UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2018

☐ **TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE EXCHANGE ACT**

For the transition period from _____ to _____

Commission file number: 001-38244

GENPREX, INC.

(Exact name of registrant as specified in its charter)

Delaware	**90 - 0772347**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)
1701 Trinity Street, Suite 3.322, Austin, TX	**78705**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(512) 370-4081**

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

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

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☐ (Do not check if a smaller reporting company)	Smaller reporting company	☒
Emerging growth company	☒		

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. ☒

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

As of May 15, 2018, the registrant had 13,896,926 shares of voting common stock, par value $0.001 per share, outstanding.

GENPREX, INC.
TABLE OF CONTENTS

PART I - FINANCIAL INFORMATION

Item 1. Financial Statements.

Genprex, Inc.

Condensed Balance Sheets (unaudited)

	March 31, 2018	December 31, 2017
Assets		
Current assets:		
Cash	$ 24,485	$ 161,251
Accounts receivable	838	8,844
Prepaid expenses and other	33,074	23,479
Total current assets	58,397	193,574
Property and equipment, net	8,326	7,804
Other assets:		
Deferred offering costs	1,012,106	759,591
Intellectual property, net	307,552	298,569
Total other assets	1,319,658	1,058,160
Total assets	$ 1,386,381	$ 1,259,538
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 1,149,008	$ 629,074
Notes payable - related parties	279,288	201,890
Total current liabilities	1,428,296	830,964
Investment unit	—	—
Commitments and contingencies	—	—
Stockholders' equity:		
Common stock $0.001 par value: 200,000,000 shares authorized; 11,755,004 and 11,721,584 shares issued and outstanding, respectively	11,755	11,721
Additional paid-in capital	18,092,682	17,869,205
Accumulated deficit	(18,146,352)	(17,452,352)
Total stockholders' equity (deficit)	(41,915)	428,574
Total liabilities and stockholders' equity	$ 1,386,381	$ 1,259,538

See accompanying notes to the unaudited condensed financial statements

Genprex, Inc.

Condensed Statements of Operations (unaudited)

	Three Months Ended March 31,	
	2018	**2017**
Revenues	$ —	$ —
Cost and expenses:		
Depreciation	947	597
Research and development	51,621	68,364
General and administrative	634,063	682,342
Total costs and expenses	686,631	751,303
Operating loss	(686,631)	(751,303)
Interest income	28	—
Interest expense	(7,398)	—
Net loss	$ (694,001)	$ (751,303)
Net loss per share—basic and diluted	$ (0.06)	$ (0.07)
Weighted average number of common shares— basic and diluted	11,738,294	11,380,881

See accompanying notes to the unaudited condensed financial statements.

Genprex, Inc.

Condensed Statements of Cash Flows (unaudited)

	Three Months Ended March 31,	
	2018	**2017**
Cash flows from operating activities:		
Net loss	$ (694,001)	$ (751,303)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	947	597
Share based compensation	223,512	233,447
Changes in operating assets and liabilities:		
Accounts receivable	8,006	8,182
Prepaid expenses and other	(9,595)	4,286
Deferred offering costs	(252,515)	(28,368)
Accounts payable and accrued expenses	519,934	(116,150)
Net cash used in operating activities	(203,712)	(649,309)
Cash flows from investing activities:		
Additions to property and equipment	(1,469)	(2,751)
Additions to intellectual property	(8,983)	(20,227)
Net cash used in investing activities	(10,452)	(22,978)
Cash flows from financing activities:		
Proceeds from notes payable - related parties	77,398	—
Net cash provided by financing activities	77,398	—
Net (decrease) in cash	(136,766)	(672,287)
Cash, beginning of period	161,251	1,602,295
Cash, end of period	$ 24,485	$ 930,008

See accompanying notes to the unaudited condensed financial statements.

Note 1—Description of Business and Basis of Presentation

Genprex, Inc. ("we" or "the Company"), is a clinical stage gene therapy company developing a new approach to treating cancer, based upon a novel proprietary technology platform, including our initial product candidate, Oncoprex immunogene therapy for non-small cell lung cancer (NSCLC). Our platform technologies are designed to administer cancer fighting genes by encapsulating them into nanoscale hollow spheres called nanovesicles, which are then administered intravenously and taken up by tumor cells where they express proteins that are missing or found in low quantities. Oncoprex has a multimodal mechanism of action whereby it interrupts cell signaling pathways that cause replication and proliferation of cancer cells, re-establishes pathways for apoptosis, or programmed cell death, in cancer cells, and modulates the immune response against cancer cells. Oncoprex has also been shown to block mechanisms that create drug resistance.

We are subject to all the risks inherent in a start-up company in the biopharmaceutical industry. The biopharmaceutical industry is subject to rapid and technological change. We have numerous competitors, including major pharmaceutical and chemical companies, specialized biotechnology firms, universities and other research institutions. These competitors may succeed in developing technologies and products that are more effective than any that are being developed by us or that would render our technology and products obsolete and noncompetitive. Many of these competitors have substantially greater financial and technical resources than us. In addition, many of our competitors have significantly greater experience than us in pre-clinical testing and human clinical trials of new or improved pharmaceutical products and in obtaining FDA and other regulatory approvals on products for use in health care.

Capital Requirements, Liquidity and Going Concern Considerations

Our condensed financial statements are prepared using the generally accepted accounting principles applicable to a going concern, which contemplates the realization of assets and liquidation of liabilities in the normal course of business. However, as shown in the accompanying condensed financial statements, we have sustained substantial losses from operations since inception and have no current source of revenue. In addition, we have used, rather than provided, cash in our operations. We expect to continue to incur significant expenditures to further clinical trials for the commercial development of our patents.

Management recognizes that we must obtain additional resources to successfully commercialize our intellectual property. To date, we have received funding in the form of equity and debt, and we plan to seek additional funding in the future. However, no assurances can be given that we will be successful in raising additional capital. If we are not able to timely and successfully raise additional capital, the timing of our clinical trials, financial condition and results of operations will continue to be materially affected. These condensed financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts and classification of liabilities.

Note 2—Summary of Significant Accounting Policies

The Company's condensed financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). Accordingly, they do not include all the information and footnotes required by generally accepted accounting principles for complete financial statements. In our opinion the unaudited condensed financial statements include all adjustments (consisting of normal recurring accruals) necessary to make the unaudited condensed financial statements not misleading. Operating results for the three months ended March 31, 2018 are not necessarily indicative of the final results that may be expected for the year ending December 31, 2018. For more complete financial information, these unaudited condensed financial statements should be read in conjunction with the audited financial statements for the year ended December 31, 2017 filed with the SEC. A summary of our significant accounting policies consistently applied in the preparation of the accompanying condensed financial statements follows.

Capital Stock

In connection with the Company's completed IPO (see Subsequent Events note) in April 2018, all of the Company's Preferred Stock and Non-Voting Common Stock were converted into shares of the Company's Common Stock. The Company's Common Stock was then forward-split at a ratio of 6.6841954-to-1. Furthermore, prior to the closing of the IPO, the Company's Certificate of Incorporation was amended and restated to provide the Company with the authority to issue up to 210,000,000 shares of stock consisting of 200,000,000 shares of Common Stock at a par value of $0.001 per share and 10,000,000 shares of Preferred Stock at a par value of $0.001 per share.

Use of Estimates

The preparation of our condensed financial statements in conformity with GAAP requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the condensed financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

Cash

We consider all highly liquid short-term investments with an initial maturity of three months or less to be cash equivalents. Any amounts of cash in financial institutions which exceed FDIC insured limits expose us to cash concentration risk. We have no cash equivalents, and had $0 in excess of FDIC insured limits of $250,000 at March 31, 2018 and December 31, 2017 respectively.

Fair Value of Financial Instruments

The carrying amounts reported in the balance sheet for cash, accounts receivable, accounts payable and accrued expenses approximate fair value because of the immediate or short-term maturity of these financial instruments.

ASC 820, Fair Value Measurements and Disclosures, defines fair value, provides a consistent framework for measuring fair value under GAAP and expands fair value financial statement disclosure requirements. ASC 820's valuation techniques are based on observable and unobservable inputs. Observable inputs reflect readily obtainable data from independent sources, while unobservable inputs reflect our market assumptions. ASC 820 classifies these inputs into the following hierarchy:

Level 1:Quoted prices for identical instruments in active markets

Level 2: Quoted prices for similar instruments in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations whose inputs are observable or whose significant value drivers are observable

Level 3:Instruments with primarily unobservable value drivers.

Property and Equipment

Furniture and equipment are stated at cost. Depreciation is calculated using the straight line method over the estimated useful lives of the assets, which range from three to five years. Routine maintenance and repairs are charged to expense as incurred and major renovations or improvements are capitalized.

Research and Development Materials Costs

Research and development expenditures are comprised of costs incurred to conduct research and development activities. These include payments to collaborative research partners, including wages and associated employee benefits, facilities and overhead costs. These expenditures relate to Phase I and II clinical trials and are expensed as incurred. Purchased materials to be used in future research are capitalized and included in prepaid expenses.

Awards

In 2010, we were awarded $4.5 million from the State of Texas Emerging Technology Fund ("TETF"). The award was received in two tranches of $2.25 million during 2010 and 2011. The award proceeds were used for the development and future commercialization of our nanomolecular therapy product for the treatment of cancer. In consideration for the award, we provided the TETF with an "Investment Unit", consisting of (i) a Promissory Note ("Note") and (ii) a right to purchase our equity shares ("Warrant"). The funds received for this award were assigned to the Investment Unit, and classified separately from equity as "mezzanine" in the balance sheet.

In 2010, we also were awarded approximately $244,500 from the U.S. Treasury Department for our QTDP Program Nanoparticle Therapy for Lung Cancer. The award was received during 2011 for our historical activities, and required no prospective expenditures. We accounted for these funds received as revenue at that time.

Intellectual Property

Intellectual property consists of external legal and related costs associated with patents and other proprietary technology acquired, licensed, or maintained by us that we believe contribute to a probable economic benefit toward such patents and activities. These legal costs incurred in connection with the patent applications and patent maintenance are capitalized. Intellectual property is stated at cost, to be amortized on a straight-line basis over the estimated useful lives of the assets.

Accounting for Stock-Based Compensation

We use the fair value-based method of accounting for stock-based compensation for options granted to employees, independent consultants and contractors. We measure options granted at fair value determined as of the grant date, and recognize the expense over the periods in which the related services are rendered based on the terms and conditions of the award. Generally, where the award only has a service condition, the requisite service period is the same as the vesting period.

Financial Instruments

We have elected the Fair Value Option to account for the Investment Unit at fair value as a combined hybrid financial instrument containing a Warrant and a Note (see Investment Unit Note). Prior to its exercise, the Warrant component was not classified within equity, as the exercise price of the warrants was affected by the market price of our stock in a future qualifying financing transaction and was not considered to be indexed to our own stock. The Note is not classified within liabilities, as our management can determine the timing of the repayment obligation, if any. As a result, the Warrant and Note that comprised the Investment Unit were aggregated and classified within the mezzanine section of the balance sheet.

Due to the contingent terms of the financial instruments, changes in the fair value of the Investment Unit were calculated and realized in earnings. There were no changes in the fair value of the Investment Unit at March 31, 2018.

Long-Lived Assets

We review long-lived assets and certain identifiable intangibles held and used for possible impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. In evaluating the fair value and future benefits of its intangible assets, management performs an analysis of the anticipated undiscounted future net cash flow of the individual assets over the remaining amortization period. We recognize an impairment loss if the carrying value of the asset exceeds the expected future cash flows. During the three months ended March 31, 2018 and the year ended December 31, 2017, there were no deemed impairments of our long-lived assets.

Recent Accounting Developments

Accounting pronouncements issued but not effective until after March 31, 2018 are not expected to have a significant effect on our financial condition, results of operations, or cash flows.

Note 3—Intellectual Property

We have exclusive license agreements on thirty (30) issued and two (2) pending patents for technologies developed by researchers at the National Cancer Institute, The University of Texas MD Anderson Cancer Center, and The University of Texas Southwestern Medical Center. These patents comprise various therapeutic, diagnostic, technical and processing claims. These license rights will be amortized on a straight-line basis over the estimated period of useful lives of the underlying patents or the license agreements.

Note 4—Investment Unit

The Texas Emerging Technology Fund (“TETF”) was created as an incentive for economic development to the Texas economy by providing financial support that leverages private investment for the creation of high-quality technology jobs in Texas. The award received required us to comply with certain performance conditions to ensure the monies the Company received were used for development activities in the state of Texas, and that we maintained our corporate nexus in Texas. Further, in connection with the award, the Company issued an Investment Unit to the TETF. As further described below, the Investment Unit consists of a Promissory Note and a Right to Purchase.

Promissory Note

The Promissory Note is an obligation to repay the $4.5 million principal amount, with interest accrued at 8% per annum, but only if an event of default occurs prior to August 13, 2020. If no event of default occurs prior to August 13, 2020, the Promissory Note and all related interest will be cancelled.

Consistent with the stated objectives of the TETF, an event of default that would trigger the repayment obligation under the Promissory Note is our failure to maintain our principal place of business or our principal executive offices headquartered in the State of Texas (referred to as the "Residency Requirement") until August 13, 2020.

Warrant

The Warrant is an obligation to issue (a Right to purchase by the TETF) shares of the same class of stock to be issued in a "First Qualifying Financing Transaction," at 80% of the per share transaction value (effectively a 20% discount). Alternatively, the TETF could exercise its right to purchase at any time prior to the occurrence of a First Qualifying Financial Transaction for $0.001 per share.

The Warrant included a provision that required changes in the strike price, driven by the pricing of the "First Qualifying Financing Transaction." As a result, the Warrants embedded in the Investment Unit were accounted for as a derivative financial instrument and classified outside from equity under ASC 815-40-15 as the settlement adjustment from the future transaction did not permit for the strike price to be considered fixed.

On March 12, 2014, the TETF exercised its Right to Purchase for $0.001 per share, and we issued to the TETF an aggregate of 184,797 shares of our Series B preferred stock. These shares were subsequently forward-split and converted to 1,235,219 shares of Common Stock in connection with our IPO.

Accounting for the Investment Unit

We accounted for the Investment Unit as a hybrid financial instrument under FASB Statement 155, and measured the Investment Unit at the amount of proceeds received from the TETF award. The First Qualifying Financial Transaction occurred during December 2013, resulting in an adjustment to the fair value of the Investment Unit in the amount of approximately $2.5 million. The TETF exercised the Warrant for $0.001 per share. We received notice of purchase from the TETF during March 2014, and issued 184,797 shares of series B Preferred Stock, which has since been converted to 1,235,219 shares of Common Stock upon completion of the Company's IPO. Upon exercise by the TETF of the Warrant, the remaining component within the Investment Unit was the Promissory Note. The Investment Unit was valued at zero, because our obligation to repay the Promissory Note arises from an event of default (a failure to maintain the Texas Residency Requirement), which is an event which rests entirely within our control.

Note 5—Equity

Stock Issuances

During the quarter ended March 31, 2018, we issued (i) 33,420 shares of Common Stock, taking into account the forward-split ratio from the Company's IPO, for service provided to us, valued at $176,650.

During the year ended December 31, 2017, we issued (i) 207,206 shares of Common Stock, taking into account the forward-split ratio from the Company's IPO, for service provided to us, valued at $1,095,230 and we issued (ii) 22,473 shares of Series G Preferred Stock, which has since been converted to Common Stock and forward-split representing 150,211 shares of Common Stock, for cash of $793,971.

Preferred Stock

In connection with the Company's IPO, all Preferred Stock included in Series A through Series G, totaling 1,394,953 shares at December 31, 2017, were converted to 9,324,177 shares of Common Stock as a result of the forward-split (See Capital Stock Note). Upon the completion of the IPO, the Company is authorized to issue 10,000,000 shares of Preferred Stock at a par value of $0.001 per share, none of which is outstanding as of March 31, 2018.

Common Stock

Upon the completion of the IPO, all of the Company's Non-Voting Common Stock automatically converted to into Voting Common Stock on a one-to-one basis. Immediately following the completion of the IPO, the Company is authorized to issue 200,000,000 shares of Common Stock at a par value of $0.001 per share, which includes 200,000,000 shares of Voting Common Stock at a par value of $0.001.

Common Stock Purchase Warrants

Common Stock purchase warrant activity for the period and year ended March 31, 2018 and December 31, 2017 respectively are as follows:

	Number of Warrants	Weighted Avg. Exercise Price
Outstanding at January 1, 2017	748,060	$ 5.17
Issued	—	—
Cancelled or expired	—	—
Exercised	—	—
Outstanding at December 31, 2017	748,060	$ 5.17
Issued	—	—
Cancelled or expired	—	—
Exercised	—	—
Outstanding at March 31, 2018	748,060	$ 5.17

Stock Options

We have outstanding stock options to purchase 2,628,749 shares of Common Stock, taking into account the forward-split ratio from the Company's IPO, that have been granted to various employees, vendors and independent contractors. These options vest over periods ranging from twelve (12) to forty-eight (48) months, are exercisable for a period of ten years, and enable the holders to purchase shares of our Common Stock at exercise prices ranging from $0.001 - $5.286. The per-share fair values of these options range from $0.001 to $2.68, based on Black-Scholes-Merton pricing models with the following assumptions. The weighted average remaining contractual term for the outstanding options at March 31, 2018 and December 31, 2017 is 7.01 and 7.26 years, respectively.

There was no stock option activity for the three months ended March 31, 2018. Stock option activity for the quarter and year ended March 31, 2018 and December 31, 2017, respectively, is as follows:

	Number of Shares	Weighted Avg. Exercise Price
Outstanding at January 1, 2017	2,628,749	$ 1.31
Options granted	—	—
Options exercised	—	—
Options expired	—	—
Outstanding at December 31, 2017	2,628,749	$ 1.31
Options granted	—	—
Options exercised	—	—
Options expired	—	—
Outstanding at March 31, 2018	2,628,749	$ 1.31

Note 6—Related Party Transactions

Domecq Sebastian, LLC

Domecq-Sebastian LLC ("Domecq") is an entity affiliated with David Nance, a former director and officer who is now deceased. During December 2017, we entered into a promissory note with Domecq for a total amount of $200,000 that carries a 15% interest rate and is due and payable on or before March 31, 2018. The note carries a 18% default interest on amounts paid after the maturity date. This note was subsequently repaid in full in April 2018.

Introgen Research Institute

Introgen Research Institute ("IRI") is a Texas-based technology company, currently affiliated with Rodney Varner, our CEO. In April 2009, prior to Mr. Varner becoming an officer and director of our Company in August 2012, we entered into an Assignment and Collaboration Agreement with IRI, providing us with the exclusive right to commercialize a portfolio of intellectual property. This agreement was amended in 2011 to include additional sublicensing of additional intellectual property made available to IRI from the University of Texas MD Anderson Cancer Center ("UTMDACC").

Rodney Varner

Rodney Varner is the Company's Chief Executive Officer. On March 28, 2018, we entered into a promissory note with Rodney Varner, Trustee, for a total amount of $45,000 that carries a 0% interest rate and is due and payable on or the earlier of (i) five days after funding of the Company's initial public offering, or (ii) April 30, 2018, the maturity date. If paid after the maturity date, the note carries a 10% interest rate. This note was paid in full prior to the maturity date in April 2018.

Viet Ly

Viet Ly manages several investment funds that have provided the Company with investment funds since 2013. On March 9, 2018, we entered into a promissory note with Viet Ly for a total amount of $25,000 that carries a 0% interest rate and is due and payable on or before June 9, 2018, the maturity date. If paid after the maturity date, the note carries a 10% interest rate. This note was paid in full prior to the maturity date in April 2018.

Note 7—Commitments and Contingencies

Commitments

We have entered into a clinical trial agreement with the University of Texas MD Anderson Cancer Center to administer a Phase I/II clinical trial, combining FUS1-nanoparticles and Erlotinib in Stage IV lung cancer patients. The trial is expected to run through early 2019 with a projected total cost of approximately $2 million. Payments are due and payable when invoiced throughout the clinical trial period. The agreement may be terminated at any time.

In 2009, we agreed to assume certain contractual and other obligations of IRI in consideration for the sublicense rights, expertise, and assistance associated with the assignment of certain technologies and intellectual property. We also agreed to pay royalties of one percent (1%) on sales of resulting Licensed Products, for a period of 21 years following the termination of the last of the MD Anderson License Agreement and Sublicense Agreement, to IRI and we assumed patent prosecution costs and an annual minimum royalty of $20,000 payable to the National Institutes of Health ("NIH").

Our $191,393 payment obligation to the National Institutes of Health ("NIH") represented a current obligation, of which $15,393 of 2016 patent prosecution costs were paid in the fourth quarter of 2016 and $176,000 was included in Accounts Payable at December 31, 2016 (consisting of accrued annual royalties of $140,000 and patent costs of $36,000). During the first quarter of 2017, we modified the terms of our accrued royalty obligation to NIH. Under the modified agreement, NIH agreed to extinguish $120,000 of the accrued royalties payable to them in consideration for payment by us of (i) accrued patent costs of $36,000, (ii) a royalty payment of $20,000, and (iii) a contingent payment of $240,000, increasing at $20,000 per year starting in 2018, to be paid upon our receipt of FDA approval. The payments for the patent costs of $36,000 and royalties of $20,000 were paid during the second quarter of 2017.

As a result of our modified agreement with the NIH, we have recognized the exchange of the $120,000 fixed obligation for the $240,000 contingent obligation as a $120,000 reduction to intellectual property expense (classified within General and Administrative Expense) during the first quarter of 2017. The $240,000 contingent obligation (and related expense) will be recognized when we obtain regulatory approval (the event that triggers the payment obligation).

Contingencies

From time to time we may become subject to threatened and/or asserted claims arising in the ordinary course of our business. Management is not aware of any matters, either individually or in the aggregate, that are reasonably likely to have a material impact on our Company's financial condition, results of operations or liquidity.

During October 2017, we received an informal demand from a former financial advisor, claiming that it is entitled to a warrant to purchase shares of common stock equal to three (3) percent of our outstanding shares at December 1, 2015. We believe this asserted claim lacks merit, and we intend to defend the claim vigorously.

Note 8—Income Taxes

The provision for income taxes differs from the amount computed by applying the statutory federal income tax rate to income before provision for income taxes. The sources and tax effects of the differences are as follows:

Income tax provisions at the federal statutory rate	34%
Effect of operating losses	-34%
	0%

At December 31, 2017, we have a net operating loss carryforward of approximately $8.0 million for Federal and state purposes. This loss will be available to offset future taxable income. If not used, this carryforward will begin to expire in 2029. The deferred tax asset relating to the operating loss carryforward has been fully reserved at March 31, 2018 and December 31, 2017. The principal differences between the operating loss for income tax purposes and reporting purposes are shares issued for services and share-based compensation and a temporary difference in depreciation expense.

Note 9—Subsequent Events

Initial Public Offering

On April 3, 2018, the Company completed its IPO, whereby the Company sold an aggregate of 1,280,000 shares of its common stock, at $5.00 per share, resulting in estimated net proceeds of $5,025,000 after underwriting discounts, commissions and estimated offering expenses of $895,000. Additionally, the underwriters have been issued warrants to purchase common stock equal to 3% of the securities sold in the IPO, or 38,400 shares of Common Stock.

2018 Equity Incentive Plan

The Company's board of directors and stockholders has approved and adopted the Company's 2018 Equity Incentive Plan ("2018 Plan"), which became effective on the completion of the IPO on April 3, 2018. The 2018 Plan provides for the grant of incentive stock options ("ISOs"), nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance-based stock awards, other forms of equity compensation and performance cash awards. ISOs may be granted only to employees. All other awards may be granted to employees, including officers, and to the Company's non-employee directors and consultants, and affiliates.

A total of 4,160,000 shares of Common Stock are available under the 2018 Plan, which includes 554,963 shares of Common Stock reserved for issuance under our 2009 Equity Incentive Plan that were added to 2018 Plan. No further grants will be made under the 2009 Plan and any shares subject to outstanding stock options under the 2009 Plan that would otherwise be returned to the 2009 Plan will instead be added to the shares initially reserved under the 2018 Plan.

In addition, the number of shares of common stock reserved for issuance under the 2018 Plan will automatically increase on January 1 of each year, beginning on January 1, 2019 by 5% of the total number of shares of the Company's Common Stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by the administrator of the 2018 Plan.

2018 Employee Stock Purchase Plan

The Company's board of directors and stockholders has approved and adopted the Company's 2018 Employee Stock Purchase Plan ("ESPP"), which became effective on the completion of the IPO on April 3, 2018. The ESPP authorizes the issuance of 208,500 shares of the Company's common stock pursuant to purchase rights granted to our eligible employees. The number of shares of common stock reserved for issuance will automatically increase on January 1 of each calendar year, from January 1, 2019 by the lesser of 2% of the total number of shares of our common stock outstanding on December 31 of the preceding calendar year or a number determined by the administrator of the ESPP.

Leases

On April 16, 2018, the Company executed a service agreement with CIC Innovation Communities, LLC, to establish and lease offices at the Cambridge Innovation Center at 1 Broadway, Floor 14, Cambridge, MA 02142. The Company does not have a long-term agreement in place to occupy this location, but rather occupies on a month-to-month basis.

On April 16, 2018, the Company also executed a space utilization agreement with the Board of Regents of the University of Texas System to establish and lease offices at the Dell Medical School located 1701 Trinity Street, Suite 3.322, Austin, Texas 78705. The Company pays $4,000 per month to occupy this location and the lease is effective until October 31, 2018.

Private Investment

On May 9, 2018, the Company completed a private placement, whereby the Company sold to investors an aggregate of 828,500 shares of its common stock at $12.07 per share and warrants to purchase up to 621,376 shares of the Company's common stock with an initial exercise price equal to $15.62 per share. The per share price and warrant exercise price will automatically be adjusted lower, if applicable, based on the volume weighted average daily prices on the three days after the registration statement is declared effective and the Company's shareholders approve the transaction. In no event will the purchase price or warrant exercise price be less than $4.25 per share. The Company received net proceeds of $9,250,000 after commissions and expenses. Maxim Group LLC served as the placement agent.

Warrants

The Company plans to issue warrants to purchase shares of common stock at no less than $5.00 per share to key service providers and consultants in conjunction with past and future services provided to the Company. The Company plans to issue warrants to purchase (i) 425,000 shares of common stock to Cancer Revolution, LLC, (ii) 225,000 shares of common stock to Cancer Biotech, LLC, (iii) 144,352 shares of common stock to Inception Capital Management, LLC, and (iv) 50,000 shares of common stock to World Wide Holdings, LLC.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed financial statements and related notes included in this Quarterly Report on Form 10-Q and the audited financial statements and notes thereto as of and for the year ended December 31, 2017 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on form 10-K filed with the Securities and Exchange Commission, or SEC, on April 17, 2018. Unless the context requires otherwise, references in this Quarterly Report on Form 10-Q to "we," "us," and "our" refer to Genprex, Inc.

Forward-Looking Statements

This Management's Discussion and Analysis of Financial Condition and Results of Operations ("MD&A") contains certain forward-looking statements. Historical results may not indicate future performance. Our forward-looking statements reflect our current views about future events, are based on assumptions and are subject to known and unknown risks and uncertainties that could cause actual results to differ materially from those contemplated by these statements. Factors that may cause differences between actual results and those contemplated by forward- looking statements include, but are not limited to, those discussed in "Risk Factors" as set forth in Part II, Item 1A, "Risk Factors" in this Quarterly Report on Form 10-Q and in our other filings with the SEC. We undertake no obligation to publicly update or revise any forward-looking statements, including any changes that might result from any facts, events, or circumstances after the date hereof that may bear upon forward- looking statements. Furthermore, we cannot guarantee future results, events, levels of activity, performance, or achievements.

Overview

Genprex™ is a clinical stage gene therapy company developing a new approach to treating cancer, based upon a novel proprietary technology platform, including our initial product candidate, Oncoprex immunogene therapy for non-small cell lung cancer (NSCLC). Our platform technologies are designed to administer cancer fighting genes by encapsulating them into nanoscale hollow spheres called nanovesicles, which are then administered intravenously and taken up by tumor cells where they express proteins that are missing or found in low quantities. Oncoprex has a multimodal mechanism of action whereby it interrupts cell signaling pathways that cause replication and proliferation of cancer cells, re-establishes pathways for apoptosis, or programmed cell death, in cancer cells, and modulates the immune response against cancer cells. Oncoprex has also been shown to block mechanisms that create drug resistance.

Researchers at MD Anderson have conducted a Phase I clinical trial and the Phase I portion of a Phase I/II clinical trial and are conducting the Phase II portion of that Phase I/II clinical trial in non-small cell lung cancer, or NSCLC. MD Anderson researchers have collaborated with other researchers to identify other genes, such as those in the 3p21.3 chromosomal region, that may act as tumor suppressors or have other cancer fighting functions. Data from preclinical studies performed by others suggest that product candidates that could be derived from our technology platform could be effective against other types of cancer, including breast, head and neck, renal cell (kidney), and soft tissue cancer, as well as NSCLC. Therefore, our platform technologies may allow delivery of a number of cancer fighting genes, alone or in combination with other cancer therapies, to combat multiple types of cancer.

JOBS Act and Recent Accounting Pronouncements

The JOBS Act, enacted in 2012, provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended, for complying with new or revised accounting standards. In other words, an "emerging growth company" can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

We have implemented all new accounting pronouncements that are in effect and may affect our condensed financial statements and we do not believe that there are any other new accounting pronouncements that have been issued that would have a material impact on our financial position or results of operations.

Critical Accounting Policies and Significant Judgments and Estimates

Our condensed financial statements have been prepared in accordance with generally accepted accounting principles in the United States, or GAAP. 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 condensed financial statements, as well as the reported expenses incurred during the reporting periods. Our estimates are based on our 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.

We believe that the following accounting policies are the most critical to aid in fully understanding and evaluating our reported financial results, and they require our most difficult, subjective or complex judgments, resulting from the need to make estimates about the effect of matters that are inherently uncertain.

Research and Development Costs

We record accrued expenses for costs invoiced from research and development activities conducted, on our behalf, by third-party service providers, which include the conduct of pre-clinical studies and clinical trials and contract manufacturing activities. We record the costs of research and development activities based upon the amount of services provided, and we include these costs in accrued liabilities in the balance sheets and within research and development expense in the statement of operations. These costs are a significant component of our research and development expenses.

We estimate the amount of work completed through discussions with internal personnel and external service providers as to the progress or stage of completion of the services and the agreed-upon fee to be paid for such services. We make significant judgments and estimates in determining the accrued balance in each reporting period. As actual costs become known, we adjust our accrued estimates. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed, the number of patients enrolled and the rate of patient enrollment may vary from our estimates and could result in us reporting amounts that are too high or too low in any particular period. Our accrued expenses are dependent, in part, upon the receipt of timely and accurate reporting from clinical research organizations and other third-party service providers. To date, there have been no material differences from our accrued expenses to actual expenses.

Income Taxes

Deferred tax assets or liabilities are recorded for temporary differences between financial statement and tax basis of assets and liabilities, using enacted rates in effect for the year in which the differences are expected to reverse. A valuation allowance is recorded if it is more likely than not that a deferred tax asset will not be realized. We have provided a full valuation allowance on our deferred tax assets, which primarily consist of cumulative net operating losses from April 1, 2009 (inception) to March 31, 2018. Due to our history of operating losses since inception and losses expected to be incurred in the foreseeable future, a full valuation allowance was considered necessary.

Impairment of Long-Lived Assets

Management reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount may not be realizable or at a minimum annually during the fourth quarter of the year. If an evaluation is required, the estimated future undiscounted cash flows associated with the asset are compared to the asset's carrying value to determine if an impairment of such asset is necessary. The effect of any impairment would be to expense the difference between the fair value of such asset and its carrying value.

Components of our Results of Operations and Financial Condition

Operating expenses

We classify our operating expenses into three categories: research and development, general and administrative and depreciation.

Research and development. Research and development expenses consist primarily of:

- costs incurred to conduct research, such as the discovery and development of our current and potential product candidates;
- costs related to production of clinical supplies, including fees paid to contract manufacturers;
- fees paid to clinical consultants, clinical trial sites and vendors, including clinical research organizations in conjunction with implementing and monitoring our clinical trials and acquiring and evaluating clinical trial data, including all related fees, such as patient screening fees, laboratory work and statistical compilation and analysis; and
- costs related to compliance with drug development regulatory requirements.

We recognize all research and development costs as they are incurred. Clinical trial costs, contract manufacturing and other development costs incurred by third parties are expensed as the contracted work is performed.

We expect our research and development expenses to increase in the future as we advance our current and potential product candidates into and through clinical trials and pursue regulatory approval of our current and potential product candidates in the United States and Europe. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming. The actual probability of success for our current and potential product candidates may be affected by a variety of factors including the quality of our current and potential product candidates, early clinical data, investment in our clinical program, competition, manufacturing capability and commercial viability. We may never succeed in achieving regulatory approval for any of our current and potential product candidates. As a result of the uncertainties discussed above, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of our current and potential product candidates.

General and administrative. General and administrative expense consists of personnel related costs, which include salaries, as well as the costs of professional services, such as accounting and legal, facilities, information technology and other administrative expenses. We expect our general and administrative expense to increase follwing the completion of our IPO due to the anticipated growth of our business and related infrastructure as well as accounting, insurance, investor relations and other costs associated with being a public company.

Depreciation. Depreciation expense consists of depreciation on our property and equipment. We depreciate our assets over their estimated useful life. We estimate computer and office equipment to have a 5-year life.

Results of Operations

Comparison of the Three Months Ended March 31, 2018 and 2017

The following summarizes our results of operations for the three months ended March 31, 2018 and 2017.

Research and Development Expense

Research and development expense consists primarily of costs related to the discovery and development of our current and potential product candidates; costs related to production of clinical supplies, including fees paid to contract manufacturers, fees paid to clinical consultants, clinical trial sites and vendors, including clinical research organizations in conjunction with implementing and monitoring our clinical trials and acquiring and evaluating clinical trial data; and costs related to compliance with drug development regulatory requirements.

Research and development expense was $51,621 for the three months ended March 31, 2018 as compared to $68,364 for the three months ended March 31, 2017. This decrease of $16,743 was primarily due to the slowing of our clinical trial, during the first quarter of 2018, while we prepare our data, including pre-clinical data, data from our completed Phase I clinical trial, and interim data from our current Phase I/II clinical trial, for submission to the FDA in anticipation of discussions concerning possible pathways for obtaining marketing approval of Oncoprex for treatment of non-small cell lung cancer.

General and Administrative Expense

General and administrative expense primarily consists of personnel costs, travel, information technology, facilities, and professional service fees. Professional services fees primarily consist of legal, accounting and consulting costs.

General and administrative expense for the three months ended March 31, 2018 was $634,063 as compared to $682,342 for the three months ended March 31, 2017. The $48,279 decrease in general and administrative expense is mostly due to tightening of expenses toward the end of our IPO in preparation for expansion directly following the IPO.

We expect general and administrative expense to increase due to additional legal, accounting, insurance, investor relations and other costs associated with being a public company.

Interest Expense. Interest expense was $7,398 and $0 for each of the three month periods ended March 31, 2018 and 2017. The increase in $7,398 was due to short-term loans acquired by the Company at the end of 2018 and during the first three months of 2018.

Depreciation Expense. Depreciation expense was $947 and $597 for the three months ended March 31, 2018 and 2017, respectively. Depreciation is generated from our fixed assets, which consist only of computer equipment at this time.

Liquidity and Capital Resources

From our inception through March 31, 2018, we have never generated revenue from product sales and have incurred net losses in each year since inception. As of March 31, 2018, we had an accumulated deficit of $18,146,352. We have funded our operations primarily through the sale and issuance of capital stock. During 2017, we sold 22,473 shares of Series G preferred stock at $35.33 per share for a total of $793,971. This stock was subsequently converted to 150,211 shares of common stock at $5.29 per share prior to the closing of our initial public offering.

As of March 31, 2018, we had $24,485 in cash.

We do not expect to generate revenue from product sales unless and until we successfully complete development of, obtain regulatory approval for and begin to commercialize one or more of our current and potential product candidates, which we expect will take a number of years and which is subject to significant uncertainty. Accordingly, we anticipate that we will need to raise additional capital to fund our future operations. Until such time as we can generate substantial revenue from product sales, if ever, we expect to finance our operating activities through a combination of equity offerings and debt financings and we may seek to raise additional capital through strategic collaborations. However, we may be unable to raise additional funds or enter into such arrangements when needed on favorable terms, or at all, which would have a negative impact on our financial condition and could force us to delay, limit, reduce or terminate our development programs or commercialization efforts or grant to others rights to develop or market product candidates that we would otherwise prefer to develop and market ourselves. Failure to receive additional funding could cause us to cease operations, in part or in full. Furthermore, even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital due to favorable market conditions or strategic considerations.

The following table sets forth the primary sources and uses of cash for the three months ended March 31, 2018 and 2017:

	Three Months ended March 31,	
	2018	2017
Net cash used in operating activities	$ (203,712)	$ (649,309)
Net cash used in investing activities	(10,452)	(22,978)
Net cash provided by financing activities	77,398	—
Net increase (decrease) in cash and cash equivalents	$ (136,766)	$ (672,287)

Cash used in operating activities

Net cash used in operating activities was $203,712 and $649,309 for the three months ended March 31, 2018 and 2017, respectively. The $445,597 decrease in net cash used in operating activities was primarily due to an increase in expenses related to our initial public offering in the first quarter of 2018 compared to 2017 and also an increase in payments made to professionals and consultants.

Cash used in investing activities

Net cash used in investing activities was $10,452 and $22,978 for the three months ended March 31, 2018 and 2017, respectively. The decrease of $12,526 was primarily due to increased patent prosecution expenses in 2017.

Cash provided by financing activities

Net cash provided by financing activities was $77,398 and $0 during the three months ended March 31, 2018 and, 2017, respectively. The $77,398 increase in net cash provided by financing activities was due to greater investment provided to the company during the 2018 year than the prior year.

Item 4. Controls and Procedures. Disclosure Controls and Procedures

Disclosure Controls and Procedures

As required by Rules 13a-15(b) and 15d-15(b) of the Exchange Act, our management with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2018. The term "disclosure controls and procedures" as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of March 31, 2018, our Chief Executive Officer and our Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the quarter ended March 31, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations of Disclosure Controls and Internal Control over Financial Reporting

Because of their inherent limitations, our disclosure controls and procedures and our internal control over financial reporting may not prevent material errors or fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. The effectiveness of our disclosure controls and procedures and our internal control over financial reporting is subject to risks, including that the controls may become inadequate because of changes in conditions or that the degree of compliance with our policies or procedures may deteriorate.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings

We are not subject to any litigation.

In October 2017, we received an informal demand from a former financial advisor, claiming that it is entitled to a warrant to purchase shares of common stock equal to three percent of our outstanding shares as of December 1, 2015, with "piggyback" registration rights. We believe this asserted claim lacks merit, and we intend to defend the claim vigorously. We have not reflected any expense or any effect on our capitalization or otherwise related to this demand because it is not yet possible to determine whether any effect is probable or reasonably estimable.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. You should carefully consider each of the following risks, together with all other information set forth in this Quarterly Report on Form 10-Q, including the condensed financial statements and the related notes, before making a decision to purchase, hold or sell our common stock. If any of the following risks actually occurs, our business could be harmed. In that case, the trading price of our common stock could decline, and you may lose all or part of your investment.

Risks Related to Our Financial Position and Need for Additional Capital

We will require substantial additional funding, which may not be available to us on acceptable terms, or at all, and, if not so available, may require us to delay, limit, reduce or cease our operations.

We intend to use the proceeds from the recently completed initial public offering and private placement of our securities to advance Oncoprex through clinical development, as well as for other purposes. Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is expensive. We will require substantial additional future capital in order to complete clinical development and commercialize Oncoprex. If the FDA requires that we perform additional preclinical studies or clinical trials, our expenses will further increase beyond what we currently expect and the anticipated timing of any potential approval of Oncoprex would likely be delayed. Further, there can be no assurance that the costs we will need to incur to obtain regulatory approval of Oncoprex will not increase.

We will continue to require substantial additional capital to continue our clinical development and commercialization activities. Because successful development of our current and potential product candidates is uncertain, we are unable to estimate the actual amount of funding we will require to complete research and development and commercialize our products under development.

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

- the progress, costs, results and timing of our clinical trials for Oncoprex;
- the outcome, costs and timing of seeking and obtaining FDA and any other regulatory approvals;
- the ability of third parties to deliver materials and provide services for us;
- the costs associated with securing and establishing commercialization and manufacturing capabilities;
- market acceptance of our current and potential product candidates;
- the costs of acquiring, licensing or investing in businesses, products, product candidates and technologies;
- our ability to maintain, expand and enforce the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- our need and ability to hire additional management and scientific and medical personnel;
- the effect of competing drug candidates and new product approvals;
- our need to implement additional internal systems and infrastructure, including financial and reporting systems; and
- the economic and other terms, timing of and success of our existing licensing arrangements and any collaboration, licensing or other arrangements into which we may enter in the future.

Some of these factors are outside of our control. We expect that the net proceeds from the recently completed initial public offering and private placement of our securities and our existing cash and marketable securities will be sufficient to fund our current operations through at least the next 18 months. This period could be shortened if there are any significant increases in planned spending on development programs or more rapid progress of development programs than anticipated. We believe that our existing capital resources and the proceeds of our initial public offering and private placement may not be sufficient to enable us to complete the development and commercialization of Oncoprex. Accordingly, we expect that we may need to raise additional funds in the future.

We may seek additional funding through a combination of equity offerings, debt financings, government or other third-party funding, commercialization, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. Additional funding may not be available to us on acceptable terms or at all. In addition, the terms of any financing may adversely affect the holdings or the rights of our stockholders. Any new equity securities we issue could have rights, preferences, and privileges superior to those of holders of our existing capital stock. In addition, the issuance of additional shares by us, or the possibility of such issuance, may cause the market price of our shares to decline. Any debt financing secured by us in the future could involve restrictive covenants relating to our capital-raising activities and other financial and operational matters, which may make it more difficult for us to obtain additional capital and to pursue business opportunities.

If we are unable to obtain funding on a timely basis, we may be required to significantly curtail one or more of our research or development programs, our ability to continue to support our business growth and to respond to business challenges could be significantly limited, and we could be forced to halt operations. Accordingly, our business may fail, in which case you would lose the entire amount of your investment in our common stock.

We also could be required to seek funds through arrangements with collaborative partners or otherwise that may require us to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us.

Our independent registered public accounting firm has indicated that our financial condition raises substantial doubt as to our ability to continue as a going concern.

Our financial statements have been prepared assuming that we will continue to operate as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. Our independent registered public accounting firm included in its audit opinion for the years ended December 31, 2017 and 2016 a statement that there is substantial doubt as to our ability to continue as a going concern as a result of our recurring losses and financial condition on December 31, 2017 and 2016, unless we are able to obtain additional financing, enter into strategic alliances and/or sell assets. The reaction of investors to the inclusion of a going concern statement by our auditors, our current level of cash resources and our potential inability to continue as a going concern may materially adversely affect our share price and our ability to raise new capital or enter into strategic alliances. If we become unable to obtain additional capital and to continue as a going concern, we may have to liquidate our assets and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our financial statements.

We have never been profitable, we have no products approved for commercial sale, and to date we have not generated any revenue from product sales. As a result, our ability to reduce our losses and reach profitability is unproven, and we may never achieve or sustain profitability.

We have never been profitable and do not expect to be profitable in the foreseeable future. We have not yet submitted any drug candidates for approval by regulatory authorities in the United States or elsewhere. From our inception on April 1, 2009, to March 31, 2018, we incurred an accumulated deficit of approximately $18.1 million. We incurred net losses of approximately $0.7 million and approximately $3.3 million for the quarter ended March 31, 2018 and the year ended December 31, 2017, respectively.

To date, we have devoted most of our financial resources to our corporate overhead and research and development, including our preclinical development activities and clinical trials. We have not generated any revenues from product sales. We expect to continue to incur losses for the foreseeable future, and we expect these losses to increase as we continue our development of, and seek regulatory approvals for our current and potential product candidates, prepare for and begin the commercialization of any approved products, and add infrastructure and personnel to support our continuing product development efforts. We anticipate that any such losses could be significant for the next several years. If Oncoprex or any of our other potential product candidates fails in clinical trials or does not gain regulatory approval, or if our drug candidates do not achieve market acceptance, we may never become profitable. As a result of the foregoing, we expect to continue to experience net losses and negative cash flows for the foreseeable future. These net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. In addition, our expenses could increase if we are required by the FDA to perform studies or trials in addition to those currently expected, or if there

are any delays in completing our clinical trials or the development of any of our drug candidates. The amount of future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenues.

We have a limited operating history and we expect a number of factors to cause our operating results to fluctuate on an annual basis, which may make it difficult to predict our future performance.

We are a clinical stage gene therapy company with a limited operating history. Our operations to date have been limited to conducting clinical and preclinical research. We have not yet obtained any regulatory approvals for any of our drug candidates. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a longer operating history or approved products on the market. Our operating results are expected to significantly fluctuate from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Factors relating to our business that may contribute to these fluctuations include:

- any delays in regulatory review and approval of our current and potential product candidates in clinical development, including our ability to receive approval from the FDA for Oncoprex;
- delays in the commencement, enrollment and timing of clinical trials;
- the success of our clinical trials through all phases of clinical development;
- potential side effects of our current and potential product candidates that could delay or prevent approval or cause an approved drug to be taken off the market;
- our ability to obtain additional funding to develop product candidates;
- our ability to identify and develop additional drug candidates beyond Oncoprex;
- competition from existing products or new products that continue to emerge;
- the ability of patients or healthcare providers to obtain coverage or sufficient reimbursement for our products;
- our ability to adhere to clinical trial requirements directly or with third parties such as contract research organizations, or CROs;
- our dependency on third-party manufacturers to manufacture our products and key ingredients;
- our ability to establish or maintain collaborations, licensing or other arrangements, particularly with MD Anderson;
- our ability to defend against any challenges to our intellectual property including, claims of patent infringement;
- our ability to enforce our intellectual property rights against potential competitors;
- our ability to secure additional intellectual property protection for our drug candidates in development and associated technologies;
- our ability to attract and retain key personnel to manage our business effectively; and
- potential product liability claims.

Accordingly, the results of any historical quarterly or annual periods should not be relied upon as indications of future operating performance.

Risks Related to Development and Commercialization of Our Current and Potential Product Candidates

Our success depends greatly on the success of our development of Oncoprex for the treatment of non-small cell lung cancer, and our pipeline of product candidates beyond this lead indication is extremely early stage and limited.

At this time we are actively pursuing development of only one product candidate, Oncoprex for non-small cell lung cancer. Therefore, we are dependent on the success of Oncoprex in the near term. We cannot provide you any assurance that we will be able to successfully advance Oncoprex through the development process, or that any development problems we experience in the future will not cause significant delays or unanticipated costs, or that such development problems can be solved. We may also experience delays in developing a sustainable, reproducible and scalable manufacturing process or transferring that process to commercial partners, or developing or validating product release assays in a timely manner, which may prevent us from completing our clinical trials or commercializing our products on a timely or profitable basis, if at all. Immunotherapy, gene therapy and biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of uncertainty. Because Oncoprex and our other potential product candidates are based upon novel technology, it is difficult to predict whether, either as stand-alone therapies or in combination with other drugs, they will show consistently favorable results and to predict the time and cost of their development

and of subsequently obtaining regulatory approval. Few gene therapy products have been approved in the United States or Europe. We may find it difficult to enroll patients in our clinical studies, which could delay or prevent clinical studies of our current and potential product candidates. We may encounter delays in our clinical studies, or we may fail to demonstrate safety and efficacy to the satisfaction of FDA and other regulatory authorities. We may not be successful in our efforts to identify or discover additional product candidates, or to develop product candidates that we have identified.

Negative public opinion and increased regulatory scrutiny of gene therapy and genetic research may damage public perception of our current and potential product candidates or adversely affect our ability to conduct our business or obtain regulatory approvals for our current and potential product candidates.

Public perception may be influenced by claims that gene therapy is unsafe, and gene therapy may not gain the acceptance of the public or the medical community. In particular, our success will depend upon physicians specializing in the treatment of those diseases that our current and potential product candidates target prescribing treatments that involve the use of our current and potential product candidates in lieu of, or in addition to, existing treatments with which they are already familiar and for which greater clinical data may be available. More restrictive government regulations or negative public opinion would have a negative effect on our business or financial condition and may delay or impair the development and commercialization of our current and potential product candidates or demand for any products we may develop. Adverse events in our clinical trials, even if not ultimately attributable to our current and potential product candidates, and the resulting publicity could lead to increased governmental regulation, unfavorable public perception, potential regulatory delays in the testing or approval of our potential product candidates, stricter labeling requirements for those product candidates that are approved and a decrease in demand for any such product candidates. Concern about the environmental spread of our product, whether real or anticipated, may hinder the commercialization of our products.

Delays in the commencement, enrollment and completion of clinical trials could result in increased costs to us and delay or limit our ability to obtain regulatory approval for Oncoprex and our other potential product candidates.

Oncoprex has been tested in only one prior Phase I clinical study, involving 31 patients. In that study, Oncoprex was tested as a monotherapy. We believe that the best path for development is to develop a combination therapy of Oncoprex in combination with erlotinib and possibly other drugs. We have an ongoing Phase I/II clinical trial testing Oncoprex in combination with erlotinib. Enrollment was completed in March 2015 for the Phase I portion of this clinical trial, in which 18 patients were enrolled. The Phase II portion of our Phase I/II clinical trial is at an early stage, with a limited number of patients enrolled, and the favorable results observed so far may not continue in the current clinical trial or be replicated in other clinical trials, especially those involving larger numbers of patients. Even if the Phase I/II trial is successful, success in early clinical studies may not be indicative of results obtained in later studies. The results from our Phase I/II trial may not demonstrate sufficient safety and efficacy to support the submission of marketing approval for Oncoprex. Before we request marketing approval, the FDA may require us to conduct additional clinical studies, or evaluate subjects for an additional follow-up. Unless an accelerated approval process is allowed by the FDA, one or more Phase III studies is normally required for approval.

Delays in the commencement, enrollment and/or completion of clinical trials could increase our product development costs or delay or limit the regulatory approval of our current and potential product candidates. We do not know whether any future trials or studies of our other potential product candidates will begin on time or will be completed on schedule, if at all. The start or end of a clinical study is often delayed or halted due to changing regulatory requirements, changes in the proposed regulatory approval pathway for a drug candidate, manufacturing challenges, including delays or shortages in available drug product, required clinical trial administrative actions, slower than anticipated patient enrollment, changing standards of care, availability or prevalence of use of a comparative drug or required prior therapy, clinical outcomes or financial constraints. For instance, delays or difficulties in patient enrollment or difficulties in retaining trial participants can result in increased costs, longer development times or termination of a clinical trial. Clinical trials of a new product candidate require the enrollment of a sufficient number of patients, including patients who are suffering from the disease the product candidate is intended to treat and who meet other eligibility criteria. Rates of patient enrollment are affected by many factors, including the size of the patient population, the eligibility criteria for the clinical trial, that include the age and condition of the patients and the stage and severity of disease, the nature of the protocol, the proximity of patients to clinical sites and the availability of effective treatments and/or availability of other investigational treatment options for the relevant disease.

As the second phase of a Phase I/II clinical trial, MD Anderson researchers are conducting a Phase II clinical trial evaluating Oncoprex in combination with erlotinib in NSCLC. Enrollment eligibility criteria for this clinical trial are broad and include stage IV and recurrent NSCLC not potentially curable by radiotherapy or surgery, whether or not the patients have received prior chemotherapy, and whether or not they have an activating EGFR mutation. The Phase II trial began in June 2015 and is ongoing at MD Anderson. Ten patients have been entered and nine are evaluable for response under the trial protocol, because they have received 2 or more cycles of treatment. Preliminary analysis of the data from these patients further supported our belief that Oncoprex may provide medical benefit in several subpopulations of NSCLC patients for which there is an unmet medical need, and may provide pathways for accelerated approval.

As a result of these initial findings, in April 2016, we suspended enrollment of new patients in this Phase II clinical trial to collect additional trial data and have it analyzed in order to seek FDA guidance as to whether the protocol for this clinical trial could be modified to expand enrollment and also to divide the patients into cohorts with a view toward seeking accelerated approval in one or more of these cohort populations. We expect to present our findings to the FDA within the next several months. Although the clinical trial is currently closed to new patient enrollment, it is not terminated, and is considered "ongoing" because activities such as patient follow-up and further data collection and analysis continue.

If we reach an agreement with the FDA regarding expanded patient enrollment and defined patient cohorts, then we plan to amend the trial protocol accordingly and proceed with the amended protocol at MD Anderson and several additional clinical trial sites. Amendments to the Phase II clinical trial protocol will require approval of the Investigational Review Board, or IRB, of each site where the amended trial is conducted. If we do not reach an agreement with the FDA on these changes, then we plan to reopen enrollment in the current version of the Phase II trial at MD Anderson and at additional clinical trial sites. In that event, we will need to provide MD Anderson with plans and funding to move ahead with the trial. Whether under the original protocol or a revised protocol, we intend to use a portion of the proceeds of the recently completed initial public offering of our common stock to add additional clinical trial sites.

A product candidate can unexpectedly fail at any stage of preclinical and clinical development. The historical failure rate for product candidates is high due to scientific feasibility, safety, efficacy, changing standards of medical care and other variables. The results from preclinical testing or early clinical trials of a product candidate may not predict the results that will be obtained in later phase clinical trials of the product candidate. We, the FDA or other applicable regulatory authorities may suspend clinical trials of a product candidate at any time for various reasons, including, but not limited to, a belief that subjects participating in such trials are being exposed to unacceptable health risks or adverse side effects, or other adverse initial experiences or findings. We may not have the financial resources to continue development of, or to enter into collaborations for, a product candidate if we experience any problems or other unforeseen events that delay or prevent regulatory approval of, or our ability to commercialize, product candidates, including:

- inability to obtain sufficient funds required for a clinical trial;
- inability to reach agreements on acceptable terms with current or prospective contract research organizations, or CROs, and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- negative or inconclusive results from our clinical trials or the clinical trials of others for product candidates similar to ours, leading to a decision or requirement to conduct additional preclinical testing or clinical trials or abandon a program;
- serious and unexpected drug-related side effects experienced by subjects in our clinical trials or by individuals using drugs similar to our current and potential product candidates;
- conditions imposed by the FDA or comparable foreign authorities regarding the scope or design of our clinical trials;
- delays in enrolling research subjects in clinical trials;
- high drop-out rates and high fail rates of research subjects;
- inadequate supply or quality of product candidate components or materials or other supplies necessary for the conduct of our clinical trials;
- greater than anticipated clinical trial costs;
- poor effectiveness of our current and potential product candidates during clinical trials; or
- unfavorable FDA or other regulatory agency inspection and review of a clinical trial site or vendor.

We may have difficulty engaging or retaining clinical trial sites and/or enrolling patients in our clinical trials, which could delay or prevent development of our current and potential product candidates.

Identifying and qualifying patients to participate in clinical trials of our current and potential product candidates is critical to our success. The timing of our clinical trials depends on the speed at which we can engage and retain clinical trial sites and recruit patients to participate in testing our current and potential product candidates. We have experienced delays in some of our clinical trials in the past due to difficulties with enrollment and we may experience similar delays in the future. We have suspended enrollment of new patients in the Phase II portion of our Phase I/II clinical trial evaluating Oncoprex in combination with erlotinib in NSCLC, and we may experience difficulties with enrollment upon reopening enrollment for the trial under the current protocol or a modified protocol. If patients are unwilling to participate in our clinical trials because of negative publicity from adverse events in the industry or in the trials for other third party product candidates, or for other reasons, including competitive clinical trials for similar patient populations,

the timeline for engaging sites, recruiting patients, conducting studies and obtaining regulatory approval of potential products may be delayed. These delays could result in increased costs, delays in advancing our product development, delays in testing the effectiveness of our technology or termination of the clinical trials altogether.

We or our clinical trial sites may not be able to identify, recruit and enroll a sufficient number of patients, or those with the required or desired characteristics in a clinical trial, to complete our clinical trials in a timely manner. Patient enrollment is affected by factors including:

- severity of the disease under investigation;
- design of the clinical trial protocol, including the fact that certain of our clinical trials are randomized to current treatments;
- size of the patient population;
- eligibility criteria for the clinical trial in question;
- perceived risks and benefits of the product candidate under study;
- general level of excitement for the treatment approach;
- comments on social media;
- proximity and availability of clinical trial sites for prospective patients;
- availability of competing therapies and clinical trials;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians; and
- ability to monitor patients adequately during and after treatment.

We currently plan to seek initial marketing approval in the United States and subsequently in Europe. We may not be able to initiate or continue clinical trials if we cannot enroll a sufficient number of eligible patients to participate in the clinical trials required by the FDA or the European Medicines Agency, or EMA, or other regulatory agencies. Our ability to successfully initiate, enroll and complete a clinical trial in any foreign country is subject to numerous risks unique to conducting business in foreign countries, including:

- difficulty in establishing or managing relationships with CROs and physicians;
- different standards for the conduct of clinical trials;
- our inability to locate qualified local consultants, physicians and partners; and
- the potential burden of complying with a variety of foreign laws, medical standards and regulatory requirements, including the regulation of pharmaceutical and biotechnology products and treatments.

If we have difficulty enrolling a sufficient number of patients to conduct our clinical trials as planned, we may need to delay, limit or terminate ongoing or planned clinical trials, any of which would have an adverse effect on our business.

Any product candidate we advance through clinical trials may not have favorable results in later clinical trials or receive regulatory approval.

Clinical failure can occur at any stage of our clinical development. Clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or nonclinical studies. In addition, data obtained from trials and studies are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may delay, limit or prevent regulatory approval. Success in preclinical studies and early clinical trials does not ensure that subsequent clinical trials will generate the same or similar results or otherwise provide adequate data to demonstrate the efficacy and safety of a product candidate. Thirty-one patients were treated in our first Phase I clinical trial of Oncoprex used as a monotherapy, and 28 patients have been enrolled to date (out of a possible total of 57) in our current Phase I/II clinical trial of Oncoprex in combination with erlotinib in NSCLC. Of the 28 patients, 18 were enrolled in the Phase I portion of the Phase I/II trial, and three of these 18 are also enrolled in the Phase II portion. Safety and efficacy results to date may not continue to be obtained as additional patients are treated, and may not be duplicated in future clinical trials. A number of companies in the pharmaceutical industry, including those with greater resources and experience than ours, have suffered significant setbacks in clinical trials, even after seeing promising results in earlier clinical trials.

In addition, the design of a clinical trial can determine whether its results will support approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. We may be unable to design and execute a clinical trial to support regulatory approval. Further, clinical trials of potential products often reveal that it is not practical or feasible to continue development efforts.

If Oncoprex is found to be unsafe or lack efficacy, we will not be able to obtain regulatory approval for it and our business would be harmed.

In some instances, there can be significant variability in safety and/or efficacy results between different trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in composition of the patient populations, adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. We do not know whether any clinical trials we or any of our potential future collaborators may conduct will demonstrate the consistent or adequate efficacy and safety that would be required to obtain regulatory approval and market any products. If we are unable to bring Oncoprex to market, or to acquire other products that are on the market or can be developed, our ability to create stockholder value will be limited.

Even if we obtain regulatory approval of our current and potential product candidates, the products may not gain market acceptance among physicians, patients, hospitals, cancer treatment centers, third-party payors and others in the medical community.

Ethical, social and legal concerns about gene therapy and genetic research could result in additional regulations restricting or prohibiting the products and processes we may use. Even with the requisite approvals, the commercial success of our current and potential product candidates will depend in part on the medical community, patients, and third-party payors accepting gene therapy products in general, and our current and potential product candidates in particular, as medically useful, cost-effective and safe. Any product that we bring to the market may not gain market acceptance by physicians, patients, third-party payors and others in the medical community. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become profitable. The degree of market acceptance of these product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the clinical indications for which our current and potential product candidates are approved;
- physicians, hospitals, cancer treatment centers and patients considering our current and potential product candidates as a safe and effective treatment;
- the potential and perceived advantages of our current and potential product candidates over alternative treatments;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- limitations or warnings contained in the labeling approved by the FDA;
- the timing of market introduction of our current and potential product candidates as well as competitive products;
- the cost of treatment in relation to alternative treatments;
- the availability of adequate coverage, reimbursement and pricing by third-party payors and government authorities;

- the willingness of patients to pay out-of-pocket in the absence of coverage by third-party payors, including government authorities;
- the willingness, ability and availability of healthcare providers that can comply with the transportation, handling, and temperature-controlled storage requirements associated with our current and potential product candidates;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and
- the effectiveness of our sales and marketing efforts.

Even if a potential product displays a favorable efficacy and safety profile in preclinical and clinical trials, market acceptance of the product will not be known until after it is launched. Our efforts to educate the medical community and third-party payors on the benefits of the product candidates may require significant resources and may never be successful. Such efforts to educate the marketplace may require more resources than are required by the conventional technologies marketed by our competitors and may be restricted by the allowed label.

Our current and potential product candidates may have undesirable side effects that may delay or prevent marketing approval, or, if approval is received, require them to be taken off the market, require them to include safety warnings or otherwise limit their sales.

In our Phase I clinical trial of Oncoprex as a monotherapy, the only serious adverse events, defined as grade 3, 4 or 5 events under the Common Terminology Criteria for Adverse Events, or CTCAE, published by the U.S. Department of Health and Human Services, were grade 3 fever and grade 3 hypotension, and the only dose-limiting toxicities were two episodes of transient grade 3 hypophosphatemia (abnormally low levels of phosphate in the blood).

The Phase I portion of our Phase I/II trial combining Oncoprex with erlotinib was a dose escalation study with the primary purpose of determining the MTD. Dose Limiting Toxicities were defined as grade 3, 4, or 5 events during the first cycle of treatment that were considered to be treatment related. At dose level 1 (Oncoprex .045 mg/kg plus erlotinib 100 mg), one subject had grade 3 adverse events of fatigue, muscle weakness, and hyponatremia (low sodium level) considered to be related to the study treatment (erlotinib); therefore, three additional subjects were treated at this dose level (six subjects total), none of whom suffered a Dose Limiting Toxicity. At dose level 2 (Oncoprex .06 mg/kg plus erlotinib 100 mg), there were no Dose Limiting Toxicities. At dose level 3 (Oncoprex .45 mg/kg plus erlotinib 150 mg), one subject had a grade 3 rash considered to be related to the study treatment (erlotinib); therefore, an additional three subjects were treated at this dose level (six subjects total). No additional subjects suffered a Dose Limiting Toxicity at dose level 3. At dose level 4 (Oncoprex .06 mg/kg plus erlotinib 150 mg), there were no Dose Limiting Toxicities; thus dose level 4 was determined to be the MTD. None of the 10 subjects treated to date in the Phase II portion of the Phase I/II trial suffered a Dose Limiting Toxicity.

Additional or unforeseen side effects from Oncoprex or any of our other potential product candidates could arise either during clinical development or, if approved, after the approved product has been marketed. A showing that Oncoprex or any other product candidate causes undesirable or unacceptable side effects could interrupt, delay or halt clinical trials and result in the failure to obtain or suspension or termination of marketing approval from the FDA and other regulatory authorities, or result in marketing approval from the FDA and other regulatory authorities only with restrictive label warnings.

If any of our current and potential product candidates receives marketing approval and we or others later identify undesirable or unacceptable side effects caused by such products:

- regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies;
- we may be required to change instructions regarding the way the product is administered, conduct additional clinical trials or change the labeling of the product;
- we may be subject to limitations on how we may promote the product;
- sales of the product may decrease significantly;
- regulatory authorities may require us to take our approved product off the market;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us or our potential future collaborators from achieving or maintaining market acceptance of the affected product or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenues from the sale of our products.

We may face product liability claims.

In the event Oncoprex or any of our other potential product candidates is approved for marketing by the FDA and other regulatory authorities, we may face potential product liability. If successful claims are brought against us, we may incur substantial liability and costs. If the use of our current and potential product candidates harms patients, or is perceived to harm patients even when such harm is unrelated to our current and potential product candidates, our regulatory approvals could be revoked or otherwise negatively impacted, and we could be subject to costly and damaging product liability claims.

Our internal computer systems, or those used by our CROs, contractors or consultants, may fail or suffer security breaches.

Despite the implementation of security measures, our internal computer systems and those of our CROs, contractors and consultants are vulnerable to damage from computer viruses and unauthorized access, as well as being vulnerable to other system difficulties, failures or disruptions. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, and the further development and commercialization of our current and potential product candidates could be delayed.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our CROs, contractors and consultants, could be subject to power shortages, telecommunications failures, wildfires, water shortages, floods, earthquakes, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. Our ability to obtain clinical supplies of our current and potential product candidates could be disrupted if the operations of our contract manufacturers are affected by a man-made or natural disaster or other business interruption. Unfavorable global economic conditions could adversely affect our business, financial condition, or results of operations.

We do not carry insurance for all categories of risk that our business may encounter. In particular, we do not carry product liability insurance covering any clinical trials liability that we may incur. Although we intend to obtain such insurance before we market any product, there can be no assurance that we will secure adequate insurance coverage or that any such insurance coverage will be sufficient to protect our operations to significant potential liability in the future. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our financial position and results of operations.

We face competition from other biotechnology and pharmaceutical companies and our operating results will suffer if we fail to compete effectively.

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. We have competitors in the United States, Europe and elsewhere, including major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical and generic drug companies and universities and other research institutions. Many of our competitors have greater financial and other resources, such as larger research and development staff and more experienced marketing and manufacturing organizations than we do. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and manufacturing pharmaceutical products. These companies also have significantly greater research, sales and marketing capabilities and collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the product candidates that we develop obsolete. As a result of these factors, our competitors may succeed in obtaining patent protection and/or FDA approval or discovering, developing and commercializing drugs for the cancer indications that we are targeting before we do or may develop drugs that are deemed to be more effective or gain greater market acceptance than ours. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. In addition, many universities and private and public research institutes may become active in our target disease areas. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis, technologies and drug products that are more effective or less costly than any product candidates that we are currently developing or that we may develop, which could render our products obsolete or noncompetitive.

There are a number of drugs approved and under development for treatment of lung cancer. Treatments competitive with our primary product candidates generally fall into the following categories: chemotherapies such as cisplatin, carboplatin, docetaxel and

pemetrexed; targeted therapies such as erlotinib, gefitinib, afatinib and osimertinib (marketed as Tagrisso® by AstraZeneca Pharmaceuticals), and immunotherapies such as checkpoint inhibitors and CAR and CAR T cells, and oncolytic virus-based technology. Data indicate that Oncoprex, when combined with certain targeted therapies and immunotherapies, may enhance the benefit of those therapies; therefore, we believe that Oncoprex could be administered in combination with targeted therapies and immunotherapies and thus may not be a direct competitor of those drugs. In addition, new drug candidates are constantly being conceived and developed. Any such competing therapy may be more effective and/or cost-effective than ours.

If our competitors market products that are more effective, safer or less expensive or that reach the market sooner than our future products, if any, we may not achieve commercial success. In addition, because of our limited resources, it may be difficult for us to stay abreast of the rapid changes in each technology. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render our technologies or product candidates obsolete, less competitive or not economical.

Risks Related to Regulatory Approval and Marketing of Our Current and Potential Product Candidates and Other Legal Compliance Matters

We cannot be certain that Oncoprex will receive regulatory approval, and without regulatory approval we will not be able to market Oncoprex.

Our business currently depends largely on the successful development and commercialization of Oncoprex. Our ability to generate revenue related to product sales, if ever, will depend on the successful development and regulatory approval of Oncoprex for the treatment of cancer. Even if we complete the necessary clinical studies, we cannot predict when or if we will obtain regulatory approval to commercialize a product candidate. Further, if we do obtain regulatory approval, it may only apply to a more narrow indication than we expect. Even if we obtain regulatory approval for a product candidate, our products will remain subject to regulatory scrutiny.

We currently have no products approved for sale and we cannot guarantee that we will ever have marketable products. The development of a product candidate and issues relating to its approval and marketing are subject to extensive regulation by the FDA in the United States and regulatory authorities in other countries, with regulations differing from country to country. We are not permitted to market our current and potential product candidates in the United States until we receive approval of a Biologics License Application, or BLA, from the FDA. We have not submitted any marketing applications for any of our current and potential product candidates.

BLAs must include extensive preclinical and clinical data and supporting information to establish the product candidate's safety and effectiveness for each desired indication. BLAs must also include significant information regarding the chemistry, manufacturing and controls for the product. Obtaining approval of a BLA is a lengthy, expensive and uncertain process, and we may not be successful in obtaining approval. The FDA review processes can take years to complete and approval is never guaranteed. If we submit a BLA to the FDA, the FDA must decide whether to accept or reject the submission for filing. We cannot be certain that any submissions will be accepted for filing and review by the FDA. Regulators in other jurisdictions have their own procedures for approval of product candidates. Even if a product is approved, the FDA may limit the indications for which the product may be marketed, require extensive warnings on the product labeling or require expensive and time-consuming clinical trials or reporting as conditions of approval. Regulatory authorities in countries outside of the United States and Europe also have requirements for approval of drug candidates with which we must comply with prior to marketing in those countries. Obtaining regulatory approval for marketing of a product candidate in one country does not ensure that we will be able to obtain regulatory approval in any other country. In addition, delays in approvals or rejections of marketing applications in the United States, Europe or other countries may be based upon many factors, including regulatory requests for additional analyses, reports, data, preclinical studies and clinical trials, regulatory questions regarding different interpretations of data and results, changes in regulatory policy during the period of product development and the emergence of new information regarding our current and potential product candidates or other products. Also, regulatory approval for any of our current and potential product candidates may be withdrawn.

If we are unable to obtain approval from the FDA, or other regulatory agencies, for Oncoprex, or if, subsequent to approval, we are unable to successfully commercialize Oncoprex or our other potential product candidates, we will not be able to generate sufficient revenue to become profitable or to continue our operations.

In addition, the clinical trial requirements of the FDA, the European Medicines Agency, or EMA, and other regulatory agencies and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of the potential products. The regulatory approval process for novel product candidates such as ours can be more expensive and take longer than for other, better known or extensively studied pharmaceutical or other product candidates.

Regulatory requirements governing gene therapy products have changed frequently and may continue to change in the future. For example, in January 2017, the FDA Oncology Center of Excellence, or the Center of Excellence, was created to leverage the combined skills of regulatory scientists and reviewers with expertise in drugs, biologics, and devices (including diagnostics). While the Center of Excellence is designed to help expedite the development of oncology and malignant hematology-related medical products and support an integrated approach in the clinical evaluation of drugs, biologics and devices for the treatment of cancer, the new Center of Excellence may initially create confusion within the FDA and especially in the Center of Biologics and Research that is the primary review division for Oncoprex. Gene therapy clinical trials conducted at institutions that receive funding for recombinant DNA research from the U.S. National Institutes of Health, or the NIH, are also subject to review by the NIH Office of Biotechnology Activities' Recombinant DNA Advisory Committee, or the RAC. Although the FDA decides whether individual gene therapy protocols may proceed, the RAC review process can impede the initiation of a clinical trial, even if the FDA has reviewed the study and approved its initiation. Conversely, the FDA can put an Investigational New Drug application, or IND, on a partial or complete clinical hold even if the RAC has provided a favorable review. Also, before a clinical trial can begin at an NIH-funded institution, that institution's institutional review board, or IRB, and its Institutional Biosafety Committee will have to review the proposed clinical trial to assess the safety of the study. In addition, adverse developments in clinical trials of gene therapy products conducted by others may cause the FDA or other regulatory bodies to change the requirements for performing studies or for obtaining approval of any of our current and potential product candidates.

These regulatory review committees and advisory groups, and the new guidelines they promulgate, may lengthen the regulatory review process, require us to perform additional studies, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our current and potential product candidates or lead to significant post-approval limitations or restrictions. As we advance our current and potential product candidates, we will be required to consult with these regulatory and advisory groups and comply with applicable guidelines. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product to market could decrease our ability to generate sufficient revenue to maintain our business.

If the FDA does not find the manufacturing facilities of our future contract manufacturers acceptable for commercial production, we may not be able to commercialize any of our current and potential product candidates.

We do not intend to manufacture the pharmaceutical products that we plan to sell. We are currently utilizing contract manufacturers for the production of the active pharmaceutical ingredients and the formulation of drug product for the trials of Oncoprex currently being conducted or will need to be conducted prior to seeking regulatory approval. However, we do not have agreements for supplies of Oncoprex or any of our other potential product candidates and we may not be able to reach agreements with these or other contract manufacturers for sufficient supplies to commercialize Oncoprex if it is approved. Additionally, the facilities used by any contract manufacturer to manufacture Oncoprex or any of our other potential product candidates must be the subject of a satisfactory inspection before the FDA approves the product candidate manufactured at that facility. We are completely dependent on these third-party manufacturers for compliance with the requirements of U.S. and non-U.S. regulators for the manufacture of our finished products. If our manufacturers cannot successfully manufacture materials that conform to our specifications and the FDA's current good manufacturing practices, or cGMP, standards and other requirements of any governmental agency to whose jurisdiction we are subject, our current and potential product candidates will not be approved or, if already approved, may be subject to recalls. Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured our current and potential product candidates, including:

- the possibility that we are unable to enter into a manufacturing agreement with a third party to manufacture our current and potential product candidates;
- the possible breach of the manufacturing agreements by the third parties because of factors beyond our control; and
- the possibility of termination or nonrenewal of the agreements by the third parties before we are able to arrange for a qualified replacement third-party manufacturer.

Any of these factors could cause the delay of approval or commercialization of our current and potential product candidates, cause us to incur higher costs or prevent us from commercializing our current and potential product candidates successfully. Furthermore, if any of our current and potential product candidates are approved and contract manufacturers fail to deliver the required commercial quantities of finished product on a timely basis at commercially reasonable prices and we are unable to find one or more replacement manufacturers capable of production at a substantially equivalent cost, in substantially equivalent volumes and quality and on a timely basis, we would likely be unable to meet demand for our products and could lose potential revenue. It may take several years to establish an alternative source of supply for our current and potential product candidates and to have any such new source approved by the government agencies that regulate our products.

We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws and other federal and state healthcare laws, and the failure to comply with such laws could result in substantial penalties. Our employees, independent contractors, consultants, principal investigators, CROs, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of fraud, misconduct or other illegal activity by our employees, independent contractors, consultants, principal investigators, CROs, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to: comply with the laws of the FDA and similar foreign regulatory bodies; provide true, complete and accurate information to the FDA and similar foreign regulatory bodies; comply with manufacturing standards we have established; comply with federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations in the United States and similar foreign fraudulent misconduct laws; or report financial information or data accurately or to disclose unauthorized activities to us. If we obtain FDA approval for any of our current and potential product candidates and begin commercializing those products in the United States, our potential exposure under such laws would increase significantly, and our costs associated with compliance with such laws would likely also increase. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, including off-label uses of our products, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of patient recruitment for clinical trials, creating fraudulent data in our preclinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of fines or other sanctions. The laws that may affect our ability to operate include, but are not limited to:

- the Federal Anti-Kickback Statute, which prohibits, among other things, individuals and entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- federal civil and criminal false claims laws and civil monetary penalty laws, including the civil False Claims Act, which impose criminal and civil penalties, through government, civil whistleblower or qui tam actions, on individuals and entities for, among other things, knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid, or other third-party payors that are false, fictitious or fraudulent, or knowingly making, using or causing to be made or used, a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- the Federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private), willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false, fictitious or fraudulent statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses, as well as their respective business associates that perform services for them that involve the creation, use, maintenance or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization;
- the federal physician payment transparency requirements, sometimes referred to as the "Physician Payments Sunshine Act," created under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education

Reconciliation Act, collectively the Affordable Care Act, and its implementing regulations, which require certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the United States Department of Health and Human Services information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;

- the U.S. Federal Food, Drug and Cosmetic Act, or FDCA, which prohibits, among other things, the adulteration or misbranding of drugs and medical devices; and
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers. Additionally, we are subject to state and foreign equivalents of each of the healthcare laws described above, among others, some of which may be broader in scope and may apply regardless of the payor.

It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent inappropriate conduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Efforts to ensure that our business arrangements will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of any of our current and potential product candidates outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

Coverage and reimbursement may be limited or unavailable in certain market segments for our current and potential product candidates, if approved, which could make it difficult for us to sell our current and potential product candidates profitably.

The commercial success of any current or future product candidate will depend upon the degree of market acceptance by physicians, patients, insurance companies and other third party payors, and others in the medical community. Even if we obtain approval to commercialize our current and potential product candidates outside of the United States, a variety of risks associated with international operations could materially affect our business. Due to the novel nature of our technology, we face uncertainty related to pricing and reimbursement for our current and potential product candidates. The insurance coverage and reimbursement status of newly approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for new or current products could limit our ability to market those products and decrease our ability to generate revenue. If market opportunities for our current and potential product candidates are smaller than we believe they are, our revenues may be adversely affected and our business may suffer.

Successful sales of our products, if our current and potential product candidates are approved, depend on the availability of coverage and adequate reimbursement from third-party payors. In addition, because our current and potential product candidates represent new approaches to the treatment of cancer, we cannot be sure that coverage and reimbursement will be available for, or accurately estimate the potential revenue from, our current and potential product candidates. Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors are critical to new product acceptance.

Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which drugs and treatments they will cover and the amount of reimbursement. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including, but not limited to, the third-party payor's determination that use of a product is:

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

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors, and coverage and reimbursement for products can differ significantly from payor to payor. As a result, obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our products and to justify the level of coverage and reimbursement relative to other therapies, with no assurance that coverage and adequate reimbursement will be obtained. Third party payors may also have difficulty in determining the appropriate coverage of Oncoprex and our other potential product candidates that are combination products, if approved, due to the fact that they are combination products that include another drug. To the extent there are any delays in determining such coverage or inadequate coverage and reimbursement for all aspects of our combination therapies, it would adversely affect the market acceptance, demand and use of our current and potential product candidates. Any denial in coverage or reduction in reimbursement from Medicare or other government programs may result in a similar denial or reduction in payments from private payors, which may adversely affect our future profitability.

We intend to seek approval to market our current and potential product candidates in both the United States and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for our current and potential product candidates, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in the European Union, the pricing of biologics is subject to governmental control and other market regulations which could put pressure on the pricing and usage of our current and potential product candidates. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. In addition, market acceptance and sales of our current and potential product candidates will depend significantly on the availability of coverage and adequate reimbursement from third-party payors for our current and potential product candidates and may be affected by existing and future health care reform measures.

Healthcare legislative reform measures may have a material adverse effect on our business and results of operations.

Third-party payors, whether domestic or foreign, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could affect our ability to sell our products profitably. In particular, in 2010, the Affordable Care Act was enacted in the United States. The Affordable Care Act and its implementing regulations, among other things, subjected biological products to potential competition by lower-cost biosimilars, revised the methodology by which rebates owed by manufacturers to the state and federal government for covered outpatient drugs and certain biologics, including our current and potential product candidates, under the Medicaid Drug Rebate Program are calculated, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program, extended the Medicaid Drug Rebate program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations, subjected manufacturers to new annual fees and taxes for certain branded prescription drugs, and provided incentives to programs that increase the federal government's comparative effectiveness research. The current Presidential Administration and U.S. Congress may seek to modify, repeal, or otherwise invalidate all, or certain provisions of, the Affordable Care Act. There have been judicial and Congressional challenges to certain aspects of the Affordable Care Act. As a result, there have been delays in the implementation of, and action taken to repeal or replace, certain aspects of the Affordable Care Act. While the extent to which any such changes may affect our business is uncertain, steps have been taken to repeal and replace certain aspects of the Affordable Care Act.

Since January 2017, President Trump has signed two Executive Orders designed to delay the implementation of certain provisions of the Affordable Care Act or otherwise circumvent some of the requirements for health insurance mandated by the Affordable Care Act. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the Affordable Care Act. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the Affordable Care Act have been signed into law. The Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain Affordable Care Act-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amends the Affordable Care Act, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". Congress also could consider subsequent legislation to repeal or repeal and replace other elements of the Affordable Care Act. We continue to evaluate the possible impact of the Affordable Care Act, as amended, and the possible repeal and/or replacement of the Affordable Care Act on our business.

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

- the demand for our current and potential product candidates, if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

We and our contract manufacturers are subject to significant regulation with respect to manufacturing our products. The manufacturing facilities on which we rely may not continue to meet regulatory requirements and have limited capacity.

We are currently utilizing contract manufacturers for the production of the active pharmaceutical ingredients and the formulation of drug product for our trials of Oncoprex. However, we do not have agreements for supplies of Oncoprex or any of our other potential product candidates. Each supplier may require licenses to manufacture such components if such processes are not owned by the supplier or in the public domain and we may be unable to transfer or sublicense the intellectual property rights we may have or later obtain with respect to such activities.

All entities involved in the preparation of therapeutics for clinical trials or commercial sale, including our existing contract manufacturers for Oncoprex, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical trials must be manufactured in accordance with cGMP. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of contaminants, or to inadvertent changes in the properties or stability of our current and potential product candidates that may not be detectable in final product testing. We or our contract manufacturers must supply all necessary documentation in support of a BLA on a timely basis and must adhere to the FDA's good laboratory practices, or GLP, and cGMP regulations enforced by the FDA through its facilities inspection program. Our facilities and quality systems and the facilities and quality systems of some or all of our third-party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our current and potential product candidates or any of our other potential products. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our current and potential product candidates or our other potential products or the associated quality systems for compliance with the regulations applicable to the activities being conducted. If these facilities do not pass a pre-approval plant inspection, FDA approval of the products may not be granted.

The regulatory authorities also may, at any time following approval of a product for sale, audit our manufacturing facilities or those of our third-party contractors. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and/or time-consuming for us or a third party to implement and that may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business.

If we or any of our third-party manufacturers fail to maintain regulatory compliance, the FDA can impose regulatory sanctions including, among other things, refusal to approve a pending application for a new drug product or biologic product or revocation of a pre-existing approval. As a result, our business, financial condition and results of operations may be materially harmed.

Additionally, if supply from one approved manufacturer is interrupted, there could be a significant disruption in commercial supply. An alternative manufacturer would need to be qualified through a BLA supplement which could result in further delay. The regulatory agencies may also require additional studies if a new manufacturer is relied upon for commercial production. Switching manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

These factors could cause the delay of clinical trials, regulatory submissions, required approvals or commercialization of our current and potential product candidates, cause us to incur higher costs and prevent us from commercializing our products successfully. Furthermore, if our suppliers fail to meet contractual requirements, and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical trials may be delayed or we could lose potential revenue.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We may become subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous materials and certain waste products, including numerous environmental, health and safety laws and regulations, such as those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations may in the future involve the use of hazardous materials, including chemicals and biological materials. Our operations may also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Risks Related to Our Dependence on Third Parties

We may not be successful in establishing and maintaining development and commercialization collaborations, which could adversely affect our ability to develop certain of our current and potential product candidates and our financial condition and operating results.

Because developing pharmaceutical products, conducting clinical trials, obtaining regulatory approval, establishing manufacturing capabilities and marketing approved products are expensive, we may enter into collaborations with companies that have the required expertise. Additionally, if any of our current and potential product candidates receives marketing approval, we may enter into sales and marketing arrangements with third parties. If we are unable to enter into arrangements on acceptable terms, if at all, we may be unable to effectively market and sell our products in our target markets. We expect to face competition in seeking appropriate collaborators. Moreover, collaboration arrangements are complex and time consuming to negotiate, document and implement and they may require substantial resources to maintain. We may not be successful in our efforts to establish and implement collaborations or other alternative arrangements for the development of our current and potential product candidates.

When we collaborate with a third party for development and commercialization of a product candidate, we can expect to relinquish some or all of the control over the future success of that product candidate to the third party.

One or more of our collaboration partners may not devote sufficient resources to the commercialization of our current and potential product candidates or may otherwise fail in their commercialization. The terms of any collaboration or other arrangement that we establish may contain provisions that are not favorable to us. In addition, any collaboration that we enter into may be unsuccessful in the development and commercialization of our current and potential product candidates. In some cases, we may be responsible for continuing preclinical and initial clinical development of a product candidate or research program under a collaboration arrangement, and the payment we receive from our collaboration partner may be insufficient to cover the cost of this development. If we are unable to reach agreements with suitable collaborators for our current and potential product candidates, we would face increased costs, we may be forced to limit the number of our current and potential product candidates we can commercially develop or the territories in which we commercialize them. As a result, we might fail to commercialize products or programs for which a suitable collaborator cannot be found. If we fail to achieve successful collaborations, our operating results and financial condition could be materially and adversely affected.

We rely, and expect to continue to rely, on third parties to conduct, supervise and monitor our clinical trials, and if these third parties perform in an unsatisfactory manner, it may harm our business.

We rely on CROs and clinical trial sites to ensure our clinical trials are conducted properly and on time. While we have agreements governing their activities, we may have limited influence over their actual performance. We control only certain aspects of our CROs' activities. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities.

We and our CROs are required to comply with the GCPs for conducting, recording and reporting the results of clinical trials to assure that the data and reported results are credible and accurate and that the rights, integrity and confidentiality of clinical trial participants are protected. The FDA enforces these GCPs through periodic inspections of study sponsors, principal investigators and clinical trial sites. If we or our CROs fail to comply with applicable GCPs, the clinical data generated in our future clinical trials may be deemed unreliable, and the FDA may require us to perform additional clinical trials before approving any marketing applications. Upon inspection, the FDA may determine that our clinical trials did not comply with GCPs. In addition, our ongoing and future clinical trials will require a sufficient number of test subjects to evaluate the safety and effectiveness of our current and potential

product candidates. Accordingly, if our CROs fail to comply with these regulations or fail to recruit a sufficient number of patients, we may be required to repeat such clinical trials, which would delay the regulatory approval process.

Our CROs are not our employees, and we are not able to directly monitor whether or not they devote sufficient time and resources to our clinical and nonclinical programs. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities that could harm our competitive position. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols or regulatory requirements, or for any other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our current and potential product candidates. As a result, our financial results and the commercial prospects for our current and potential product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

We rely, and expect to continue to rely, on third parties to distribute, manufacture and perform release testing for our current and potential product candidates and other key materials and if such third parties do not carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approvals for our current and potential product candidates.

We intend to continue to rely on third-party contract manufacturing organizations, or CMOs, to produce our current and potential product candidates and other key materials and on third-party contract testing organizations, or CTOs, for the establishment and performance of validated product release assays, but we have not entered into binding agreements with any such CMOs or CTOs to support commercialization. Additionally, any CMO may not have experience producing our current and potential product candidates at commercial levels and may not achieve the necessary regulatory approvals or produce our products at the quality, quantities, locations and timing needed to support commercialization. We may change our manufacturing process, and there can be no guarantee that the regulatory authorities will approve any new process in a timely manner or ever. Also, as a consequence of the manufacturing change, there may be a requirement to do more preclinical safety or efficacy studies, develop new manufacturing and release assays and/or repeat all or part of the ascending dose safety study in animals or humans. Regulatory requirements ultimately imposed could adversely affect our ability to test, manufacture or market products.

Although we intend to rely on third-party manufacturers for commercialization, we currently utilize a sole source manufacturer to support our clinical trials. We may be unable to negotiate binding agreements with this manufacturer or additional manufacturers to support our commercialization activities at commercially reasonable terms.

No manufacturer we know of currently has the experience or ability to produce our current and potential product candidates at reasonable commercial levels or under full commercial requirements. We may encounter technical or scientific issues related to manufacturing or development that we may be unable to resolve in a timely manner or with available funds. Further, we have not completed the characterization and validation activities necessary for commercial and regulatory approvals. If our manufacturing and testing partners do not obtain such regulatory approvals, our commercialization efforts may be harmed.

Even if we timely develop a manufacturing process for Oncoprex and successfully transfer it to third-party manufacturers, if such third-party manufacturers are unable to produce our current and potential product candidates in the necessary quantities, or in compliance with current Good Manufacturing Practices, or cGMP, or in compliance with pertinent regulatory requirements, and within our planned time frame and cost parameters, the development and sales of our products, if approved, may be materially harmed. The facilities used by our contract manufacturers to manufacture our current and potential product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit our BLA to the FDA. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with cGMPs for the manufacture of our current and potential product candidates. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our current and potential product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly affect our ability to develop, obtain regulatory approval for or market our current and potential product candidates, if approved. In addition, any failure to achieve and maintain compliance with these laws, regulations and standards could subject us to the risk that we may have to suspend the manufacturing of our current and potential product candidates or that obtained approvals could be revoked, which would adversely affect our business and reputation.

In addition, any significant disruption in our supplier relationships could harm our business. We source key materials, devices and equipment from third parties, either directly through agreements with suppliers or indirectly through our manufacturers who have agreements with suppliers. There is a small number of suppliers for certain key materials and components that are used to manufacture our current and potential product candidates. Such suppliers may not sell these key materials to our manufacturers at the times or

quantities we need them or on commercially reasonable terms. We may not have any control over the process or timing of the acquisition of these key materials by our manufacturers.

We also expect to rely on other third parties to store and distribute our products for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our current and potential product candidates or commercialization of our products, if approved, producing additional losses and depriving us of potential product revenue.

We have completed and may in the future complete related party transactions that were not and may not be conducted on an arm's length basis.

Our leading drug candidate, Oncoprex, is based upon patents and related technology covered by a patent and technology license agreement between The University of Texas MD Anderson Cancer Center, or MD Anderson, and Introgen Therapeutics, Inc. (such technology license agreement is referred to as the "MD Anderson License Agreement"), under which we have rights to patents covering use of various genes, including the TUSC2 gene, for treatment of cancer, as well as know-how and related intellectual property. In 2007, the MD Anderson License Agreement was sublicensed by Introgen Therapeutics, Inc. to Introgen Research Institute, Inc., a Texas corporation (IRI) and in 2009 this sublicense was assigned by IRI to us, and we granted back to IRI a nonexclusive, royalty-free license to use and practice the licensed technology for non-commercial research purposes. As consideration for this assignment, we agreed to assume all of IRI's obligations to MD Anderson under the MD Anderson License Agreement, including ongoing patent related expenses and royalty obligations. IRI also agreed in 2011 to provide additional technology licensing opportunities and services to us in return for monthly payments and our obligation to pay to IRI a royalty of one percent (1%) on sales of products licensed to us under the MD Anderson License Agreement. We also granted a non-exclusive, royalty-free sublicense to IRI in 2011 for non-commercial research purposes. IRI's obligations to provide additional technology licensing opportunities and services to us, and our obligation to make monthly payments to IRI, were terminated in 2012; however, our obligation to pay the one percent (1%) royalty to IRI upon sales of products licensed to us under the MD Anderson License Agreement is ongoing. This royalty obligation continues for 21 years after the later of the termination of the MD Anderson License Agreement and the termination of the sublicense assigned by IRI to us. IRI is controlled by Rodney Varner and his immediate family members. Mr. Varner is currently Chairman of our board of directors, having joined our board of directors on August 15, 2012, and has been our President and Chief Executive Officer since August 29, 2012; accordingly, in 2009 and 2011, when the above referenced agreements between IRI and Genprex were entered into, Mr. Varner was neither a member of our board of directors nor an executive officer of Genprex. When the 2011 agreement was entered into, Mr. Varner was deemed to be an "affiliate of the Company due to his beneficial ownership of approximately 39% of our issued and outstanding shares. Although we believe that these transactions were conducted on an arm's length basis, it is possible that the terms were less favorable to us than they might have been in a transaction with an unrelated party. We have adopted a written related-person transactions policy that sets forth our policies and procedures regarding the identification, review, consideration and oversight of related-person transactions.

Risks Related to Our Intellectual Property

If we fail to obtain or protect our intellectual property, our business will be impaired.

If we are unable to obtain or protect intellectual property rights related to our current and potential product candidates, we may not be able to compete effectively in our markets. Third party claims of intellectual property infringement may prevent or delay our development and commercialization efforts. We may not be successful in obtaining or maintaining necessary rights to product components and processes for our development pipeline through acquisitions and end licenses.

If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business. We may be involved in lawsuits to protect or enforce our patents or the patents or our licensors, which could be expensive, time-consuming, and/or unsuccessful.

Obtaining and maintaining patent protection depends upon compliance with various procedural, document submission, fee payment, and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for noncompliance with these requirements. Issued patents covering our current and potential product candidates could be found invalid or unenforceable if challenged in court, or could expire before we obtain product approval. The scope of our issued patents could be found to be narrower and provide less protection than we anticipate.

If we fail to comply with our obligations in the agreements under which we license intellectual property rights from MD Anderson, or otherwise experience disruptions to our business relationships with MD Anderson or other future licensors, we could lose license rights that are important to our business.

Under our license agreement with MD Anderson, we hold a worldwide, exclusive license to, among other things, manufacture and market products utilizing certain inventions that are critical to our business. We expect to enter into additional license agreements in the future. Our existing license agreement imposes various diligence, royalty and other obligations on us, and we expect that future license agreements will impose various diligence, milestone payment, royalty and other obligations on us. If we fail to comply with our obligations under these agreements, or we are subject to a bankruptcy, the licensor may have the right to terminate the license, in which event we would not be able to market products covered by the license. See "Business—License and Collaboration Agreements" for a description of our license agreements with MD Anderson, which includes a description of the termination provisions of these agreements.

We may need to obtain licenses from third parties to advance our research or allow commercialization of our current and potential product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we may be required to expend significant time and resources to develop or license replacement technology. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could harm our business significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our current product candidates or future products, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties.

In certain cases, patent prosecution of our licensed technology may be controlled solely by the licensor. If our licensors fail to obtain and maintain patent or other protection for the proprietary intellectual property we license from them, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, and our competitors could market competing products using the intellectual property. In certain cases, we control the prosecution of patents resulting from licensed technology. In the event we breach any of our obligations related to such prosecution, we may incur significant liability to our licensing partners. Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues and is complicated by the rapid pace of scientific discovery in our industry. Disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

The intellectual property rights we have licensed from MD Anderson are subject to the rights of the U.S. government.

The rights we have obtained pursuant to our license agreement with MD Anderson are made subject to the rights of the U.S. government to the extent that the technology covered by the licensed intellectual property was developed under a funding agreement between MD Anderson and the U.S. government. Additionally, to the extent there is any conflict between our license agreement with MD Anderson and applicable laws or regulations, applicable laws and regulations will prevail. Similarly, to the extent there is any conflict between our license agreement with MD Anderson and MD Anderson's funding agreement with the US government, the terms of the funding agreement will prevail. Some, and possibly all, of our licensed intellectual property rights from MD Anderson have been developed in the course of research funded by the U.S. government. As a result, the U.S. government may have certain rights to intellectual property embodied in our current or future products pursuant to the Bayh-Dole Act of 1980. Government rights in certain inventions developed under a government-funded program include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right to require us, or an assignee or exclusive licensee to such inventions, to grant licenses to any of these inventions to a third party if the U.S. government determines that adequate steps have not been taken to commercialize the invention, that government action is necessary to meet public health or safety needs, that government action is necessary to meet requirements for public use under federal regulations, or that the right to use or sell such inventions is exclusively licensed to an entity within the U.S. and substantially manufactured outside the U.S. without the

U.S. government's prior approval. Additionally, we may be restricted from granting exclusive licenses for the right to use or sell our inventions created pursuant to such agreements unless the licensee agrees to additional restrictions (e.g., manufacturing substantially all of the invention in the U.S.). The U.S. government also has the right to take title to these inventions if we fail to disclose the invention to the government and fail to file an application to register the intellectual property within specified time limits. In addition, the U.S. government may acquire title in any country in which a patent application is not filed within specified time limits. Additionally, certain inventions are subject to transfer restrictions during the term of these agreements and for a period thereafter, including sales of products or components, transfers to foreign subsidiaries for the purpose of the relevant agreements, and transfers to certain foreign third parties. If any of our intellectual property becomes subject to any of the rights or remedies available to the U.S. government or third parties pursuant to the Bayh-Dole Act of 1980, this could impair the value of our intellectual property and could adversely affect our business. The U.S. government has not exercised any of these rights or provided us with any notice of its intent to exercise any of these rights with respect to any of the intellectual property licensed to us by MD Anderson. We are not aware of any instance in which the U.S. government has ever exercised any such rights with respect to any technologies or other intellectual property developed under funding agreements with the U.S. government.

If we are unable to protect our intellectual property rights or if our intellectual property rights are inadequate for our technology and product candidates, our competitive position could be harmed.

Our commercial success will depend in part on our ability and the ability of our licensors to obtain and maintain patent and other intellectual property protection in the United States and other countries with respect to our proprietary technology and products. We rely on trade secret, patent, copyright and trademark laws, and confidentiality, licensing and other agreements with employees and third parties, all of which offer only limited protection. We seek to protect our proprietary position by filing and prosecuting patent applications in the United States and abroad related to our novel technologies and products that are important to our business.

The patent positions of biotechnology and pharmaceutical companies generally are highly uncertain, involve complex legal and factual questions and have in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patents, including those patent rights licensed to us by third parties, are highly uncertain. The steps we or our licensors have taken to protect our proprietary rights may not be adequate to preclude misappropriation of our proprietary information or infringement of our intellectual property rights, both inside and outside of the United States. Further, the examination process may require us or our licensors to narrow the claims for our pending patent applications, which may limit the scope of patent protection that may be obtained if these applications issue. The rights already granted under any of our currently issued patents or those licensed to us and those that may be granted under future issued patents may not provide us with the proprietary protection or competitive advantages we are seeking. If we or our licensors are unable to obtain and maintain patent protection for our technology and products, or if the scope of the patent protection obtained is not sufficient, our competitors could develop and commercialize technology and products similar or superior to ours, and our ability to successfully commercialize our technology and products may be adversely affected. It is also possible that we or our licensors will fail to identify patentable aspects of inventions made in the course of our development and commercialization activities before it is too late to obtain patent protection on them. It is also possible that as research and development progresses, the direction of our intellectual property strategy and patent portfolio will change, resulting in strategic business decisions to allow certain patents or patent applications to be abandoned or lapse.

With respect to patent rights, we do not know whether any of the pending patent applications relating to any of our current and potential product candidates will result in the issuance of patents that effectively protect our technology or products, or if any of our licensors' issued patents will effectively prevent others from commercializing competitive technologies and products. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or in some cases not at all, until they are issued as a patent. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions.

Our pending applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, issued patents that we have licensed from third parties may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in the loss of patent protection, the narrowing of claims in such patents or the invalidity or unenforceability of such patents, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection for our technology and products. Protecting against the unauthorized use of our or our licensor's patented technology, trademarks and other intellectual property rights is expensive, difficult and may in some cases not be possible. In some cases, it may be difficult or impossible to detect third-party infringement or misappropriation of our intellectual property rights, even in relation to issued patent claims, and proving any such infringement may be even more difficult.

Third-party claims of intellectual property infringement may prevent or delay our development and commercialization efforts.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and *inter partes* reexamination proceedings before the US Patent and Trademark Office, or US PTO, and corresponding foreign patent offices. Numerous US and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are pursuing development candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our current and potential product candidates may be subject to claims of infringement of the patent rights of third parties.

Third parties may in the future assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our current and potential product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our current and potential product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our current and potential product candidates, or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire.

Similarly, if any third-party patents were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy, the holders of any such patents may be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our current and potential product candidates. Defense of these claims, regardless of their merit, may involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

We may not be successful in obtaining or maintaining necessary rights to product components and processes for our development pipeline through acquisitions and in-licenses.

Presently we believe that we have rights to the intellectual property, through licenses from third parties and under patents that we own, to develop our current and potential product candidates. Because our programs may involve additional product candidates that may require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license or use these proprietary rights. In addition, our current and potential product candidates may require specific formulations to work effectively and efficiently and these rights may be held by others. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment. If we are unable to successfully obtain rights to required third-party intellectual property rights, our business, financial condition and prospects for growth could suffer.

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights.

We may from time to time seek to enforce our intellectual property rights against infringers when we determine that a successful outcome is probable and may lead to an increase in the value of the intellectual property. If we choose to enforce our patent rights against a party, then that individual or company has the right to ask the court to rule that such patents are invalid or should not be enforced. Additionally, the validity of our patents and the patents we have licensed may be challenged if a petition for post grant proceedings such as *inter partes* review and post grant review is filed within the statutorily applicable time with the US PTO. These lawsuits and proceedings are expensive and would consume time and resources and divert the attention of managerial and scientific personnel even if we were successful in stopping the infringement of such patents. In addition, there is a risk that the court will decide that such patents are not valid and that we do not have the right to stop the other party from using the inventions. There is also the risk

that, even if the validity of such patents is upheld, the court will refuse to stop the other party on the ground that such other party's activities do not infringe our intellectual property rights. In addition, in recent years the U.S. Supreme Court modified some tests used by the US PTO in granting patents over the past 20 years, which may decrease the likelihood that we will be able to obtain patents and increase the likelihood of a challenge of any patents we obtain or license.

If we are not able to adequately prevent disclosure of trade secrets and other proprietary information, the value of our technology and products could be significantly diminished.

We rely on trade secrets to protect our proprietary technologies, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

Our reliance on third parties may require us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Because we rely on third parties to manufacture our current and potential product candidates, and because we collaborate with various organizations and academic institutions on the advancement of our current and potential product candidates, we must, at times, share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our manufacturers, collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, such as trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, are used inappropriately to create new inventions or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business.

In addition, these agreements typically restrict the ability of our collaborators, advisors, employees and consultants to publish data potentially relating to our trade secrets. Our academic collaborators typically have rights to publish data, provided that we are notified in advance and may delay publication for a specified time in order to secure our intellectual property rights arising from the collaboration. In other cases, publication rights are controlled exclusively by us, although in some cases we may share these rights with other parties. We may also conduct joint research and development programs that may require us to share trade secrets under the terms of research and development partnerships or similar agreements. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets through breach of these agreements, independent development or publication of information including our trade secrets in cases where we do not have proprietary or otherwise protected rights at the time of publication. A competitor's discovery of our trade secrets may impair our competitive position and have an adverse impact on our business.

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

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

Interference proceedings provoked by third parties or brought by us may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

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

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the US PTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and/or applications. We employ an outside firm and rely on our outside counsel to pay these fees due to non-US patent agencies. The US PTO and various non-US governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market and this circumstance would have a material adverse effect on our business.

Issued patents covering our current and potential product candidates could be found invalid or unenforceable if challenged in court.

If we, MD Anderson or one of our future licensing partners initiated legal proceedings against a third party to enforce a patent covering one of our current and potential product candidates, the defendant could counterclaim that the patent covering our product candidate is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the US PTO, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover our current and potential product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our current and potential product candidates. Such a loss of patent protection would have a material adverse impact on our business.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

We may in the future employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and independent contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of any of our employee's former employer or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely impact our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We may be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patents or other intellectual property. We may have potential ownership disputes arising, for example, from conflicting obligations of consultants, collaborators or others who are involved in developing our current and potential product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

The United States has enacted and is currently implementing wide-ranging patent reform legislation. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts and the U.S. PTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

We have not yet registered the trademark for Oncoprex, and failure to secure such registration could adversely affect our business.

While we own pending trademark applications for the marks "GENPREX" and "ONCOPREX", these marks have not yet been approved by the U.S. Patent and Trademark Office. During trademark registration proceedings, we may receive rejections. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the US PTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. Moreover, any name we propose to use with our current and potential product candidates in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Risks Related to Employee Matters and Managing Growth

We have no sales, marketing or distribution experience and we will have to invest significant resources to develop those capabilities or enter into acceptable third-party sales and marketing arrangements.

We have no sales, marketing or distribution experience. To develop sales, distribution and marketing capabilities, we will have to invest significant amounts of financial and management resources, some of which will need to be committed prior to any confirmation that Oncoprex or any of our other potential product candidates will be approved by the FDA. For product candidates for which we decide to perform sales, marketing and distribution functions ourselves or through third parties, we could face a number of additional risks, including that we or our third-party sales collaborators may not be able to build and maintain an effective marketing or sales force, and we may experience difficulty in managing the growth of our organization. If we use third parties to market and sell our products, we may have limited or no control over their sales, marketing and distribution activities on which our future revenues may depend.

We will need to expand our operations and increase the size of our company, and we may experience difficulties in managing growth.

As of May 15, 2018, we had four full-time employees and one part-time employee. As we advance our current and potential product candidates through preclinical studies and clinical trials, we will need to increase our product development, scientific and administrative headcount to manage these programs. In addition, to meet our obligations as a public company, we may need to increase our general and administrative capabilities. Our management, personnel and systems currently in place may not be adequate to support this future growth. If we are unable to successfully manage this growth and increased complexity of operations, our business may be adversely affected.

We may not be able to manage our business effectively if we are unable to attract and retain key personnel and consultants.

We may not be able to attract or retain qualified management, finance, scientific and clinical personnel and consultants due to the intense competition for qualified personnel and consultants among biotechnology, pharmaceutical and other businesses. If we are not able to attract and retain necessary personnel and consultants to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

We are highly dependent on the development, regulatory, commercialization and business development expertise of our management team, key employees and consultants. Any of our executive officers or key employees or consultants may terminate their employment at any time. If we lose one or more of our executive officers or key employees or consultants, our ability to implement our business strategy successfully could be seriously harmed. Replacing executive officers, key employees and consultants may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain regulatory approval of and commercialize products successfully. Competition to hire and retain employees and consultants from this limited pool is intense, and we may be unable to hire, train, retain or motivate these additional key personnel and consultants. Our failure to retain key personnel or consultants could materially harm our business.

In addition, we have scientific and clinical advisors and consultants who assist us in formulating our research, development and clinical strategies. These advisors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us and typically they will not enter into non-compete agreements with us. If a conflict of interest arises between their work for us and their work for another entity, we may lose their services. In addition, our advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with ours.

We may use our financial and human resources to pursue a particular research program or product candidate and fail to capitalize on programs or product candidates that may be more profitable or for which there is a greater likelihood of success.

Because we have limited resources, we may forego or delay pursuit of opportunities with certain programs or product candidates or for indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs for product candidates may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through strategic collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate, or we may allocate internal resources to a product candidate in a therapeutic area in which it would have been more advantageous to enter into a partnering arrangement.

If we engage in future acquisitions or strategic partnerships, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

We may evaluate and enter into various acquisitions and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies, or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- the issuance of our equity securities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;

- the diversion of our management's attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and marketing approvals; and
- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In addition, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense. Moreover, we may not be able to locate suitable acquisition opportunities and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

Risks Related to Owning Our Common Stock

The market price of our common stock may be highly volatile, and you may lose all or part of your investment.

The market price of our common stock is likely to be volatile. Our stock price could be subject to wide fluctuations in response to a variety of factors, including the following:

- adverse results or delays in preclinical or clinical trials;
- reports of adverse events in other gene therapy products or clinical trials of such products;
- inability to obtain additional funding;
- any delay in filing an IND or BLA for any of our current and potential product candidates and any adverse development or perceived adverse development with respect to the FDA's review of that IND or BLA;
- failure to develop successfully and commercialize our current and potential product candidates;
- failure to maintain our existing strategic collaboration or enter into new collaborations;
- failure by us or our licensors and strategic collaboration partners to prosecute, maintain or enforce our intellectual property rights;
- changes in laws or regulations applicable to future products;
- inability to obtain adequate product supply for our current and potential product candidates or inability to do so at acceptable prices;
- adverse regulatory decisions;
- introduction of new products, services or technologies by our competitors;
- failure to meet or exceed financial projections we may provide to the public;
- failure to meet or exceed the financial projections of the investment community;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us, our strategic collaboration partners or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- additions or departures of key scientific or management personnel;
- significant lawsuits, including patent or stockholder litigation;
- changes in the market valuations of similar companies;

- sales of our common stock by us or our stockholders in the future; and
- trading volume of our common stock.

In addition, companies trading in the stock market in general, and The Nasdaq Capital Market in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance.

Nasdaq may delist our securities from its exchange, which could limit investors' ability to make transactions in our securities and subject us to additional trading restrictions.

Our common stock is listed on The Nasdaq Capital Market. We cannot assure you that, in the future, our securities will meet the continued listing requirements to be listed on The Nasdaq Capital Market. If The Nasdaq Capital Market delists our common stock, we could face significant material adverse consequences, including:

- a limited availability of market quotations for our securities;
- a determination that our common stock is a "penny stock" which will require brokers trading in our common stock to adhere to more stringent rules and possibly resulting in a reduced level of trading activity in the secondary trading market for our common stock;
- a limited amount of news and analyst coverage for our company; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price.

Global credit and financial markets have experienced extreme volatility and disruptions in past years, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. We cannot assure you that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, or do not improve, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget.

We have no intention of declaring dividends in the foreseeable future.

The decision to pay cash dividends on our common stock rests with our board of directors and will depend on our earnings, unencumbered cash, capital requirements and financial condition. We do not anticipate declaring any dividends in the foreseeable future, as we intend to use any excess cash to fund our operations. Investors in our common stock should not expect to receive dividend income on their investment, and investors will be dependent on the appreciation of our common stock to earn a return on their investment.

We are an emerging growth company, and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an emerging growth company, as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years following the year in which we completed the recently completed initial public offering of our common stock, although circumstances could cause us to lose that status earlier. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of the recently completed initial public offering of our common stock, (b) in which we have total annual gross revenue of at least $1 billion or (c) in which we are deemed to be a large accelerated filer, which requires the market value of our common stock that is held by non-affiliates to exceed $700 million as of the prior June 30th, and (2) the date on which we have issued more than $1 billion in nonconvertible debt during the prior three-year period.

Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company" which would allow us to take advantage of many of the same exemptions from disclosure requirements including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. As a result, changes in rules of U.S. generally accepted accounting principles or their interpretation, the adoption of new guidance or the application of existing guidance to changes in our business could significantly affect our financial position and results of operations.

We will incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to existing and new compliance initiatives.

As a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. We will be subject to the reporting requirements of the Securities Exchange Act of 1934, or the Exchange Act, which will require, among other things, that we file with the Securities and Exchange Commission, or the SEC, annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and The Nasdaq Capital Market to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as "say on pay" and proxy access. Recent legislation permits emerging growth companies to implement many of these requirements over a longer period and up to five years from the pricing of the recently completed initial public offering of our common stock. We intend to take advantage of this new legislation but cannot guarantee that we will not be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. Stockholder activism, the current political environment and government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

We expect the rules and regulations applicable to public companies to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition and results of operations. The increased costs will decrease our net income or increase our net loss, and may require us to reduce costs in other areas of our business or increase the prices of our products or services. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

We may be exposed to risks relating to evaluations of controls required by Sarbanes-Oxley Act of 2002.

Pursuant to Sarbanes-Oxley Act of 2002, our management will be required to report on, and our independent registered public accounting firm may in the future be required to attest to, the effectiveness of our internal control over financial reporting. Although we prepare our condensed financial statements in accordance with accounting principles generally accepted in the United States of America, our internal accounting controls may not meet all standards applicable to companies with publicly traded securities. If we fail to implement any required improvements to our disclosure controls and procedures, we may be obligated to report control deficiencies and our independent registered public accounting firm may not be able to certify the effectiveness of our internal controls over financial reporting. In either case, we could become subject to regulatory sanction or investigation. Further, these outcomes could damage investor confidence in the accuracy and reliability of our condensed financial statements.

Failure to continue improving our accounting systems and controls could impair our ability to comply with the financial reporting and internal controls requirements for publicly traded companies.

As a public company, we operate in a demanding regulatory environment, which requires us to comply with the Sarbanes-Oxley Act of 2002, and the related rules and regulations of the SEC. Company responsibilities required by the Sarbanes-Oxley Act include establishing corporate oversight and adequate internal control over financial reporting and disclosure controls and procedures. Effective internal controls are necessary for us to produce reliable financial reports and are important to help prevent financial fraud.

We may need to retain additional finance capabilities and build our financial infrastructure as a public company. Section 404(a) of the Sarbanes-Oxley Act requires annual management assessments of the effectiveness of our internal control over financial reporting, starting with the second annual report that we would expect to file with the SEC. However, for as long as we remain an "emerging growth company" as defined in the JOBS Act, we have and intend to continue to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act. We may continue to take advantage of these reporting exemptions until we are no longer an "emerging growth company." If we cannot provide reliable financial reports or prevent fraud, our business and results of operations could be harmed and investors could lose confidence in our reported financial information.

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

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 cumulative change in its equity ownership by "5-percent shareholders" of greater than 50 percentage points (by value) over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards, or NOLs, and certain other pre-change tax attributes (such as research tax credits) to offset its post-change taxable income and taxes, as applicable, may be limited. We have completed multiple rounds of financing since our inception which may have resulted in an ownership change or could result in an ownership change in the future. We have not completed a Section 382 and 383 analysis regarding any limitations on our NOLs and research and development credit carryforwards and such limitations could be significant. We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As a result, our ability to use our NOLs and research and development credit carryforwards to offset our U.S. federal taxable income and taxes, as applicable, may be subject to limitations, which could potentially result in increased future tax liability to us. In addition, at the state level, similar rules may apply and there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after the lock-up and other legal restrictions on resale lapse, the market price of our common stock could decline. There were 13,896,926 shares of common stock outstanding as of May 15, 2018. Of these shares, 1,180,000 of the 1,280,000 shares sold in our initial public offering are freely tradable, without restriction, in the public market.

The remaining 12,716,926 shares offering are restricted as a result of securities laws or lock-up agreements. The lock-up agreements pertaining to our initial public offering will expire on September 24, 2018, 180 days from the date of the underwriting agreement entered into in connection with our initial public offering. Network 1 Financial Securities, Inc., the underwriter of our initial public offering, may, however, in its sole discretion, permit our officers, directors and other stockholders who are subject to lock-up agreements to sell shares prior to the expiration of the lock-up agreements. These remaining shares will generally become available for sale in the public market as follows:

- up to 345,086 restricted or control shares are eligible for sale, subject to compliance with applicable securities laws; and
- up to another 11,509,918 restricted shares will be eligible for sale upon the expiration of lock-up agreements, also subject to compliance with applicable securities laws.

In addition, as of May 15, 2018, 7,575,209 shares of common stock that are either subject to outstanding options, reserved for future issuance under our equity incentive plan or subject to outstanding warrants will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements and applicable securities laws. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the market price of our common stock could decline.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We intend to seek to raise additional funds, and we may finance acquisitions or develop strategic relationships, in each case by issuing equity or convertible debt securities in addition to the shares issued in the recently completed initial public offering of our common stock, which would reduce the percentage ownership of our existing stockholders. Our board of directors has the authority, in some instances without action or vote of the stockholders, to issue our authorized but unissued shares of common or preferred stock. Our amended and restated certificate of incorporation authorizes us to issue up to 200,000,000 shares of voting common stock and 10,000,000 shares of preferred stock. Future issuances of common or preferred stock would reduce your influence over matters on which stockholders vote and would be dilutive to earnings per share. In addition, any newly issued preferred stock could have rights, preferences and privileges senior to those of the common stock. Those rights, preferences and privileges could include, among other things, the establishment of dividends that must be paid prior to declaring or paying dividends or other distributions to holders of our common stock or providing for preferential liquidation rights. These rights, preferences and privileges could negatively affect the rights of holders of our common stock, and the right to convert such preferred stock into shares of our common stock at a rate or price that would have a dilutive effect on the outstanding shares of our common stock.

Initially, the aggregate number of shares of our common stock that may be issued pursuant to stock awards under our 2018 Plan is 6,788,749 shares. Additionally, the number of shares of our common stock reserved for issuance under our 2018 Plan will automatically increase on January 1 of each year, beginning on January 1, 2019 and continuing through and including January 1, 2028, by 5% of the total number of shares of our capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by our board of directors. Unless our board of directors elects not to increase the number of shares available for future grant each year, our stockholders may experience additional dilution, which could cause our stock price to fall.

If securities or industry analysts do not publish research or reports about us, or if they adversely change their recommendations regarding our common stock, then our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us, our industry and our market. If no analyst elects to cover us and publish research or reports about us, the market for our common stock could be severely limited and our stock price could be adversely affected. In addition, if one or more analysts ceases coverage of us or fails to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline. If one or more analysts who elect to cover us issue negative reports or adversely change their recommendations regarding our common stock, our stock price could decline.

The concentration of our common stock ownership by our current management may limit your ability to influence corporate matters.

Our directors and executive officers beneficially own and are able to vote in the aggregate approximately 22.0% of our outstanding common stock. Accordingly, our directors and executive officers, as stockholders, will continue to have the ability to exert significant influence over all corporate activities, including the election or removal of directors and the outcome of tender offers, mergers, proxy contests or other purchases of common stock that could give our stockholders the opportunity to realize a premium over the then-prevailing market price for their shares of common stock. This concentrated control will limit your ability to influence corporate matters and, as a result, we may take actions that purchasers in the recently completed initial public offering of our common stock do not view as beneficial. In addition, such concentrated control could discourage others from initiating changes of control. In such cases, the perception of our prospects in the market may be adversely affected and the market price of our common stock may decline.

Certain provisions in our organizational documents could enable our board of directors to prevent or delay a change of control.

Our organizational documents contain provisions that may have the effect of discouraging, delaying or preventing a change of control of, or unsolicited acquisition proposals, that a stockholder might consider favorable. These include provisions:

- requiring a majority vote of the outstanding shares of common stock to amend the bylaws;
- provide that the authorized number of directors may be changed only by resolution of the board of directors;
- provide that the board of directors or any individual director may only be removed with cause and the affirmative vote of the holders of at least 66-2/3% of the voting power of all of our then outstanding common stock;
- provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- divide our board of directors into three classes;

- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner and also specify requirements as to the form and content of a stockholder's notice;
- do not provide for cumulative voting rights (therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose);
- provide that special meetings of our stockholders may be called only by the chairman of the board, our Chief Executive Officer or by the board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors; and
- provide that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors or officers to us or our stockholders, (iii) any action asserting a claim against us arising pursuant to any provision of the Delaware General Corporation Law or our certificate of incorporation or bylaws, or (iv) any action asserting a claim against us governed by the internal affairs doctrine. This exclusive forum provision may limit a stockholder's ability to bring such an action in a judicial forum that it finds favorable for such actions and may discourage such actions.

Furthermore, our board of directors has the authority to issue shares of preferred stock in one or more series and to fix the rights and preferences of these shares without stockholder approval. Any series of preferred stock is likely to be senior to our common stock with respect to dividends, liquidation rights and, possibly, voting rights. The ability of our board of directors to issue preferred stock also could have the effect of discouraging unsolicited acquisition proposals, thus adversely affecting the market price of our common stock.

In addition, Delaware law makes it difficult for stockholders that recently have acquired a large interest in a corporation to cause the merger or acquisition of the corporation against the directors' wishes. Under Section 203 of the Delaware General Corporation Law, a Delaware corporation may not engage in any merger or other business combination with an interested stockholder for a period of three years following the date that the stockholder became an interested stockholder except in limited circumstances, including by approval of the corporation's board of directors.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

Recent Sales of Unregistered Securities

During the three months ended March 31, 2018, we issued and sold the following unregistered securities (excluding those previously disclosed in a Quarterly Report on Form 10-Q or in a Current Report on Form 8-K), in each case giving effect to the conversion of each share of our outstanding preferred stock into one share of our common stock and the 6.6841954-for-1 forward split of our common stock effected in connection with the completion of our initial public offering in April 2018:

(1) On January 1, 2018, we issued 33,421 shares of our common stock to a consultant in consideration of services provided by the consultant.

The offer, sale and issuance of the securities described in paragraph (1) was deemed to be exempt from registration under the Securities Act in reliance on Section 4(2) (or Regulation D promulgated thereunder) in that the issuance of securities to the accredited investor did not involve a public offering. The recipient of securities in this transaction acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions. The recipient of securities in this transaction was an accredited investor under Rule 501 of Regulation D.

The recipient of securities in this transaction had adequate access, through employment, business or other relationships, to information about us.

Use of Proceeds

On December 29, 2017, our Registration Statement on Form S-1, as amended (file No. 333-219386) was declared effective by the SEC for our initial public offering of common stock. We issued 1,280,000 shares of common stock at an offering price of $5.00 per share for gross proceeds of $6.4 million. After deducting underwriting discounts, commissions and offering costs incurred by us of $1.375 million, the net proceeds from the offering were $5.025 million. The offering was completed on April 3, 2018. The lead

underwriter for the offering was Network 1 Financial Securities, Inc. No offering costs were paid or are payable, directly or indirectly, to our directors or officers, to persons owning 10% or more of any class of our equity securities, or to any of our affiliates.

We used approximately $200,000 of the net proceeds of our initial public offering to repay a loan from Domecq Sebastian, LLC, an owner of 10% or more of our common stock, as discussed under "Certain Relationships and Related Transactions, and Director Independence – Loan from Domecq Sebastian, LLC."

We used approximately $25,000 of the net proceeds of our initial public offering to repay a loan from Viet Ly, an owner of 10% or more of our common stock, as discussed under "Certain Relationships and Related Transactions, and Director Independence – Loan from Viet Ly."

We used approximately $45,000 of the net proceeds of our initial public offering to repay a loan from Rodney Varner, our Chief Executive Officer and an owner of 10% or more of our common stock, as discussed under "Certain Relationships and Related Transactions, and Director Independence – Loan from Rodney Varner."

There has been no material change in the expected use of the net proceeds from our initial public offering as described in the final prospectus filed with the SEC on March 29, 2018 relating to the recently completed initial public offering of our common stock. Through May 15, 2018, we have used approximately $685,000 of the net proceeds from the offering. Pending such uses, we plan to continue investing the unused proceeds from the recently completed initial public offering of our common stock in fixed, non-speculative income instruments.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Item 6. Exhibits

The exhibits listed on the Index to Exhibits following the signature page are filed as part of this Quarterly Report on Form 10-Q.

INDEX TO EXHIBITS

Exhibit Number	Description of Exhibit
31.1*	Certification of Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
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 Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Document

*Filed herewith.

SIGNATURES

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

GENPREX, INC.

Date: May 15, 2018

By: /s/ Rodney Varner
Rodney Varner
Chief Executive Officer
(Principal Executive Officer)

By: /s/ Ryan Confer
Ryan Confer
Chief Financial Officer
(Principal Financial Officer)

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, J. Rodney Varner, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Genprex, Inc., a Delaware corporation (the "registrant");

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 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)) 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) 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

   (c) 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.

5. The registrant's other certifying officer 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 15, 2018

By: /s/ Rodney Varner
J. Rodney Varner
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Ryan M. Confer, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Genprex, Inc., a Delaware corporation (the "registrant");

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 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)) 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) 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

   (c) 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.

5. The registrant's other certifying officer 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 15, 2018

By: /s/ Ryan Confer
Ryan Confer
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATIONS OF CEO AND CFO 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 on Form 10-Q of Genprex, Inc. (the "Company") for the period ended March 31, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned, J. Rodney Varner, Chief Executive Officer of the Company, and Ryan M. Confer, Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that to the best of his 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 15, 2018

By: /s/ Rodney Varner
J. Rodney Varner
Chief Executive Officer
(Principal Executive Officer)

By: /s/ Ryan Confer
Ryan M. Confer
Chief Financial Officer
(Principal Financial Officer)

This certification accompanies the Report, 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, as amended (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.