UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2017

OR

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

For the transition period from _____ to _____.

Commission File Number: 001-38096

G1 THERAPEUTICS, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**26-3648180**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
79 T.W. Alexander Drive 4501 Research Commons, Suite 100 Research Triangle Park, NC	**27709**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (919) 213-9835

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 (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). 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 the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒ (Do not check if a small reporting company)	Small 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 July 31, 2017, the registrant had 28,285,478 shares of common stock, $0.0001 par value per share, outstanding.

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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

G1 Therapeutics, Inc.
Condensed Consolidated Balance Sheets (unaudited)
(in thousands, except share and per share amounts)

	June 30, 2017 (unaudited)	December 31, 2016
Assets		
Current assets		
Cash and cash equivalents	$ 132,675	$ 47,305
Prepaid expenses and other assets	1,093	596
Total current assets	133,768	47,901
Property and equipment, net	333	311
Total assets	$ 134,101	$ 48,212
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities		
Accounts payable	$ 5,132	$ 2,605
Accrued expenses	5,278	2,853
Warrant liability	—	167
Total current liabilities	10,410	5,625
Commitments and contingencies		
Series C redeemable convertible preferred stock $0.0001 par value, 0 shares authorized, issued and outstanding on June 30, 2017 (unaudited), 17,000,000 shares authorized, 5,609,398 issued and outstanding on December 31, 2016; (liquidation preference of $51,673 on December 31, 2016)	—	51,424
Series B redeemable convertible preferred stock $0.0001 par value, 0 shares authorized, issued and outstanding on June 30, 2017 (unaudited), 23,000,000 shares authorized, 7,642,734 issued and outstanding on December 31, 2016; (liquidation preference of $35,722 on December 31, 2016)	—	40,355
Series A redeemable convertible preferred stock $0.0001 par value, 0 shares authorized, issued and outstanding on June 30, 2017 (unaudited), 14,996,692 shares authorized, 4,998,895 issued and outstanding on December 31, 2016; (liquidation preference of $14,431 on December 31, 2016)	—	14,431
Series 1 redeemable convertible preferred stock $0.0001 par value, 0 shares authorized, issued and outstanding on June 30, 2017 (unaudited), 2,112,025 shares authorized, 682,026 issued and outstanding on December 31, 2016; (liquidation preference of $931 on December 31, 2016)	—	1,370
Stockholders' equity (deficit)		
Common stock, $0.0001 par value, 120,000,000 shares and 73,000,000 shares authorized as of June 30, 2017 and December 31, 2016, respectively; 28,312,144 and 1,504,947 shares issued as of June 30, 2017 and December 31, 2016, respectively; 28,285,478 and 1,478,281 shares outstanding as of June 30, 2017 and December 31, 2016, respectively	3	—
Treasury stock, 26,666 shares	(8)	(8)
Additional paid-in capital	220,232	—
Accumulated deficit	(96,536)	(64,985)
Total stockholders' equity (deficit)	123,691	(64,993)
Total liabilities, mezzanine equity and equity	$ 134,101	$ 48,212

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

G1 Therapeutics, Inc.
Condensed Consolidated Statements of operations and comprehensive loss (unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Revenue	$ —	$ —	$ —	$ —
Operating expenses				
Research and development	13,667	6,454	24,752	10,326
General and administrative	1,712	975	3,006	3,050
Total operating expenses	15,379	7,429	27,758	13,376
Operating loss	(15,379)	(7,429)	(27,758)	(13,376)
Other income (expense)				
Other income	185	50	260	62
Change in fair value in warrant liability and other liabilities	—	—	(41)	(19)
Total other income, net	185	50	219	43
Net loss	$ (15,194)	$ (7,379)	$ (27,539)	$ (13,333)
Accretion of redeemable convertible preferred stock	(289)	(986)	(4,757)	(1,995)
Net loss attributable to common stockholders	$ (15,483)	$ (8,365)	$ (32,296)	$ (15,328)
Net loss per share attributable to common stockholders, basic and diluted	$ (1.09)	$ (5.63)	$ (4.09)	$ (10.34)
Weighted average common shares outstanding, basic and diluted	14,208,115	1,486,303	7,887,341	1,481,761

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

G1 Therapeutics, Inc.
Condensed Consolidated Statements of Cash Flows (unaudited)
(amounts in thousands)

	Six Months Ended June 30,	
	2017	**2016**
Cash flows from operating activities		
Net loss	$ (27,539)	$ (13,333)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	32	26
Stock-based compensation	1,317	539
Gain/loss on disposal of property and equipment	—	6
Increase in fair value of warrant activity	41	19
Change in operating assets and liabilities		
Prepaid expenses and other assets	(497)	235
Accounts payable and accrued expenses	4,629	1,862
Net cash used in operating activities	(22,017)	(10,646)
Cash flows from investing activities		
Purchases of property and equipment	(34)	(85)
Net cash used in investing activities	(34)	(85)
Cash flows from financing activities		
Proceeds from stock options and warrants exercised	13	5
Proceeds from Series C preferred stock	—	50,000
Issuance costs for preferred share financings	—	(249)
Proceeds from initial public offering, net of underwriting fees and commissions	108,503	—
Payment of public offering costs	(1,095)	—
Net cash provided by financing activities	107,421	49,756
Net change in cash and cash equivalents	85,370	39,025
Cash and cash equivalents		
Beginning of period	47,305	22,938
End of period	$ 132,675	$ 61,963
Non-cash investing and financing activities		
Accretion of redeemable convertible preferred stock	$ 4,757	$ 1,995
Purchases of equipment with accounts payable and accrued expenses	$ 20	$ -
Conversion of preferred stock and preferred warrants to common stock and common warrants	$ 112,337	$ -
Deferred offering costs reclassified to additional paid-in capital	$ 1,398	$ -
Costs for public offering in accounts payable	$ 303	$ -

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

1. Business Description

G1 Therapeutics, Inc. (the "Company") is a clinical-stage biopharmaceutical company based in Research Triangle Park, North Carolina dedicated to the discovery and development of novel therapeutics for the treatment of cancer. The Company was incorporated on May 19, 2008 in the state of Delaware.

The Company focuses on cyclin-dependent kinases (CDKs), a family of proteins that plays an important role in the growth and proliferation of all human cells. The Company has focused its CDK research on developing potent and selective inhibitors of the kinases CDK4 and CDK6, collectively known as CDK4/6, a validated and promising class of targets for anti-cancer therapeutics. The Company is currently advancing two CDK4/6 inhibitor product candidates in clinical development, trilaciclib and G1T38, each of which has broad therapeutic potential in many forms of cancer and may serve as the backbone of multiple combination regimens.

Trilaciclib, the Company's most advanced clinical-stage candidate, is a potential first-in-class intravenous CDK4/6 inhibitor designed to preserve hematopoietic stem and progenitor cells and enhance immune system function during chemotherapy. Based on compelling response rates and favorable tolerability shown in early-stage trials, trilaciclib is currently being evaluated in four randomized trials: two Phase 1b/2a trials in patients with small cell lung cancer, or SCLC, an additional Phase 2 trial in combination with Tecentriq in SCLC and a Phase 2 in patients with triple-negative breast cancer, or TNBC.

G1T38, the Company's second clinical-stage candidate, is a potential best-in-class oral CDK4/6 inhibitor, to be used in combination with other targeted therapies to treat multiple cancers. A Phase 1 trial of G1T38 in 75 healthy volunteers showed a favorable safety profile, and the Company initiated a Phase 1/2 trial in ER+, HER2- breast cancer in January 2017.

As part of the Company's strategy to develop wholly-owned proprietary combinations, the Company is advancing the development of G1T48, a potential first/best-in-class oral selective estrogen receptor degrader, or SERD, which is targeted for the treatment of ER+ breast cancer.

The Company's financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. As of June 30, 2017, the Company had an accumulated deficit of $96.5 million. The Company has reported a net loss in all fiscal periods since inception and expects to incur substantial losses in the future to conduct research and development and pre-commercialization activities. These factors raised substantial doubt about its ability to continue as a going concern prior to the Company's initial public offering (the "IPO").

On May 22, 2017, the Company closed its IPO of 7,781,564 shares of the Company's common stock at a public offering price of $15.00 per share, including 781,564 shares of common stock issued upon exercise by the underwriters of their option to purchase additional shares. The gross proceeds from the IPO were $116.7 million and net proceeds were $107.1 million, after deducting underwriting discounts and commissions and other offering expenses payable by the Company.

Upon completion of the Company's IPO, all outstanding preferred stock was automatically converted into an aggregate of 18.9 million shares of common stock. In connection with the IPO, the Board of Directors and the stockholders of the Company approved a one-for-three reverse stock split of the Company's common stock. The reverse stock split became effective on May 11, 2017. All share and per share amounts in the condensed consolidated financial statements have been retroactively adjusted for all periods presented to give effect to the reverse stock split, including reclassifying an amount equal to the reduction in par value to accumulated deficit. The authorized number of shares of common stock was increased to 120.0 million to be effective as of the date of effectiveness of the Company's registration statement for its IPO.

As of June 30, 2017, the Company had cash and cash equivalents of $132.7 million. The Company expects that its existing cash and cash equivalents will enable it to fund its operating expenses and capital expenditure requirements for at least 24 months. The failure of the Company to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on the Company's results of operations and financial condition.

2. Basis of Presentation and Summary of Significant Accounting Policies

Basis of Presentation and Consolidation

The accompanying condensed consolidated financial statements of the Company have been prepared in accordance with generally accepted accounting principles in the United States of America ("U.S. GAAP"). The year-end condensed balance sheet data was derived from audited financial statements but does not include all disclosures required by U.S. GAAP.

The information presented in the condensed consolidated financial statements and related notes as of June 30, 2017, and for the three and six months ended June 30, 2017 and 2016, is unaudited. The December 31, 2016 condensed consolidated balance sheet included herein was derived from the audited financial statements as of that date, but does not include all disclosures, including notes, required by GAAP for complete financial statements.

Use of estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and the accompanying notes. On an ongoing basis, the Company's management evaluates its estimates which include, but are not limited to, estimates related to accrued expenses, accrued external clinical costs, stock-based compensation expense and deferred tax asset valuation allowance. The Company bases its estimates on historical experience and other market specific or other relevant assumptions it believes to be reasonable under the circumstances. Actual results could differ from those estimates.

Unaudited Interim Condensed Consolidated Financial Statements

The accompanying interim condensed consolidated financial statements and the related footnote disclosures are unaudited. These unaudited interim condensed consolidated financial statements have been prepared in accordance with U.S. GAAP on the same basis as the audited consolidated financial statements and in the opinion of management, reflect all adjustments of a normal, recurring nature that are necessary for the fair statement of the Company's financial position as of June 30, 2017 and its results of operations and cash flows for the six months ended June 30, 2017 and 2016. The results for the six months ended June 30, 2017 are not necessarily indicative of the results expected for the full fiscal year or any future period. These interim financial statements should be read in conjunction with the financial statements and notes set forth in the Company's registration statement on Form S-1 under the Securities Act of 1933, as amended, declared effective by the SEC on May 16, 2017.

Income taxes

The Company did not record a federal or state income tax benefit for the three and six months ended June 30, 2017 and 2016 due to its conclusion that a full valuation allowance is required against the Company's deferred tax assets.

Income taxes are accounted for using the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to temporary differences between the financial statements carrying amounts of assets and liabilities and their respective tax bases, operating loss carryforwards, and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

In accordance with Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) 740, *Accounting for Income Taxes*, the Company reflects in the financial statements the benefit of positions taken in a previously filed tax return or expected to be taken in a future tax return only when it is considered 'more-likely-than-not' that the position taken will be sustained by a taxing authority. As of June 30, 2017 and December 31, 2016, the Company had no unrecognized income tax benefits and correspondingly there is no impact on the Company's effective income tax rate associated with these items. The Company's policy for recording interest and penalties relating to uncertain income tax positions is to record them as a component of income tax expense in the accompanying statements of operations. As of June 30, 2017 and December 31, 2016, the Company had no such accruals.

Stock-Based Compensation

The primary type of stock-based payments utilized by the Company are stock options. The Company accounts for stock-based employee compensation arrangements by measuring the cost of employee services received in exchange for all equity awards granted based on the fair value of the award on the grant date. The fair value of each employee stock option is estimated on the date of grant using an options pricing model. The Company currently uses the Black-Scholes valuation model to estimate the fair value of its share-

based payments. The model requires management to make a number of assumptions including expected volatility, expected life, risk-free interest rate and expected dividends.

The Company accounts for stock-based non-employee compensation arrangements by recording the expense of such services based on the fair value of the equity instrument as estimated using the Black-Scholes pricing model. The fair value of the equity instrument is charged to operating expense over the term of the service agreement.

Recent Accounting Pronouncements

In October 2016, the FASB issued ASU No. 2016-17, *Consolidation (Topic 810): Interests Held through Related Parties That Are under Common Control*, which amends the consolidation guidance on how a reporting entity that is a single decision maker of a variable interest entity should treat indirect interest in the entity held through related parties that are under common control. This guidance is effective for annual periods beginning after December 15, 2016, including interim periods within those annual periods, with early adoption permitted. The Company adopted this ASU on January 1, 2017. The adoption of this standard did not have a material impact on the Company's financial statements.

In March 2016, the FASB issued ASU No. 2016-09, *Compensation—Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*. The FASB issued ASU 2016-09 to simplify several aspects of the accounting for share-based payment transactions, including the income tax consequences. This ASU is effective for annual and interim periods ending after December 15, 2016, with early adoption permitted. This ASU was adopted by the Company for the year ended December 31, 2016. The adoption of this standard did not have a material impact on its financial statements.

In November 2014, the FASB issued ASU No. 2014-16, *Determining Whether the Host Contract in a Hybrid Financial Instrument Issued in the Form of a Share Is More Akin to Debt or to Equity*. The guidance requires an entity to determine the nature of the host contract by considering all stated and implied substantive terms and features of the hybrid financial instrument, weighing each term and feature on the basis of the relevant facts and circumstances (commonly referred to as the whole-instrument approach). ASU 2014-16 applies to all entities and is effective for annual periods beginning after December 15, 2015, and interim periods thereafter. The ASU was adopted by the Company for the year ended December 31, 2016. Adoption of this standard did not have material impact on its financial statements.

In August 2014, the FASB issued ASU No. 2014-15, *Presentation of Financial Statements—Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*, requiring management to evaluate whether events or conditions could impact an entity's ability to continue as a going concern for at least one year after the date that the financial statements are issued and to provide disclosures if necessary. Disclosures will be required if conditions give rise to substantial doubt and the type of disclosure will be determined based on whether management's plans will be able to alleviate the substantial doubt. The ASU was effective for the first annual period ending after December 15, 2016, and for annual periods and interim periods thereafter with early application permitted. The ASU was adopted by the Company for the fourth quarter ended December 31, 2016. Refer to updated disclosures in Note 1 for the impact of this adoption.

In June 2014, the FASB issued ASU No. 2014-12, *Compensation – Stock Compensation (Topic 718): Accounting for Share-Based Payments When the Terms of an Award Provide That a Performance Target Could be Achieved* after the Requisite Service Period, which requires the Company to assess share-based awards with performance targets that could be achieved after the requisite service period for potential treatment as performance conditions. Under the ASU, compensation expense is to be recognized when the performance target is deemed probable and should represent the compensation expense attributable to the periods for which service has already been rendered. If the performance target is reached prior to achievement of the service period, the remaining unrecognized compensation cost should be recognized over the remaining service period. The ASU is effective for annual and interim periods beginning after December 15, 2015 with early adoption permitted. This ASU was adopted by the Company for the year ended December 31, 2016. The adoption of this standard did not have a material impact on its financial statements.

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments*. The FASB issued ASU 2016-09 to improve U.S. GAAP by providing guidance on the cash flow statement classification of eight specific areas where there is existing diversity in practice. The FASB expects that the guidance in this ASU will reduce the current and potential future diversity in practice in such areas. This ASU is effective for annual and interim periods beginning after December 15, 2017, with early adoption permitted. The Company is currently evaluating the impact of the adoption of this ASU on the Company's financial statements.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*. This guidance revises the accounting related to leases by requiring lessees to recognize a lease liability and a right-of-use asset for all leases. The new lease guidance also simplifies the accounting for sale and leaseback transactions. This ASU is effective for annual reporting periods beginning after December 15, 2018

and early adoption is permitted. The Company is currently evaluating the impact of the adoption of this ASU on the Company's financial statements.

In May 2014, the FASB and the International Accounting Standards Board jointly issued ASU No. 2014-09, *Revenue from Contracts with Customers*, which supersedes the revenue recognition requirements in ASC 605 and most industry-specific guidance. The new standard requires that an entity recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods and services. The update also requires additional disclosures about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgements and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. ASU 2014-09 is effective for public entities for annual and interim periods within those annual periods beginning after December 15, 2017. The Company is currently evaluating the method of adoption and the potential impact this standard may have on its financial position and results of operations.

3. Fair Value Measurements

The Company provides disclosure of financial assets and financial liabilities that are carried at fair value based on the price that would be received upon sale of an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. Fair value measurements may be classified based on the amount of subjectivity associated with the inputs to fair valuation of these assets and liabilities using the following three levels:

Level 1 — Inputs are unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date.

Level 2 — Inputs include quoted prices for similar assets and liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active, inputs other than quoted prices that are observable for the asset or liability and inputs that are derived principally from or corroborated by observable market data by correlation or other means.

Level 3 — Unobservable inputs that reflect the Company's estimates of the assumptions that market participants would use in pricing the asset or liability. The Company develops these inputs based on the best information available, including its own data.

The carrying amounts of cash, cash equivalents, accounts payable and accrued liabilities approximate fair value because of their short-term nature.

At June 30, 2017 and December 31, 2016 these financials instruments and respective fair values have been classified as follows (in thousands):

	Quoted prices in active markets for identical assets (Level 1) (unaudited)	Significant other observable inputs (Level 2) (unaudited)	Significant other unobservable inputs (Level 3) (unaudited)	Balance at June 30, 2017 (unaudited)
Assets				
Money market funds	$ 116,613	$ —	$ —	$ 116,613
Certificates of Deposit	15,107	—	—	15,107
Total assets at fair value:	$ 131,720	$ —	$ —	$ 131,720
Liabilities:				
Warrant Liability	$ —	$ —	$ —	$ —
Total liabilities at fair value:	$ —	$ —	$ —	$ —

	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant other unobservable inputs (Level 3)	Balance at December 31, 2016
Assets				
Money market funds	$ 31,730	$ —	$ —	$ 31,730
Certificates of Deposit	15,041	—	—	15,041
Total assets at fair value:	$ 46,771	$ —	$ —	$ 46,771
Liabilities:				
Warrant Liability	$ —	$ —	$ 167	$ 167
Total liabilities at fair value:	$ —	$ —	$ 167	$ 167

During the three and six months ended June 30, 2017 and the year ended December 31, 2016, there were no changes in valuation techniques.

4. Property and equipment

Property and equipment consists of the following (in thousands):

	June 30, 2017 (unaudited)	December 31, 2016
Computer equipment	$ 84	$ 67
Laboratory equipment	207	207
Furniture and fixtures	81	64
Leasehold improvements	80	80
Construction in progress	20	—
Accumulated depreciation	(139)	(107)
Property and equipment, net	$ 333	$ 311

Depreciation expenses relating to property and equipment were $20 and $32 for the three and six months ended June 30, 2017, respectively, and $13 and $26 for the three and six months ended June 30, 2016, respectively.

5. Patent license agreement

On November 23, 2016, the Company entered into a license agreement with the Board of Trustees of the University of Illinois (the University), which was amended on March 24, 2017. Pursuant to the license agreement, as amended, the University licensed patent rights to the Company, with rights of sublicense, to make, have made, use, import, sell and offer for sale products covered by certain patent rights owned by the University. The rights licensed to the Company are exclusive, worldwide, non-transferable rights, for all fields of use. Under the terms of the agreement the Company paid a one-time only, non-refundable license issue fee in the amount of $0.5 million which was charged to research and development expense in the fourth quarter of 2016.

The Company is also obligated to pay annual maintenance fees to the University. All annual minimum payments are fully creditable against any royalty payments made by the Company. Under the terms of the agreement, the Company must pay the University a royalty percentage on all net sales of products and a share of sublicensing revenues. The University is eligible to receive milestone payments of up to $2.625 million related to the initiation and execution of clinical trials and first commercial sale of a product in multiple countries. The Company is also responsible for all future patent prosecution costs.

The term of the license agreement will continue until the later of (i) the expiration of the last valid claim within the patent rights covering the product in such country, (ii) the expiration of market exclusivity in such country and (iii) the 10th anniversary of the first commercial sale in such country. The University may terminate the agreement in the event (i) the Company fails to pay any amount or make any report when required to be made and fails to cure such failure within thirty (30) days after receipt of notice from the University, (ii) is in breach of any provision of the agreement and fails to remedy within forty-five (45) days after receipt of notice, (iii) makes a report to the University under the agreement that is determine to be materially false, (iv) declares insolvency or bankruptcy or (v) takes an action that causes patent rights or technical information to be subject to lien or encumbrance and fails to

remedy any such breach with in forty-five (45) days of receipt of notice from the University. The Company may terminate the agreement at any time on written notice to the University at least ninety (90) days prior to the termination date specified in the notice. Upon expiration or termination of the agreement, all rights revert to the University.

6. Accrued expenses

Accrued expenses are comprised as follows (in thousands):

	June 30, 2017 (unaudited)	December 31, 2016
Accrued external research and professional fees	$ 753	$ 295
Accrued external clinical study costs	3,956	1,897
Accrued compensation expense	498	617
Deferred rent	71	44
Accrued expenses	$ 5,278	$ 2,853

7. Common Stock and Preferred Stock

Common Stock

The Company is authorized to issue 120.0 million shares of common stock. Holders of common stock are entitled to one vote per share. Holders of common stock are entitled to receive dividends, as, if and when declared by the Company's Board of Directors.

Preferred Stock

Upon completion of the Company's IPO, all outstanding preferred stock was automatically converted into an aggregate of 18.9 million shares of common stock. The Company is also authorized to issue 5.0 million shares of undesignated preferred stock in one or more series. As of June 30, 2017, no shares of preferred stock were issued or outstanding.

Shares Reserved for Future Issuance

The Company has reserved for future issuance the following number of shares of common stock:

	June 30, 2017 (unaudited)	December 31, 2016
Conversion of Series C Preferred Stock on a fully-diluted basis	—	5,609,398
Conversion of Series B Preferred Stock on a fully-diluted basis	—	7,642,734
Conversion of Series A Preferred Stock on a fully-diluted basis	—	4,998,895
Conversion of Series 1 Preferred Stock on a fully-diluted basis	—	682,026
Common stock warrants issued with promissory notes	—	16,666
Other common stock warrants	—	3,466
Series 1 Preferred Stock warrants issued with promissory notes	—	21,978
Common stock options outstanding	3,757,557	3,690,058
Options available for grant under Equity Incentive Plans	1,932,000	176,919
	5,689,557	22,842,140

8. Stock-based Compensation

2011 Equity Incentive Plan

In March 2011, the Company adopted the 2011 Equity Incentive Plan (the "2011 Plan"). The 2011 Plan provided for the direct award or sale of the Company's common stock and for the grant of stock options to employees, directors, officers, consultants and advisors of the Company. The 2011 Plan was subsequently amended in August 2012, October 2013, February 2015, December 2015, April 2016 and November 2016 to allow for the issuance of additional shares of common stock. In connection with the adoption of the 2017 Plan (as defined below), the 2011 Plan was terminated and no further awards will be made under the 2011 Plan.

2017 Equity Incentive Plan

In May 2017, the Company adopted the 2017 Equity Incentive Plan (the "2017 Plan"). The 2017 Plan provided for the direct award or sale of the Company's common stock and for the grant of up to 1,932,000 stock options to employees, directors, officers, consultants and advisors of the Company. The 2017 Plan provides for the grant of incentive stock options, non-statutory stock options or restricted stock.

Under both the 2011 Plan and the 2017 Plan, options to purchase the Company's common stock may be granted at a price no less than the fair market value of a share of common stock on the date of grant. The fair value shall be the closing sales price for a share as quoted on any established securities exchange for such grant date or the last preceding date for which such quotation exists. Vesting terms of options issued are determined by the board of directors or compensation committee of the board. The Company's stock options vest based on terms in the stock option agreements. Stock options have a maximum term of ten years.

As of June 30, 2017, there were a total of 1,932,000 shares of common stock available for future issuance under the 2017 Plan.

Stock Option Expense

The Company recognizes compensation costs related to stock options granted to employees based on the estimated fair value of the awards on the date of grant, net of estimated forfeitures. The grant date fair value of the stock-based awards is generally recognized on a straight-line basis over the requisite service period, which is generally the vesting period of the respective awards. Share-based awards granted to non-employee directors as compensation for serving on the Company's Board of Directors are accounted for in the same manner as employee share based compensation awards.

During the three and six months ended June 30, 2017, the Company recorded employee share-based compensation expense of $353 and $674, respectively. During the three and six months ended June 30, 2016, the Company recorded employee share-based compensation expense of $205 and $333, respectively.

The company recognizes compensation costs related to stock options granted to non-employees based on the estimated fair value of the awards on the date of grant in the same manner as employees; however, the fair value of the stock options granted to non-employees is re-measured each reporting period until the service is complete, and the resulting increase or decrease in value, if any, is recognized as expense or income, respectively, during the period the related services are rendered.

During the three and six months ended June 30, 2017, the Company recorded non-employee share-based compensation expense of $416 and $643, respectively. During the three and six months ended June 30, 2016, the Company recorded non-employee share-based compensation expense of $113 and $206, respectively.

The Company calculates the fair value of stock options using the Black-Scholes option pricing model. The Black-Scholes option-pricing model requires the use of subjective assumptions, including the expected volatility of the Company's common stock, the assumed dividend yield, the expected term of the Company's stock options and the fair value of the underlying common stock on the date of grant.

Stock options— Black-Scholes inputs

The fair value of stock options was estimated using the following weighted-average assumptions for the three and six months ended June 30, 2017 and June 30, 2016:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
	(unaudited)		(unaudited)	
Expected volatility	74.2 - 75.1%	74.7 - 77.3%	74.2 - 79.3%	74.7 - 77.3%
Weighted-average risk free rate	1.9 - 2.0%	1.2 - 1.4%	1.9 - 2.1%	1.2 - 1.4%
Dividend yield	—%	—%	—%	—%
Expected term (in years)	6.04	6.02	6.05	6.02

The table below summarizes the stock-based compensation expense recognized in our statement of operations by classification (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
	(unaudited)		(unaudited)	
Research and development	$ 610	$ 205	$ 1,004	$ 354
General and administrative	159	113	313	185
Total stock-based compensation expense	$ 769	$ 318	$ 1,317	$ 539

Stock Option Activity

Stock option activity for the six months ended June 30, 2017 is as follows:

	Options outstanding	Weighted average exercise price	Weighted average Remaining contractual for life (Years)	Aggregate intrinsic value
				(in thousands)
Balance as of December 31, 2016	3,690,058	$ 2.13	8.4	$ 17,463
Cancelled	—	$ —		
Granted	119,997	8.18		
Exercised	(52,498)	0.33		
Balance as of June 30, 2017	3,757,557	$ 2.36	8.0	$ 56,680
Exercisable at December 31, 2016	1,396,191	0.84	7.8	$ 8,410
Vested at December 31, 2016 and expected to vest	3,690,058	2.13	8.4	$ 17,463
Exercisable at June 30, 2017	1,876,012	1.36	7.6	$ 30,132
Vested at June 30, 2017 and expected to vest	3,757,557	2.36	8.0	$ 56,680

9. Net loss per common share

Net loss per common share

Basic net loss per common share is computed using the weighted average number of common shares outstanding during the period including nominal issuances of common stock warrants. Diluted net loss per common share is computed using the sum of the weighted average number of common shares outstanding during the period and, if dilutive, the weighted average number of potential shares of common stock, including the assumed exercise of stock options, stock warrants and unvested restricted common stock. For the three months ended June 30, 2017 and 2016 and for the six months ended June 30, 2017 and 2016, the following potentially dilutive securities have been excluded from the computations of diluted weighted-average shares outstanding because the effect would be anti-dilutive:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
	(unaudited)		(unaudited)	
Stock options issued and outstanding	3,793,433	3,097,794	3,760,300	2,853,131
Stock warrants	20,503	25,444	22,960	25,444
	3,813,936	3,123,238	3,783,260	2,878,575

Amounts in the table above reflect the common stock equivalents of the noted instruments.

The following table summarizes the calculation of the basic and diluted net loss per common share (in thousands, except share and per share amounts):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
	(unaudited)		(unaudited)	
Numerator:				
Loss from operations	$ (15,194)	$ (7,379)	$ (27,539)	$ (13,333)
Less: accretion of redeemable convertible preferred stock	(289)	(986)	(4,757)	(1,995)
Net loss attributable to common stockholders	$ (15,483)	$ (8,365)	$ (32,296)	$ (15,328)
Denominator:				
Weighted-average basic and diluted common shares	14,208,115	1,486,303	7,887,341	1,481,761
Basic and diluted net loss per common share	$ (1.09)	$ (5.63)	$ (4.09)	$ (10.34)

10. Related party transactions

Two co-founders and shareholders of the Company held consulting agreements with the Company relating to their continued development work. The founders received consulting fees of approximately $14 for the three months ended June 30, 2017 and June 30, 2016 and $27 for the six months ended June 30, 2017 and June 30, 3016, under the agreements.

The Company paid approximately $2 and $5 to the Chairman of the Board of Directors for consulting services during the three months ended June 30, 2017 and June 30, 2016, respectively and $8 and $9 for the six months ended June 30, 2017 and June 30, 2016, respectively.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and related notes included elsewhere in this quarterly report. This discussion and other parts of this quarterly report contain forward-looking statements that involve risks and uncertainties, such as statements of our plans, objectives, expectations and intentions. As a result of many factors, including those factors set forth in the "Risk Factors" section of this quarterly report, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a clinical-stage biopharmaceutical company focused on the discovery and development of novel therapeutics for the treatment of cancer. Our two clinical assets are based on our core understanding of cyclin-dependent kinases, or CDKs, a family of proteins that play an important role in the growth and proliferation of all human cells. Two particular CDKs, CDK4 and CDK6, collectively known as CDK4/6, represent a validated and promising class of targets for anti-cancer therapeutics. We have leveraged our deep expertise in CDK4/6 biology to discover and develop two highly potent and selective CDK4/6 inhibitors that may have broad applicability across multiple cancer indications. We believe we are the only company with two distinct clinical-stage CDK4/6 inhibitors, trilaciclib and G1T38, each of which has the potential to be the backbone therapy of multiple combination regimens.

CDK4/6 is required for growth and proliferation in certain normal cell types, such as hematopoietic stem and progenitor cells, or HSPCs. HSPCs reside in the bone marrow and are the "reservoir" from which all blood and immune system cells are formed. Additionally, CDK4/6 plays an integral role in the growth and proliferation of certain types of tumors. Tumors that rely on CDK4/6 to grow and proliferate are referred to as CDK4/6-dependent tumors, and include the most common kinds of prostate and breast cancer. Alternatively, some tumors can grow and proliferate without CDK4/6 activity and are referred to as CDK4/6-independent. CDK4/6 independent tumors include small cell lung cancer, or SCLC, and triple-negative breast cancer, or TNBC. Our two CDK4/6 inhibitors were rationally designed to treat distinct patient populations with different combination regimens. Trilaciclib is in development in combination with chemotherapy for the treatment of patients with CDK4/6-independent tumors. G1T38 is in development in combination with targeted therapies for the treatment of patients with CDK4/6-dependent tumors.

Trilaciclib, our most advanced candidate, is a potential first-in-class intravenous CDK4/6 inhibitor we rationally designed to preserve HSPCs and enhance immune system function during chemotherapy. Chemotherapy has significant clinical utility and continues to be the most effective treatment for many cancers. However, it also damages HSPCs (myelosuppression) and the immune system (immunosuppression), leading to severe adverse effects and limiting anti-tumor activity. We believe that if the beneficial effects of chemotherapy (i.e. potent tumor cell killing) could be maximized, while minimizing the deleterious side-effects of myelosuppression and immunosuppression, patient outcomes would be significantly improved.

Based on compelling response rates and favorable tolerability in early-stage trials, trilaciclib is currently being evaluated in four randomized trials: two Phase 1b/2a trials in patients with SCLC, an additional Phase 2 trial in combination with Tecentriq in SCLC and a Phase 2 trial in patients with TNBC. We have completed the Phase 1b parts of the two SCLC trials, and presented the results of the Phase 1b part of the first-line SCLC trial at the 2017 American Society of Clinical Oncology (ASCO) Annual Meeting. We have completed enrollment of the Phase 2a part of the first-line SCLC trial, with top-line data expected in the first quarter of 2018. Enrollment for the Phase 2a trial in second/ third-line SCLC is being increased by approximately 30 patients and completion of enrollment is expected in the second quarter of 2018. These additional patients will receive a topotecan dose of 1.5 mg/m^2 + trilaciclib, which is designed to complement data from patients who are receiving a topotecan dose of 0.75 mg/m^2 + trilaciclib; both doses are in the FDA-approved topotecan label. Preliminary data from this trial and the TNBC trial are expected later in 2018.

G1T38, our second clinical-stage candidate, is a potential best-in-class oral CDK4/6 inhibitor being developed to be used in combination with other targeted therapies to treat multiple cancers. We rationally designed G1T38 to improve upon and address the shortcomings of the approved CDK4/6 inhibitors Ibrance and Kisqali and others in development. Our preclinical data and early clinical data indicate the potential for continuous daily dosing and improved antitumor activity and tolerability. A Phase 1 trial of G1T38 in 75 healthy volunteers showed a favorable safety profile leading to the initiation of a Phase 1/2 trial in ER+, HER2- breast cancer (in combination with Faslodex) in January 2017. Our plans for G1T38 include its use in other cancers, serving as the backbone of multiple combination regimens.

As part of our strategy to develop wholly owned proprietary combinations that complement our CDK4/6 portfolio, we are advancing the preclinical development of G1T48, a potential first/best-in-class oral selective estrogen receptor degrader, or SERD. We expect to develop G1T48 as a single agent and in combination with G1T38 for the treatment of ER+, HER2- breast cancer. Based on compelling preclinical efficacy and safety data, we expect to file an investigational new drug application, or IND, for G1T48 in the

fourth quarter of 2017. We plan to continue to leverage our proprietary assets and knowledge of CDK4/6 biology to explore additional combination treatments and to build a fully integrated oncology company.

Financial Overview

Since our inception in 2008, we have devoted substantially all of our resources to synthesizing, acquiring, testing and developing our product candidates, including conducting preclinical studies and clinical trials and providing general and administrative support for these operations as well as securing intellectual property protection for our product candidates. We do not have any products approved for sale and have not generated any revenues from product sales. We recorded $0 million of revenue for the three and six months ended June 30, 2017 and the year ended December 31, 2016. To date, we have financed our operations primarily through the sale of equity securities.

On May 22, 2017, we closed our initial public offering ("IPO") of 7,781,564 shares of common stock at a public offering price of $15.00 per share, including 781,564 shares of common stock issued upon exercise by the underwriters of their option to purchase additional shares. The gross proceeds from the IPO were $116.7 million and net proceeds were $107.1 million, after deducting underwriting discounts and commissions and other offering expenses payable by us.

As of June 30, 2017, we had an accumulated deficit of $96.5 million. Substantially all of our net losses have resulted from costs incurred in connection with our research and development programs and from general and administrative expenses associated with our operations. We expect to continue to incur significant expenses and increasing operating losses over at least the foreseeable future. We expect our expenses will increase substantially in connection with our ongoing and future activities as we:

- continue development of our product candidates, including initiating additional clinical trials of trilaciclib and G1T38 and completing preclinical studies and potentially initiating clinical trials of our preclinical-stage product candidate, G1T48;
- identify and develop new product candidates;
- seek marketing approvals for our product candidates that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- achieve market acceptance of our product candidates in the medical community and with third-party payors;
- maintain, expand and protect our intellectual property portfolio;
- hire additional personnel;
- enter into collaboration arrangements, if any, for the development of our product candidates or in-license other products and technologies;
- add operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts; and
- incur increased costs as a result of operating as a public company.

License agreement with the University of Illinois

In November 2016, we entered into a license agreement with the University of Illinois, or UIC, pursuant to which we obtained an exclusive, worldwide license to make, have made, use, import, sell and offer for sale SERDs, including G1T48, covered by certain patent rights owned UIC. The rights licensed to us are for all fields of use. Under the terms of the agreement, as amended, we paid a one-time only, non-refundable upfront fee of $0.5 million, and are required to pay UIC low single-digit royalties on all net sales of products and a share of any sublicensing revenues. We are also obligated to pay annual maintenance fees, which are fully creditable against any royalty payments made by us. We may also be required to pay UIC milestone payments of up to an aggregate of $2.625 million related to the initiation and execution of clinical trials and first commercial sale of a product in multiple countries. We are responsible for all future patent prosecution costs.

Components of our Results of Operations

Research and Development Expenses

The largest component of our total operating expenses since inception has been research and development activities, including the preclinical and clinical development of our product candidates.

Research and development costs are expensed as incurred. Our research and development expense primarily consists of:

- salaries and personnel-related costs, including bonuses, benefits and any stock-based compensation, for our scientific personnel performing or managing out-sourced research and development activities;
- costs incurred under agreements with contract research organizations and investigative sites that conduct preclinical studies and clinical trials;
- costs related to manufacturing pharmaceutical active ingredients and drug products for preclinical studies and clinical trials;
- costs related to upfront and milestone payments under in-licensing agreements;
- fees paid to consultants and other third parties who support our product candidate development;
- other costs incurred in seeking regulatory approval of our product candidates; and
- allocated facility-related costs and overhead.

The successful development of our product candidates is highly uncertain. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. Accordingly, we expect research and development costs to increase significantly for the foreseeable future as programs progress. However, we do not believe that it is possible at this time to accurately project total program-specific expenses through commercialization. We are also unable to predict when, if ever, material net cash inflows will commence from our product candidates to offset these expenses. Our expenditures on current and future preclinical and clinical development programs are subject to numerous uncertainties in timing and cost to completion. The duration, costs and timing of clinical trials and development of our product candidates will depend on a variety of factors, including:

- the scope, rate of progress, and expenses of our ongoing as well as any additional clinical trials and other research and development activities;
- future clinical trial results;
- achievement of milestones requiring payments under our in-licensing agreements;
- uncertainties in clinical trial enrollment rates or drop-out or discontinuation rates of patients;
- potential additional studies requested by regulatory agencies;
- significant and changing government regulation; and
- the timing and receipt of any regulatory approvals.

We track research and development expenses on a program-by-program basis only for clinical-stage product candidates. Preclinical research and development expenses and chemical manufacturing research and development expenses are not assigned or allocated to individual development programs. We currently have two clinical-stage product candidates, trilaciclib and G1T38.

General and administrative expenses

General and administrative expenses consist of personnel costs, allocated expenses and other expenses for outside professional services, including legal, audit and accounting services. Personnel costs consist of salaries, bonuses, benefits and stock-based compensation. Other general and administrative expenses include facility-related costs not otherwise allocated to research and development expense, professional fees, expenses associated with obtaining and maintaining patents and costs of our information systems. We anticipate that our general and administrative expenses will continue to increase in the future as we increase our headcount to support our continued research and development and potential commercialization of our product candidates.

We also have incurred, and expect to continue to incur additional expenses as a public company, including expenses related to compliance with the rules and regulations of the SEC and NASDAQ, additional insurance expenses, and expenses related to investor relations activities and other administration and professional services.

Total other income, net

Total other income, net consists of interest income earned on cash and cash equivalents and the change in fair value of warrant liabilities and other liabilities.

Results of operations

Comparison of the three months ended June 30, 2017 and June 30, 2016

	Three Months Ended June 30,		Change
	2017	2016	$
	(in thousands)		
Revenue	$ —	$ —	$ —
Operating Expenses:			
Research and Development	13,667	6,454	7,213
General and Administrative	1,712	975	737
Total Operating Expenses	15,379	7,429	7,950
Loss from Operations	(15,379)	(7,429)	(7,950)
Other Income	185	50	135
Net Loss	$ (15,194)	$ (7,379)	$ (7,815)

Revenue

Revenue was $0 for the three months ended June 30, 2017 and June 30, 2016.

Research and development

Research and development expenses were $13.7 million for the three months ended June 30, 2017 compared to $6.5 million for the three months ended June 30, 2016. The increase of $7.2 million, or 112%, was primarily due to an increase of $3.5 million in our clinical program costs, which included increased costs of $2.8 million in our trials of trilaciclib in SCLC, TNBC and initiation of our trial of trilaciclib in SCLC with Tecentriq, a decrease of $0.4 million in connection with the completion of a Phase 1 trial for G1T38 in healthy normal volunteers and an increase of $1.1 million in personnel and other costs related to the trilaciclib and G1T38 clinical programs. The increase in overall research and development expenses also includes an increase of $2.1 million for external manufacturing of pharmaceutical active ingredient and drug product to support our clinical trials, an increase of $0.9 million in external research studies, an increase of $0.5 million in preclinical and drug development personnel-related costs as a result of increased headcount and fees paid to consultants, and an increase of $0.2 million in supplies and facility costs. The following table summarizes our research and development expenses for the periods indicated:

	Three Months Ended June 30,	
	2017	2016
	(in thousands)	
Clinical Expenses—trilaciclib	$ 7,497	$ 3,614
Clinical Expenses—G1T38	796	1,211
Chemical Manufacturing and Development	2,943	736
Discovery and Pre-Clinical Expenses	2,431	893
Total Research and Development Expenses	$ 13,667	$ 6,454

General and administrative

General and administrative expenses were $1.7 million for the three months ended June 30, 2017 compared to $1.0 million for the three months ended June 30, 2016. The increase of $0.7 million, or 76%, was due to an increase of $0.4 million of professional fees and an increase of $0.3 million in personnel costs due to increased headcount.

Total other income, net

Total other income, net was $0.2 million for the three months ended June 30, 2017 as compared to $0.1 million for the three months ended June 30, 2016. The increase of $0.1 million was due to additional interest income earned on a higher balance of money market funds during the three months ended June 30, 2017 as compared to the three months ended June 30, 2016.

Comparison of the six months ended June 30, 2017 and June 30, 2016

	Six Months Ended June 30,		Change
	2017	2016	$
	(in thousands)		
Revenue	$ —	$ —	$ —
Operating Expenses:			
Research and Development	24,752	10,326	14,426
General and Administrative	3,006	3,050	(44)
Total Operating Expenses	27,758	13,376	14,382
Loss from Operations	(27,758)	(13,376)	(14,382)
Other Income	219	43	176
Net Loss	$ (27,539)	$ (13,333)	$ (14,206)

Revenue

Revenue was $0 for the six months ended June 30, 2017 and June 30, 2016.

Research and development

Research and development expenses were $24.8 million for the six months ended June 30, 2017 as compared to $10.3 million for the six months ended June 30, 2016. The increase of $14.5 million, or 140%, was primarily due to an increase of $7.9 million in our clinical program costs, which included increased costs of $5.6 million due to our ongoing Phase 1b/2a clinical trials of trilaciclib in SCLC and initiation costs for the Phase 2 clinical trial of trilaciclib in TNBC, an increase of $0.1 million in connection with ongoing costs for a Phase 1/2 clinical trial in ER+, HER2- breast cancer offset by the completion of a Phase 1 trial for G1T38 in healthy normal volunteers, and $2.2 million in increased personnel costs and other costs related to the trilaciclib and G1T38 clinical programs. The increase in overall research and development expenses also includes an increase of $4.3 million in connection with external manufacturing of pharmaceutical active ingredient and drug product to support our clinical trials, an increase of $1.2 million in external research studies, an increase of $0.8 million in preclinical and drug development personnel-related costs as a result of increased headcount and fees paid to consultants, and an increase of $0.3 million in supplies and facility costs. The following table summarizes our research and development expenses allocated to trilaciclib and G1T38 and unallocated research and development expenses for the periods indicated:

	Six Months Ended June 30,	
	2017	2016
	(in thousands)	
Clinical Expenses—trilaciclib	$ 13,056	$ 5,534
Clinical Expenses—G1T38	1,720	1,334
Chemical Manufacturing and Development	5,976	1,506
Discovery and Pre-clinical Expenses	4,000	1,952
Total Research and Development Expenses	$ 24,752	$ 10,326

General and administrative

General and administrative expenses were $3.0 million for the six months ended June 30, 2017 as compared to $3.1 million for the six months ended June 30, 2016. The decrease of $0.1 million, or 1%, was due to a decrease of $0.6 million of professional fees offset by an increase of $0.5 million in personnel costs as a result of increased headcount.

Total other income, net

Total other income, net was $0.2 million for the six months ended June 30, 2017 as compared to $0 million for the six months ended June 30, 2016. The increase of $0.2 million was due to additional interest income earned on a higher balance of money market funds during the six months ended June 30, 2017 as compared to the six months ended June 30, 2016.

Liquidity and capital resources

We have incurred cumulative losses and negative cash flows from operations since our inception in 2008. As of June 30, 2017, we had an accumulated deficit of $96.5 million. We do not expect to generate substantial revenue from the commercial sale of our products in the foreseeable future and anticipate that we will continue to incur losses.

We have funded our operations through June 30, 2017 primarily through gross proceeds from private placements of our Series A, Series B and Series C convertible preferred stock of $95.8 million and net proceeds from our IPO of $107.1 million. As of June 30, 2017, we had cash and cash equivalents of $132.7 million.

Cash flows

The following table summarizes our cash flows for the periods indicated:

	Six Months Ended June 30,		Change
	2017	2016	$
	(in thousands)		
Net cash used in operating activities	$ (22,017)	$ (10,646)	$ (11,371)
Net cash used in investing activities	(34)	(85)	51
Net cash provided by financing activities	107,421	49,756	57,665
Net decrease in cash and cash equivalents	$ 85,370	$ 39,025	$ 46,345

Net cash used in operating activities

During the six months ended June 30, 2017, net cash used in operating activities was $22.0 million which consisted primarily of a net loss of $27.5 million and $0.5 million increase in prepaid expenses, partially offset by an increase in accounts payable and accrued expenses of $4.6 million related primarily to an increase in research and development activity during the period, non-cash stock compensation expense of $1.3 million and $0.1 million of other working capital adjustments.

During the six months ended June 30, 2016, net cash used in operating activities was $10.6 million, which consisted primarily of a net loss of $13.3 million offset by an increase in accounts payable and accrued expenses of $1.9 million related primarily to an increase in research and development activity during the period, $0.5 million non-cash stock compensation expense and $0.3 million decrease in prepaid expenses and other working capital adjustments.

The increase in net cash used in operating activities of $11.4 million was primarily due to an increase in research and development activity during the period.

Net cash used in investing activities

Net cash used in investing activities was $0 million for the six months ended June 30, 2017 and $0.1 million for the six months ended June 30, 2016, which represented purchases of property and equipment.

Net cash provided by financing activities

During the six months ended June 30, 2017, net cash provided by financing activities was $107.4 million, consisting primarily of $107.1 in net proceeds from our initial public offering, after deducting underwriting discounts and commissions and other expenses payable by us. A portion of these offering expenses will be settled through cash disbursements in the third quarter of 2017.

During the six months ended June 30, 2016, net cash provided by financing activities was $49.8 million, consisting of $49.8 million of net proceeds from issuance of shares of our Series C Preferred Stock.

Operating capital requirements and plan of operations

To date, we have not generated any revenue from product sales. We do not know when, or if, we will generate any revenue from product sales. We do not expect to generate significant revenue from product sales unless and until we obtain regulatory approval of and commercialize one of our current or future product candidates. We anticipate that we will continue to generate losses for the foreseeable future, and we expect the losses to increase as we continue the development of and seek regulatory approvals for our product candidates, and begin to commercialize any approved products. We are subject to all of the risks inherent in the development

of new products, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. We expect to incur additional costs associated with operating as a public company and we anticipate that we will need substantial additional funding in connection with our continuing operations.

We believe that the net proceeds from our IPO, our existing cash and cash equivalents will be sufficient to fund our projected cash needs for at least the next 24 months. In order to complete the process of obtaining regulatory approval for our product candidates and to build the sales, marketing and distribution infrastructure that we believe will be necessary to commercialize our product candidates, if approved, we will require substantial additional funding.

We have based our projections of operating capital requirements on assumptions that may prove to be incorrect and we may use all of our available capital resources sooner than we expect. Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical products, we are unable to estimate the exact amount of our operating capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- the scope, progress, results and costs of nonclinical development, laboratory testing and clinical trials for our product candidates;
- the scope, prioritization and number of our research and development programs;
- the costs, timing and outcome of regulatory review of our product candidates;
- the extent to which we enter into non-exclusive, jointly funded clinical research collaboration arrangements, if any, for the development of our product candidates in combination with other companies' products;
- our ability to establish such collaborative co-development arrangements on favorable terms, if at all;
- the achievement of milestones or occurrence of other developments that trigger payments under our license agreement and any collaboration agreements into which we enter;
- the extent to which we are obligated to reimburse, or entitled to reimbursement of, clinical trial costs under future collaboration agreements, if any;
- the extent to which we acquire or in-license product candidates and technologies, such as G1T48, and the terms of such in-licenses;
- the costs of future commercialization activities, including product sales, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval;
- revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval; and
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims.

Until such time, if ever, as we can generate substantial revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through additional collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Contractual obligations, commitments and contingencies

There were no material changes in our commitments under contractual obligations, as disclosed in "Management's Discussion and Analysis of Financial Condition and Results of Operations" contained in our Registration Statement on Form S-1, file number 333-217285, declared effective by the SEC on May 16, 2017.

Off-Balance sheet arrangements

We did not have, during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under applicable SEC rules.

JOBS Act: emerging growth company status

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act, or JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have irrevocably elected to not take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards and, as a result, will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies.

For so long as we are an emerging growth company we expect that:

- we will avail ourselves of the exemption from the requirement to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- we will avail ourselves of the exemption from the requirement to obtain an attestation and report from our auditors on the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act; and
- we will provide less extensive disclosure about our executive compensation arrangements.

We will remain an emerging growth company for up to five years, although we will cease to be an "emerging growth company" upon the earliest of: (1) the last day of the fiscal year following the fifth anniversary of our IPO, (2) the last day of the first fiscal year in which our annual revenues are $1.07 billion or more, (3) the date on which we have, during the previous rolling three-year period, issued more than $1 billion in non-convertible debt securities, and (4) the date on which we are deemed to be a "large accelerated filer" as defined in the Exchange Act.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate sensitivities, which is affected by changes in the general level of U.S. interest rates. We had cash and cash equivalents of $132.7 million as of June 30, 2017, which consists of deposits in banks, including checking accounts, money market accounts and certificates of deposit. Such interest-earning instruments carry a degree of interest rate risk; however, historical fluctuations in interest income have not been significant. Due to the short-term nature of our cash equivalents, a sudden change in interest rates would not be expected to have material effect on our business, financial condition or results of operations. We had no outstanding debt as of June 30, 2017.

We are not currently exposed to significant market risk related to changes in foreign currency exchange rates; however, our operations may be subject to fluctuations in foreign currency exchange rates in the future.

Inflation generally affects us by increasing our cost of labor. We do not believe that inflation had a material effect on our business financial condition or results of operations during the three months ended June 30, 2017.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Business Officer, evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2017. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by the 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 Securities and Exchange

Commission’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 officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our 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 June 30, 2017, our principal executive officer and our principal 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 was no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the period covered by this Quarterly Report on Form 10-Q that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

We are not currently subject to any material pending legal proceedings.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with all of the other information in this quarterly report, including our financial statements and related notes, before investing in our common stock. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that affect us. If any of the following risks occur, our business, operating results and prospects could be materially harmed. In that event, the price of our common stock could decline, and you could lose part or all of your investment.

Risks related to our financial position and need for additional capital

We have incurred significant operating losses since our inception. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability.

We have incurred significant operating losses since our inception. We incurred net losses of $20.3 million for the year ended December 31, 2015, $30.3 million for the year ended December 31, 2016, and $27.5 million for the six months ended June 30, 2017. As of June 30, 2017, we had an accumulated deficit of $96.5 million. Our most advanced clinical-stage product candidate, trilaciclib, is currently in four clinical trials, two Phase 1b/2a trials and two Phase 2 trials. Our other clinical-stage product candidate, G1T38, is currently in a Phase 1/2 clinical trial. It may be several years, if ever, before we have a product candidate ready for commercialization. To date, we have financed our operations primarily through sales of our preferred and common stock. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. The net losses we incur may fluctuate significantly from quarter to quarter. We anticipate that our expenses will increase substantially if and as we:

- continue development of our product candidates, including initiating additional clinical trials of trilaciclib and G1T38 and completing preclinical studies and potentially initiating clinical trials of our preclinical-stage product candidate, G1T48;
- identify and develop new product candidates;
- seek marketing approvals for our product candidates that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- achieve market acceptance of our product candidates in the medical community and with third-party payors;
- maintain, expand and protect our intellectual property portfolio;
- hire additional personnel;
- enter into collaboration arrangements, if any, for the development of our product candidates or in-license other products and technologies;
- achieve milestones requiring payment under our in-licensing programs;
- add operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts; and
- incur increased costs as a result of operating as a public company.

Because of the numerous risks and uncertainties associated with developing pharmaceutical drugs, we are unable to predict the extent of any future losses or when we will become profitable, if at all. In addition, our expenses could increase beyond expectations if we are required by the Food and Drug Administration, or FDA, or foreign regulatory agencies, to perform studies and clinical trials in addition to those that we currently anticipate, or if there are any delays in our or our partners completing clinical trials or the development of any of our product candidates.

To become and remain profitable, we must develop and eventually commercialize a product or products with significant market potential. This will require us to be successful in a range of challenging activities, including the following:

- completing clinical trials of our product candidates that meet their clinical endpoints;
- obtaining marketing approval for our product candidates;
- manufacturing, marketing and selling those products for which we may obtain marketing approval; and
- achieving market acceptance of our product candidates in the medical community and with third-party payors.

We may never succeed in these activities and, even if we do, may never generate revenues that are significant or large enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of the company and could impair our ability to raise capital, maintain our discovery and preclinical development efforts, expand our business or continue our operations and may require us to raise additional capital that may dilute your ownership interest. A decline in the value of our company could also cause you to lose all or part of your investment.

Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

We are an early-stage biopharmaceutical company. Biopharmaceutical drug development is a highly speculative undertaking and involves a substantial degree of risk. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, developing our technology, identifying potential product candidates, undertaking preclinical studies, and conducting clinical trials of trilaciclib and G1T38. We have not yet demonstrated our ability to successfully complete large-scale, pivotal clinical trials, obtain marketing approvals, manufacture a commercial scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Typically, it takes several years to develop one new drug from the time it is discovered to when it is available for treating patients. In addition, as a new business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will need to transition from a company with a research focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

We will need substantial additional funding. If we are unable to raise capital when needed, we would be compelled to delay, reduce or eliminate our product development programs or commercialization efforts.

The development of pharmaceutical drugs is capital-intensive. We expect our expenses to increase in parallel with our ongoing activities, particularly as we conduct larger-scale clinical trials of, and seek marketing approval for, our product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. We may also need to raise additional funds sooner if we choose to pursue additional indications and/or geographies for our product candidates or otherwise expand more rapidly than we presently anticipate. Furthermore, we have incurred and expect to continue to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our clinical programs, development efforts or any future commercialization efforts.

As of June 30, 2017, we had $132.7 million in cash and cash equivalents. We believe that, based upon our current operating plan, our existing capital resources, together with the net proceeds from our IPO, will be sufficient to fund our anticipated operations for at least 24 months. Our future capital requirements and the period for which we expect our existing resources to support our operations may vary significantly from what we expect. Our monthly spending levels vary based on new and ongoing research and development and other corporate activities. Because the length of time and activities associated with successful research and development of our product candidates is highly uncertain, we are unable to estimate the actual funds we will require for development and any approved marketing and commercialization activities. In addition, our future capital requirements will depend on many factors, and could increase significantly as a result of many factors, including:

- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for our product candidates;
- the scope, prioritization and number of our research and development programs;
- the costs, timing and outcome of regulatory review of our product candidates;
- the extent to which we enter into non-exclusive, jointly funded clinical research collaboration arrangements, if any, for the development of our product candidates in combination with other companies' products;

- our ability to establish collaboration arrangements for the development of our product candidates on favorable terms, if at all;
- the achievement of milestones or occurrence of other developments that trigger payments under our license agreement and any collaboration agreements into which we may enter, if any;
- the extent to which we are obligated to reimburse, or entitled to reimbursement of, clinical trial costs under future collaboration agreements, if any;
- the extent to which we acquire or in-license product candidates and technologies, such as G1T48, and the terms of such in-licenses;
- the costs of future commercialization activities, including product sales, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval;
- revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval; and
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims.

Conducting preclinical studies and clinical trials is a time-consuming, expensive and uncertain process that can take years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that may not be commercially available for several years, if ever. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. Volatility in the financial markets have generally made equity and debt financing more difficult to obtain, and may have a material adverse effect on our ability to meet our fundraising needs. We cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our shares to decline.

If we are unable to obtain funding on a timely basis, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs or the commercialization of any product candidate or be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of private and public equity financings, debt financings, collaborations, strategic alliances and licensing arrangements. The sale of additional equity or convertible debt securities would dilute all of our stockholders. The incurrence of indebtedness would result in increased fixed payment obligations, and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights, limitations on declaring dividends and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through collaborations, strategic alliances or licensing arrangements with third parties, and we could be required to do so at an earlier stage than otherwise would be desirable. In connection with any such collaborations, strategic alliances or licensing arrangements, we may be required to relinquish valuable rights to our intellectual property, future revenue streams, research programs or product candidates, grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves, or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects.

Risks related to development of our product candidates

Initial success in our ongoing clinical trials may not be indicative of results obtained when these trials are completed or in later stage trials.

We are currently evaluating trilaciclib in four clinical trials: two Phase 1b/2a trials in patients with small cell lung cancer, or SCLC, an additional Phase 2 trial in combination with Tecentriq in SCLC and a Phase 2 trial in patients with triple-negative breast cancer, or TNBC. While trilaciclib has shown compelling response rates and favorable tolerability in early-stage trials, including the completed Phase 1b parts of the two Phase 1b/2a trials in SCLC, these trials are not complete, and we may not see such favorable data in these

ongoing or in future clinical trials involving trilaciclib. Similarly, favorable results obtained from early-stage trials of G1T38 may not be replicated in the ongoing Phase 1/2 trial in ER+, HER2- breast cancer or in any future clinical trials. Furthermore, there can be no assurance that any of our clinical trials will ultimately be successful or support further clinical development of any of our product candidates. There is a high failure rate for drugs and biologics proceeding through clinical trials. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in clinical development even after achieving promising results in earlier studies, and any such setbacks in our clinical development could have a material adverse effect on our business and operating results.

Preliminary and interim data from our clinical studies, including the Phase 1b parts of our Phase 1b/2a trials of trilaciclib, may change as more patient data become available.

Preliminary or interim data from our clinical studies, including those from the Phase 1b parts of our Phase 1b/2a trials of trilaciclib, are not necessarily predictive of final results. Preliminary and interim data are subject to the risk that one or more of the clinical outcomes may materially change, as more patient data become available and we issue our final clinical study report. As a result, preliminary and interim data should be viewed with caution until the final data are available. Material adverse changes in the final data compared to the interim data could significantly harm our business prospects.

We are very early in our development efforts. If we are unable to successfully develop and commercialize our product candidates or experience significant delays in doing so, our business will be materially harmed.

We currently do not have any products that have gained marketing approval. We have invested substantially all of our efforts and financial resources identifying and developing our CDK4/6 inhibitor product candidates, trilaciclib and G1T38, and our oral SERD product candidate, G1T48. Our ability to generate product revenues, which may not occur for several years, if ever, will depend on the successful development and eventual commercialization of trilaciclib, for which two Phase 1b/2a clinical trials and two Phase 2 trials are ongoing, G1T38, for which one Phase 1/2 trial is ongoing, and G1T48, which is currently in preclinical development. We currently generate no revenues from sales of any drugs, and we may never be able to develop or commercialize a marketable drug. Each of our product candidates will require development, management of development and manufacturing activities, marketing approval in multiple jurisdictions, obtaining manufacturing supply, building of a commercial organization, substantial investment and significant marketing efforts before we generate any revenues from drug sales.

We have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biopharmaceutical area. For example, to execute our business plan, we will need to successfully:

- execute development activities for our product candidates, including successful enrollment in and completion of clinical trials;
- obtain required marketing approvals for the development and commercialization of our product candidates;
- obtain and maintain patent and trade secret protection and regulatory exclusivity for our product candidates and ensure that we do not infringe the valid patent rights of third parties;
- protect, leverage and expand our intellectual property portfolio;
- establish and maintain clinical and commercial manufacturing capabilities or make arrangements with third-party manufacturers for clinical and commercial manufacturing;
- build and maintain robust sales, distribution and marketing capabilities, either on our own or in collaboration with strategic partners, if our product candidates are approved;
- gain acceptance for our product candidates, if approved, by patients, the medical community and third-party payors;
- compete effectively with other therapies;
- obtain and maintain healthcare coverage and adequate reimbursement;
- maintain a continued acceptable safety profile for our product candidates following approval, if approved;
- develop and maintain any strategic relationships we elect to enter into, if any;
- enforce and defend intellectual property rights and claims; and
- manage our spending as costs and expenses increase due to preclinical development, clinical trials, marketing approvals and commercialization.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which would materially harm our business. If we do not receive marketing approvals for our product candidates, we may not be able to continue our operations.

Our development of a CDK4/6 inhibitor to treat CDK4/6-independent tumors is novel, unproven and rapidly evolving and may never lead to a marketable product.

Our clinical-stage product candidate, trilaciclib, is a potent and selective CDK4/6 inhibitor we are developing to initially target patients with CDK4/6-independent tumors. The use of a CDK4/6 inhibitor in combination with chemotherapy to treat patients with CDK4/6-independent tumors is a novel approach to the treatment of cancer, and we believe that we are the only company currently developing a CDK4/6 inhibitor for this patient population. The scientific evidence to support the feasibility of developing this product candidate is both preliminary and limited. Even though trilaciclib has demonstrated positive results in preclinical studies and early-stage clinical trials, we may not succeed in demonstrating safety and efficacy of trilaciclib in larger-scale clinical trials.

Advancing this novel therapy creates significant challenges for us, including:

- obtaining marketing approval, as the FDA and other regulatory authorities have limited experience with commercial development of CDK4/6 inhibitor therapies for cancer;
- educating medical personnel regarding the potential safety benefits, as well as the challenges, of incorporating our product candidates, if approved, into their treatment regimens; and
- establishing sales and marketing capabilities upon obtaining any marketing approval to gain market acceptance of a novel therapy.

If we experience delays or difficulties in the enrollment of patients in clinical trials, development of our product candidates may be delayed or prevented, which would have a material adverse effect on our business.

Identifying and qualifying patients to participate in clinical trials for our product candidates is critical to our success. In particular, because we are initially focused on patients with diseases with genetically defined tumors, our ability to enroll eligible patients may be limited or may result in slower enrollment than we anticipate. We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials. Patient enrollment may be affected by many factors including:

- the severity of the disease under investigation;
- the eligibility criteria for the clinical trial in question;
- the perceived risks and benefits of the product candidate under study;
- the efforts to facilitate timely enrollment in clinical trials;
- the patient referral practices of physicians;
- the availability of competing therapies and clinical trials; and
- the proximity and availability of clinical trial sites for prospective patients.

If we experience delays or difficulties in the enrollment of patients in clinical trials, our clinical trials may be delayed or terminated. Any delays in completing our clinical trials will increase our costs, delay or prevent our product candidate development and approval process, and jeopardize our ability to commence product sales and generate revenue. Any of these occurrences may harm our business, financial condition and prospects significantly.

Clinical drug development involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and may experience delays in obtaining, or ultimately be unable to obtain, the approval of our product candidates.

The risk of failure in drug development is high. Trilaciclib is currently being studied in two Phase 1b/2a clinical trials and two Phase 2 clinical trials, G1T38 is currently being studied in one Phase 1/2 clinical trial and G1T48 is in preclinical development. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical development and conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical trials are expensive, difficult to design and implement and can take several years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. Further, the results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses,

and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. It is impossible to predict when or if any of our product candidates will prove effective or safe in humans or will receive marketing approval.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates. Clinical trials may be delayed, suspended or prematurely terminated because costs are greater than we anticipate or for a variety of reasons, such as:

- delay or failure in reaching agreement with the FDA or a comparable foreign regulatory authority on a trial design that we are able to execute;
- delay or failure in obtaining authorization to commence a trial or inability to comply with conditions imposed by a regulatory authority regarding the scope or design of a clinical trial;
- delays in reaching, or failure to reach, agreement on acceptable terms with prospective trial sites and prospective contract research organizations, or CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- inability, delay, or failure in identifying and maintaining a sufficient number of trial sites, many of which may already be engaged in other clinical programs;
- delay or failure in recruiting and enrolling suitable subjects to participate in a trial;
- delay or failure in having subjects complete a trial or return for post-treatment follow-up;
- clinical sites and investigators deviating from the clinical protocol, failing to conduct the trial in accordance with regulatory requirements, or dropping out of a trial;
- failure to initiate or delay of or failure to complete a clinical trial as a result of an Investigational New Drug Application, or IND, being placed on clinical hold by the FDA, or for other reasons;
- lack of adequate funding to continue a clinical trial, including unforeseen costs due to enrollment delays, requirements to conduct additional clinical trials and increased expenses associated with the services of our CROs and other third parties;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- regulators, or a Data Safety Monitoring Board, or DSMB, if one is used for our clinical trials, may require that we suspend or terminate our clinical trials for various reasons, including noncompliance with regulatory requirements, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, or a finding that the participants are being exposed to unacceptable health risks;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient;
- the FDA or other regulatory authorities may require us to submit additional data or impose other requirements before permitting us to initiate a clinical trial; or
- there may be changes in governmental regulations or administrative actions.

Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of marketing approval for our product candidates. Further, the FDA may disagree with our clinical trial design and our interpretation of data from clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design for our clinical trials.

If we are required to conduct additional clinical trials or other studies of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other studies, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval for our product candidates at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings that would reduce the potential market for our products or inhibit our ability to successfully commercialize our products;
- be subject to additional post-marketing restrictions and/or requirements; or
- have the product removed from the market after obtaining marketing approval.

Our product development costs will also increase if we experience delays in preclinical and clinical development or receiving the requisite marketing approvals. We do not know whether any of our preclinical studies or clinical trials will need to be restructured or will be completed on schedule, or at all. Significant preclinical or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

Risks related to marketing approval of our product candidates

If we are not able to obtain, or if there are delays in obtaining, required marketing approvals, we will not be able to commercialize our product candidates, and our ability to generate revenue will be materially impaired.

Our product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, distribution, import and export are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, current good manufacturing practice, or cGMP, requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, including periodic inspections by FDA and other regulatory authorities, requirements regarding the distribution of samples to physicians and recordkeeping. Before we can commercialize any of our product candidates, each such product candidate must be approved by the FDA pursuant to a new drug application, or NDA, in the United States, by the European Medicines Agency, or EMA, pursuant to a marketing authorization application, or MAA, in the European Union, and by similar regulatory authorities outside the United States prior to commercialization.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive and takes several years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate. We have not received approval to market any of our product candidates from regulatory authorities in any jurisdiction. We have limited experience in planning and conducting the clinical trials required for marketing approvals, and we expect to rely on third-party contract research organizations, or CROs, to assist us in this process. Obtaining marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process, and in many cases the inspection of manufacturing facilities by the regulatory authorities. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical studies or clinical trials. Our product candidates could be delayed in receiving, or fail to receive, marketing approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;

- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA or other submission to obtain marketing approval in the United States or elsewhere;
- third-party manufacturers or our clinical or commercial product candidates may be unable to meet the FDA's cGMP requirements or similar requirements of foreign regulatory authorities; and
- the approval requirements or policies of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

In addition, even if we were to obtain approval, regulatory authorities may approve our product candidates for fewer or more limited indications than we request, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

If we experience delays in obtaining approval or if we fail to obtain approval of our product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenues will be materially impaired.

Our product candidates may cause undesirable side effects that could delay or prevent their marketing approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

Undesirable side effects caused by our product candidates could cause us or the FDA or other regulatory authorities to interrupt, delay or halt our clinical trials and could result in more restrictive labels or the delay or denial of marketing approval by the FDA or other regulatory authorities of our product candidates. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of these or other side effects. In such an event, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. In addition to this, the drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

Further, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of patients, rare and severe side effects of our product candidates may only be uncovered with a significantly larger number of patients exposed to the product candidate. If our product candidates receive marketing approval and we or others identify undesirable side effects caused by such product candidates (or any other similar drugs) after such approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw or limit their approval of such product candidates;
- regulatory authorities may require the addition of labeling statements, such as a "boxed" warning or a contraindication;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we may be required to change the way such product candidates are distributed or administered, conduct additional clinical trials or change the labeling of the product candidates;
- regulatory authorities may require a Risk Evaluation and Mitigation Strategy plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools;
- we may be subject to regulatory investigations and government enforcement actions;
- we may decide to remove such product candidates from the marketplace after they are approved;
- we could be sued and held liable for injury caused to individuals exposed to or taking our product candidates; and
- our reputation may suffer.

We believe that any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidates and could substantially increase the costs of commercializing our product candidates, if approved, and significantly impact our ability to successfully commercialize our product candidates and generate revenues.

A Breakthrough Therapy Designation by the FDA, even if granted for any of our product candidates, may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that our product candidates will receive marketing approval.

We do not currently have Breakthrough Therapy Designation for any of our product candidates but may seek such designation. A Breakthrough Therapy Designation may be granted to a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and for which preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs that have been designated as Breakthrough Therapies, interaction and communication between the FDA and the sponsor can help to identify the most efficient path for development. Drugs designated as Breakthrough Therapies are also eligible for accelerated approval.

Designation as a Breakthrough Therapy is within the discretion of the FDA. Accordingly, even if we believe, after completing early clinical trials, that one of our product candidates meets the criteria for designation as a Breakthrough Therapy, the FDA may disagree and instead determine not to grant such designation. In any event, the receipt of a Breakthrough Therapy designation by itself for a product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as a Breakthrough Therapy, the FDA may later decide that such product candidates no longer meet the conditions for qualification.

A Fast Track Designation by the FDA, even if granted for any of our product candidates, may not lead to a faster development or regulatory review or approval process and does not increase the likelihood that our product candidates will receive marketing approval.

We do not currently have Fast Track Designation for any of our product candidates but may seek such designation. If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for FDA Fast Track Designation. The FDA has broad discretion whether to grant this designation. Even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even if we do receive Fast Track Designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw Fast Track Designation if it believes that the designation is no longer supported by data from our clinical development program. Many drugs that have received Fast Track Designation have failed to obtain drug approval.

Any product candidate for which we obtain marketing approval will be subject to extensive post-marketing regulatory requirements and could be subject to post-marketing restrictions or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products, when and if any of them are approved.

If the FDA or a comparable foreign regulatory authority approves any of our product candidates, activities such as the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. The FDA or a comparable foreign regulatory authority may also impose requirements for costly post-marketing preclinical studies or clinical trials and surveillance to monitor the safety or efficacy of the product. The FDA closely regulates the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding use of their products, and if we promote our products beyond their approved indications, we may be subject to enforcement actions or prosecution arising from that off-label promotion. Violations of the Federal Food, Drug, and Cosmetic Act relating to the promotion of prescription drugs may lead to investigations alleging violations of federal and state healthcare fraud and abuse and other laws, as well as state consumer protection laws.

In addition, later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning or untitled letters;

- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

Non-compliance with European Union requirements regarding safety monitoring or pharmacovigilance can also result in significant financial penalties. Similarly, failure to comply with the European Union's requirements regarding the protection of personal information can also lead to significant penalties and sanctions.

The FDA's policies may change and additional government regulations may be enacted that could prevent, limit or delay marketing approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

Our relationships with customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Although we do not currently have any drugs on the market, once we begin commercializing our product candidates, we will be subject to additional healthcare statutory and regulatory requirements and enforcement by federal government and the states and foreign governments in the jurisdictions in which we conduct our business. Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or paying remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid; 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;
- the federal false claims laws impose criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making 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, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services; 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;
- the federal physician payment transparency requirements, sometimes referred to as the "Sunshine Act" under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, require manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report to the Centers for Medicare & Medicaid Services, or CMS, information related to payments and other transfers of value to physicians and teaching hospitals and the ownership and investment interests of physicians and their immediate family members in such manufacturers;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, which also imposes obligations on certain covered entity healthcare providers, health plans, and healthcare

clearinghouses as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers;
- some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and
- state and foreign laws also govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of products from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Current and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the MMA, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and certain disabled people and introduced a reimbursement methodology based on average sales prices for physician-administered drugs. In addition, this law provided authority for limiting the number of drugs that will be covered in any therapeutic class. Cost reduction initiatives and other provisions of this law and future laws could decrease the coverage and price that we will receive for any approved products. While the MMA only applies to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Therefore, any limitations in reimbursement that results from the MMA may result in reductions in payments from private payors.

In March 2010, the ACA became law. The ACA is a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms.

Among the provisions of the ACA of importance to our potential product candidates are the following:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic products;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- expansion of healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices;
- extension of manufacturers' Medicaid rebate liability;
- expansion of eligibility criteria for Medicaid programs;
- expansion of the entities eligible for discounts under the Public Health Service Act's pharmaceutical pricing program;

- new requirements to report financial arrangements with physicians and teaching hospitals;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

The current administration supports a repeal of the ACA and an Executive Order has been signed commanding federal agencies to try to waive or delay requirements of the ACA that impose economic or regulatory burdens on states, families, the health-care industry and others. The Executive Order also declares that the administration will seek the "prompt repeal" of the law and that the government should prepare to "afford the States more flexibility and control to create a more free and open healthcare market." At this time, the immediate impact of the Executive Order is not clear. In addition, other legislative changes have been proposed and adopted since the ACA was enacted. These new laws may result in additional reductions in Medicare and other healthcare funding.

We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we will receive for any approved product. Any reduction in payments from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals, if any, of our product candidates, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing conditions and other requirements.

Our future growth may depend, in part, on our ability to penetrate foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future profitability may depend, in part, on our ability to commercialize our product candidates in foreign markets. In order to market and sell our products in the European Union and many other jurisdictions, we or our third-party collaborators must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and economic areas and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The marketing approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We or these third parties may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by FDA. Additionally, a failure or delay in obtaining marketing approval in one jurisdiction may have a negative effect on the marketing approval process in others. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials. Obtaining foreign marketing approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products in any market. If we obtain approval of our product candidates and ultimately commercialize our product candidates in foreign markets, we would be subject to additional risks and uncertainties, including:

- our customers' ability to obtain reimbursement for our product candidates in foreign markets;
- our inability to directly control commercial activities because we are relying on third parties;
- the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements;
- different medical practices and customs in foreign countries affecting acceptance in the marketplace;
- import or export licensing requirements;

- longer accounts receivable collection times;
- longer lead times for shipping;
- language barriers for technical training;
- reduced or no protection on pharmaceutical products or their use in some foreign countries;
- the unwillingness of courts in some foreign jurisdictions to enforce patents even when valid and infringed in that country;
- the possibility of pre-grant or post-grant review proceedings in certain foreign countries that allow a petitioner to hold up patent rights for an extended period or permanently by challenging the patent filing at the patent office of that country;
- the possibility of a compulsory license issued by a foreign country that allows a third party company or a government to manufacture, use or sell our products with a government-set low royalty to us;
- the existence of additional potentially relevant third-party intellectual property rights;
- foreign currency exchange rate fluctuations; and
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute.

Foreign sales of our product candidates could also be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions and changes in tariffs.

Governments outside the United States tend to impose strict price controls, which may adversely affect our revenues, if any.

In some countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially.

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 harm our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations 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 the amount of the liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against other potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

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 discovery, preclinical development or production efforts. Our 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 rely on, and expect to continue to rely on, third parties to conduct our clinical trials for our product candidates. If these third parties do not successfully carry out their contractual duties, comply with regulatory requirements or meet expected deadlines, we may not be able to obtain marketing approval for or commercialize our product candidates, and our business could be substantially harmed.

We do not have the ability to independently conduct clinical trials. We rely on medical institutions, clinical investigators, contract laboratories and other third parties, such as CROs, to conduct or otherwise support clinical trials for our product candidates. We expect to rely heavily on these parties for performance of clinical trials for our product candidates. Nevertheless, we will be responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards.

We, our investigators, and our CROs will be required to comply with regulations, including good clinical practice, or GCP, and other related requirements for conducting, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate, and that the trial patients are adequately informed of the potential risks of participating in clinical trials and their rights are protected. These regulations are enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities for any drugs in clinical development. The FDA enforces GCPs through periodic inspections of clinical trial sponsors, principal investigators and trial sites. If we, our investigators or our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be called into question and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before considering our marketing applications for approval. We cannot assure you that, upon inspection, the FDA will determine that any of our future clinical trials will comply with GCPs.

In addition, our clinical trials must be conducted with product candidates produced under cGMPs. Our failure or the failure of our investigators or CROs to comply with these requirements may require us to repeat clinical trials, which would delay the marketing approval process and could also subject us to enforcement action. We also are required to register certain clinical trials and post the results of such completed clinical trials involving product candidates for which we receive marketing approval on a government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Although we intend to design the clinical trials for our product candidates, CROs will administer all of the clinical trials. As a result, many important aspects of our development programs, including their conduct and timing, will be outside of our direct control. Our reliance on third parties to conduct future clinical trials will also result in less direct control over the management of data developed through clinical trials than would be the case if we were relying entirely upon our own staff. Communicating with outside parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Outside parties may:

- have staffing difficulties;
- fail to comply with contractual obligations;
- experience regulatory compliance issues;
- undergo changes in priorities or become financially distressed;
- make errors in the design, management or retention of our data or data systems; and/or
- form relationships with other entities, some of which may be our competitors.

These factors may materially adversely affect the willingness or ability of third parties to conduct our clinical trials and may subject us to unexpected cost increases that are beyond our control. If the CROs do not perform clinical trials in a satisfactory manner, breach their obligations to us or fail to comply with regulatory requirements, the development, marketing approval and commercialization of our product candidates may be delayed, we may not be able to obtain marketing approval and commercialize our product candidates, or our development program may be materially and irreversibly harmed. If we are unable to rely on clinical data collected by our CROs, we could be required to repeat, extend the duration of, or increase the size of any clinical trials we conduct and this could significantly delay commercialization and require significantly greater expenditures.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, any clinical trials such CROs are associated with may be extended, delayed or terminated, and we may not be able to obtain marketing approval for or successfully commercialize our product candidates. As a result, we believe that our financial results and the commercial prospects for our product candidates in the subject indication would be harmed, our costs could increase and our ability to generate revenue could be delayed.

We contract with third parties for the manufacture of our product candidates for preclinical studies and clinical trials and expect to continue to do so for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or drugs or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not currently own or operate, nor do we have any plans to establish in the future, any manufacturing facilities or personnel. We rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for preclinical studies and clinical trials, as well as for the commercial manufacture of our drugs if any of our product candidates receive marketing approval. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or drugs or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

The facilities used to manufacture our product candidates must be evaluated by the FDA pursuant to inspections that will be conducted after we submit our marketing applications to the FDA to ensure compliance with cGMP. We do not control the manufacturing process of, and will be completely dependent on, our contract manufacturers for compliance with cGMPs in connection with the manufacture of our product candidates. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the regulatory requirements of the FDA or others, we will not be able to use the products produced at 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 finds that these facilities do not comply with cGMP, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain marketing approval for or market our product candidates, if approved. Further, our failure, or the failure of our third party manufacturers, to comply with these or other applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or drugs, if approved, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business and supplies of our product candidates.

We may be unable to establish any agreements with third-party manufacturers or do so on acceptable terms. Even if we are able to establish agreements with third party manufacturers, reliance on third party manufacturers entails additional risks, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how; and
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

Our product candidates and any other drugs that we may develop may compete with other product candidates and approved drugs for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us.

Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. If our current contract manufacturers cannot perform as agreed, we may be required to replace such manufacturers. Although we believe that there are several potential alternative manufacturers who could manufacture our product candidates, we may incur added costs and delays in identifying and qualifying any such replacement.

Our current and anticipated future dependence upon others for the manufacture of our product candidates or drugs may adversely affect our future profit margins and our ability to commercialize any drugs that receive marketing approval on a timely and competitive basis.

We, or our third-party manufacturers, may be unable to successfully scale-up manufacturing of our product candidates in sufficient quality and quantity, which would delay or prevent us from developing our product candidates and commercializing approved products, if any.

In order to conduct large-scale clinical trials of our product candidates, we will need to manufacture them in large quantities. We, or any of our manufacturing partners, may be unable to successfully increase the manufacturing capacity for any of our product candidates in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up activities. If we, or any manufacturing partners, are unable to successfully scale up the manufacture of our product candidates in sufficient quality and quantity, the development, testing, and clinical trials of that product candidate may be delayed or infeasible, and regulatory approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business.

The third parties upon which we rely for the supply of the active pharmaceutical ingredients, formulations, and drug products are our sole sources of supply and have limited capacity, and the loss of any of these suppliers could harm our business.

The active pharmaceutical ingredients, or API, formulations and drug products for our product candidates are supplied to us from single source suppliers with limited capacity. Our ability to successfully develop our product candidates, and to ultimately supply our commercial drugs in quantities sufficient to meet the market demand, depends in part on our ability to obtain the API, formulations and drug products in accordance with cGMP requirements and in sufficient quantities for commercialization and clinical trials. We do not currently have arrangements in place for a redundant or second-source supply of any such API, formulation or drug product in the event any of our current suppliers cease their operations for any reason.

We do not know whether our suppliers will be able to meet our demand, either because of the nature of our agreements with those suppliers, our limited experience with those suppliers or our relative importance as a customer to those suppliers. It may be difficult for us to assess their ability to timely meet our demand in the future based on past performance. While our suppliers have generally met our demand for their products on a timely basis in the past, they may subordinate our needs in the future to their other customers.

For all of our product candidates, we intend to identify and qualify additional manufacturers to provide API, formulations and drug products prior to submission of an NDA to the FDA and/or an MAA to the EMA. Establishing additional or replacement suppliers for the API, formulations and drug products for our product candidates, if required, may not be accomplished quickly. If we are able to find a replacement supplier, such replacement supplier would need to be qualified, or we may have to perform comparative studies comparing the drug product from a new manufacturer to the product used in any completed clinical trials. All of this may require additional marketing approval, which could result in further delay. While we seek to maintain adequate inventory of the API, formulations and drug products for our product candidates, any interruption or delay in the supply of components or materials, or our inability to obtain such API, formulation and drug product from alternate sources at acceptable prices in a timely manner could impede, delay, limit or prevent our development efforts, which could harm our business, results of operations, financial condition and prospects.

We may seek to establish additional collaborations, and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans.

Our drug development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. For some of our product candidates, we may decide to collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing drugs and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. The terms of any collaborations or other arrangements that we may establish may not be favorable to us.

We may also be restricted under existing collaboration agreements from entering into future agreements on certain terms with potential collaborators. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate drug revenue.

In addition, any collaboration that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations. Any such collaboration may require us to incur non-recurring or other charges, increase our near- and long-term expenditures and pose significant integration or implementation challenges or disrupt our management or business. These transactions would entail numerous operational and financial risks, including exposure to unknown liabilities, disruption of our business and diversion of our management's time and attention in order to manage a collaboration, incurrence of substantial debt or dilutive issuances of equity securities to pay transaction consideration or costs, higher than expected collaboration or integration costs, write-down of assets or goodwill or impairment charges, increased amortization expenses and difficulty and cost in facilitating the collaboration.

Lastly, disagreements between parties to a collaboration arrangement regarding clinical development and commercialization matters can lead to delays in the development process or commercializing the applicable product candidate and, in some cases, termination of the collaboration arrangement. These disagreements can be difficult to resolve if neither of the parties has final decision-making authority. Collaborations with pharmaceutical or biotechnology companies and other third parties often are terminated or allowed to expire by the other party. Any such termination or expiration would adversely affect us financially and could harm our business reputation.

Risks related to the commercialization of our product candidates

Even if any of our product candidates receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

If any of our product candidates receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the timing of our receipt of any marketing approvals;
- the terms of any approvals and the countries in which approvals are obtained;
- the efficacy and safety and potential advantages and disadvantages compared to alternative treatments;
- the prevalence and severity of any side effects associated with our products;
- the indications for which our products are approved;
- adverse publicity about our products or favorable publicity about competing products;
- the approval of other products for the same indications as our products;
- our ability to offer our products for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the success of our physician education programs;
- the strength of our marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement, including patient cost-sharing programs such as copays and deductibles; and
- any restrictions on the use of our products together with other medications.

If any product we commercialize fails to achieve market acceptance, it could have a material and adverse effect on our business, financial condition, results of operation and prospects.

We face substantial competition, which may result in others discovering, developing or commercializing competing products before or more successfully than we do.

The development and commercialization of new drug products is highly competitive. We face competition with respect to our current product candidates and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of the disease indications for which we are developing our product candidates. Some of these competitive products and therapies are based on scientific approaches that are the same as or similar to our approach, and others are based on entirely different approaches. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

Specifically, there are a large number of companies developing or marketing treatments for cancer, including many major pharmaceutical and biotechnology companies. If trilaciclib is approved, it would compete with (a) existing growth factor support treatments, (b) if approved, rovalpituzumab tesirine (Rova-T), an antibody drug conjugate currently being developed by Abbvie for the treatment of patients with SCLC, (c) if approved, the multiple immune checkpoint inhibitors in clinical trials for the treatment of patients with SCLC and TNBC, and (d) multiple approved drugs or drugs that may be approved in the future for indications for which we may develop trilaciclib. If G1T38 is approved, it would compete with (a) Pfizer's approved CDK4/6 inhibitor, Ibrance, (b) Novartis's approved CDK4/6 inhibitor, Kisqali, (c) if approved, the CDK4/6 inhibitor product candidate currently in clinical development by Eli Lilly, (d) if approved, other non-selective CDK4/6 inhibitor product candidates in clinical development, including product candidates being developed by FLX Bio and OncoMed Pharmaceuticals, and (e) multiple approved drugs or drugs that may be approved in the future for indications for which we may develop G1T38. If G1T48 is approved, it would compete with (a) the approved intramuscular SERD, Faslodex, being marketed by AstraZeneca, (b) if approved, other oral SERDs in development by Radius Health, Genentech, AstraZeneca and Novartis; and (c) multiple approved drugs or drugs that may be approved in the future for indications for which we may develop G1T48.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other marketing approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market and/or slow our marketing approval. Some of the important competitive factors affecting the success of all of our product candidates, if approved, are likely to be their efficacy, safety, convenience, price and the availability of reimbursement from government and other third-party payors.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical studies, conducting clinical trials, obtaining marketing approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Even if we are able to commercialize any product candidates, such drugs may become subject to unfavorable pricing regulations or third-party coverage and reimbursement policies, which would harm our business.

The regulations that govern marketing approvals, pricing and reimbursement for new drugs vary widely from country to country. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product candidate in a particular country, but then be subject to price regulations that delay our commercial launch of the product candidate, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the product candidate in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval.

Our ability to commercialize any product candidates successfully also will depend in part on the extent to which coverage and reimbursement for these product candidates and related treatments will be available from government authorities, private health insurers and other organizations. In the United States, the principal decisions about reimbursement for new medicines are typically made by the CMS, an agency within the U.S. Department of Health and Human Services, as CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare. Private payors tend to follow CMS to a substantial degree. It is difficult to predict what CMS will decide with respect to reimbursement. Reimbursement agencies in Europe may be more conservative than CMS. For example, a number of cancer drugs are generally covered and paid for in the United States, but have not been approved for reimbursement in certain European countries. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of payments for particular drugs. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for drugs. We cannot be sure that coverage will be available for any product candidate that we commercialize and, if coverage is available, the level of payments. Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

In addition to CMS and private payors, professional organizations such as the National Comprehensive Cancer Network and the American Society of Clinical Oncology can influence decisions about reimbursement for new medicines by determining standards of care. In addition, many private payors contract with commercial vendors who sell software that provide guidelines that attempt to limit utilization of, and therefore reimbursement for, certain products deemed to provide limited benefit to existing alternatives. Such organizations may set guidelines that limit reimbursement or utilization of our products.

There may be significant delays in obtaining reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or similar regulatory authorities outside the United States. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved drugs that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize drugs and our overall financial condition.

We currently have no marketing and sales force. If we are unable to establish effective sales or marketing capabilities or enter into agreements with third parties to sell or market our product candidates, we may not be able to effectively sell or market our product candidates, if approved, or generate product revenues.

We do not currently have a sales or marketing infrastructure and have limited experience in the sale, marketing or distribution of drugs. To achieve commercial success for any approved product candidate for which we retain sales and marketing responsibilities, we must build our sales, marketing, managerial, and other non-technical capabilities or make arrangements with third parties to perform these services. There are risks involved with both establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time consuming and could delay any drug launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our product candidates on our own include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future drugs;
- the lack of complementary drugs to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we enter into arrangements with third parties to perform sales, marketing and distribution services, our drug revenues or the profitability of these drug revenues to us are likely to be lower than if we were to market and sell any product candidates that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and market our product candidates or may be unable to do so when needed or on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our product candidates effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates that receive marketing approval or any such commercialization may experience delays or limitations. If we are not successful in commercializing our product candidates, either on our own or through collaborations with one or more third parties, our business, results of operations, financial condition and prospects will be materially adversely affected.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

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

- decreased demand for any product candidates or products that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue;
- reduced resources of our management to pursue our business strategy; and
- the inability to successfully commercialize any products that we may develop.

We currently hold $10.0 million in product liability insurance coverage in the aggregate, with a per incident limit of $10.0 million, which may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of our product candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Risks related to our intellectual property

If we are unable to obtain and maintain intellectual property protection for our technology and products, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and products may be impaired and, if we infringe the valid patent rights of others, we may be prevented from making, using or selling our products or may be subject to damages or penalties.

Our success depends in large part on our ability to obtain and maintain patents in the United States and other countries that adequately protect our proprietary technology and products. We seek to protect our proprietary position by filing patent applications in the United States and in foreign countries that cover our novel product candidates and their uses, pharmaceutical formulations and dosages, and processes for the manufacture of them. Our patent portfolio currently includes both patents and patent applications.

The patent prosecution process is expensive and time-consuming. We may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. We may choose not to seek patent protection for certain innovations and may choose not to pursue patent protection in certain jurisdictions. Under the laws of certain jurisdictions, patents or other intellectual property rights may be unavailable or limited in scope. It is also possible that we will fail to identify patentable aspects of our research and development before it is too late to obtain patent protection.

We currently solely own or exclusively license our patents and patent applications and we have the right to control the prosecution of the in-licensed patent applications. In the future, we may choose to in-license additional patents or patent applications from third parties that we conclude are useful or necessary for our business goals. We may not have the right to control the preparation, filing, prosecution or maintenance of such patent applications. Therefore, if we do license additional patents or patent applications in the

future, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. 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. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The U.S. Patent and Trademark Office, or U.S. PTO, recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, became effective on March 16, 2013. The Leahy-Smith Act also created certain new administrative adversarial proceedings, discussed below. It is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

The U.S. Supreme Court has issued opinions in patent cases in the last few years that many consider may weaken patent protection in the United States, either by narrowing the scope of patent protection available in certain circumstances, holding that certain kinds of innovations are not patentable or generally otherwise making it easier to invalidate patents in court. Additionally, there have been recent proposals for additional changes to the patent laws of the United States and other countries that, if adopted, could impact our ability to obtain patent protection for our proprietary technology or our ability to enforce our proprietary technology. Depending on future actions by the U.S. Congress, the U.S. courts, the U.S. PTO and the relevant law-making bodies in other countries, 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.

Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and in other countries. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, 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 of our technology and products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Likewise, a court could uphold and enforce a third party patent that it rules we have infringed, which would subject us to damages or prevent us from making, using or selling our products.

During patent prosecution in the United States and in most foreign countries, a third party can submit prior art or arguments to the reviewing patent office to attempt to prevent the issuance of a competitor’s patent. For example, our pending patent applications may be subject to a third-party preissuance submission of prior art to the U.S. PTO or an Observation in Europe. Such submission may convince the receiving patent office not to issue the patent. In addition, if the breadth or strength of protection provided by our patents and patent applications is reduced by such third party submission, it could affect the value of our resulting patent or dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

The risks described here pertaining to our patents and other intellectual property rights also apply to any intellectual property rights that we may license in the future, and any failure to obtain, maintain and enforce these rights could have a material adverse effect on our business. In some cases we may not have control over the prosecution, maintenance or enforcement of the patents that we license, and our licensors may fail to take the steps that we believe are necessary or desirable in order to obtain, maintain and enforce the

licensed patents. Any inability on our part to adequately protect or defend our intellectual property may have a material adverse effect on our business, operating results and financial position.

Some intellectual property may have been discovered through government funded programs and thus may be subject to federal regulations such as "march-in" rights, certain reporting requirements and a preference for U.S.-based companies. Compliance with such regulations may limit our exclusive rights, and limit our ability to contract with non-U.S. manufacturers.

Many of our intellectual property rights were generated through the use of U.S. government funding and are therefore subject to certain federal regulations. As a result, the U.S. government may have certain rights to intellectual property embodied in our current or future product candidates pursuant to the Bayh-Dole Act of 1980, or Bayh-Dole Act. These U.S. 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, under certain limited circumstances, to require us to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations (also referred to as "march-in rights"). The U.S. government also has the right to take title to these inventions if we fail to disclose the invention to the government or fail to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources. In addition, the U.S. government requires that any products embodying the subject invention or produced through the use of the subject invention be manufactured substantially in the United States. The manufacturing preference requirement can be waived if the owner of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. manufacturers may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property. To the extent any of our current or future intellectual property is generated through the use of U.S. government funding, the provisions of the Bayh-Dole Act may similarly apply.

We may become involved in administrative adversarial proceedings in the U.S. PTO or in the patent offices of foreign countries brought by a third party to attempt to cancel or invalidate our patent rights, which could be expensive, time consuming and cause a loss of patent rights.

The Leahy-Smith Act created for the first time new procedures to challenge issued patents in the United States, including post-grant review and *inter partes* review proceedings, which some third parties have been using to cause the cancellation of selected or all claims of issued patents of competitors. For a patent with a priority date of March 16, 2013 or later, a petition for post-grant review can be filed by a third party in a nine month window from issuance of the patent. A petition for *inter partes* review can be filed immediately following the issuance of a patent if the patent was filed prior to March 16, 2013. A petition for *inter partes* review can be filed after the nine month period for filing a post-grant review petition has expired for a patent with a priority date of March 16, 2013 or later. Post-grant review proceedings can be brought on any ground of challenge, whereas *inter partes* review proceedings can only be brought to raise a challenge based on published prior art. These administrative adversarial actions at the U.S. PTO review patent claims without the presumption of validity afforded to U.S. patents in lawsuits in U.S. federal courts, use a lower burden of proof than used by U.S. federal courts, and interpret patent claims using a "broadest reasonable construction" instead of "plain and ordinary meaning," which is used in court litigation. Because of these differences between U.S. administrative and judicial adversarial patent proceedings, it is generally considered easier for a competitor or third party to have a U.S. patent cancelled in a patent office post-grant review or *inter partes* review proceeding than invalidated in a litigation in a U.S. federal court. If any of our patents are challenged by a third party in such a U.S. patent office proceeding, there is no guarantee that we will be successful in defending the patent, which would result in a loss of the challenged patent right to us.

Opposition or invalidation procedures are also available in most foreign countries. Many foreign authorities, such as the authorities at the European Patent Office, have only post-grant opposition proceedings, however, certain countries, such as India, have both pre-grant and post-grant opposition proceedings. These procedures have been used frequently against pharmaceutical patents in foreign countries. For example, in some foreign countries, these procedures are used by generic companies to hold up an innovator's patent rights as a means to allow the generic company to enter the market. This activity is particularly prevalent in India, China and South America and may become more prevalent in Africa and other parts of Asia as certain countries reach more established economies. If any of our patents are challenged in a foreign opposition or invalidation proceeding, we could face significant costs to defend our patents, and we may not be successful. Uncertainties resulting from the initiation, continuation or loss of such proceedings could have a material adverse effect on our ability to compete in the market place. Further, in many foreign jurisdictions, the losing party must pay the attorneys' fees of the winning party, which can be substantial.

We may have to file one or more lawsuits in court to prevent a third party from selling a product or using a product in a manner that infringes our patent, which could be expensive, time consuming and unsuccessful, and ultimately result in the loss of our proprietary market.

Because competition in our industry is intense, competitors may infringe or otherwise violate our issued patents, patents of our licensors or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement lawsuits, which can be expensive and time consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents. In addition, in a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or 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 proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. We may also elect to enter into license agreements in order to settle patent infringement claims or to resolve disputes prior to litigation, and any such license agreements may require us to pay royalties and other fees that could be significant. 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.

Because our CDK 4/6 inhibitor candidates are small molecules, after commercialization they will be subject to the patent litigation process of the Hatch Waxman Act, which allows a generic company to submit an Abbreviated New Drug Application, or ANDA, to the FDA to obtain approval to sell our drug using bioequivalence data only. Under the Hatch Waxman Act, since our candidates will be considered new chemical entities, we will have the opportunity to list all of our patents that cover our drug product or its method of use in the FDA's compendium of "Approved Drug Products with Therapeutic Equivalence Evaluation," sometimes referred to as the FDA's Orange Book. A generic company can submit an ANDA to the FDA four years after our drug approval. The submission of the ANDA by a generic company is considered a technical act of patent infringement. The generic company can certify that it will wait until the natural expiration date of our listed patents to sell a generic version of our product or can certify that one or more of our listed patents are invalid, unenforceable, or not infringed. If the latter, we will have 45 days to bring a patent infringement lawsuit against the generic company. This will initiate a challenge to one or more of our Orange Book listed patents based on arguments from the generic company that either our patent is invalid, unenforceable or not infringed. Under the Hatch Waxman Act, if a lawsuit is brought, the FDA is prevented from issuing a final approval on the generic drug until the earlier of seven-and-a-half years from our drug approval or a final decision of a court holding that our asserted patent claims are invalid, unenforceable or not infringed. If we do not properly list our relevant patents in the Orange Book, or timely file a lawsuit in response to a certification from a generic company under an ANDA, or if we do not prevail in the resulting patent litigation, we can lose our proprietary market, which can rapidly become generic. Further, even if we do correctly list our relevant patents in the Orange Book, bring a lawsuit in a timely manner and prevail in that lawsuit, it may be at a very significant cost to us of attorneys' fees and employee time and distraction over a long period. Further, it is common for more than one generic company to try to sell an innovator drug at the same time, and so we may be faced with the cost and distraction of multiple lawsuits. We may also determine it is necessary to settle the lawsuit in a manner that allows the generic company to enter our market prior to the expiration of our patent or otherwise in a manner that adversely affects the strength, validity or enforceability of our patent.

A number of pharmaceutical companies have been the subject of intense review by the U.S. Federal Trade Commission or a corresponding agency in another country based on how they have conducted or settled drug patent litigation, and certain reviews have led to an allegation of an anti-trust violation, sometimes resulting in a fine or loss of rights. We cannot be sure that we would not also be subject to such a review or that the result of the review would be favorable to us, which could result in a fine or penalty.

The U.S. Federal Trade Commission, or FTC, has brought a number of lawsuits in federal court in the past few years to challenge Hatch Waxman ANDA litigation settlements between innovator companies and generic companies as anti-competitive. The FTC has taken an aggressive position that anything of value is a payment, whether money is paid or not. Under their approach, if an innovator as part of a patent settlement agrees not to launch or delay launch of an authorized generic during the 180-day period granted to the first generic company to challenge an Orange Book listed patent covering an innovator drug, or negotiates a delay in entry without payment, the FTC may consider it an unacceptable reverse payment. The biopharmaceutical industry argues that such agreements are rational business decisions to dismiss risk and are immune from antitrust attack if the terms of the settlement are within the scope of the exclusionary potential of the patent. In 2013, the U.S. Supreme Court, in a five-to-three decision in *FTC v. Actavis, Inc.* rejected both the biopharmaceutical industry's and FTC's arguments with regard to so-called reverse payments, and held that whether a "reverse payment" settlement involving the exchange of consideration for a delay in entry is subject to an anticompetitive analysis depends on five considerations: (a) the potential for genuine adverse effects on competition; (b) the justification of payment; (c) the patentee's ability to bring about anticompetitive harm; (d) whether the size of the payment is a workable surrogate for the patent's weakness; and (e) that antitrust liability for large unjustified payments does not prevent litigating parties from settling their lawsuits, for example, by allowing the generic to enter the market before the patent expires without the patentee's paying the generic. Furthermore, whether a reverse payment is justified depends upon its size, its scale in relation to the patentee's anticipated future litigation costs, its independence from other services for which it might represent payment, as was the case in *Actavis*, and the lack of

any other convincing justification. The Court held that reverse payment settlements can potentially violate antitrust laws and are subject to the standard antitrust rule-of-reason analysis, with the burden of proving that an agreement is unlawful on the FTC and leaving to lower courts the structuring of such rule of reason analysis. If we are faced with drug patent litigation, including Hatch Waxman litigation with a generic company, we could be faced with such an FTC challenge based on that activity, including how or whether we settle the case, and even if we strongly disagree with the FTC's position, we could face a significant expense or penalty.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights covering our products and technology, including interference or derivation proceedings before the U.S. PTO. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue developing and marketing our products and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

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

Filing, prosecuting and defending patents on our product candidates in all countries throughout the world would be prohibitively expensive, and therefore we only file for patent protection in selected countries. The requirements for patentability may differ in certain countries, particularly in developing countries. Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws.

The laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, Europe, India, China and certain other countries do not allow patents for methods of treating the human body. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions that do not favor patent protection on drugs. This could make it difficult for us to stop the infringement of our patents or the misappropriation of our other intellectual property rights. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own drugs and, further, may export otherwise infringing drugs to territories where we have patent protection, if our ability to enforce our patents to stop infringing activities is inadequate. These drugs may compete with our product candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and resources from other aspects of our business. Furthermore, while we intend to protect our intellectual property rights in the major markets for our product candidates, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our product candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate.

A number of foreign countries have stated that they are willing to issue compulsory licenses to patents held by innovator companies on approved drugs to allow the government or one or more third party companies to sell the approved drug without the permission of the innovator patentee where the foreign government concludes it is in the public interest. India, for example, has used such a procedure to allow domestic companies to make and sell patented drugs without innovator approval. There is no guarantee that patents covering any of our drugs will not be subject to a compulsory license in a foreign country, or that we will have any influence over if or how such a compulsory license is granted. Further, Brazil allows its regulatory agency ANVISA to participate in deciding whether to grant a drug patent in Brazil, and patent grant decisions are made based on several factors, including whether the patent meets the requirements for a patent and whether such a patent is deemed in the country's interest. In addition, several other countries have created laws that make it more difficult to enforce drug patents than patents on other kinds of technologies. Further, under the treaty on the Trade-Related Aspects of Intellectual Property, or TRIPS, as interpreted by the Doha Declaration, countries in which drugs are manufactured are required to allow exportation of the drug to a developing country that lacks adequate manufacturing capability. Therefore, our drug markets in the United States or foreign countries may be affected by the influence of current public policy on patent issuance, enforcement or involuntary licensing in the healthcare area.

In addition, in November 2015, members of the World Trade Organization, or the WTO, which administers TRIPS, voted to extend the exemption against enforcing pharmaceutical drug patents in least developed countries until 2033. We currently have no patent

applications filed in least developed countries, and our current intent is not to file in these countries in the future, at least in part due to this WTO pharmaceutical patent exemption.

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 U.S. PTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and/or applications. We have systems in place to remind us to pay these fees, and we employ an outside firm and rely on our outside counsel to pay these fees due to non-U.S. patent agencies. 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.

Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Litigation or other legal proceedings relating to intellectual property claims, with or without merit, is unpredictable and generally expensive and time consuming and is likely to divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities.

We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating or from successfully challenging our intellectual property rights. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

If we fail to comply with our obligations under the license agreement with the University of Illinois, we could lose license rights that are necessary for developing and commercializing G1T48.

Our exclusive license with the University of Illinois, or UIC, for technology relating to G1T48 imposes various development, commercialization, royalty payment, diligence and other obligations on us. Specifically, we are required to:

- pay UIC a minimum annual fee and potential milestone payments;
- pay UIC low single-digit royalties on all net sales of products and a share of any sublicensing revenues;
- use commercially reasonable efforts to bring products to market;
- provide financial reports to UIC;
- file, prosecute, defend and maintain patent rights; and
- indemnify UIC against certain claims and maintain insurance coverage.

If we breach any of these obligations, UIC may have the right to terminate the license, which would result in our being unable to develop, manufacture and sell products that are covered by the licensed technology, including G1T48, or in a competitor’s gaining access to the licensed technology.

We may be subject to claims by third parties asserting that our employees or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Many of our employees 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 do not use the proprietary information or know-

how of others in their work for us, we may be subject to claims that these employees or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. Litigation may be necessary to defend against these claims.

In addition, while it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Our and their assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to management.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patents for some of our technology and product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We seek to protect our confidential proprietary information, in part, by entering into confidentiality and invention or patent assignment agreements with our employees and consultants, however, we cannot be certain that such agreements have been entered into with all relevant parties. Moreover, to the extent we enter into such agreements, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

Risks related to employee matters, managing growth and other risks related to our business

We currently have a limited number of employees, and our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

We are an early-stage clinical development company, and, as of June 30, 2017, had only 33 employees and five executive officers. We are highly dependent on the research and development, clinical and business development expertise of Mark A. Velleca, M.D., Ph.D., our President and Chief Executive Officer, Rajesh Malik, M.D., our Chief Medical Officer, Gregory Mossinghoff, our Chief Business Officer, Jay Strum, Ph.D., our Chief Scientific Officer, as well as the other principal members of our management, scientific and clinical team. Although we have entered into employment agreements with our executive officers, each of them may terminate their employment with us at any time. Other than for Dr. Velleca and Dr. Malik, we do not maintain "key person" insurance for any of our executives or other employees. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

Recruiting and retaining qualified scientific, clinical, manufacturing, sales and marketing personnel will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees 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 successfully develop, obtain marketing approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. Failure to succeed in clinical trials may make it more challenging to recruit and retain qualified scientific personnel. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

We expect to expand our development and regulatory capabilities and potentially implement sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

To manage our anticipated development and expansion, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Also, our management may need to divert a disproportionate amount of its attention away from its day-to-day activities and devote a substantial amount of time to managing these development activities. Due to our limited resources, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. This may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. The physical expansion of our operations may lead to significant costs and may divert financial resources from other projects, such as the development of our product candidates. If our management is unable to effectively manage our expected development and expansion, our expenses may increase more than expected, our ability to generate or increase our revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize our product candidates, if approved, and compete effectively will depend, in part, on our ability to effectively manage the future development and expansion of our company.

Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. The recent global financial crisis caused extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn, such as the recent global financial crisis, could result in a variety of risks to our business, including our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption. Any of the foregoing could harm our business, and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

Our business and operations could suffer in the event of system failures.

Despite the implementation of security measures, our internal computer systems and those of our third-party CROs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Furthermore, we have little or no control over the security measures and computer systems of our third-party CROs and other contractors and consultants. While we have not experienced any such system failure, accident, or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our programs. For example, the loss of clinical trial data for our product candidates could result in delays in our marketing approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications or other data or applications relating to our technology or product candidates, or inappropriate disclosure of confidential or proprietary information, we could incur liabilities and the further development of our product candidates could be delayed.

Our employees, principal investigators, CROs and consultants may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk that our employees, principal investigators, CROs and consultants may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violate the regulations of the FDA and other regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities; healthcare fraud and abuse laws and regulations in the United States and abroad; or laws that require the reporting of financial information or data accurately. In particular, sales, marketing and 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, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials or creating fraudulent data in our preclinical studies or clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of conduct applicable to all of our employees, but 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 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 civil, criminal and administrative penalties, damages, 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 of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

We may expend our limited resources to pursue a particular product candidate and fail to capitalize on product candidates that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on specific product candidates. As a result, we may forgo or delay pursuit of opportunities with other product candidates 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 and product candidates for specific indications may not yield any commercially viable product candidates. 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 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.

We may acquire businesses or drugs, or form strategic alliances, in the future, and we may not realize the benefits of such acquisitions.

We may acquire additional businesses or drugs, form strategic alliances or create joint ventures with third parties that we believe will complement or augment our existing business. If we acquire businesses with promising markets or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to successfully integrate them with our existing operations and company culture. We may encounter numerous difficulties in developing, manufacturing and marketing any new drugs resulting from a strategic alliance or acquisition that delay or prevent us from realizing their expected benefits or enhancing our business. We cannot assure you that, following any such acquisition, we will achieve the expected synergies to justify the transaction.

We or the third parties upon which we depend may be adversely affected by earthquakes or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Earthquakes or other natural disasters could severely disrupt our operations and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business.

Risks related to our common stock

The price of our common stock may be volatile and fluctuate substantially.

The market price of shares of our common stock could be subject to wide fluctuations in response to many risk factors listed in this section, and others beyond our control, including:

- results of preclinical and clinical trials of our product candidates, including trilaciclib, G1T38 and G1T48;
- results of clinical trials of our competitors' products;
- regulatory actions with respect to our products or our competitors' products;
- actual or anticipated fluctuations in our financial condition and operating results;
- publication of research reports by securities analysts about us or our competitors or our industry;
- our failure or the failure of our competitors to meet analysts' projections or guidance that we or our competitors may give to the market;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- additions and departures of key personnel;
- strategic decisions by us or our competitors, such as acquisitions, collaborations, divestitures, spin-offs, joint ventures, strategic investments or changes in business strategy;

- the passage of legislation or other regulatory developments in the United States and other countries affecting us or our industry;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- sales of our common stock by us, our insiders or our other stockholders;
- speculation in the press or investment community;
- announcement or expectation of additional financing efforts;
- changes in accounting principles;
- changes in the structure of healthcare payment systems;
- terrorist acts, acts of war or periods of widespread civil unrest;
- natural disasters and other calamities;
- changes in market conditions for pharmaceutical and biopharmaceutical stocks;
- changes in general market, industry and economic conditions; and
- the other factors described in this “Risk Factors” section.

In addition, the stock market has experienced significant volatility, particularly with respect to pharmaceutical, biotechnology and other life sciences company stocks. The volatility of pharmaceutical, biotechnology and other life sciences company stocks often does not relate to the operating performance of the companies represented by the stock. In the past, securities class action litigation has often been initiated against companies following periods of volatility in their stock price. This type of litigation could result in substantial costs and divert our management’s attention and resources, and could also require us to make substantial payments to satisfy judgments or to settle litigation.

Our executive officers, directors and principal stockholders and their affiliates, if they choose to act together, will continue to have the ability to exercise significant influence over all matters submitted to stockholders for approval.

Our executive officers and directors, combined with our stockholders who owned more than 5% of our outstanding common stock, in the aggregate, beneficially own shares representing over a majority of our outstanding capital stock. As a result, if these stockholders were to choose to act together, they would be able to influence our management and affairs and the outcome of matters submitted to our stockholders for approval, including the election of directors and any sale, merger, consolidation, or sale of all or substantially all of our assets. This concentration of ownership control may adversely affect the market price of our common stock by:

- delaying, deferring or preventing a change in control;
- entrenching our management and the board of directors;
- impeding a merger, consolidation, takeover or other business combination involving us that other stockholders may desire; and/or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our certificate of incorporation and our by-laws may discourage, delay or prevent a merger, acquisition or other change in control of our company that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Although we believe these provisions collectively provide for an opportunity to obtain greater value for stockholders by requiring potential acquirers to negotiate with our board of directors, they would apply even if an offer rejected by our board of directors were considered beneficial by some stockholders. Among other things, these provisions:

- establish a classified board of directors such that only one of three classes of directors is elected each year;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;

- limit the manner in which stockholders can remove directors from our board of directors;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call stockholder meetings;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a "poison pill" that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least two-thirds of the voting power of all of the then-outstanding shares of capital stock that would be entitled to vote generally in the election of directors to amend or repeal specified provisions of our certificate of incorporation or by-laws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Our certificate of incorporation includes a forum selection clause, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us.

Our certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for any stockholder to bring (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, officers, or employees to us or to our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law or our certificate of incorporation or by-laws, or (iv) any action asserting a claim governed by the internal affairs doctrine; in all cases subject to the court's having personal jurisdiction over the indispensable parties named as defendants. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock is deemed to have notice of and consented to the foregoing provisions. This forum selection provision in our certificate of incorporation may limit our stockholders' ability to obtain a favorable judicial forum for disputes with us. It is also possible that, notwithstanding the forum selection clause included in our certificate of incorporation, a court could rule that such a provision is inapplicable or unenforceable.

If securities or industry analysts do not publish research or reports about our business, or if they publish negative evaluations of our stock or negative reports about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. We may never obtain research coverage by industry or financial analysts. If no or few analysts commence coverage of us, the trading price of our stock would likely decrease. Even if we do obtain analyst coverage, there can be no assurance that analysts will cover us or provide favorable coverage. If one or more of the analysts who covers us downgrades our stock or changes his or her opinion of our stock, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our stock price or trading volume to decline.

We are an "emerging growth company," and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. We will remain an emerging growth company until the earlier of (i) the last day of the fiscal year in which we have total annual gross revenues of $1.07 billion or more; (ii) the last day of the fiscal year following the fifth anniversary of the date of the completion of our IPO; (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the Securities and Exchange Commission, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002;

- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- providing only two years of audited financial statements in addition to any required unaudited interim financial statements and a correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure in our initial registration statement;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

We may choose to take advantage of some, but not all, of the available exemptions. We have taken advantage of reduced reporting burdens in the prospectus for our IPO, and will continue to take advantage of these reduced reporting requirements for as long as we remain an emerging growth company. In particular, in the prospectus relating to our IPO, we provided only two years of audited financial statements and did not include all of the executive compensation information that would have been required if we were not an emerging growth company. We cannot predict whether investors will find our common stock less attractive if we 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.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to 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 exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

We have incurred and will continue to incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, and particularly after we are no longer an emerging growth company, we have incurred and will continue to incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The NASDAQ Stock Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance.

We are evaluating these rules and regulations, and cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, we will first be required to furnish a report by our management on our internal control over financial reporting for the year ending December 31, 2017. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

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

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, a corporation that undergoes an "ownership change," is subject to limitations on its ability to use its pre-change net operating loss carryforwards, or NOLs, and other pre-change tax attributes (such as research tax credits) to offset its post-change income or taxes. For these purposes, an ownership change generally occurs where the equity ownership of one or more stockholders or groups of stockholders who owns at least 5% of a corporation's stock increases its ownership by more than 50 percentage points over its lowest ownership percentage within a three year period. We may have experienced such ownership changes in the past, and we may experience shifts in our stock ownership, some of which are outside the Company's control. These ownership changes may subject our existing NOLs or credits to substantial limitations under Sections 382 and 383. Accordingly, we may not be able to utilize a material portion of our NOLs or credits. As of December 31, 2016, we had federal NOLs of approximately $46.8 million. Limitations on our ability to utilize those NOLs to offset U.S. federal taxable income could potentially result in increased future tax liability to us. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

We do not anticipate paying any cash dividends on our capital stock in the foreseeable future.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for our stockholders for the foreseeable future.

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

Recent Sales of Unregistered Equity Securities

During the period between April 1, 2017 and June 30, 2017, two investors exercised warrants to purchase an aggregate of 40,368 shares of our common stock at a weighted average price of $0.72 per share. We received net proceeds of $1,040 from the exercise of one investor's warrant; the other investor exercised its warrants on a cashless basis.

We deemed these exercises of warrants as exempt pursuant to Section 4(a)(2) of the Securities Act. Each of the recipients of securities in any transaction exempt from registration either received or had adequate access, through employment, business or other relationships, to information about us. On June 2, 2017, we filed a registration statement on Form S-8 under the Securities Act to register all of the shares of our common stock subject to outstanding options and all shares of our common stock otherwise issuable pursuant to our equity compensation plans.

Use of Proceeds from Registered Securities

On May 22, 2017, we completed our IPO and sold 7,781,564 shares of our common stock, including 781,564 shares of our common stock pursuant to the full exercise by the underwriters of an option to purchase additional shares, at a public offering price of $15.00 per share for an aggregate offering of approximately $116.7 million. The offer and sale of the shares in the IPO were registered under the Securities Act pursuant to a registration statement on Form S-1 (File No. 333-217285), which was initially filed on April 13, 2017 and declared effective on May 16, 2017, and a registration statement on Form S-1 filed pursuant to Rule 462(b) of the Securities Act (File No. 333-218045), which became effective on May 16, 2017. Following the sale of the shares in connection with the closing of our IPO, the offering was complete. J.P. Morgan Securities LLC acted as book-running manager of the offering, and Cowen and Company LLC, Needham & Company, LLC and Wedbush Securities Inc. acted as co-managers for the offering. We received aggregate net proceeds from the IPO of approximately $107.1 million, after deducting underwriting discounts and commissions and other offering expenses payable by us. None of the underwriting discounts and commissions or other offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates.

We have invested the net proceeds of our IPO in accordance with our investment policy. There has been no material change in our planned use of the net proceeds from the offering as described in our final prospectus filed with the Securities and Exchange Commission pursuant to Rule 424(b) under the Securities Act on May 17, 2017.

Item 3. Defaults Upon Senior Securities.

Not Applicable.

Item 4. Mine Safety Disclosures.

Not Applicable.

Item 5. Other Information.

Not Applicable.

Item 6. Exhibits.

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K (File No. 001-38096) filed May 26, 2017)
3.2	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 of the Registrant's Current Report on Form 8-K (File No. 001-38096) filed May 26, 2017)
10.1	2017 Employee, Director and Consultant Equity Plan and forms of award agreements thereunder (incorporated by reference to Exhibit 10.3 of the Registrant's Registration Statement on Form S-1/A (File No. 333- 217285) filed May 8, 2017)
31.1*	Certification of Principal 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 Principal 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*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Principal 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 Linkbase Document

* Filed herewith.

SIGNATURES

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

Company Name

Date: August 9, 2017

By: /s/ Mark A. Velleca, M.D., Ph.D.
Mark A. Velleca, M.D., Ph.D.
President, Chief Executive Officer (principal executive officer)

Date: August 9, 2017

By: /s/ Gregory J. Mossinghoff
Gregory J. Mossinghoff
Chief Business Officer (principal financial officer)

Exhibit Index

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* Filed herewith.

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, Mark A. Velleca, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of G1 Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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 small business issuer, 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 small business issuer's internal control over financial reporting; and

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

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

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

Date: August 9, 2017

By: /s/ Mark A. Velleca, M.D., Ph.D.
Mark A. Velleca, M.D., Ph.D.
President and 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, Gregory J. Mossinghoff, certify that:

1. I have reviewed this Quarterly Report on 10-Q of G1 Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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; and

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

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

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

Date: August 9, 2017

By: /s/ Gregory J. Mossinghoff
Gregory J. Mossinghoff
Chief Business Officer
(Principal Financial Officer)

Exhibit 32.1

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

In connection with the Quarterly Report of G1 Therapeutics, Inc. (the "Company") on Form 10-Q for the period ending June 30, 2017 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned 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 result of operations of the Company.

Date: August 9, 2017

By: /s/ Mark A. Velleca, M.D., Ph.D.
Mark A. Velleca, M.D., Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of G1 Therapeutics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.

Exhibit 32.2

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

In connection with the Quarterly Report of G1 Therapeutics, Inc. (the "Company") on Form 10-Q for the period ending June 30, 2017 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned 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 result of operations of the Company.

Date: August 9, 2017

By: /s/ Gregory J. Mossinghoff
Gregory J. Mossinghoff
Chief Business Officer
(Principal Financial Officer)

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of G1 Therapeutics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.