontinence episodes per day compared to placebo. We have completed the ASTRID trial, including our review of the full data sets from the clinical trial, and have determined that there is not a sufficient path forward to warrant additional clinical development of enobosarm to treat SUI. We have therefore discontinued further development of enobosarm to treat SUI, including discontinuing the related durability and open-label safety extension studies we initiated before we received topline data from the ASTRID trial. We have also discontinued any further development of our SARM technology generally.

Following the announcement of the ASTRID trial results, our board of directors commenced a process of evaluating strategic alternatives to maximize stockholder value. To assist with this process, our board of directors engaged a financial advisory firm to help explore our available strategic alternatives, including possible mergers and business combinations, a sale of part or all of our assets, and collaboration and licensing arrangements. On March 6, 2019, we and Oncternal announced the signing of the Agreement and Plan of Merger and Reorganization, dated March 6, 2019, by and among the Company, Merger Sub and Oncternal, or the Original Merger Agreement. Upon

the terms and subject to the satisfaction of the conditions described in the Merger Agreement, including approval of the transaction by our stockholders and Oncternal's stockholders, a wholly-owned subsidiary of GTx will be merged with and into Oncternal, or the Merger, with Oncternal surviving the Merger as a wholly-owned subsidiary of GTx. See "*Note 1. Pending Merger with Oncternal Therapeutics, Inc.*" in the accompanying Notes to the Condensed Financial Statements for further discussion regarding the Merger. In connection with our receipt of the Recent SARD Information and Oncternal's evaluation of the Recent SARD Information, on April 30, 2019, we entered into an Amendment No. 1 to the Original Merger Agreement with Oncternal and Merger Sub, as described in more detail in "*Note 2. Business and Basis of Presentation — Subsequent Events*" in the accompanying Notes to the Condensed Financial Statements.

Although we have entered into the Merger Agreement and intend to consummate the Merger, there is no assurance that we will be able to successfully consummate the Merger on a timely basis, or at all. If, for any reason, the Merger is not completed, we will reconsider our strategic alternatives and could pursue one or more of the following courses of action:

- ***Continue development of our SARD program.*** As set forth above, we have been conducting preclinical studies in order to determine if we can identify an appropriate SARD compound to move forward into additional preclinical studies required for the potential submission of an IND to enable the initiation of a first-in-human clinical trial, if any. Accordingly, if, for any reason, the Merger is not consummated, we may determine to move forward with additional preclinical research and studies of our SARD compounds. However, our existing capital resources may not be adequate to enable us to conduct and complete any IND-enabling studies of a SARD compound, particularly in light of the additional preclinical research that would be required in order to reconcile the conflicting preclinical SARD data we have received to date and to determine whether an appropriate SARD compound can potentially be advanced into any IND-enabling preclinical studies in a timely manner, if at all. Even if we are able to successfully complete such additional preclinical research and to conduct and complete any IND-enabling studies of a SARD compound, which we may not be able to do with our existing capital resources, we will in any event require significant additional financial resources in order to initiate and complete initial human clinical trials of a SARD compound and to otherwise further the development of our SARD program. As a result, we may also resume our efforts to seek additional funds through potential collaborative, partnering or other strategic arrangements to provide us with the necessary resources for the development of our SARD technology.

- ***Pursue potential collaborative, partnering or other strategic arrangements for our SARM assets, including a sale or other divestiture of our SARM assets***. We have discontinued further development of our SARM technology, including enobosarm, and do not currently have any plans to resume development of our SARM technology. We continue our efforts to seek potential collaborative, partnering or other strategic arrangements for our SARM assets, including a sale or other divestiture of our SARM assets.

- ***Pursue another strategic transaction like the Merger.*** Our board of directors may elect to pursue an alternative strategy, one of which may be a strategic transaction similar to the Merger.

- ***Dissolve and liquidate our assets.*** If, for any reason, the Merger is not consummated and we are unable to identify and complete an alternative strategic transaction like the Merger or potential collaborative, partnering or other strategic arrangements for our SARM assets, or to continue to operate our business due to our inability to identify an appropriate SARD compound to move forward into potential IND-enabling studies or to raise additional funding for the development of our SARD program or otherwise, we may be required to dissolve and liquidate our assets. In such case, we would be required to pay all of our debts and contractual obligations, and to set aside certain reserves for potential future claims, and there can be no assurances as to the amount or timing of available cash left to distribute to our stockholders after paying our debts and other obligations and setting aside funds for reserves.

Financial Highlights

Our net loss for the three months ended March 31, 2019 was $5.8 million. We expect to incur significant operating losses for the foreseeable future depending on the extent of our preclinical and any clinical development activities and, if any such development activities are successful, potentially seeking regulatory approval of any potential future 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®, the rights to which we sold to a third party in the third quarter of 2012. We do not expect to receive regulatory

approval for the commercial sale of any product candidates for the foreseeable future, if at all.

At March 31, 2019, we had cash, cash equivalents and short-term investments of $21.2 million compared to $28.5 million at December 31, 2018. In May 2018, we sold 1.5 million shares of common stock under our At-the-Market Equity Offering℠ Sales Agreement, or the ATM Sales Agreement, with Stifel, Nicolaus & Company, Incorporated, or Stifel, and raised net proceeds of $24.5 million.

To conserve our cash resources, we have substantially reduced our workforce since November 2018 and have ceased our SARM development activities and all other operations except for day-to-day business operations, completing ongoing SARD preclinical studies and those activities necessary to complete the Merger. In the first quarter of 2019, due to the entry into the Merger Agreement with Oncternal, our board of directors committed to reducing our workforce down to a total of eleven full-time employees, who will remain with us until the closing of the transaction to assist with our day-to-day business operations, including continuing our ongoing SARD preclinical studies, and those activities necessary to complete the Merger. All employees affected by the workforce reduction will be eligible to receive, among other things, specified severance payments based on the applicable employee's level and years of service with us and the continuation of group health insurance coverage. In addition, the affected employees will also be eligible for full vesting acceleration of their outstanding stock options as well as an extension of the post-termination exercise period for their outstanding stock options. As a result of the workforce reduction and prior termination of three employees earlier in the first quarter of 2019, we incurred total severance-related charges for these employees of approximately $1.0 million in the first quarter of 2019 and could incur up to an additional $500,000 contingent upon the closing of the Merger. We did not record a non-cash charge related to the modification of outstanding stock options in connection with the workforce reduction.

If the Merger is not completed, based on our current business plan and spending assumptions as a standalone company, 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 for at least the next 12 months. We have based our cash sufficiency estimates on our current business plan and our assumptions that may prove to be wrong. We could utilize our available capital resources sooner than we currently expect, and we could need additional funding sooner than currently anticipated.

Our existing capital resources may not be adequate to enable us to conduct and complete any IND-enabling studies of a SARD compound, particularly in light of the additional preclinical research that will be required in order to reconcile the conflicting preclinical SARD data we have received to date and to determine whether an appropriate SARD compound can potentially be advanced into any IND-enabling preclinical studies in a timely manner, if at all. Even if we are able to successfully complete such additional preclinical research and to conduct and complete any IND-enabling studies of a SARD compound, which we may not be able to do with our existing capital resources, we will in any event require significant additional financial resources in order to initiate and complete initial human clinical trials of a SARD compound and to otherwise further the development of its SARD program. If we are unable to raise sufficient additional funds for the development of our SARD program, whether through potential collaborative, partnering or other strategic arrangements or otherwise, or if we otherwise determine to discontinue the development of our SARD program, whether as a result of our recent receipt of new preclinical data from an independent laboratory that showed that at higher dose concentrations the SARD compounds tested demonstrated partial androgen receptor agonist activity or otherwise, we will likely determine to cease operations.

While we have been able to fund our operations to date, we have no ongoing collaborations for the development and commercialization of any product candidates and no source of revenue, nor do we expect to generate product revenue for the foreseeable future. We do not have any commitments for future external funding. In addition, although we have entered into an At-the-Market Equity Offering℠ Sales Agreement with Stifel, Nicolaus & Company, Incorporated, or the ATM Sales Agreement, under which approximately $25.0 million of shares of our common stock remained available for sale at March 31, 2019, it is unlikely we could raise sufficient funds under the ATM Sales Agreement to permit us to initiate and complete any initial human clinical trials of a SARD compound, and given our currently-depressed stock price, the ATM Sales Agreement is not otherwise expected to be a practical source of liquidity for us at this time. Further, given our currently-depressed stock price, we are significantly limited in our ability to sell shares of common stock under the ATM Sales Agreement since the issuance and sale of our common stock under the ATM Sales Agreement, if it occurs, would be effected under a registration statement on Form S-3 that we filed with the Securities and Exchange Commission, and in accordance with the rules governing those registration statements, we generally can only sell shares of our common stock under that registration statement in an amount not to exceed one-third of our public float, which limitation for all practical purposes precludes our ability to obtain any meaningful funding through the ATM Sales Agreement at this time.

Until we can generate a sufficient amount of product revenue, which we may never do, we will need to finance future cash needs through potential collaborative, partnering or other strategic arrangements, as well as through public or private equity offerings or debt financings or a combination of the foregoing. If we are unable to raise additional funds, we will need to continue to reduce our expenditures in order to preserve our cash. Further cost-cutting measures that we may take may not be sufficient to enable us to meet our cash requirements, and they may negatively affect our business and our ability to derive any value from our SARD program. In any event, in order to further the development of our SARD program, if at all, we will need to raise substantial additional capital. Our failure to do so would likely result in our determining to cease operations.

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 2019 to be significantly less than fiscal year 2018 primarily due to the completion of the ASTRID trial and termination of the related extension studies and due to the reductions in headcount during the fourth quarter of 2018 and the first quarter of 2019.

There is a substantial risk that any drug development program may not produce revenue. Moreover, because of the uncertainties inherent in drug 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.

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 condensed 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, 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 filed with the Securities and Exchange Commission on March 18, 2019, we believe that the following accounting policies are most critical to aid you in fully understanding and evaluating our reported financial results.

Research and Development Expenses

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 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 is based upon 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 fair value of each stock option is amortized into compensation expense on a straight-line basis between the grant date for the award and each vesting date.

The following table summarizes share-based compensation expense included within the condensed statements of operations for the three months ended March 31, 2019 and 2018:

	Three Months Ended March 31,	
	2019	2018
	(in thousands)	
Research and development expenses	$ 105	$ 281
General and administrative expenses	403	407
Total share-based compensation	$ 508	$ 688

Share-based compensation expense recorded in the condensed statement of operations as general and administrative expense for the three months ended March 31, 2019 and 2018 included share-based compensation expense related to deferred compensation arrangements for our non-employee directors of $28,000 and $42,000, respectively. At March 31, 2019, the total compensation cost related to non-vested stock options not yet recognized was approximately $5.3 million with a weighted average expense recognition period of 2.76 years.

Results of Operations

Three Months Ended March 31, 2019 and 2018

Research and Development Expenses

The following table identifies the research and development expenses for our SARD technology and our discontinued SARM program, as well as research and development expenses pertaining to our other research and development efforts, for both 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 March 31, 2019	2018
		(in thousands)	
Enobosarm			
Treatment of postmenopausal women with SUI (1 mg and 3 mg)	**SARM**	$ 712	$ 9,703
SARDs			
Treatment of castration resistant prostate cancer	**SARD**	883	210
Other research and development		839	1,087
Total research and development expenses		$ 2,434	$ 11,000

Research and development expenses decreased from $11.0 million for the three months ended March 31, 2018 to $2.4 million for the three months ended March 31, 2019.

Research and development expenses for enobosarm for the treatment of postmenopausal women with SUI substantially decreased from the three months ended March 31, 2018 since, during the third quarter of 2018, we announced that the ASTRID trial failed to achieve statistical significance on the primary endpoint of the proportion of patients with a greater than 50% reduction in incontinence episodes per day compared to placebo and we discontinued the related durability and open-label safety extension studies.

Research and development expenses for the SARD program for the three months ended March 31, 2019 increased from the three months ended March 31, 2018 due to more preclinical research expenses and personnel costs related to the program being incurred during 2019 period than in the comparable period. If the Merger is not completed and if we determine to continue our efforts to develop our SARD technology, our research and development expenses for our SARD technology would increase in 2019.

“Other research and development” expenses for three months ended March 31, 2019 decreased from the prior year period primarily due to the decrease in expenses relating to our two phase 2 clinical trials evaluating enobosarm in women with estrogen receptor positive and androgen receptor positive breast cancer and androgen receptor positive triple negative breast cancer. The wind down activities for each of these clinical trials were completed during the first quarter of 2019.

General and Administrative Expenses

General and administrative expenses of $3.5 million for the three months ended March 31, 2019 increased from $2.7 million for the three months ended March 31, 2018. General and administrative expenses increased primarily due to legal and other costs related to the Merger with Oncternal.

Liquidity and Capital Resources

At March 31, 2019, we had cash, cash equivalents and short-term investments of $21.2 million compared to $28.5 million at December 31, 2018. Net cash used in operating activities was $7.3 million and $11.1 million for the three months ended March 31, 2019 and 2018, respectively, and resulted primarily from funding our operations.

Net cash provided by investing activities was $25,000 for the three months ended March 31, 2019 and resulted from the maturities of short-term investments of $200,000 offset by the purchase of short-term investments of $175,000. Net cash provided by investing activities was $10.9 million for the three months ended March 31, 2018 and resulted primarily from the maturities of short-term investments of $16.0 million offset by the purchase of short-term investments of $5.1 million.

Net cash used in financing activities for the three months ended March 31, 2018 was $643,000 for tax payments related to shares withheld for vested restricted stock units.

In February 2018, we entered into the ATM Sales Agreement pursuant to which we may offer and sell, from time to time, through Stifel, shares of our common stock having an aggregate offering price of up to $50 million. We are not obligated to sell any shares under the ATM Sales Agreement. Subject to the terms and conditions of the sales agreement, Stifel will use commercially reasonable efforts, consistent with its normal trading and sales practices, applicable state and federal law, rules and regulations and the rules of the Nasdaq Capital Market, to sell shares from time to time based upon our instructions, including any price, time or size limits specified by us. Under the ATM Sales Agreement, Stifel may sell shares by any method deemed to be an "at-the-market" offering as defined in Rule 415 under the Securities Act of 1933, as amended, or any other method permitted by law, including in privately negotiated transactions. We will pay Stifel a commission of up to 3.0% of the aggregate gross proceeds from each sale of shares. In May 2018, we sold 1.5 million shares of our common stock under the ATM Sales Agreement for net proceeds of $24.5 million. As of March 31, 2019, we had approximately $25.0 million of common stock remaining available to be sold under the ATM Sales Agreement. However, it is unlikely we could raise sufficient funds under the ATM Sales Agreement to permit us to initiate and complete any initial human clinical trials of a SARD compound, if at all, and given our currently-depressed stock price, the ATM Sales Agreement is not otherwise expected to be a practical source of liquidity for us at this time. Further, given our currently-depressed stock price, we are significantly limited in our ability to sell shares of common stock under the ATM Sales Agreement since the issuance and sale of our common stock under the ATM Sales Agreement, if it occurs, would be effected under a registration statement on Form S-3 that we filed with the Securities and Exchange Commission, and in accordance with the rules governing those registration statements, we generally can only sell shares of our common stock under that registration statement in an amount not to exceed one-third of our public float, which limitation for all practical purposes precludes its ability to obtain any meaningful funding through the ATM Sales Agreement at this time.

To conserve our cash resources, we have substantially reduced our workforce since November 2018 and have ceased our SARM development activities and all other operations except for day-to-day business operations, completing ongoing SARD preclinical studies and those activities necessary to complete the Merger. If the Merger is not completed, based on our current business plan and spending assumptions as a standalone company, 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 for at least the next 12 months. We have based our cash sufficiency estimates on our current business plan and our assumptions that may prove to be wrong. We could utilize our available capital resources sooner than we currently expect, and we could need additional funding sooner than currently anticipated.

Our existing capital resources may not be adequate to enable us to conduct and complete any IND-enabling studies of a SARD compound, particularly in light of the additional preclinical research that would be required in order to reconcile the conflicting preclinical SARD data we have received to date and to determine whether an appropriate SARD compound can potentially be advanced into any IND-enabling preclinical studies in a timely manner, if at all. Even if we are able to successfully complete such additional preclinical research and to conduct and complete any IND-enabling studies of a SARD compound, which we may not be able to do with our existing capital resources, we will in any event require significant additional financial resources in order to initiate and complete initial human clinical trials of a SARD compound and to otherwise further the development of our SARD program. If we are unable to raise sufficient additional funds for the development of our SARD program, whether through potential collaborative, partnering or other strategic arrangements or otherwise, or if we otherwise determine to discontinue the development of our SARD program, whether as a result of our recent receipt of new

preclinical data from an independent laboratory that showed that at higher dose concentrations the SARD compounds tested demonstrated partial androgen receptor agonist activity or otherwise, we will likely determine to cease operations.

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 potential future product candidates, if any. Our future funding requirements will depend on many factors, including:

- our ability to successfully complete the Merger;
- the scope, rate of progress and cost of our preclinical and potential future clinical development programs;
- the terms and timing of any potential collaborative, partnering 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;
- potential future preclinical studies and clinical trial results;
- the cost and timing of regulatory filings and/or approvals to commercialize any potential future 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 have no ongoing collaborations for the development and commercialization of any product candidates and no source of revenue, nor do we expect to generate product revenue for the foreseeable future. We 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 will need to finance future cash needs through potential collaborative, partnering or other strategic arrangements, as well as through public or private equity offerings or debt financings or a combination of the foregoing. If we are unable to raise additional funds, we will need to continue to reduce our expenditures in order to preserve our cash. Further cost-cutting measures that we may take may not be sufficient to enable us to meet our cash requirements, and they may negatively affect our business and our ability to derive any value from our SARD program. In any event, in order to further the development of our SARD program, if at all, we will need to raise substantial additional capital. Our failure to do so would likely result in our determining to cease operations.

To the extent that we raise additional funds through potential collaborations, partnering or other strategic arrangements, it may be necessary to relinquish rights to some of our technologies or product candidates and intellectual property rights thereof, or grant licenses on terms that are not favorable to us, any of which could result in our stockholders having little or no continuing interest in our SARD program and/or SARM assets 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 substantially dilutive private placements of our common stock and warrants in March 2014, November 2014 and September 2017, in addition to a registered direct offering of our common stock that we completed in October 2016 and the sale of our common stock pursuant to the ATM Sales Agreement. Our stockholders will experience additional, perhaps substantial, dilution should we again raise additional funds by issuing equity securities. Any additional debt or equity financing 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 the ASTRID trial to meet its primary endpoint and the resulting significant uncertainty regarding our prospects to continue as a going concern. If we are

unable to complete the Merger, 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, uncertainties with respect to the prospects for our early-stage SARD program as an effective treatment for men with CRPC, particularly in light of our recent receipt of new preclinical data from an independent laboratory that showed that at higher dose concentrations the SARD compounds tested demonstrated partial androgen receptor agonist activity, the sufficiency of our capital resources, potential future management turnover, and volatility and instability in the global financial markets. As a result of these and other factors, there is no guarantee that sufficient additional funding will be available to us on acceptable terms, or at all.

Contractual Obligations

At March 31, 2019, we had contractual obligations as follows:

	Payment Due by Period (in thousands)				
Contractual Obligations(1)	**Total**	**Less than 1 year**	**1-3 years**	**4-5 years**	**More than 5 years**
Operating lease obligations(2)	$ 41	$ 41	$ —	$ —	$ —

(1) This table does not include any royalty obligations under our SARM and SARD license agreements with UTRF as the timing and likelihood of such payments are not known. In addition to the minimum payments due under our SARM and SARD license agreements, we may be required to pay royalties on any net sales of product if we receive regulatory approval for a SARM, including enobosarm, or SARD product candidate and successfully market the product. Additionally, if we sublicense rights under our SARM or SARD license agreements, we also are obligated to pay a sublicense royalty on any licensing fee or milestone payments we may receive from a sublicensee.

(2) Our commitment under the operating lease consists of payments related to a lease for office space at 175 Toyota Plaza, Memphis, Tennessee, which expired on April 30, 2019.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

During the three months ended March 31, 2019, 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 filed with the Securities and Exchange Commission on March 18, 2019.

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 first quarter of 2019 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II: OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Litigation Related to the Merger

On April 10, 2019, a purported stockholder of GTx commenced a putative class action lawsuit captioned *Wheby v. GTx, Inc. et al.* in the U.S. District Court for the District of Delaware, naming as defendants GTx, Michael G. Carter, J. Kenneth Glass, Marc S. Hanover, J. R. Hyde, III, Garry A. Neil, Kenneth S. Robinson, and Robert J. Wills, collectively comprising the members of GTx's board of directors, its CEO (who is also a director), and the Chairman of the board of directors, Oncternal, and Merger Sub (the "Wheby Action").

On April 11, 2019, a purported stockholder of GTx commenced a putative class action lawsuit captioned *Miller v. GTx, Inc. et al.* in the U.S. District Court for the District of Delaware, naming as defendants GTx, GTx's board of directors, Oncternal, and Merger Sub (the "Miller Action").

On April 11, 2019, a purported stockholder of GTx commenced a putative class action lawsuit captioned *Kopanic v. GTx, Inc. et al.* in the U.S. District Court for the Southern District of New York, naming as defendants GTx and GTx's board of directors (the "Kopanic Action").

On April 23, 2019, a purported stockholder of GTx commenced a putative class action lawsuit captioned *Tabb v. GTx, Inc. et al.* in the U.S. District Court for the District of Delaware, naming as defendants GTx and GTx's board of directors (the "Tabb Action").

On May 1, 2019, a purported stockholder of GTx commenced a putative class action lawsuit captioned *Living Seas LLC v. GTx, Inc. et al.* in the U.S. District Court for the District of Delaware, naming as defendants GTx and GTx's board of directors (the "Living Seas Action").

On May 7, 2019, a purported stockholder of GTx commenced a putative class action lawsuit captioned *Cooper v. GTx, Inc. et al.* in the U.S. District Court for the Southern District of New York, naming as defendants GTx and GTx's board of directors (the "Cooper Action", together with the Living Seas Action, the Tabb Action, the Kopanic Action, the Miller Action, and the Wheby Action, the "Recent Actions").

Collectively, the Recent Actions allege violations of Sections 14(a) and 20(a) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), as well as Rule 14a-9 promulgated thereunder, in connection with GTx's filing of a registration statement on Form S-4 in connection with the Merger with the U.S. Securities and Exchange Commission (the "Registration Statement").

The Living Seas Action, Wheby Action, Kopanic Action and Miller Action each separately assert that the Registration Statement is materially deficient and misleading because it failed to disclose information regarding (i) GTx's and Oncternal's financial projections, (ii) communications and purported conflicts of interest between Oncternal and members of GTx's board of directors and management regarding their future employment with the combined successor company, and (iii) the confidentiality agreements entered into between GTx and other potential strategic partners during the process leading up the signing of the Original Merger Agreement. The Tabb Action asserts that the Registration Statement is materially deficient and misleading on the basis of assertions (ii) and (iii), as contained in the preceding sentence. The Cooper Action asserts that the Registration Statement is materially deficient and misleading on the basis of assertions (i) through (iii), as contained in the first sentence of this paragraph, while adding a fourth assertion that the Registration Statement is materially deficient and misleading because (iv) the terms of other bids provided to GTx by other bidders during negotiations were not disclosed in the Registration Statement.

As relief, the Recent Actions each separately seek an order, among other things, enjoining the defendants from closing the proposed transaction or taking any steps to consummate the Merger and/or awarding rescissory damages.

We and our board of directors believe that the above-described claims are without merit and intend to vigorously defend these actions. We cannot predict the outcome of or estimate the possible loss or range of loss from any of these matters. It is possible that additional, similar complaints may be filed or the complaints described above will be amended. If this occurs, we do not intend to announce the filing of each additional, similar complaint or any amended complaint unless it contains allegations that are substantially distinct from those made in the pending actions described above.

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 filed with the Securities and Exchange Commission on March 18, 2019.

Risks Related to the Merger

The exchange ratio set forth in the Merger Agreement is not adjustable based on the market price of our common stock, so the merger consideration at the closing of the Merger may have a greater or lesser value than at the time the Merger Agreement was signed.*

The Merger Agreement has set the exchange ratio for the Oncternal capital stock, and the exchange ratio is based on the outstanding capital stock of Oncternal and our outstanding common stock, in each case immediately prior to the closing of the Merger. Applying the exchange ratio formula in the Merger Agreement, the former Oncternal stockholders immediately before the Merger are expected to own approximately 77.5% of our outstanding capital stock immediately following the Merger, and our stockholders immediately before the Merger are expected to own approximately 22.5% of our outstanding capital stock immediately following the Merger, subject to certain assumptions. Under certain circumstances further described in the Merger Agreement, however, these ownership percentages may be adjusted upward or downward based on cash levels of the respective companies at the closing of the Merger, and as a result, either our stockholders or the Oncternal stockholders could own less of the combined company than expected.

Any changes in the market price of our common stock before the completion of the Merger will not affect the number of shares of our common stock issuable to Oncternal's stockholders pursuant to the Merger Agreement. Therefore, if before the completion of the Merger the market price of our common stock declines from the market price on the date of the Merger Agreement, then Oncternal's stockholders could receive merger consideration with substantially lower value than the value of such merger consideration on the date of the Merger Agreement. Similarly, if before the completion of the Merger the market price of our common stock increases from the market price of our common stock on the date of the Merger Agreement, then Oncternal's stockholders could receive merger consideration with substantially greater value than the value of such merger consideration on the date of the Merger Agreement. The Merger Agreement does not include a price-based termination right. Because the exchange ratio does not adjust as a result of changes in the market price of our common stock, for each one percentage point change in the market price of our common stock, there is a corresponding one percentage point rise or decline, respectively, in the value of the total merger consideration payable to Oncternal's stockholders pursuant to the Merger Agreement.

Failure to complete the Merger may result in either our or Oncternal's payment of a termination fee to the other party and could significantly harm the market price of our common stock and negatively affect the future business and operations of each company.

If the Merger is not completed and the Merger Agreement is terminated under certain circumstances, we or Oncternal may be required to pay the other party a termination fee of up to $2.0 million. Even if a termination fee is not payable in connection with a termination of the Merger Agreement, both we and Oncternal will have incurred significant fees and expenses, which must be paid whether or not the Merger is completed. Further, if the Merger is not completed, it could significantly harm the market price of our common stock.

In addition, if the Merger Agreement is terminated and our or Oncternal's board of directors determines to seek another business combination, there can be no assurance that either we or Oncternal will be able to find a partner

and close an alternative transaction on terms that are as favorable or more favorable than the terms set forth in the Merger Agreement.

The Merger is subject to approval of the Merger Agreement by our stockholders and the Oncternal stockholders. Failure to obtain these approvals would prevent the closing of the Merger.

Before the Merger can be completed, each of Oncternal and our stockholders must approve the Merger Agreement. Additionally, the Merger Agreement must be approved by multiple classes of Oncternal preferred stockholders, one class of which is held by a sole stockholder, Shanghai Pharmaceutical (USA) Inc., which has not executed a voting agreement and has not otherwise agreed to vote in favor of the Merger Agreement. Although Oncternal expects to receive stockholder approval from Shanghai Pharmaceutical (USA) Inc. approximately two months after the date of the Merger Agreement, there can be no assurance that all of the necessary stockholder approvals will be obtained. Failure to obtain the required stockholder approvals, including as a result of Shanghai Pharmaceutical (USA) Inc. refusing to approve the transactions contemplated by the Merger Agreement, may result in a material delay in, or the abandonment of, the Merger. Any delay in completing the Merger may materially adversely affect the timing and benefits that are expected to be achieved from the Merger.

The Merger may be completed even though certain events occur prior to the closing that materially and adversely affect us or Oncternal.

The Merger Agreement provides that either we or Oncternal can refuse to complete the Merger if there is a material adverse change affecting the other party between March 6, 2019, the date of the Merger Agreement, and the closing of the Merger. However, certain types of changes do not permit either party to refuse to complete the Merger, even if such change could be said to have a material adverse effect on us or Oncternal, including:

- general business, economic or political conditions or conditions generally affecting the industries in which Oncternal or we, as applicable, operate;
- any natural disaster or any acts of war, armed hostilities or terrorism;
- any changes in financial, banking or securities markets;
- with respect to us, any change in the stock price or trading volume of our shares excluding any underlying effect that may have caused such change;
- with respect to us, failure to meet internal or analysts' expectations or projects or the results of operations;
- any clinical trial programs or studies, including any adverse data, event or outcome arising out of or related to any such programs or studies;
- any change in accounting requirements or principles or any change in applicable laws, rules, or regulations or the interpretation thereof;
- any effect resulting from the announcement or pendency of the Merger or any related transactions; and
- the taking of any action, or the failure to take any action, either by us or Oncternal, required to comply with the terms of the Merger Agreement.

If adverse changes occur and we and Oncternal still complete the Merger, the market price of the combined organization's common stock may suffer. This in turn may reduce the value of the Merger to our stockholders, Oncternal's stockholders or the stockholders of both entities.

Some of our and Oncternal's officers and directors have interests in the Merger that are different from our and Oncternal's respective stockholders and that may influence them to support or approve the Merger without regard to the interests of our or Oncternal's respective stockholders.

Certain of our and Oncternal's officers and directors participate in arrangements that provide them with interests in the Merger that are different from the interests of our and Oncternal's respective stockholders, including, among others, the continued service as an officer or director of the combined organization, severance benefits, the acceleration of stock option vesting, continued indemnification and the potential ability to sell an increased number of shares of common stock of the combined organization in accordance with Rule 144 under the Securities Act of 1933, as amended.

For example, we have entered into employment agreements with certain of our executive officers that may result in the receipt by such executive officers of cash severance payments and other benefits in the event of a covered termination of employment of each executive officer's employment. The closing of the Merger will also result in the acceleration of vesting of options to purchase shares of our common stock held by our executive officers and directors, whether or not there is a covered termination of such officer's employment. In addition, and for example, certain of Oncternal's directors and executive officers have options, subject to vesting, to purchase shares of Oncternal's common stock which, at the closing of the Merger, shall be converted into and become options to purchase shares of our common stock, certain of Oncternal's directors and executive officers are expected to become directors and executive officers of ours upon the closing of the Merger, and all of Oncternal's directors and executive officers are entitled to certain indemnification and liability insurance coverage pursuant to the terms of the Merger Agreement. These interests, among others, may influence our and Oncternal's officers and directors to support or approve the Merger.

The market price of our common stock following the Merger may decline as a result of the Merger.

The market price of our common stock may decline as a result of the Merger for a number of reasons including if:

- investors react negatively to the prospects of the combined organization's product candidates, business and financial condition following the Merger;
- the effect of the Merger on the combined organization's business and prospects is not consistent with the expectations of financial or industry analysts; or
- the combined organization does not achieve the perceived benefits of the Merger as rapidly or to the extent anticipated by financial or industry analysts.

Our and Oncternal's securityholders will have a reduced ownership and voting interest in, and will exercise less influence over the management of, the combined organization following the closing of the Merger as compared to their current ownership and voting interest in the respective companies.*

After the completion of the Merger, our and Oncternal's current securityholders will own a smaller percentage of the combined organization than their ownership in their respective companies prior to the Merger. Immediately after the Merger, it is currently estimated that Oncternal securityholders will own approximately 77.5% of the common stock of the combined organization, and our securityholders, whose shares of our common stock will remain outstanding after the Merger, will own approximately 22.5% of the common stock of the combined organization. These estimates are based on the anticipated exchange ratio and are subject to adjustment as provided in the Merger Agreement. See also the risk factor above titled, "*The exchange ratio set forth in the Merger Agreement is not adjustable based on the market price of our common stock, so the merger consideration at the closing of the Merger may have a greater or lesser value than at the time the Merger Agreement was signed.*"

In addition, the nine member board of directors of the company will initially include six individuals with prior affiliations with Oncternal and two individuals with prior affiliations with us. Consequently, our securityholders and Oncternal's securityholders will be able to exercise less influence over the management and policies of the combined organization following the closing of the Merger than they currently exercise over the management and policies of their respective companies.

Our and Oncternal's stockholders may not realize a benefit from the Merger commensurate with the ownership dilution they will experience in connection with the Merger.

If the combined organization is unable to realize the strategic and financial benefits currently anticipated from the Merger, our and Oncternal's stockholders will have experienced substantial dilution of their ownership interests in their respective companies without receiving the expected commensurate benefit, or only receiving part of the commensurate benefit to the extent the combined organization is able to realize only part of the expected strategic and financial benefits currently anticipated from the Merger.

The combined company will need to raise additional capital by issuing securities or debt or through licensing or other strategic arrangements, which may cause dilution to the combined company's stockholders or restrict the combined company's operations or impact its proprietary rights.

The combined company may be required to raise additional funds sooner than currently planned. In this regard, while the exchange ratio may be impacted by cash levels of the respective companies at the closing of the Merger, the Merger Agreement does not condition the completion of the Merger upon either company holding a minimum amount of cash at the effective time of the Merger. If either or both we or Oncternal hold less cash at the time of the closing Merger than the parties currently expect, the combined company will need to raise additional capital sooner than expected. Additional financing may not be available to the combined company when it needs it or may not be available on favorable terms. To the extent that the combined company raises additional capital by issuing equity securities, such an issuance may cause significant dilution to the combined company's stockholders' ownership and the terms of any new equity securities may have preferences over the combined company's common stock. Any debt financing the combined company enters into may involve covenants that restrict its operations. These restrictive covenants may include limitations on additional borrowing and specific restrictions on the use of the combined company's assets, as well as prohibitions on its ability to create liens, pay dividends, redeem its stock or make investments. In addition, if the combined company raises additional funds through licensing, partnering or other strategic arrangements, it may be necessary to relinquish rights to some of the combined company's technologies or product candidates and proprietary rights, or grant licenses on terms that are not favorable to the combined company.

During the pendency of the Merger, neither we nor Oncternal may be able to enter into a business combination with another party at a favorable price because of restrictions in the Merger Agreement, which could adversely affect their respective businesses.

Covenants in the Merger Agreement impede our and Oncternal's ability to make acquisitions, subject to certain exceptions relating to fiduciary duties, as set forth below, or to complete other transactions that are not in the ordinary course of business pending completion of the Merger. As a result, if the Merger is not completed, the parties may be at a disadvantage to their competitors during such period. In addition, while the Merger Agreement is in effect, each party is generally prohibited from soliciting, initiating, encouraging or entering into certain extraordinary transactions, such as a merger, sale of assets, or other business combination outside the ordinary course of business with any third party, subject to certain exceptions relating to fiduciary duties. Any such transactions could be favorable to such party's stockholders.

Certain provisions of the Merger Agreement may discourage third parties from submitting alternative takeover proposals, including proposals that may be superior to the arrangements contemplated by the Merger Agreement.

The terms of the Merger Agreement prohibit both Oncternal and ourselves from soliciting alternative takeover proposals or cooperating with persons making unsolicited takeover proposals, except in limited circumstances when such party's board of directors determines in good faith that an unsolicited alternative takeover proposal is or is reasonably likely to lead to a superior takeover proposal and that failure to cooperate with the proponent of the proposal would be reasonably likely to be inconsistent with the applicable board's fiduciary duties.

Because the lack of a public market for Oncternal's capital stock makes it difficult to evaluate the value of Oncternal's capital stock, the stockholders of Oncternal may receive shares of our common stock in the Merger that have a value that is less than, or greater than, the fair market value of Oncternal's capital stock.

The outstanding capital stock of Oncternal is privately held and is not traded in any public market. The lack of a public market makes it extremely difficult to determine the fair market value of Oncternal. Because the percentage of our common stock to be issued to Oncternal's stockholders was determined based on negotiations between the parties, it is possible that the value of our common stock to be received by Oncternal's stockholders will be less than the fair market value of Oncternal, or we may pay more than the aggregate fair market value for Oncternal.

If the conditions to the Merger are not met, the Merger will not occur.

Even if the Merger is approved by our stockholders and the stockholders of Oncternal, specified conditions must be satisfied or waived to complete the Merger. We cannot assure you that all of the conditions will be satisfied or waived. If the conditions are not satisfied or waived, the Merger will not occur or will be delayed, and we and Oncternal each may lose some or all of the intended benefits of the Merger.

Six class action lawsuits have been filed and additional lawsuits may be filed against us, our board of directors, Oncternal, and/or Merger Sub relating to the Merger. An adverse ruling in any such lawsuit may prevent the Merger from being consummated.*

Between April 10, 2019 and May 7, 2019, six purported stockholder class action lawsuits were filed, naming us and our board of directors as defendants. Collectively, these lawsuits allege, among other things, violations of Sections 14(a) and 20(a) of the Exchange Act, as well as Rule 14a-9 promulgated thereunder, in connection with our filing of the registration statement on Form S-4 that we filed with the SEC in connection with the Merger. As relief, these lawsuits each separately seek an order, among other things, enjoining the defendants from closing the proposed transaction or taking any steps to consummate the Merger and/or awarding rescissory damages. We and our board of directors believe that the above-described claims are without merit and intend to vigorously defend these actions. We cannot predict the outcome of or estimate the possible loss or range of loss from any of these matters. It is possible that additional, similar complaints may be filed or the complaints described above will be amended. It is possible that these complaints will be further amended to make additional claims and/or that additional lawsuits making similar or additional claims relating to the Merger will be brought.

One of the conditions to completion of the Merger is the absence of any order being in effect that prohibits the consummation of the Merger. Accordingly, if any of these plaintiffs or any future plaintiff is successful in obtaining an order enjoining consummation of the Merger, then such order may prevent the Merger from being completed, or from being completed within the expected time frame. See “Item 1. Legal Proceedings” in this Quarterly Report on Form 10-Q for more information about the lawsuits related to the Merger that have been filed.

Risks Related to Our Financial Condition and Our Need for Additional Financing, and Additional Risks Related to the Merger

There is no assurance that the Merger will be completed in a timely manner or at all. If the Merger is not consummated, our business could suffer materially and our stock price could decline.

The closing of the Merger is subject to the satisfaction or waiver of a number of closing conditions, as described above, including the required approvals by our and Oncternal’s stockholders (including stockholder approval from one of Oncternal’s significant stockholders, Shanghai Pharmaceutical (USA) Inc., which holds all of the outstanding shares of one series of Oncternal’s preferred stock that must approve the transactions contemplated by the Merger Agreement) and other customary closing conditions. See the risk factors above titled, “*The Merger is subject to approval of the Merger Agreement by our stockholders and the Oncternal stockholders. Failure to obtain these approvals would prevent the closing of the Merger*” and “*If the conditions to the Merger are not met, the Merger will not occur.*” If the conditions are not satisfied or waived, including as a result of Shanghai Pharmaceutical (USA) Inc. refusing to approve the transactions contemplated by the Merger Agreement, the Merger may be materially delayed or abandoned. If the Merger is not consummated, our ongoing business may be adversely affected and, without realizing any of the benefits of having consummated the Merger, we will be subject to a number of risks, including the following:

- we have incurred and expect to continue to incur significant expenses related to the Merger even if the Merger is not consummated;
- we could be obligated to pay Oncternal a termination fee of up to $2.0 million under certain circumstances set forth in the Merger Agreement;
- the market price of our common stock may decline to the extent that the current market price reflects a market assumption that the Merger will be completed; and
- matters relating to the Merger have required and will continue to require substantial commitments of time and resources by our remaining management and employees, which could otherwise have been devoted to other opportunities that may have been beneficial to us.

We also could be subject to further litigation related to any failure to consummate the Merger or to perform our obligations under the Merger Agreement. If the Merger is not consummated, these risks may materialize and may adversely affect our business, financial condition and the market price of our common stock.

If the Merger is not completed, we may be unsuccessful in completing an alternative transaction on terms that are as favorable as the terms of the Merger with Oncternal, or at all, and we may otherwise be unable to continue to operate our business. Our board of directors may decide to pursue our dissolution and liquidation. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities.*

Our assets currently consist primarily of cash, cash equivalents and short-term investments, our SARD and SARM assets, the remaining value, if any, of our deferred tax assets, our listing on The Nasdaq Capital Market and the Merger Agreement with Oncternal. While we have entered into the Merger Agreement with Oncternal, the closing of the Merger may be delayed or may not occur at all and there can be no assurance that the Merger will deliver the anticipated benefits we expect or enhance stockholder value. If we are unable to consummate the Merger, our board of directors may elect to pursue an alternative strategy, one of which may be a strategic transaction similar to the Merger. Attempting to complete an alternative transaction like the Merger will be costly and time consuming, and we can make no assurances that such an alternative transaction would occur at all. Alternatively, our board of directors may elect to continue our operations to determine if we can identify an appropriate SARD compound to move forward into additional preclinical studies required for the potential submission of an IND to enable the initiation of a first-in-human clinical trial, if any. However, our existing capital resources may not be adequate to enable it to conduct and complete any IND-enabling studies of a SARD compound, particularly in light of the conflicting preclinical SARD data we have received to date and the additional preclinical research that would be required to determine whether an appropriate SARD compound can potentially be advanced into any IND-enabling preclinical studies in a timely manner, if at all. Even if we are able to successfully complete such additional preclinical research and to conduct and complete any IND-enabling studies of a SARD compound, which we may not be able to do with our existing capital resources, we will in any event require significant additional financial resources in order to initiate and complete initial human clinical trials of a SARD compound and to otherwise further the development of our SARD program. Our board of directors may also resume our efforts to seek potential collaborative, partnering or other strategic arrangements for our SARM or SARD assets, including a sale or other divestiture of one or both of these assets. Our board of directors could instead decide to abandon these efforts, including any further SARD development, and pursue a dissolution and liquidation of our company. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such decision, as with the passage of time the amount of cash available for distribution will be reduced as we continue to fund our operations, including our SARD preclinical development efforts. In addition, if our board of directors were to approve and recommend, and our stockholders were to approve, a dissolution and liquidation of our company, we would be required under Delaware corporate law to pay our outstanding obligations, as well as to make reasonable provision for contingent and unknown obligations, prior to making any distributions in liquidation to our stockholders. Our commitments and contingent liabilities may include severance obligations, regulatory and preclinical obligations, and fees and expenses related to the Merger. As a result of this requirement, a portion of our assets may need to be reserved pending the resolution of such obligations. In addition, we may be subject to litigation or other claims related to a dissolution and liquidation. If a dissolution and liquidation were pursued, our board of directors, in consultation with its advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of our common stock could lose all or a significant portion of their investment in the event of a liquidation, dissolution or winding up of the company.

The issuance of shares of our common stock to Oncternal stockholders in the Merger will substantially dilute the voting power of our current stockholders.*

If the Merger is completed, each outstanding share of Oncternal common stock will be converted into the right to receive a number of shares of our common stock equal to the exchange ratio determined pursuant to the Merger Agreement. Immediately following the Merger, the former Oncternal stockholders immediately before the Merger are expected to own approximately 77.5% of our outstanding capital stock, and our stockholders immediately before the Merger are expected to own approximately 22.5% of our outstanding capital stock, subject to certain assumptions. Accordingly, the issuance of shares of our common stock to Oncternal stockholders in the Merger will reduce significantly the relative voting power of each share of our common stock held by our current stockholders. Consequently, our stockholders as a group will have significantly less influence over the management and policies of the combined company after the Merger than prior to the Merger. These estimates are based on the anticipated exchange ratio and are subject to adjustment as provided in the Merger Agreement. See also the risk factor above titled, "*The exchange ratio set forth in the Merger Agreement is not adjustable based on the market price of our common stock, so the merger consideration at the closing of the Merger may have a greater or lesser value than at the time the Merger Agreement was signed.*"

Our stockholders may not receive any payment on the CVRs and the CVRs may otherwise expire valueless.*

If the Merger is completed, we and certain other parties will enter into the CVR Agreement pursuant to which, for each share of our common stock held, our stockholders of record as of immediately prior to the effective time of the Merger will receive one CVR entitling such holders to receive in the aggregate 75% of any net proceeds received

during the 15-year period after the closing of the Merger from the grant, sale or transfer of rights to our SARD or SARM technology that occurs during the 10-year period after the closing of the Merger (or in the 11th year if based on a term sheet approved during the initial 10-year period) and, if applicable, to receive royalties on the sale of any SARD products by the combined company during the 15-year period after the closing of the Merger. We recently received and evaluated new preclinical data from an independent laboratory of an academic researcher engaged by us, which, among other things, showed that at higher dose concentrations, the SARD compounds tested by the independent laboratory demonstrated partial androgen receptor agonist activity. The academic researcher pointed out that if these results translate to the clinical setting where there is little or no dose separation between antagonist activity and agonist activity, the future of the SARD program as an effective treatment of men with CRPC would likely not be viable. This information was in conflict with other independent laboratory preclinical data previously received by our senior management and with internal preclinical data generated by us, that included: (1) conflicting *in vitro* data showing either partial agonist activity or no partial agonist activity, (2) *in vivo* data showing no evidence of agonist activity, and (3) data from another independent laboratory showing the dose-dependent suppression of enzalutamide-resistant prostate cancer tumors in a rat xenograft model. Considering this conflicting information, it was concluded that additional preclinical studies were required to better understand SARDs and their mechanism of action, and to reconcile the conflicting *in vitro* and *in vivo* findings. In connection with the receipt of the new preclinical data, in addition to amending the Merger Agreement, we and Oncternal amended the form of CVR Agreement to, among other things: (i) increase from 50% to 75% the portion of the net proceeds the CVR holders will be entitled to under the CVR Agreement, and (ii) provide that Oncternal (as our successor in interest) will be obligated to use commercially reasonable efforts to either develop or divest our SARD technology, as the Oncternal board of directors shall determine in its sole discretion, and to divest our SARM technology, subject to certain limitations. Accordingly, Oncternal may decide, in its sole discretion, to abandon the development of our SARD technology following the Merger and would then be obligated only to use commercially reasonable efforts to divest the SARD technology, subject to certain limitations. Likewise, Oncternal is obligated only to use commercially reasonable efforts to divest the SARM technology, subject to certain limitations, and in light of the results of the ASTRID trial, Oncternal has no current intent to develop the SARM technology. In addition, the CVRs will not be transferable, will not have any voting or dividend rights, and interest will not accrue on any amounts potentially payable on the CVRs. Accordingly, the right of any of our stockholders to receive any future payment on or derive any value form the CVRs will be contingent solely upon the achievement of the foregoing events within the time periods specified in the CVR Agreement and if these events are not achieved for any reason within the time periods specified in the CVR Agreement, no payments will be made under the CVRs, and the CVRs will expire valueless. In addition, as set forth above, Oncternal (as our successor in interest) has agreed only to use commercially reasonable efforts to either develop or divest the SARD technology, as the Oncternal board of directors shall determine in its sole discretion, and to divest our SARM technology, subject to certain limitations, which allows for the consideration of a variety of factors in determining the efforts that the combined company is required to use to develop or divest (in Oncternal's sole discretion) our SARD technology and to divest our SARM technology, and it does not require the combined company to take all possible actions to continue efforts to develop or divest the SARD technology and to divest our SARM technology. Accordingly, under certain circumstances the combined company may not be required to continue efforts to develop or divest the SARD technology and to divest our SARM technology, which would have an adverse effect on the value, if any, of the CVRs. Furthermore, the CVRs will be unsecured obligations of the combined company and all payments under the CVRs, all other obligations under the CVR Agreement and the CVRs and any rights or claims relating thereto will be subordinated in right of payment to the prior payment in full of all current or future senior obligations of the combined company. Finally, the U.S. federal income tax treatment of the CVRs is unclear. There is no legal authority directly addressing the U.S. federal income tax treatment of the receipt of, and payments on, the CVRs, and there can be no assurance that the Internal Revenue Service, would not assert, or that a court would not sustain, a position that could result in adverse U.S. federal income tax consequences to holders of the CVRs.

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

As of March 31, 2019, we had an accumulated deficit of $605.9 million. Our net loss for the three months ended March 31, 2019 was $5.8 million and we expect to incur significant operating losses for the foreseeable future depending on the extent of our preclinical and any clinical development activities and, if any such development activities are successful, potentially seeking regulatory approval of any potential future product candidates. These

losses, among other things, have had and will continue to have an adverse effect on our stockholders' equity and working capital.

A substantial portion of our recent efforts and expenditures have been devoted to, and our prospects were substantially dependent upon, the development of enobosarm for the treatment of postmenopausal women with SUI. However, in September 2018, we announced that our placebo-controlled Phase 2 clinical trial of enobosarm to evaluate the change in frequency of daily SUI episodes following 12 weeks of treatment, or the ASTRID trial, failed to achieve statistical significance on the primary endpoint of the proportion of patients with a greater than 50% reduction in incontinence episodes per day compared to placebo. The failure of the ASTRID trial to achieve its primary endpoint has significantly depressed our stock price and has severely harmed our ability to raise additional capital and to secure potential collaborative, partnering or other strategic arrangements for our SARM assets, and consequently, our prospects to continue as a going concern have been severely diminished. Following our review of the full data sets from the ASTRID trial, we determined to discontinue further development of enobosarm to treat SUI and to otherwise discontinue any further development of our SARM technology generally. We continue our efforts to seek potential collaborative, partnering or other strategic arrangements for our SARM assets, including a sale or other divestiture of our SARM assets. We have for many years actively pursued, but have been unable to successfully enter into, potential collaborative, partnering or other strategic arrangements for our SARM assets. If we are unable to ultimately enter into any such arrangements for our SARM assets, we will not receive any return on our investment in enobosarm and our other SARMs.

As a result of our decision to discontinue our SARM development efforts, our development activities have been focused solely on conducting preclinical studies to determine if we can identify an appropriate SARD compound to move forward into additional preclinical studies required for the potential submission of an IND to enable the initiation of a first-in-human clinical trial. However, as a result of our recent receipt of new preclinical data from an independent laboratory that showed that at higher dose concentrations the SARD compounds tested demonstrated partial androgen receptor agonist activity along with the resultant uncertainty with respect to the overall preclinical data for SARDs to date, additional preclinical research would be required in order to determine whether an appropriate SARD compound can potentially be advanced into any IND-enabling preclinical studies. Our existing capital resources, however, may not be adequate to enable us to conduct and complete any IND-enabling studies of a SARD compound, particularly in light of the additional preclinical research that would be required in order to reconcile the conflicting preclinical SARD data we have received to date and to determine whether an appropriate SARD compound can potentially be advanced into any IND-enabling preclinical studies in a timely manner, if at all. Even if we are able to successfully complete such additional preclinical research and to conduct and complete any IND-enabling studies of a SARD compound, which we may not be able to do with our existing capital resources, we will in any event require significant additional financial resources in order to initiate and complete initial human clinical trials of a SARD compound and to otherwise further the development of our SARD program. Accordingly, if, for any reason, the Merger is not consummated, we may resume our efforts to seek additional funds through potential collaborative, partnering or other strategic arrangements to provide us with the necessary resources for the development of our SARD program. In addition, our preclinical evaluation of our SARD technology is at very early stage and is subject to the substantial risk and probability of failure inherent in the development of early-stage 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. 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®, 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®, we also currently have no sources of revenue.

If the Merger is not completed and we are unable to raise sufficient additional funds for the development of our SARD program, whether through potential collaborative, partnering or other strategic arrangements or otherwise, or if we otherwise determine to discontinue the development of our SARD program, whether as a result of our receipt of new preclinical data from an independent laboratory that showed that at higher dose concentrations the SARD compounds tested demonstrated partial androgen receptor agonist activity or otherwise, we will likely determine to cease operations. Even if we are able to successfully complete additional preclinical research to determine whether an appropriate SARD compound can potentially be advanced into any IND-enabling preclinical studies and to raise additional funds to permit the continued development of our SARD program, if we and/or any potential collaborators are unable to develop and commercialize our SARDs or SARM technology, if development is further

delayed or is eliminated, or if sales revenue from any SARD or partnered SARM products upon receiving marketing approval, if ever, is insufficient, we may never become profitable and we will not be successful.

If we do not successfully complete the Merger, we will need to raise substantial additional capital and may be unable to raise the capital necessary to permit the continued development of our SARD program, which would force us to delay, reduce or eliminate our SARD program and would likely cause us to cease operations.*

At March 31, 2019, we had cash, cash equivalents and short-term investments of $21.2 million. If the Merger is not completed, based on our current business plan and spending assumptions as a standalone company, 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 for at least the next 12 months. We have based our cash sufficiency estimates on our current business plan and our assumptions that may prove to be wrong. We could utilize our available capital resources sooner than we currently expect, and we could need additional funding sooner than currently anticipated.

Our existing capital resources may not be adequate to enable us to conduct and complete any IND-enabling studies of a SARD compound, particularly in light of the additional preclinical research that would be required in order to reconcile the conflicting preclinical SARD data we have received to date and to determine whether an appropriate SARD compound can potentially be advanced into any IND-enabling preclinical studies in a timely manner, if at all. Even if we are able to successfully complete such additional preclinical research and to conduct and complete any IND-enabling studies of a SARD compound, which we may not be able to do with our existing capital resources, we will in any event require significant additional financial resources in order to initiate and complete initial human clinical trials of a SARD compound and to otherwise further the development of our SARD program. If we are unable to raise sufficient additional funds for the development of our SARD program, whether through potential collaborative, partnering or other strategic arrangements or otherwise, or if we otherwise determine to discontinue the development of our SARD program, whether as a result of our receipt of new preclinical data from an independent laboratory that showed that at higher dose concentrations the SARD compounds tested demonstrated partial androgen receptor agonist activity or otherwise, we will likely determine to cease operations.

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

- our ability to successfully complete the Merger;
- the scope, rate of progress and cost of our preclinical and potential future clinical development programs;
- the terms and timing of any potential collaborative, partnering 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;
- potential future preclinical studies and clinical trial results;
- the cost and timing of regulatory filings and/or approvals to commercialize any potential future 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 have no ongoing collaborations for the development and commercialization of any product candidates and no source of revenue, nor do we expect to generate product revenue for the foreseeable future. We do not have any commitments for future external funding. In addition, although we have entered into an At-the-Market Equity Offering^{SM} Sales Agreement with Stifel, Nicolaus & Company, Incorporated, or the ATM Sales Agreement, under which approximately $25.0 million of shares of our common stock remained available for sale at March 31, 2019, it is unlikely we could raise sufficient funds under the ATM Sales Agreement to permit us to initiate and complete any initial human clinical trials of a SARD compound, if at all, and given our currently-depressed stock price, the ATM Sales Agreement is not otherwise expected to be a practical source of liquidity for us at this time. Further, given our currently-depressed stock price, we are

significantly limited in our ability to sell shares of common stock under the ATM Sales Agreement since the issuance and sale of our common stock under the ATM Sales Agreement, if it occurs, would be effected under a registration statement on Form S-3 that we filed with the Securities and Exchange Commission, and in accordance with the rules governing those registration statements, we generally can only sell shares of our common stock under that registration statement in an amount not to exceed one-third of our public float, which limitation for all practical purposes precludes our ability to obtain any meaningful funding through the ATM Sales Agreement at this time.

Until we can generate a sufficient amount of product revenue, which we may never do, we will need to finance future cash needs through potential collaborative, partnering or other strategic arrangements, as well as through public or private equity offerings or debt financings or a combination of the foregoing. If we are unable to raise additional funds, we will need to continue to reduce our expenditures in order to preserve our cash. Further cost-cutting measures that we may take may not be sufficient to enable us to meet our cash requirements, and they may negatively affect our business and our ability to derive any value from our SARD program. In any event, in order to further the development of our SARD program, we will need to raise substantial additional capital. Our failure to do so would likely result in our determining to cease operations.

To the extent that we raise additional funds through potential collaborations, partnering or other strategic arrangements, it may be necessary to relinquish rights to some of our technologies or product candidates and intellectual property rights thereof, or grant licenses on terms that are not favorable to us, any of which could result in our stockholders having little or no continuing interest in our SARD program and/or SARM assets 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 substantially dilutive private placements of our common stock and warrants in March 2014, November 2014 and September 2017, in addition to a registered direct offering of our common stock that we completed in October 2016 and the sale of our common stock pursuant to the ATM Sales Agreement. Our stockholders will experience additional, perhaps substantial, dilution should we again raise additional funds by issuing equity securities. Any additional debt or equity financing 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 the ASTRID trial to meet its primary endpoint and the resulting significant uncertainty regarding our prospects to continue as a going concern. If we are unable to complete the Merger, 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, uncertainties with respect to the prospects for our early-stage SARD program as an effective treatment for men with CRPC, particularly in light of our receipt of preclinical data demonstrating partial agonist activity in the SARD compounds tested, the sufficiency of our capital resources, potential future management turnover, and volatility and instability in the global financial markets. As a result of these and other factors, there is no guarantee that sufficient additional funding will be available to us on acceptable terms, or at all.

We are substantially dependent on our remaining employees to facilitate the consummation of the Merger.

We have substantially reduced our workforce since November 2018 and as of March 31, 2019, we had only 13 full-time employees. Our ability to successfully complete the Merger depends in large part on our ability to retain our remaining personnel. Despite our efforts to retain these employees, one or more may terminate their employment with us on short notice. The loss of the services of any of these employees could potentially harm our ability to consummate the Merger, to run our day-to-day business operations, as well as to fulfill our reporting obligations as a public company.

The pendency of the Merger could have an adverse effect on the trading price of our common stock and our business, financial condition and prospects.

While there have been no significant adverse effects to date, the pendency of the Merger could disrupt our business in many ways, including:

- the attention of our remaining management and employees may be directed toward the completion of the Merger and related matters and may be diverted from our day-to-day business operations; and

- third parties may seek to terminate or renegotiate their relationships with us as a result of the Merger, whether pursuant to the terms of their existing agreements with us otherwise.

Should they occur, any of these matters could adversely affect the trading price of our common stock or harm our business, financial condition and prospects.

Risks Related to Our Development Activities

We were substantially dependent on the success of enobosarm, and the recent failure of the ASTRID trial to meet its primary endpoint has severely diminished enobosarm's prospects and our prospects to continue as a going concern. As we are now focused solely on our SARD program, our failure to obtain funding for and to advance the development of our SARD program would likely require us to cease operations.*

A substantial portion of our recent efforts and expenditures have been devoted to, and our prospects were substantially dependent upon, the development of enobosarm for the treatment of postmenopausal women with SUI. However, in September 2018, we announced that the ASTRID trial failed to achieve statistical significance on the primary endpoint of a greater than 50% reduction in incontinence episodes per day compared to placebo. The failure of the ASTRID trial to achieve its primary endpoint has significantly depressed our stock price and has severely harmed our ability to raise additional capital and to secure potential collaborative, partnering or other strategic arrangements for our SARM assets, and consequently, our prospects to continue as a going concern have been severely diminished. Following our review of the full data sets from the ASTRID trial, we determined to discontinue further development of enobosarm to treat SUI and to otherwise discontinue any further development of our SARM program generally. We continue our efforts to seek potential collaborative, partnering or other strategic arrangements for our SARM assets, including a sale or other divestiture of our SARM assets. We have for many years actively pursued, but have been unable to successfully enter into, potential collaborative, partnering or other strategic arrangements for our SARM assets. If we are unable to ultimately enter into any such arrangements for our SARM assets, we will not receive any return on our investment in enobosarm and our other SARMs.

As a result of our decision to discontinue our SARM development efforts, our development activities have been focused solely on conducting preclinical studies to determine if we can identify an appropriate SARD compound to move forward into additional preclinical studies required for the potential submission of an IND to enable the initiation of a first-in-human clinical trial. However, we recently received new preclinical data from an independent laboratory of an academic researcher engaged by us, which, among other things, showed that at higher dose concentrations, the SARD compounds tested by the independent laboratory demonstrated partial androgen receptor agonist activity. The academic researcher pointed out that if these results translate to the clinical setting where there is little or no dose separation between antagonist activity and agonist activity, the future of the SARD program as an effective treatment of men with CRPC would likely not be viable. This information was in conflict with other independent laboratory preclinical data previously received by our senior management and with internal preclinical data generated by us, that included: (1) conflicting *in vitro* data showing either partial agonist activity or no partial agonist activity, (2) *in vivo* data showing no evidence of agonist activity, and (3) data from another independent laboratory showing the dose-dependent suppression of enzalutamide-resistant prostate cancer tumors in a rat xenograft model. Considering this conflicting information, it was concluded that additional preclinical studies were required to better understand SARDs and their mechanism of action, and to reconcile the conflicting *in vitro* and *in vivo* findings. Accordingly, additional preclinical research would be required in order to determine whether an appropriate SARD compound can potentially be advanced into any IND-enabling preclinical studies. Our existing capital resources, however, may not be adequate to enable us to conduct and complete any IND-enabling studies of a SARD compound, particularly in light of the additional preclinical research that would be required in order to reconcile the conflicting preclinical SARD data we have received to date and to determine whether an appropriate SARD compound can potentially be advanced into any IND-enabling preclinical studies in a timely manner, if at all. Even if we are able to successfully complete such additional preclinical research and to conduct and complete any IND-enabling studies of a SARD compound, which we may not be able to do with our existing capital resources, we will in any event require significant additional financial resources in order to initiate and complete initial human clinical trials of a SARD compound and to otherwise further the development of its SARD program. In addition, the preclinical evaluation of our SARD technology is at a very early stage and is subject to the substantial risk and probability of failure inherent in the development of early-stage programs.

In any event, if the Merger is not completed and we are unable to raise sufficient additional funds for the development of our SARD program, whether through potential collaborative, partnering or other strategic arrangements or otherwise, or if we otherwise determines to discontinue the development of our SARD program, whether as a result of our recent receipt of new preclinical data from an independent laboratory that showed that at

higher dose concentrations the SARD compounds tested demonstrated partial androgen receptor agonist activity or otherwise, we will likely determine to cease operations.

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

Significant additional clinical development, financial resources and personnel would be required to obtain necessary regulatory approvals for any potential future SARD or SARM 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 top-line or interim results of a clinical trial do not necessarily predict final results. In this regard, from time to time, we have and may in the future publish or report top-line, interim or other preliminary data from our clinical trials, which data is based on a preliminary analysis of then-available efficacy and safety data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data from the applicable trial. As a result, the top-line results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Similarly, interim or other preliminary data from clinical trials that we may conduct may not be indicative of the final results of the trial and are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Top-line, interim and other preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from such top-line, interim or other preliminary data we previously published. As a result, top-line, interim or preliminary data should be viewed with caution until the final data are available.

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, in September 2018, we announced that the ASTRID trial failed to achieve statistical significance on the primary endpoint of the proportion of patients with a greater than 50% reduction in incontinence episodes per day compared to placebo. The failure of the ASTRID trial to achieve its primary endpoint has significantly depressed our stock price and has severely harmed our ability to raise additional capital and to secure potential collaborative, partnering or other strategic arrangements for our SARM assets, and consequently, our prospects to continue as a going concern have been severely diminished. Likewise, during the third quarter of 2017, we determined that there were insufficient patients achieving clinical benefit from enobosarm treatment to continue our Phase 2 proof-of-concept clinical trial evaluating enobosarm in patients with advanced AR positive triple-negative breast cancer, or TNBC. Additionally, in the third quarter of 2017, we decided not to pursue additional clinical development of enobosarm to treat women with ER positive, AR positive advanced breast cancer after evaluating the breast cancer environment where the treatment paradigms are shifting to immunotherapies and/or combination therapies, along with the time and cost of conducting the necessary clinical trials for potential approval, even though we announced that our Phase 2 clinical trial of enobosarm in this indication achieved its primary endpoint in both the 9 mg and 18 mg cohorts of the clinical trial. Following our review of the full data sets from the ASTRID trial, we determined to discontinue further development of enobosarm to treat SUI and to otherwise discontinue any further development of our SARM program generally. We continue our efforts to seek potential collaborative, partnering or other strategic arrangements for our SARM assets, including a sale or other divestiture of our SARM assets. We have for many years actively pursued, but have been unable to successfully enter into, potential collaborative, partnering or other strategic arrangements for our SARM assets. If we are unable to ultimately enter into any such arrangements for our SARM assets, we will not receive any return on our investment in enobosarm and our other SARMs.

In the first quarter of 2015, we entered into an exclusive worldwide license agreement with UTRF to develop its proprietary SARD technology and we are currently focused solely on the further development of our SARD program. Our preclinical evaluation of our SARD technology is at an early stage and is subject to the substantial risk and probability of failure inherent in the development of early-stage programs. We will in any event require significant additional financial resources in order to initiate and complete initial human clinical trials of a SARD compound and to otherwise further the development of our SARD program. If our research and preclinical development of our SARD program is unsuccessful, is discontinued and/or we are not able to obtain sufficient funding to advance the development of our SARD program, we will likely cease operations.

Significant delays in preclinical studies and clinical testing could materially impact our product development costs. For example, as a result of our recent receipt of new preclinical data from an independent laboratory that showed that at higher dose concentrations the SARD compounds tested demonstrated partial androgen receptor agonist activity along with the resultant uncertainty with respect to the overall preclinical data for SARDs to date, additional preclinical research would be required in order to determine whether an appropriate SARD compound can potentially be advanced into any IND-enabling preclinical studies. Such additional preclinical research will increase our costs, and we cannot be certain that our existing capital resources will be adequate to enable us to conduct and complete any IND-enabling studies of a SARD compound. In any event, we do not know whether our potential future preclinical studies and clinical trials will need to be modified or will be completed on schedule, if at all. 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 us or our potential collaborators' ability to commercialize any 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 or any potential collaborators may experience substantial delays in obtaining these authorizations;
- we or any potential collaborators may be delayed in reaching, or may fail to reach, agreement on acceptable terms with prospective clinical research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- additional preclinical studies or clinical trials may produce negative, inconclusive or further conflicting results, which may require us or any potential collaborators to conduct additional preclinical or clinical testing, such as the additional preclinical research that would be required to determine whether an appropriate SARD compound can potentially be advanced into any IND-enabling preclinical studies 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 preclinical development or clinical trials;
- patient registration or enrollment in clinical trials may be slower than we anticipate resulting in significant delays, additional costs and/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;
- our product candidates may not have the desired effects or may include undesirable side effects; and
- changes in regulatory requirements, policies and guidelines.

If any of these events were to continue to occur in the future and, as a result, we or any potential collaborators have significant delays in or termination of potential future 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 any potential future 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 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. Mild transient elevations in liver enzymes that were within normal limits were observed in our Phase 2 proof-of-concept clinical trial of enobosarm to treat postmenopausal women with SUI, except for one patient with levels greater than 1.5 times the upper limit of

normal which returned to normal following her 12-week treatment period. Reductions in total cholesterol, low-density lipoproteins, or LDL, HDL and triglycerides were also observed. Results of the placebo-controlled ASTRID study in postmenopausal women with SUI indicated that enobosarm was generally safe and well tolerated, and reported adverse events were generally mild to moderate in intensity and similar across all treatment groups. Mild transient elevations in hepatic enzymes and changes in lipid profile were dose dependent, and consistent with results seen in previous trials. In addition, in our 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, a serious adverse event, or SAE, was assessed as possibly related to enobosarm. Although doses up to 30 mg have been evaluated in short duration studies, the 3 mg dose that was the subject of the ASTRID trial and higher enobosarm doses that may potentially be tested by potential future collaborators in later stage longer duration trials, if any, 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.

If the incidence of serious or other adverse events related to enobosarm or any other SARD or SARM 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 potential future 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 adoption and 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 the Merger is not completed and we do not establish collaborative, partnering or other strategic arrangements for our SARD program and SARM assets or otherwise raise substantial additional capital, we will likely determine to cease operations.*

Our current strategy is dependent on our ability to secure potential collaborative, partnering or other strategic arrangements with other pharmaceutical and biotechnology companies to assist us in furthering development and potential commercialization of any SARD and SARM product candidates, and to otherwise obtain funding for such activities. For example, we are currently focused solely on the further development of our SARD program; however, our existing capital resources may not be adequate to enable us to conduct and complete any IND-enabling studies of a SARD compound, particularly in light of the additional preclinical research that would be required in order to reconcile the conflicting preclinical SARD data we have received to date and to determine whether an appropriate SARD compound can potentially be advanced into any IND-enabling preclinical studies in a timely manner, if at all. Even if we are able to successfully complete such additional preclinical research and to conduct and complete any IND-enabling studies of a SARD compound, which we may not be able to do with our existing capital resources, we will in any event require significant additional financial resources in order to initiate and complete initial human clinical trials of a SARD compound and to otherwise further the development of our SARD program. Accordingly, if, for any reason, the Merger is not consummated, we may resume our efforts to seek additional funds through potential collaborative, partnering or other strategic arrangements to provide us with the necessary resources for the development of our SARD program. We face significant competition in seeking such arrangements, and such arrangements are complex and time consuming to negotiate and document. In any event, we may not be successful in entering into new collaborative, partnering or other strategic arrangements with third parties for the further development of our SARD program (or our SARD assets) on acceptable terms, or at all. In this regard, we have for many years actively pursued, but have been unable to successfully enter into, potential

collaborative, partnering or other strategic arrangements for our SARM assets and we likewise have not been successful to date in entering into potential collaborative, partnering or other strategic arrangements for our SARD program. Moreover, as a result of our recent receipt of new preclinical data from an independent laboratory that showed that at higher dose concentrations the SARD compounds tested demonstrated partial androgen receptor agonist activity, which data conflicts with certain other preclinical data previously received by us, this new preclinical data along with the resultant uncertainty with respect to the overall preclinical data for SARDs to date may negatively impact or preclude altogether our prospects for entering into potential collaborative, partnering or other strategic arrangements for our SARD program. In addition, we are unable to predict when, if ever, we will enter into any potential collaborative, partnering or other such strategic arrangements because of the numerous risks and uncertainties associated with establishing such arrangements, and we have otherwise been unsuccessful, for many years, in our efforts to establish such arrangements. In any event, if the Merger is not completed and we are unable to raise sufficient additional funds for the development of our SARD program, whether through potential collaborative, partnering or other strategic arrangements or otherwise, or if we otherwise determine to discontinue the development of our SARD program, we will likely determine to cease operations. In addition, because we have discontinued our SARM development efforts, if we are unable to ultimately enter into any potential collaborative, partnering or other such strategic arrangements for our SARM assets, we will not receive any return on our investment in enobosarm and our other SARMs.

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, if the Merger is not completed, we intend to continue to seek to establish, partnering, collaborative and similar strategic arrangements with third parties to develop and commercialize any potential 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. As of the date of this report, we have no ongoing collaborations for the development and commercialization of any product candidate. We may not be able to locate third-party collaborators to develop and market any product candidates, and we lack the necessary financial resources to develop any 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 clinical and commercial drug supplies in sufficient quantities, in the required timeframe, at an acceptable cost, and with appropriate quality control, clinical development and commercialization of any potential future 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 any 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 and expect to continue to rely on third-party vendors for drug substance and drug product manufacturing, including drug substance for SARDs used in our current and potential future preclinical studies. If the contract manufacturers that we are currently utilizing to meet our supply needs for SARD compounds or any potential future SARD product candidates prove incapable or unwilling to continue to meet our supply needs, we could experience a delay in conducting any additional preclinical or clinical trials of SARD compounds or any potential future SARD product candidates. 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 our 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 any potential future product candidates.

Use of third-party manufacturers may increase the risk that we will not have adequate drug supplies for preclinical, clinical and commercial use.

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

- 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 drug supplies, including SARD compounds, it will be more difficult for us to develop any product candidates and compete effectively. Our potential future 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 any potential future 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 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 any potential future product candidates.

Risks Related to Our Intellectual Property

If we lose our licenses from UTRF, we may be unable to continue our business and, if the Merger is completed, the CVR holders may not receive any proceeds from our SARD or SARM technology.*

We have licensed intellectual property rights and technology from UTRF used in substantially all of our business. Our license agreements with UTRF, under which we were granted rights to enobosarm and other SARM compounds, and to SARD compounds and, for both, to methods of use thereof, 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 enobosarm and other SARM compounds and/or SARD compounds and the intellectual property covered by those agreements to market, distribute and sell licensed products, which may prevent us from continuing our business and would likely cause us to cease operations altogether.

In addition, if the Merger is completed and the combined company breaches its obligations under one or both license agreements, resulting in a termination of the relevant agreement, then the combined company may not be able to develop or divest the SARD technology or divest the SARM technology. As a result, the combined company may not receive proceeds from the transfer of rights to the applicable technologies or the sale of SARD or SARM technology. If the combined company does not receive any such proceeds, then the CVR holders would not receive any payments on the CVRs.

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, if any, will depend in part on obtaining and maintaining patent and trade secret protection for any product candidates that we may develop, as well as the methods for treating patients in the product indications using these product candidates. We will be able to protect any potential future 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.

Even if any potential future product candidates and/or 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

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.

The activities associated with the development and commercialization of drug candidates are subject to comprehensive regulation by the FDA, other regulatory agencies in the United States and by comparable authorities in other countries, including the European Medicines Agency, or 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 product candidate in any jurisdiction, and we do not expect to obtain FDA, EMA or any other regulatory approvals to market any potential future 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 Strategy, 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. Failure to obtain approval in one jurisdiction may negatively impact our ability to obtain approval elsewhere.

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, including Phase 4 clinical studies. For example, in October 2009, we received a Complete Response Letter from the FDA regarding our new drug application, or NDA, for toremifene 80 mg to reduce fractures in men with prostate cancer on androgen deprivation therapy 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 other toremifene-based products. Although we evaluated the potential submission of a marketing authorization application, or MAA, to the 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 determined that the data from the POWER trials was 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 elected not 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, we were unable to file with the FDA a NDA for enobosarm 3 mg for the prevention and treatment of muscle wasting in patients with advanced NSCLC.

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 product candidates 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 in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 18, 2019 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 and for which we may obtain regulatory approval 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 may not gain market acceptance for its stated indication among physicians, patients, health care payors and the medical community despite regulatory approval. 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 become and/or remain a preferred course of treatment;
- the ability to offer our product candidates for sale at competitive prices;
- relative convenience and ease of administration compared to alternative treatment;
- the strength of marketing and distribution support; and
- sufficient third-party coverage or reimbursement.

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 potential future 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 any such product candidates. Either of these options would be expensive and time-consuming. 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 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, both governmental and private. Changes in the coverage and/or 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 Healthcare Reform Act, which, among other initiatives, implemented cost containment and other measures that could adversely affect revenues from sales of product candidates, including an increase in the drug rebates that manufacturers must pay under Medicaid for brand name prescription drugs and extension of these rebates to Medicaid managed care and a requirement that manufacturers provide a 50% discount on the negotiated price of Medicare Part D brand name drugs utilized by Medicare Part D beneficiaries during the coverage gap (the so-called “donut hole”)(which discount has subsequently been increased to 70% in 2019).

The provisions of the Healthcare Reform Act have been subject to judicial and Congressional challenges, as well as efforts by the Trump administration to modify certain requirements of the Healthcare Reform Act by executive branch order. For example, on January 20, 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the Healthcare Reform Act to waive, defer, grant exemptions from, or delay the implementation of any provision of the Healthcare Reform Act that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. On October 12, 2017, President Trump signed another Executive Order directing certain federal agencies to propose regulations or guidelines to provide small businesses with greater opportunities to form association health plans, expand the availability of short-term, limited duration insurance, and allow employees to make use of certain employer-paid health benefits, called health reimbursement arrangements, to pay for health insurance that does not meet all Healthcare Reform Act requirements. In addition, citing legal guidance from the U.S. Department of Justice, the U.S. Department of Health and Human Services, or HHS, concluded that cost-sharing reduction, or CSR, payments to insurance companies required under the Healthcare Reform Act had not received necessary appropriations from Congress. President Trump subsequently discontinued these payments. The loss of the CSR payments is expected to increase premiums on certain policies issued by qualified health plans under the Healthcare Reform Act. Certain administrative actions have been subject to judicial challenge. In Congress, there have been a number of legislative initiatives to modify, repeal and/or replace portions

of the Healthcare Reform Act. Tax reform legislation enacted at the end of 2017 eliminated the tax penalty for individuals who do not maintain sufficient health insurance coverage beginning in 2019. The Bipartisan Budget Act of 2018 contained various provisions that affect coverage and reimbursement of drugs, including an increase in the discount that manufacturers of Medicare Part D brand name drugs must provide to Medicare Part D beneficiaries during the coverage gap from 50% to 70% starting in 2019. Congress may consider other legislation to modify, repeal and/or replace certain elements of the Healthcare Reform Act. In December 2018, a federal district court judge, in a challenge brought by a number of state attorneys general, found the Healthcare Reform Act unconstitutional in its entirety because, once Congress repealed the individual mandate provision, there was no longer a basis to rely on Congressional taxing authority to support enactment of the law. Pending appeals, which could take some time, the Healthcare Reform Act is still operational in all respects. We continue to evaluate the effect that the Healthcare Reform Act and its possible repeal, replacement or modification may have on our business. Such legislation and other healthcare reform measures that may be adopted in the future could have a material adverse effect on our industry generally and on our ability to successfully commercialize our product candidates, if approved.

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 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 HHS 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 health care reform, as evidenced by the initial enactment of, as well as the efforts to repeal, replace and/or modify the Healthcare Reform Act in the United States. Federal and state legislatures within the United States and foreign governments will likely continue to consider other 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. For example, there has been increasing administrative, legislative and enforcement interest in the United States with respect to drug pricing practices. There have been several U.S. Congressional inquiries and legislative and administrative initiatives at the federal and state levels intended to, among other things, bring more transparency to drug pricing and modify government program reimbursement for drugs. We cannot

predict what health care reform initiatives may be adopted in the future. Further federal, state and foreign legislative and regulatory developments are likely, and we expect ongoing initiatives to increase pressure on drug pricing, which 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.

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 $10 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 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 any potential future 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.

We believe SARDs may have the potential to provide compounds that can degrade or antagonize multiple forms of the AR thereby inhibiting tumor growth in patients with CRPC, including those patients who do not respond or are resistant to current therapies. Drugs in development having potentially similar approaches to removing the AR by degradation include Arvinas Inc.’s ARV-110, which is a chimera with an AR binding moiety on one end and an E3 ligase recruiting element on the other that has recently entered Phase 1 development for the treatment of advanced prostate cancer, and Androscience Corporation’s androgen receptor degrader enhancer, ASC-J9, which is currently in development for acne and alopecia with the potential for development as a treatment for prostate cancer.

Additionally, Essa Pharma Inc. recently completed a Phase 1 study with EPI-506, an AR antagonist that targets the N-terminal domain of the AR, and has plans to develop a second generation agent. C4 Therapeutics, Inc. is developing degronimids as means to degrade the AR through the ligand binding domain associated degradation. CellCentric is developing therapies that target the histone methyltransferase enzyme to lower AR levels, and recently initiated a clinical trial with CCS1477 in prostate cancer. Oric Pharmaceuticals is targeting the glucocorticoid receptor as a means to impact men that have CRPC, and has a lead candidate ORIC-101 in preclinical testing. 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. Pfizer and Astellas Pharma market XTANDI® (enzalutamide), an oral androgen receptor antagonist, for the treatment of metastatic CRPC in men previously treated with docetaxel as well as those that have not yet received chemotherapy. XTANDI® received FDA approval in July 2018 for the treatment of men with non-metastatic CRPC. Zytiga®, sold by Johnson & Johnson, has been approved for the treatment of metastatic CRPC and metastatic high-risk castration-sensitive prostate cancer. Johnson & Johnson also received FDA approval for a second generation anti-androgen ERLEADA (apalutamide) for the treatment of men with non-metastatic castrate-resistant prostate cancer. Bayer HealthCare and Orion Corporation recently announced that the primary endpoint of increased metastatic free survival was met in a Phase 3 study of darolutamide (ODM-201) in men with CRPC without metastases and with a rising PSA. Another target in prostate cancer that is being pursued by several companies is bromodomain inhibition. Zenith Epigenetics, Gilead Sciences Inc., CellCentric, Incyte Corporation and GlaxoSmithKline are among the companies that are evaluating BET inhibitors in Phase 1-2 trials.

With respect to SARMs, there are other SARM product candidates in development that may compete with enobosarm and any future SARM product candidates, if approved for commercial sale. For example, Viking Therapeutic's VK5211 recently reported positive results from a Phase 2 study for patients recovering from non-elective hip fracture surgery. Radius Health Inc.'s RAD140 is currently being evaluated in a Phase 1 study in postmenopausal women with hormone-receptor positive locally advanced or metastatic breast cancer. GlaxoSmithKline is conducting a Phase 1 study to assess the effect of GSK2881078 on physical strength and function after 13 weeks of treatment in patients with chronic obstructive pulmonary disease, or COPD, and muscle weakness. OPKO Health's OPK88004 is enrolling in a dose ranging study to improve symptoms of benign prostatic hyperplasia (BPH) by reducing prostate size and, on the basis of data from a previous trial in 350 men, increase muscle mass and bone strength and decrease body fat.

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 Our Operations

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 and could result in significant financial, legal, regulatory, business and reputational harm to us.

Despite the implementation of security measures, our internal computer and information technology 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 potential future clinical trials involving our product candidates, if any, could result in delays in our development and regulatory filing efforts and significantly increase our costs. In addition, while all information technology operations are inherently vulnerable to inadvertent or intentional security breaches, incidents, attacks and exposures, the size, complexity, accessibility and distributed nature of our information technology systems, and the large amounts of sensitive information stored on those systems, make such systems potentially vulnerable to unintentional or malicious, internal and external attacks on our technology environment. Potential vulnerabilities can be exploited from inadvertent or intentional actions of our employees, third-party vendors, business partners, or by malicious third

parties. Attacks of this nature are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives (including, but not limited to, industrial espionage) and expertise, including organized criminal groups, "hacktivists," nation states and others. To the extent that any disruption or security breach or incident were to result in a loss of, or damage to, our data, or inappropriate disclosure of confidential, proprietary or protected health information, we could be subject to significant legal, financial and regulatory exposure and suffer reputational harm, and the development of our product candidates could be delayed. In addition, security breaches and other inappropriate access events can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above. Moreover, the prevalent use of mobile devices to access confidential information increases the risk of security breaches. While we have implemented security measures to protect our information technology systems and infrastructure, there can be no assurance that such measures will prevent service interruptions or security breaches that could adversely affect our business. 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. In addition, failure to maintain effective internal accounting controls related to security breaches and cybersecurity in general could impact our ability to produce timely and accurate financial statements and subject us to regulatory scrutiny.

If we fail to keep senior management and personnel, we may be unable to continue our business operations.*

Our success depends on our continued ability to retain and motivate highly qualified management and personnel. Significant competition exists for qualified personnel in the biotechnology field. We may incur greater costs than anticipated, or may not be successful, in retaining or motivating our existing personnel. If we are not able to keep senior management and personnel, our ability to continue our business operations could be impaired, and the value of your investment would be adversely impacted. All of our employees are at-will employees and can terminate their employment at any time.

To conserve our cash resources, we have substantially reduced our workforce since November 2018 and have ceased our SARM development activities and all other operations except for day-to-day business operations, completing ongoing SARD preclinical studies and those activities necessary to complete the Merger. As of March 31, 2019, we had only 13 full-time employees. Accordingly, we have been and are continuing to operate with a shortage of resources and may not be able to effectively conduct our operations with this limited number of employees. In addition, our ability to successfully complete the Merger depends in large part on our ability to retain our remaining personnel. Despite our efforts to retain these employees, one or more may terminate their employment with us on short notice. The loss of the services of any of these employees could potentially harm our ability to consummate the Merger, to run our day-to-day business operations, as well as to fulfill our reporting obligations as a public company.

If the Merger is not completed and we are able to raise sufficient additional funds necessary to pursue the continued development of our SARD program, we will need to hire a substantial number of additional employees. Any inability to manage future growth could harm our ability to develop and commercialize any potential future product candidates, increase our costs and adversely impact our ability to compete effectively.*

As of March 31, 2019, we had only 13 full-time employees. If the Merger is not completed and we are able to raise sufficient additional funds necessary to pursue the continued development of our SARD program, we will need to hire experienced personnel to continue to develop our SARD program and to develop and commercialize any potential future product candidates, and we will need to expand the number of our managerial, operational, financial and other employees to support that growth. Significant competition exists for qualified personnel.

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 any potential future product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively.

Management transition creates uncertainties and could harm our business.

We have in the past, and may again in the future, experience significant changes in executive leadership. 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. In any event, 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.

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 $25.60 on September 13, 2018, and a low of $0.74 on December 24, 2018, in the twelve-month period ended March 31, 2019. 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:

- our ability to consummate the transactions contemplated by the Merger Agreement, including the Merger;
- our ability to execute on our SARD development program, including our ability to conduct and complete IND-enabling studies and potentially advance one of our SARD compounds into a first-in-human clinical trial;
- our ability to raise sufficient additional funds necessary for the continued development of our SARD program, whether through potential collaborative, partnering or other strategic arrangements or otherwise;
- our ability to realize any value from our SARM assets, particularly in light of our decision to discontinue the development of enobosarm and our SARM technology generally;
- the terms and timing of any future collaborative, licensing or other strategic arrangements that we may establish;
- uncertainties created by our potential future management turnover;
- our inability to comply with the minimum listing requirements of The Nasdaq Stock Market LLC;
- 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;
- reports of unacceptable incidences of adverse events observed in any future clinical trials of any product candidates that we and/or any potential collaborators may develop;
- announcement of FDA approval or non-approval of any potential future product candidates or delays in or adverse events during the FDA review process;
- actions taken by regulatory agencies with respect to any potential future product candidates or our potential future clinical trials, if any, including regulatory actions requiring or leading to a delay or stoppage of any clinical trials;
- 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;
- the commercial success of any product approved by the FDA or its foreign counterparts;
- 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;
- if our patents covering our products candidates 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;
- competition from third parties with products in the same class of products as any potential future product candidates or products with the same active pharmaceutical ingredients as those product candidates;
- 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 our common stock and other securities by us;
- sales of our common stock by our executive officers, directors and significant stockholders;
- the low trading volume of our common stock;
- changes in accounting principles; and
- additional losses of any of our key management personnel.

In addition, the stock markets in general, and the markets for biotechnology and pharmaceutical stocks in particular, have experienced significant volatility that has often been unrelated to the operating performance of particular companies. For example, negative publicity regarding drug pricing and price increases by pharmaceutical companies has negatively impacted, and may continue to negatively impact, the markets for biotechnology and pharmaceutical stocks. Likewise, as a result of significant changes in U.S. social, political, regulatory and economic conditions or in laws and policies governing foreign trade and health care spending and delivery, including the possible repeal and/or replacement of all or portions of the Healthcare Reform Act or changes in tariffs and other restrictions on free trade stemming from the Trump Administration and foreign government policies, the financial markets could experience significant volatility that could also negatively impact the markets for biotechnology and pharmaceutical stocks. 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 development efforts.

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 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 December 5, 2016, we effected one-for-ten reverse stock split of our outstanding common stock, or the 2016 Reverse Stock Split, the primary purpose of which was to enable us to regain compliance with the Bid Price Requirement, which compliance was regained on December 20, 2016. However, the closing bid price of our common stock has recently been well below $1.00 per share, and there can be no assurance that we will 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 and requirements to maintain minimum levels of stockholders' equity or market values of our common stock, Nasdaq may notify us that we have failed to meet the minimum listing requirements and initiate the delisting process.

In addition, we are required pursuant to the terms of the Merger Agreement to submit to our stockholders a proposal to approve an amendment to our restated certification of incorporation to authorize our board of directors to effect a reverse stock split of all outstanding shares of our common stock. The approval of the reverse stock split by

our stockholders is a condition to closing, pursuant to the Merger Agreement. If this reverse stock split proposal is not approved by our stockholders, and if the parties waive this closing condition, the combined company resulting from the Merger will likely not be able to obtain compliance with the minimum bid price requirement for an initial listing on Nasdaq and, as a consequence, Nasdaq will immediately provide the combined company with written notification that our common stock will be delisted.

If our common stock is delisted, we would expect our common stock to be traded in the over-the-counter market, which could adversely affect the liquidity of our common stock. Additionally, we could face significant material adverse consequences, including:

- a limited availability of market quotations for our common stock;
- a reduced amount of news and analyst coverage for us;
- a decreased ability to issue additional securities and a concomitant substantial impairment in our ability to obtain sufficient additional capital to fund our operations and to continue as a going concern;
- reduced liquidity for our stockholders;
- potential loss of confidence by employees and potential future partners or collaborators; and
- loss of institutional investor interest and fewer business development opportunities.

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

Based solely on the most recent Schedules 13G and 13D filed with the SEC and reports filed with the SEC under Section 16 of the Exchange Act, our executive officers, directors and holders of 5% or more of our outstanding common stock, including their affiliated or associated entities, held approximately 53.5% of our outstanding common stock, and our executive officers and directors alone, including their affiliated or associated entities, held approximately 30.0% of our outstanding common stock as well as warrants to purchase up to an additional 1.0 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, the approval of the issuance of shares of our common stock pursuant to the Merger Agreement, and the approval of potential alternative 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.

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

We have a significant amount of federal and state net operating loss, or NOL, carryforwards. In this regard, as of December 31, 2018, we had net federal operating loss carryforwards of approximately $472.1 million. The federal operating loss carryforwards originating prior to 2018 will expire from 2019 to 2037 if not utilized, and state operating loss carryforwards of approximately $411.4 million will expire from 2019 to 2038 if not utilized. Our ability to use our federal and state NOL carryforwards to offset potential future taxable income and related income taxes that would otherwise be due is dependent upon our generation of future taxable income before the expiration dates of the NOL carryforwards, and we cannot predict with certainty when, or whether, we will generate sufficient taxable income to use all of our NOL carryforwards. On December 22, 2017, President Trump signed into law U.S. federal income tax legislation, informally titled the Tax Cuts and Jobs Act, or the Tax Act. Under the Tax Act, federal NOLs incurred in taxable years ending after December 31, 2017 may be carried forward indefinitely, but the deductibility of NOLs generated in taxable years beginning after December 31, 2017 is limited. It is uncertain if and to what extent various states will conform to the Tax Act. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, 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 NOL carryforwards and other pre-change tax attributes (such as research tax credits) to offset its post-change taxable income or taxes may be limited. We completed a study through December 31, 2016 to determine whether any Section 382 limitations exist and, as a result of this study and our analysis of subsequent ownership changes, we do not believe that any Section 382 limitations exist through March 31, 2019, though we have not yet conducted an in-depth analysis since the last study. Section 382 of the Code is an extremely complex provision with respect to which there are many uncertainties, however, and we have not established whether the IRS agrees with our determination. In any event, our 2016 and 2017 equity offerings, our past and potential future issuances of common stock pursuant to the ATM Sales Agreement, other future equity offerings and/or 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. In addition, the Merger, if consummated, will constitute an ownership change (within the meaning Section 382 of the Code) which could eliminate or otherwise substantially limit our federal and state NOL carryforwards. Therefore, utilization of a portion of our domestic NOL and tax credit carryforwards will likely 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 15% or more 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 15% or more 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.

Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders’ ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf, for any action asserting a claim of breach of a fiduciary duty owed by any of our current or former directors, officers, other employees or stockholders to us or to our stockholders, for any action asserting a claim arising pursuant to any provision of the General Corporation Law of the State of Delaware, or the DGCL, our restated certificate of incorporation or our amended and restated bylaws or as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware, or for any action asserting a claim governed by the internal affairs doctrine. The choice of forum provision may limit a stockholder’s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. If a court were to find the choice of forum provision contained in our amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our financial condition.

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 March 31, 2019, the average daily trading volume of our common stock on the Nasdaq was only 909,508 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-prevailing market

price of our common stock. As of March 31, 2019, we had 24,051,844 shares of common stock outstanding. In addition, as a result of the low trading volume of our common stock, which was exacerbated by the 2016 Reverse Stock Split, 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 addition, due to the limitations of our market, the volatility in the market price of our common stock and our currently-depressed stock price, stockholders may face difficulties in selling shares at attractive prices when they want to sell.

In September 2017, we completed a private placement of 5.5 million shares of our common stock and warrants to purchase 3.3 million shares of our common stock. In November 2014, we completed a private placement of 6.4 million shares of our common stock and warrants to purchase 6.4 million shares of our common stock (as adjusted to give effect to the 2016 Reverse Stock Split). Similarly, in March 2014 we completed a private placement of 1.2 million shares of our common stock and warrants to purchase 1.0 million shares of our common stock (as adjusted to give effect to the 2016 Reverse Stock Split). Pursuant to the terms of the registration rights or securities purchase agreements we entered into in connection with these private placements, we have filed registration statements under the Securities Act registering the resale of an aggregate of approximately 23.8 million shares of common stock that we issued to, or are issuable upon the exercise of warrants that we issued to, the investors in these private placements, which investors include our largest stockholders. 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 785,000 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 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.

The comprehensive U.S. tax reform bill passed in 2017 could adversely affect our business and financial condition.*

On December 22, 2017, President Trump signed the Tax Act into law, which significantly revised the Code. The Tax Act, among other things, contained significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted taxable income (except for certain small businesses), limitation of the deduction for NOLs generated in tax years beginning after December 31, 2017 to 80% of current year taxable income and elimination of carrybacks of NOLs arising in taxable years ending after December 31, 2017, one-time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits (including reducing the business tax credit for certain clinical testing expenses incurred in the testing of certain drugs for rare diseases or conditions). Notwithstanding the reduction in the corporate income tax rate, the overall impact of the Tax Act could adversely affect us. In addition, it is uncertain if and to what extent various states will conform to the Tax Act. The impact of the Tax Act on holders of our common stock is also uncertain and could be adverse. We urge our stockholders to consult with their legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our common stock.

ITEM 5. OTHER INFORMATION

In connection with the Merger, we are holding a special meeting of our stockholders, or the Special Meeting, in order to seek the stockholder approvals necessary to complete the Merger with Oncternal and related matters. The Special Meeting will be held at 9:00 a.m., Central time, on June 5, 2019 at 17 W Pontotoc Ave., Suite 100, Memphis, Tennessee 38103, unless postponed or adjourned to a later date. As a result of the calling of the Special Meeting and the Merger, our next annual meeting of stockholders will be held more than 30 days from the anniversary of the date of our 2018 annual meeting of stockholders. Following the anticipated closing of the Merger, the combined company will inform stockholders of the date of the next annual meeting of stockholders and of the relevant deadlines for submitting stockholder proposals and related matters.

ITEM 6. EXHIBITS

The following exhibits are filed or incorporated by reference as part of this Quarterly Report on Form 10-Q:

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
2.2a**	Agreement and Plan of Merger and Reorganization, dated March 6, 2019, by and among the Registrant, Oncternal Therapeutics, Inc. and Grizzly Merger Sub, Inc	8-K	000-50549	2.1	03/07/2019
2.2b**	Amendment No. 1 to Agreement and Plan of Merger and Reorganization, dated April 30, 2019, by and among Registrant, Oncternal Therapeutics, Inc. and Grizzly Merger Sub, Inc	8-K	000-50549	2.1	04/30/2019
2.3**	Form of CVR Agreement by and between the Registrant, Marc S. Hanover, as the Holders' Representative, and Computershare Investor Services, as Rights Agent.	8-K	000-50549	2.2	04/30/2019
2.4	Form of GTx Voting Agreement, dated March 6, 2019, by and between Oncternal Therapeutics, Inc., the Registrant and each of the parties named in each agreement therein	8-K	000-50549	2.3	03/07/2019
2.5	Form of Oncternal Voting Agreement, dated March 6, 2019, by and between the Registrant, Oncternal Therapeutics, Inc. and each of the parties named in each agreement therein	8-K	000-50549	2.4	03/07/2019
2.6	Form of Lock-Up Agreement, dated March 6, 2019, by each of the parties named in each agreement therein	8-K	000-50549	2.5	03/07/2019
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	Certificate of Amendment of Restated Certificate of Incorporation of GTx, Inc.	8-K	000-50549	3.1	12/05/2016
3.6	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, 3.5 and 3.6	—	—	—	—
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 on November 14, 2014 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
4.9	Form of Warrant Amendment Agreement entered into effective as of March 25, 2016 between Registrant and each holder of a Common Stock Warrant originally issued on November 14, 2014	10-Q	000-50549	4.9	05/10/2016
4.10	Form of Common Stock Warrant, issued by Registrant pursuant to the Purchase Agreement, dated September 25, 2017, between Registrant and the purchasers identified in Exhibit A therein	S-3	333-221040	4.9	10/20/2017
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	—	—	—	—
101.LAB+	XBRL Taxonomy Extension Labels Linkbase Document	—	—	—	—
101.PRE+	XBRL Taxonomy Extension Presentation Linkbase Document	—	—	—	—

** Schedules and exhibits have been omitted pursuant to Item 601(b)(2) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the SEC upon request.

+ 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.

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: May 10, 2019

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

Date: May 10, 2019

By: /s/ Jason T. Shackelford
Jason T. Shackelford, Vice President, Finance and Accounting and
Principal Financial and Accounting Officer
(Principal Financial and Accounting Officer)

EXHIBIT 31.1

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: May 10, 2019

/s/ Marc S. Hanover
Marc S. Hanover
Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

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: May 10, 2019

/s/ Jason T. Shackelford
Jason T. Shackelford
Vice President, Finance and Accounting
and Principal Financial and Accounting Officer
(Principal Financial and Accounting Officer)

EXHIBIT 32.1

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 March 31, 2019, 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: May 10, 2019

/s/ Marc S. Hanover
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.

EXHIBIT 32.2

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 March 31, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Jason T. Shackelford, Principal Financial and Accounting 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: May 10, 2019

/s/ Jason T. Shackelford
Jason T. Shackelford
Vice President, Finance and Accounting
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.