
**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 September 30, 2019

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
(State or other jurisdiction of
incorporation or organization)

26-3648180
(I.R.S. Employer
Identification No.)

700 Park Offices Drive, Suite 200
Research Triangle Park, NC 27709
(Address of principal executive offices including zip code)

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

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

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Stock, par value \$0.0001 per share	GTHX	The Nasdaq Stock Market

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 every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes 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	<input checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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 October 31, 2019, the registrant had 37,581,512 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 Balance Sheets (unaudited)
 (in thousands, except share and per share amounts)

	September 30, 2019	December 31, 2018
Assets		
Current assets		
Cash and cash equivalents	\$ 299,933	\$ 369,290
Restricted Cash	63	—
Prepaid expenses and other current assets	2,984	843
Total current assets	302,980	370,133
Property and equipment, net	3,618	1,137
Restricted Cash	437	—
Operating lease assets	10,151	—
Total assets	<u>\$ 317,186</u>	<u>\$ 371,270</u>
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	\$ 7,236	\$ 3,377
Accrued expenses	13,514	8,985
Other current liabilities	472	—
Total current liabilities	21,222	12,362
Operating lease liabilities	9,845	—
Other non-current liabilities	—	88
Total liabilities	<u>31,067</u>	<u>12,450</u>
Stockholders' equity		
Common stock, \$0.0001 par value, 120,000,000 shares authorized as of September 30, 2019 and December 31, 2018, respectively; 37,608,178 and 37,268,792 shares issued as of September 30, 2019 and December 31, 2018, respectively; 37,581,512 and 37,242,126 shares outstanding as of September 30, 2019 and December 31, 2018, respectively	4	4
Treasury stock, 26,666 shares	(8)	(8)
Additional paid-in capital	587,535	573,230
Accumulated deficit	(301,412)	(214,406)
Total stockholders' equity	<u>286,119</u>	<u>358,820</u>
Total liabilities and stockholders' equity	<u>\$ 317,186</u>	<u>\$ 371,270</u>

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

G1 Therapeutics, Inc.
Condensed Statements of Operations (unaudited)
(in thousands, except share and per share amounts)

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
Revenue	\$ —	\$ —	\$ —	\$ —
Operating expenses				
Research and development	22,941	15,873	64,510	51,605
General and administrative	11,083	4,949	27,979	11,595
Total operating expenses	<u>34,024</u>	<u>20,822</u>	<u>92,489</u>	<u>63,200</u>
Operating loss	<u>(34,024)</u>	<u>(20,822)</u>	<u>(92,489)</u>	<u>(63,200)</u>
Other income (expense)				
Other income	1,660	904	5,483	2,003
Total other income, net	<u>1,660</u>	<u>904</u>	<u>5,483</u>	<u>2,003</u>
Net loss	<u>\$ (32,364)</u>	<u>\$ (19,918)</u>	<u>\$ (87,006)</u>	<u>\$ (61,197)</u>
Net loss per share, basic and diluted	<u>\$ (0.86)</u>	<u>\$ (0.59)</u>	<u>\$ (2.32)</u>	<u>\$ (1.91)</u>
Weighted average common shares outstanding, basic and diluted	37,540,380	33,829,437	37,469,952	32,006,978

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

G1 Therapeutics, Inc.
Condensed Statements of Stockholders' Equity (unaudited)
(in thousands, except share and per share amounts)

	Common stock		Treasury stock		Additional paid-in capital	Accumulated deficit	Total stockholders' equity
	Shares	Amount	Shares	Amount			
Balance at December 31, 2018	37,268,792	\$ 4	(26,666)	\$ (8)	\$ 573,230	\$ (214,406)	\$ 358,820
Exercise of common stock options	218,890	—	—	—	269	—	269
Stock-based compensation	—	—	—	—	3,804	—	3,804
Net loss during quarter	—	—	—	—	—	(23,952)	(23,952)
Balance at March 31, 2019	37,487,682	\$ 4	(26,666)	\$ (8)	\$ 577,303	\$ (238,358)	\$ 338,941
Exercise of common stock options	42,925	—	—	—	678	—	678
Stock-based compensation	—	—	—	—	3,741	—	3,741
Net loss during quarter	—	—	—	—	—	(30,690)	(30,690)
Balance at June 30, 2019	37,530,607	\$ 4	(26,666)	\$ (8)	\$ 581,722	\$ (269,048)	\$ 312,670
Exercise of common stock options	77,571	—	—	—	1,372	—	1,372
Stock-based compensation	—	—	—	—	4,441	—	4,441
Net loss during quarter	—	—	—	—	—	(32,364)	(32,364)
Balance at September 30, 2019	37,608,178	\$ 4	(26,666)	\$ (8)	\$ 587,535	\$ (301,412)	\$ 286,119

	Common stock		Treasury stock		Additional paid-in capital	Accumulated deficit	Total stockholders' equity
	Shares	Amount	Shares	Amount			
Balance at December 31, 2017	28,420,511	\$ 3	(26,666)	\$ (8)	\$ 222,511	\$ (129,118)	\$ 93,388
Public offering (Follow-on Financings)	3,910,000	—	—	—	108,424	—	108,424
Exercise of common stock options	381,040	—	—	—	647	—	647
Stock-based compensation	—	—	—	—	1,594	—	1,594
Stock financing costs	—	—	—	—	(488)	—	(488)
Net loss during quarter	—	—	—	—	—	(20,410)	(20,410)
Balance at March 31, 2018	32,711,551	\$ 3	(26,666)	\$ (8)	\$ 332,688	\$ (149,528)	\$ 183,155
Public offering (ATM)	255,007	—	—	—	12,059	—	12,059
Exercise of common stock options	137,873	—	—	—	261	—	261
Stock-based compensation	—	—	—	—	2,101	—	2,101
Stock financing costs	—	—	—	—	(184)	—	(184)
Net loss during quarter	—	—	—	—	—	(20,868)	(20,868)
Balance at June 30, 2018	33,104,431	\$ 3	(26,666)	\$ (8)	\$ 346,925	\$ (170,396)	\$ 176,524
Public offering (Follow-on Financings)	3,450,000	1	—	—	195,097	—	195,098
Public offering (ATM)	497,001	—	—	—	24,009	—	24,009
Exercise of common stock options	114,537	—	—	—	506	—	506
Stock-based compensation	—	—	—	—	3,276	—	3,276
Stock financing costs	—	—	—	—	(240)	—	(240)
Net loss during quarter	—	—	—	—	—	(19,918)	(19,918)
Balance at September 30, 2018	37,165,969	\$ 4	(26,666)	\$ (8)	\$ 569,573	\$ (190,314)	\$ 379,255

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

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

	Nine Months Ended September 30,	
	2019	2018
Cash flows from operating activities		
Net loss	\$ (87,006)	\$ (61,197)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	215	115
Stock-based compensation	11,986	6,971
Gain/loss on disposal of property and equipment	—	7
Change in operating assets and liabilities		
Prepaid expenses and other assets	(772)	(510)
Accounts payable	2,574	(1,648)
Accrued expenses and other liabilities	3,443	3,167
Deferred rent	—	16
Net cash used in operating activities	<u>(69,560)</u>	<u>(53,079)</u>
Cash flows from investing activities		
Purchases of property and equipment	(1,616)	(598)
Investment in restricted cash account	(500)	—
Net cash used in investing activities	<u>(2,116)</u>	<u>(598)</u>
Cash flows from financing activities		
Proceeds from stock options and warrants exercised	2,319	1,414
Proceeds from public offerings, net of underwriting fees and commissions	—	339,589
Payment of public offering costs	—	(614)
Net cash provided by financing activities	<u>2,319</u>	<u>340,389</u>
Net change in cash, cash equivalents and restricted cash	<u>(69,357)</u>	<u>286,712</u>
Cash, cash equivalents and restricted cash		
Beginning of period	369,290	103,812
End of period	<u>\$ 299,933</u>	<u>\$ 390,524</u>
Non-cash operating, investing and financing activities		
Upfront project costs and other current assets in accounts payable and accrued expenses	1,040	130
Purchases of equipment in accounts payable and accrued expenses	1,080	19
Operating lease liabilities arising from obtaining right-of-use asset	8,947	—
Costs for public offering in accounts payable and accrued expenses	—	297

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

G1 Therapeutics, Inc.
Notes to financial statements
(unaudited)

1. Business Description

G1 Therapeutics, Inc. (the “Company”) is a clinical-stage biopharmaceutical company based in Research Triangle Park, North Carolina focused on the discovery, development and commercialization of novel small molecule therapeutics for the treatment of patients with cancer. The Company was incorporated on May 19, 2008 in the state of Delaware.

The Company is advancing three clinical-stage programs. Trilaciclib is a first-in-class therapy designed to improve outcomes for patients being treated with chemotherapy. Lerociclib is a differentiated oral CDK4/6 inhibitor designed to enable more effective combination treatment strategies across multiple oncology indications, including estrogen receptor-positive, HER2-negative (ER+, HER2-) breast cancer. G1T48 is a potential best-in-class oral selective estrogen receptor degrader (SERD) for the treatment of ER+ breast cancer. The Company also has an active discovery program focused on cyclin-dependent kinase targets. The Company owns the global rights to all of its product candidates.

Trilaciclib, the Company’s most advanced clinical-stage candidate, is a first-in-class therapy designed to preserve bone marrow and immune system function during chemotherapy and improve patient outcomes. The U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation for trilaciclib based on myelopreservation data from three randomized, double-blind, placebo-controlled small cell lung cancer (SCLC) clinical trials, as well as safety data collected across all completed and ongoing clinical trials. The Breakthrough Therapy program is designed to expedite development and review of drugs intended for serious or life-threatening conditions. Based on written feedback from its pre-New Drug Application (NDA) meeting with the FDA, the Company plans to begin a rolling NDA submission for trilaciclib for myelopreservation in SCLC in the fourth quarter of 2019 and complete the NDA submission in the second quarter of 2020. Based on discussions with European regulatory authorities, the Company plans to submit a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for trilaciclib for myelopreservation in SCLC in the second half of 2020. In September, the Company presented updated data from a randomized Phase 2 trial of trilaciclib in combination with chemotherapy in metastatic triple-negative breast cancer (mTNBC) demonstrating significant improvement in overall survival. These data were presented at the European Society for Medical Oncology (ESMO) Congress in September 2019 and published in *The Lancet Oncology*. The Company has shared the findings with the FDA. The Company plans to initiate additional clinical trials beginning in 2020 to evaluate the use of trilaciclib in additional tumor types and in combination with different chemotherapy regimens.

Lerociclib is a differentiated oral CDK4/6 inhibitor being developed for use in combination with other targeted therapies in multiple oncology indications, including ER+, HER2- breast cancer. In 2018, the Company reported encouraging preliminary Phase 1b data from its Phase 1/2 trial in ER+, HER2- breast cancer (in combination with fulvestrant) and will report additional Phase 1b/2a data from this trial at the San Antonio Breast Cancer Symposium on December 11, 2019. In 2020, the Company plans to initiate a pivotal trial to evaluate lerociclib in combination with fulvestrant for the treatment of ER+, HER2- breast cancer. The Company’s plans for lerociclib include potential exploration of combinations in other cancers, such as non-small cell lung cancer (NSCLC), where we initiated a Phase 1b/2 trial in 2018 in combination with the epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor, Tagrisso® (osimertinib). Data from this trial were presented at the ESMO 2019 Congress. We believe that lerociclib has the potential to be best-in-class versus marketed CDK4/6 inhibitors for patients with ER+, HER2- breast cancer and become a backbone therapy of multiple combination targeted therapy regimens for other tumors.

The Company is developing G1T48, a potential best-in-class oral SERD, as a monotherapy and in combination with oral CDK4/6 inhibitors (including lerociclib) for the treatment of ER+ breast cancer. In 2018, the Company initiated a Phase 1/2a clinical trial in ER+, HER2- breast cancer and reported preliminary data at the ESMO 2019 Congress. Based on these findings, G1 is planning to initiate a pivotal trial of G1T48 in combination with an oral CDK4/6 inhibitor in 2020.

All three investigational therapies have the potential to become new standards of care for women with breast cancer and provide benefit in the early stages of their disease, including in the adjuvant setting.

2. Basis of Presentation and Summary of Significant Accounting Policies

Basis of Presentation

The accompanying condensed financial statements of the Company have been prepared in accordance with generally accepted accounting principles in the United States of America (“U.S. GAAP”). In the opinion of management, the Company has made all

necessary adjustments, which include normal recurring adjustments necessary for a fair statement of the Company's financial position and results of operations for the interim periods presented.

The information presented in the condensed financial statements and related notes as of September 30, 2019, and for the three and nine months ended September 30, 2019 and 2018, is unaudited. The results for the three months ended September 30, 2019 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 Annual Report on Form 10-K for the year ended December 31, 2018 filed with the SEC on February 28, 2019, as amended on April 26, 2019 (collectively, "2018 Form 10-K"). The December 31, 2018 condensed 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 U.S. 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.

Research and Development

Research and development expenses consist of costs incurred to further the Company's research and development activities and include salaries and related employee benefits, manufacturing of pharmaceutical active ingredients and drug products, costs associated with clinical trials, nonclinical activities, regulatory activities, research-related overhead expenses and fees paid to expert consultants, external service providers and contract research organizations which conduct certain research and development activities on behalf of the Company. Costs incurred in the research and development of products are charged to research and development expense as incurred.

Each reporting period, management estimated and accrued research and development expenses, including external clinical study costs comprising of pre-clinical and clinical trial activities. The process involves reviewing contracts and purchase orders, identifying services that have been provided on the Company's behalf, and estimating the level of service performed and the associated cost incurred for the service when the Company has not yet been invoiced or otherwise notified of the actual costs.

Costs for preclinical studies and clinical trial activities were estimated based on an evaluation of vendors' progress towards completion of specific tasks, using data such as patient enrollment, clinical site activations or information provided by vendors regarding their actual costs incurred. Payments for these activities are based on the terms of individual contracts and payment timing may differ significantly from the period in which the services were performed. The Company determines accrual estimates through reports from and discussions with applicable personnel and outside service providers as to the progress or state of completion of trials, or the services completed. The estimates of accrued expenses as of each balance sheet date are based on the facts and circumstances known at the time.

Income taxes

The Company did not record a federal or state income tax benefit for the nine months ended September 30, 2019 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 September 30, 2019 and December 31, 2018, 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 September 30, 2019 and December 31, 2018, the Company had no such accruals.

The Company had federal and state operating loss carryforwards of approximately \$191.5 million that expire beginning in 2024 as of its fiscal year ending December 31, 2018 prior to any reductions under Section 382 of the Internal Revenue Code of 1986, as amended. Section 382 provides that a corporation that undergoes an "ownership change", as defined therein, is subject to limitations on its ability to use its pre-change net operating loss carryforwards to offset future taxable income.

In April 2019, the Company completed an evaluation study whether an "ownership change" had occurred and determined that the limitation would be approximately \$8.0 million, thereby reducing the net operating loss which remains approximately \$183.5 million at September 30, 2019. The Company continues to maintain a valuation allowance on the remaining NOL as it believes that it is more likely than not that all of the deferred tax asset associated with the NOLs will not be realized regardless of whether an "ownership change" has occurred.

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. In accordance with the implementation of ASU No. 2018-07 on January 1, 2019, the fair value of non-employee stock options will no longer be re-measured each reporting period.

Leases

We determine if an arrangement is a lease at inception. Operating lease assets represent our right to use an underlying asset for the lease term and lease liabilities represent our obligation to make lease payments arising from the lease. Operating leases are included in operating lease assets, other current liabilities, and operating lease liabilities on our balance sheet at September 30, 2019. Operating lease assets and operating lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term at commencement date. As most of our leases do not provide an implicit rate, we use our incremental borrowing rate based on the information available at commencement date to determine the present value of future payments. Our lease terms may include options to extend or terminate the lease when it is reasonably certain that we will exercise that option. Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term.

Prior period amounts continue to be reported in accordance with our historic accounting under previous lease guidance, Topic 840. See "Adoption of New Accounting Standards – Impact of Adoption of Topic 842" below, for more information about the impact of the adoption of Topic 842.

Recent Accounting Pronouncements

Adoption of New Accounting Standards

In June 2018, the FASB issued ASU No. 2018-07, *Improvements to Nonemployee Share-Based Payment Accounting* (“ASU 2018-07”). ASU 2018-07 expands the scope of Topic 718, Compensation – Stock Compensation, to include share-based payments issued to non-employees for goods or services. Consequently, non-employees and employees will be substantially aligned. ASU 2018-07 supersedes Subtopic 505-50, Equity – Equity-Based Payments to Non-Employees. The amendments are effective for fiscal years beginning after December 15, 2018. Early adoption is permitted, but not earlier than the adoption of Topic 606, Revenue from Contracts with Customers. The Company adopted ASU 2018-07 on January 1, 2019. The adoption of this standard did not have a material impact on the Company’s financial statements.

In February 2016, the FASB issued ASU No. 2016-02, *Leases* (Topic 842) (“ASU 2016-02”). 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. In January 2019, the Company adopted ASU 2016-02 using the modified retrospective transition method with an effective date as of the beginning of our fiscal year, January 1, 2019. Prior period amounts have not been adjusted and continue to be reported in accordance with our historical reporting under previous lease guidance, ASC Topic 840. As part of the adoption, we have elected to account for separate lease and associated non-lease components as a single lease component for our real estate leases.

Impact of Adoption of Topic 842

With the adoption of Topic 842 on January 1, 2019, the Company recognized operating lease assets and operating lease liabilities of \$.5 million and \$1.6 million, respectively, with the difference due to the de-recognition of current and non-current deferred rent. There was no impact to the opening accumulated deficit as of January 1, 2019.

The impact of the adoption of Topic 842 on the accompanying balance sheet as of January 1, 2019 was as follows (in thousands):

	<u>December 31, 2018</u>	<u>Adjustments Due to the Adoption of Topic 842</u>	<u>January 1, 2019</u>
Operating lease assets	\$ —	\$ 1,533	\$ 1,533
Accrued expenses	8,985	(9)	8,976
Operating lease liabilities:			
Other current liabilities	—	352	352
Non-current operating lease liabilities	—	1,278	1,278
Other non-current liabilities	88	(88)	—
Stockholders' equity	358,820	—	358,820

Recently Issued Accounting Standards

In August 2018, the FASB issued ASU No. 2018-15, *Goodwill and Other—Internal-Use Software* (Subtopic 350-40): Customer’s Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract (“ASU 2018-15”). The FASB issued ASU 2018-15 to align the requirements for capitalizing implementation costs incurred in a cloud-based hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software. ASU 2018-15 is effective for annual and interim reporting periods beginning after December 15, 2019, and early adoption is permitted. The amendments under ASU 2018-15 may be applied either retrospectively or prospectively to all implementation costs incurred after adoption. The Company is evaluating the impact of ASU 2018-15 on its financial statements and the timing of adoption.

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 September 30, 2019 and December 31, 2018 these financial instruments and respective fair values have been classified as follows (in thousands):

	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant other unobservable inputs (Level 3)	Balance at September 30, 2019
Assets				
Money market funds	\$ 282,727	\$ —	\$ —	\$ 282,727
Certificates of Deposit	15,796	—	—	15,796
Total assets at fair value:	\$ 298,523	\$ —	\$ —	\$ 298,523

	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, 2018
Assets				
Money market funds	\$ 352,934	\$ —	\$ —	\$ 352,934
Certificates of Deposit	15,501	—	—	15,501
Total assets at fair value:	\$ 368,435	\$ —	\$ —	\$ 368,435

During the three and nine months ended September 30, 2019 and the year ended December 31, 2018, there were no changes in valuation methodology.

4. Property and equipment

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

	<u>September 30, 2019</u>	<u>December 31, 2018</u>
Computer equipment	\$ 326	\$ 246
Laboratory equipment	817	611
Furniture and fixtures	1,052	293
Leasehold improvements	1,958	238
Construction in progress	—	71
Accumulated depreciation	(535)	(322)
Property and equipment, net	<u>\$ 3,618</u>	<u>\$ 1,137</u>

Depreciation expense relating to property and equipment was \$86 and \$215 for the three and nine months ended September 30, 2019, respectively and \$48 and \$115 for the three and nine months ended September 30, 2018, 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. In addition, the University is eligible to receive milestone payments of up to \$2.6 million related to the initiation and execution of clinical trials and the first commercial sale of a product and the first commercial sale of a product in another country. To date, the Company has made milestone payments totaling \$0.6 million, of which \$0.5 million was incurred during the current quarter. The Company will be responsible for any future patent prosecution costs that may arise.

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 such breach within forty-five (45) days after receipt of notice, (iii) makes a report to the University under the agreement that is determined 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 within 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):

	<u>September 30, 2019</u>	<u>December 31, 2018</u>
Accrued external research and professional fees	\$ 4,526	\$ 1,591
Accrued external clinical study costs	6,755	4,692
Accrued compensation expense	2,233	2,693
Deferred rent, current portion	—	9
Accrued expenses	<u>\$ 13,514</u>	<u>\$ 8,985</u>

7. Leases

As described in our “Note 2. Basis of Presentation and Summary of Significant Accounting Policies”, we adopted Topic 842 as of January 1, 2019. Prior period amounts have not been adjusted and continue to be reported in accordance with our historic accounting under Topic 840.

Pursuant to a lease agreement dated January 10, 2014 (the “Lease”), on April 1, 2014, the Company leased office and lab space with a free rent period and escalating rent payments; the Lease had an expiration date of July 31, 2017. The Lease was amended on January 27, 2016 to lease new larger office and lab space beginning in August 2016 with a discounted rent period and escalating rent payments and the Lease term was extended to December 31, 2022. The amendment also contained an option for a five-year renewal and a right of first refusal to lease adjacent office space. The Lease was further amended on March 27, 2017 to lease additional office space beginning in August 2017 with a discounted rent period and escalating rent payments. The Lease was amended again in January 2018 to lease additional adjacent office space beginning in August 2018 with a discounted rent period and escalating rent payments. The term of the renewal option contained in the Lease, as amended, was not included in the measurement of the operating lease asset and liability since exercise of the option was uncertain.

In November 2018, the Company signed a new lease to secure approximately 60,000 square feet of laboratory and office space at 700 Park Offices Drive in Research Triangle Park, NC (“700 Lease”). The 700 Lease commenced on September 2, 2019 and has an expiration date of September 30, 2027 for the initial term with the Company having the option to renew for an additional 5 years. The term of the renewal option contained in the Lease was not included in the measurement of the operating lease asset and liability since exercise of the option was uncertain. As part of the 700 Lease, the Company obtained a standby letter of credit in the amount of \$0.5 million related to the security deposit. This letter of credit is secured by money market funds at the financial institution. Therefore, these funds are classified as restricted cash on the balance sheet. The letter of credit will be reduced ratably on each anniversary of the commencement of the 700 Lease until the end of the lease term.

The tables below reflect the Company’s lease position and weighted-average lease terms and discount rates for our operating leases as of September 30, 2019. Operating lease liabilities are based on the net present value of the remaining lease payments over the remaining lease term. In determining the present value of lease payments, we use our incremental borrowing rate based on the information available at the lease commencement date.

<u>(in thousands)</u>	<u>Classification on the Balance Sheet</u>	<u>September 30, 2019</u>
Assets		
Operating lease assets	Operating lease assets	\$ 10,151
Total lease assets		\$ 10,151
Liabilities		
Current		
Operating	Other current liabilities	\$ 472
Non-current		
Operating	Operating lease liabilities	9,845
Total lease liabilities		\$ 10,317

Lease Term and Discount Rate	September 30, 2019
Weighted-average remaining lease term (years)	
Operating leases	7.4
Weighted-average discount rate	
Operating leases	7.7%

The table below presents information related to the lease costs for operating leases (in thousands):

(in thousands)	Classification	Three Months Ended September 30,		Nine Months Ended September 30,	
		2019	2018	2019	2018
Operating lease costs (a)	Research and development	\$ 153	\$ 75	\$ 329	\$ 211
	General and administrative	92	26	145	53
Total operating lease costs		\$ 245	\$ 101	\$ 474	\$ 264

(a) Includes variable lease costs which are immaterial.

The table below reconciles the undiscounted cash flow for each of the first five years and total of the remaining years to the operating lease liabilities recorded on the balance sheet as of September 30, 2019 (in thousands):

	Operating leases
Years ending December 31,	
2019 (excluding the nine months ended September 30, 2019)	\$ 299
2020	1,459
2021	2,015
2022	2,072
2023	1,634
Thereafter	6,534
Total future minimum lease payments	\$ 14,013
Less: present value adjustment	(3,696)
Total operating lease liabilities	\$ 10,317

Cash payments included in the measurement of our operating leases were \$389 thousand for the nine months ended September 30, 2019.

ASC 840 Disclosures

The Company elected the alternative modified transition method and included the following table previously disclosed.

The following is a schedule by years of minimum future rental payments on noncancelable operating leases as of December 31, 2018 (in thousands):

2019	\$ 680
2020	1,427
2021	1,960
2022	2,015
2023	1,577
2024 and thereafter	6,155
	\$ 13,814

8. Stockholders' Equity

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.

On March 12, 2018, the Company closed an underwritten public offering of 3,910,000 shares of common stock at a public offering price of \$9.50 per share, including 510,000 shares of common stock issued upon exercise by the underwriters of their option to purchase additional shares. The gross proceeds from the offering were \$115.3 million and net proceeds were \$107.9 million, after deducting underwriting discounts and commissions and other offering expenses payable by the Company.

On June 15, 2018, the Company entered into a Sales Agreement for an "at the market offering" arrangement with Cowen and Company, LLC ("Cowen"), which allows the Company to issue and sell shares of common stock pursuant to a shelf registration statement for total gross sales proceeds of up to \$125.0 million from time to time through Cowen, acting as its agent. Between June 18, 2018 and August 2, 2018, the Company sold 752,008 shares of common stock pursuant to this agreement resulting in \$36.1 million in net proceeds, realizing \$12.1 million in the second quarter of 2018 and the remaining \$24.0 million by August 2, 2018.

On September 21, 2018, the Company closed on an underwritten public offering of 3,450,000 shares of its common stock at a public offering price of \$0.00 per share, including 450,000 shares of common stock issued upon exercise by the underwriters of their option to purchase additional shares, pursuant to a shelf registration statement. The gross proceeds from the offering were \$207.0 million and net proceeds were \$194.9 million, after deducting underwriting discounts and commissions and other offering expenses payable by the Company.

Preferred Stock

The Company is authorized to issue 5.0 million shares of undesignated preferred stock in one or more series. As of September 30, 2019, 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:

	<u>September 30, 2019</u>	<u>December 31, 2018</u>
Common stock options outstanding	5,762,159	4,502,133
Options available for grant under Equity Incentive Plans	950,697	1,547,306
	<u>6,712,856</u>	<u>6,049,439</u>

9. 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. Effective January 1, 2018, and in accordance with the "evergreen" provision of the 2017 plan, an additional 1,066,692 shares were made available for issuance. Effective January 1, 2019, and in accordance with the "evergreen" provision of the 2017 plan, an additional 1,096,553 shares were made available for issuance.

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 September 30, 2019, there were a total of 950,697 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 nine months ended September 30, 2019, the Company recorded employee share-based compensation expense of \$4.4 million and \$11.9 million, respectively. During the three and nine months ended September 30, 2018, the Company recorded employee share-based compensation expense of \$2.7 million and \$5.2 million, 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. Prior to the adoption of ASU 2018-07 on January 1, 2019, the fair value of the stock options granted to non-employees was re-measured each reporting period until the service was complete, and the resulting increase or decrease in value, if any, was recognized as expense or income, respectively, during the period the related services were rendered. After the adoption of ASU 2018-07, stock options granted to non-employees are no longer re-measured each reporting period.

During the three and nine months ended September 30, 2019, the Company recorded non-employee share-based compensation expense of \$0 and \$0.1 million, respectively. During the three and nine months ended September 30, 2018, the Company recorded non-employee share-based compensation expense of \$0.5 million and \$1.8 million, 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 nine months ended September 30, 2019 and September 30, 2018:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Expected volatility	74.4 - 77.1%	77.3 - 86.4%	74.2 - 82.1%	74.9 - 86.5%
Weighted-average risk free rate	1.4 - 1.9%	2.7 - 2.9%	1.4 - 2.6%	2.3 - 2.9%
Dividend yield	—%	—%	—%	—%
Expected term (in years)	6.07	6.06	6.02	6.03

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

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
Research and development	\$ 1,634	\$ 1,473	\$ 4,635	\$ 3,900
General and administrative	2,807	1,803	7,351	3,071
Total stock-based compensation expense	<u>\$ 4,441</u>	<u>\$ 3,276</u>	<u>\$ 11,986</u>	<u>\$ 6,971</u>

Stock Option Activity

Stock option activity for the nine months ended September 30, 2019 is as follows:

	<u>Options outstanding</u>	<u>Weighted average exercise price</u>	<u>Weighted average</u>	
			<u>Remaining contractual life (Years)</u>	<u>Aggregate intrinsic value (in thousands)</u>
Balance as of December 31, 2018	4,502,133	\$ 14.13	7.6	\$ 46,575
Cancelled	(296,113)	\$ 19.96		
Granted	1,895,525	22.05		
Exercised	(339,386)	6.83		
Balance as of September 30, 2019	<u>5,762,159</u>	<u>\$ 16.87</u>	7.7	\$ 56,706
Exercisable at December 31, 2018	2,361,694	3.07	6.5	\$ 38,285
Vested at December 31, 2018 and expected to vest	4,502,133	14.13	7.6	\$ 46,575
Exercisable at September 30, 2019	2,813,106	7.90	6.3	\$ 47,709
Vested at September 30, 2019 and expected to vest	5,762,159	16.87	7.7	\$ 56,706

10. 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 September 30, 2019 and 2018 and for the nine months ended September 30, 2019 and 2018 the following potentially dilutive securities have been excluded from the computations of diluted weighted-average shares outstanding because the effect would be anti-dilutive:

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
	<u>(unaudited)</u>		<u>(unaudited)</u>	
Stock options issued and outstanding	5,629,344	4,482,649	5,334,298	4,258,269

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

11. Related party transactions

The Company maintains a consulting agreement with a member of the Board of Directors for scientific advisory services outside of his role on the Board of Directors that expires on June 30, 2020.

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 our 2018 Form 10-K, 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, development and commercialization of novel small molecule therapeutics for the treatment of patients with cancer. Our product portfolio is built on a drug discovery platform that targets key cellular pathways with proprietary medicinal chemistry. Our therapies are designed to enable more effective combination treatment strategies and improve outcomes for patients across multiple oncology indications.

Product Pipeline

The Company is advancing three clinical stage programs. Trilaciclib is a first-in-class therapy designed to improve outcomes for patients being treated with chemotherapy. Lerociclib is a differentiated oral CDK4/6 inhibitor designed to enable more effective combination treatment strategies across multiple oncology indications, including ER+, HER2- breast cancer. G1T48 is a potential best-in-class oral selective estrogen receptor degrader (SERD) for the treatment of ER+ breast cancer. All three investigational therapies have the potential to become new standards of care for women with breast cancer and provide benefit in the early stages of their disease, including in the adjuvant setting. The Company also has an active discovery program focused on cyclin-dependent kinase targets. The Company owns the global rights to all of its product candidates.

G1 Therapeutics Product Pipeline

Candidate	Target	MOA	Clinical Status	Global Rights
trilaciclib	CDK4/6	Short-acting intravenous CDK4/6 inhibitor Preserves HSPC and immune system function	NDA filing SCLC Phase 2 TNBC	
lerociclib	CDK4/6	Oral CDK4/6 inhibitor Inhibits tumor proliferation and growth	Phase 1/2	
G1T48	Estrogen Receptor	Oral selective estrogen receptor degrader (SERD) Inhibits estrogen receptor driven tumor proliferation	Phase 1/2	

Our CDK4/6 Inhibitor Product Candidates

CDK4/6 are key cell signaling proteins that regulate cell growth and proliferation. The CDK4/6 pathway regulates proliferation and growth of both healthy normal cells and certain tumor cells, representing a validated and promising class of targets for anti-cancer therapeutics. An example of normal cells whose growth and proliferation are regulated by CDK4/6 are 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.

We have leveraged our deep knowledge 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 lerociclib, each of which has the potential to be backbone therapy of multiple combination regimens. Our two CDK4/6 inhibitors were rationally designed to treat distinct patient populations with different combination regimens.

Trilaciclib, a short-acting intravenous (IV) therapy, is in development for use in combination with chemotherapy and chemotherapy/checkpoint inhibitor regimens. Lerociclib, an oral therapy, is in development for use in combination with other targeted therapies, including with SERDs in ER+, HER2- breast cancer

Trilaciclib: preserving bone marrow and immune system function during chemotherapy and improving patient outcomes

Chemotherapy is an effective and important weapon against cancer. However, chemotherapy does not differentiate between healthy cells and cancer cells and kills both, including important stem cells in the bone marrow (hematopoietic stem and progenitor cells, or HSPCs) that produce white blood cells, red blood cells and platelets, and immune cells. This chemotherapy-induced bone marrow damage is known as myelosuppression. When white blood cells, red blood cells and platelets become depleted, chemotherapy patients are at increased risk of infection, experience anemia and fatigue, and are at increased risk of bleeding. Myelosuppression often requires the administration of rescue interventions such as growth factors and blood or platelet transfusions and may also result in chemotherapy dose delays and reductions. Immune cell damage may decrease the ability of the immune system to fight the cancer.

Trilaciclib is a first-in-class therapy designed to preserve bone marrow and immune system function during chemotherapy and improve patient outcomes. Clinical trials have demonstrated that trilaciclib can provide myelopreservation benefits (i.e. reduction of chemotherapy-induced myelosuppression effects) and, in certain settings, trilaciclib also has the potential to improve survival. It is a short-acting CDK4/6 inhibitor that is administered intravenously prior to chemotherapy.

In preclinical studies, administration of trilaciclib prior to chemotherapy has been shown to induce transient cell-cycle arrest of HSPCs, protect HSPCs from chemotherapy-induced damage, preserve bone marrow and immune system function, protect against bone marrow exhaustion, improve complete blood counts (CBC) recovery, prevent myeloid skewing and consequent lymphopenia, and enhance T-cell effector function in the tumor microenvironment.

Following evaluation of trilaciclib in a Phase 1 trial in healthy volunteers, we initiated two Phase 1b/2 trials in patients with extensive-stage small cell lung cancer (SCLC); one in a first-line setting (in combination with carboplatin/etoposide) and the other in a second/third-line setting (in combination with topotecan). Enrollment in both trials has been completed and preliminary data from the open label Phase 1b segment were reported in 2016 and 2017. In the Phase 1b segments of these two trials, we treated 51 patients with over 250 cycles of trilaciclib and chemotherapy. There were no episodes of febrile neutropenia – one of the most common adverse consequences of these chemotherapy regimens. Further, there were no drug-related serious adverse events reported during the Phase 1b segments of these two trials. There were some adverse events reported involving fatigue and cytopenias, but those adverse events were less severe and less frequent than those generally reported in trials involving the use of chemotherapy alone.

Based on these encouraging preliminary data, we advanced both of these SCLC trials into the randomized, placebo-controlled, double-blind Phase 2 segment. Enrollment in the first-line SCLC Phase 2 trial was completed in the second quarter of 2017 and positive multi-lineage myelopreservation results were reported in March 2018, with additional data reported at the European Society for Medical Oncology (ESMO) 2018 Congress and published in *Annals of Oncology* in 2019. Enrollment in the second-/third-line SCLC Phase 2 trial was completed in the second quarter of 2018, with positive multi-lineage myelopreservation data reported in the fourth quarter of 2018 and full data presented at an oral session at the American Society of Clinical Oncology (ASCO) 2019 Annual Meeting.

Our third trial in SCLC was initiated in 2017, as part of our non-exclusive collaboration with Genentech, with the goal of exploring the use of trilaciclib in combination with chemotherapy and a checkpoint inhibitor. The trial was a randomized, placebo-controlled, double-blind Phase 2 trial of trilaciclib in combination with Tecentriq® (atezolizumab)/carboplatin/etoposide in first-line SCLC patients. We completed enrollment in February 2018 and reported positive multi-lineage myelopreservation data in November 2018. Additional data, including myelopreservation and anti-tumor efficacy findings (as measured by overall survival), were reported at the ESMO 2019 Congress.

All three SCLC trials demonstrated that trilaciclib, when added to standard of care chemotherapy or chemotherapy/checkpoint inhibitor regimens, mitigates clinically significant chemotherapy-induced myelosuppression. The U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation for trilaciclib based on myelopreservation data from our three randomized, double-blind, placebo-controlled SCLC clinical trials, as well as safety data collected across all completed and ongoing clinical trials. The Breakthrough Therapy program is designed to expedite development and review of drugs intended for serious or life-threatening conditions. Based on written feedback from its pre-New Drug Application (NDA) meeting with the FDA, the Company plans to begin a rolling NDA submission for trilaciclib for myelopreservation in SCLC in the fourth quarter of 2019 and complete the NDA submission in the second quarter of 2020. Based on discussions with European regulatory authorities, the Company plans to submit a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for trilaciclib for myelopreservation in SCLC in the second half of 2020.

Trilaciclib is also being tested outside of SCLC. In 2017 we initiated a randomized Phase 2 trial of trilaciclib in patients with first-/second-/third-line metastatic triple-negative breast cancer (mTNBC) receiving gemcitabine and carboplatin. Enrollment was completed in the second quarter of 2018. At the December 2018 San Antonio Breast Cancer Symposium (SABCS), we presented preliminary trilaciclib data demonstrating improvement in progression-free survival (PFS). In September, the Company presented

updated data demonstrating significant improvement in overall survival. These data were presented at the ESMO2019 Congress and published in The Lancet Oncology. The Company has shared the findings with the FDA. G1 is planning trials in TNBC and colorectal cancer in 2020.

Lerociclib: Our potential best-in-class oral CDK4/6 inhibitor for patients with CDK4/6-dependent tumors

Lerociclib is a differentiated oral CDK4/6 inhibitor being developed for use in combination with other targeted therapies in multiple oncology indications, including ER+, HER2- breast cancer. We rationally designed lerociclib to improve upon and address the shortcomings of the approved CDK4/6 inhibitors Ibrance® (palbociclib), Kisqali® (ribociclib) and Verzenio® (abemaciclib), with fewer dose-limiting toxicities and potential for less frequent blood count monitoring. Our preclinical data and early clinical data indicate the potential for continuous daily dosing, less dose-limiting neutropenia, and improved tolerability. A Phase 1 trial of lerociclib in 75 healthy volunteers showed a favorable safety profile, and we reported encouraging preliminary Phase 1b data from our Phase 1/2 trial in ER+, HER2- breast cancer (in combination with fulvestrant) at the ASCO 2018 Annual Meeting. Additional data from this trial will be presented at the San Antonio Breast Cancer Symposium in December 2019. Our plans for lerociclib may also include combinations in other cancers, such as non-small cell lung cancer, or NSCLC, where we initiated a Phase 1b/2 combination trial with the epidermal growth factor receptor (EGFR) inhibitor, Tagrisso® (osimertinib). Initial safety and tolerability data from this trial were presented at the ESMO 2019 Congress. We believe that lerociclib has the potential to be the backbone therapy of multiple combination targeted therapy regimens. G1 is planning to initiate a pivotal trial of lerociclib in combination with fulvestrant in ER+, HER2- breast cancer in 2020.

G1T48: Our oral SERD

G1T48 is a potential best-in-class oral SERD, which we plan to develop as a monotherapy and in combination with CDK4/6 inhibitors (including lerociclib) for the treatment of ER+, HER2- breast cancer. We believe we are in a unique position as the only emerging biopharmaceutical company with both a wholly owned oral SERD and oral CDK4/6 inhibitor, a validated combination approach in ER+, HER2- breast cancer. Based on compelling preclinical efficacy and safety data, we filed an Investigational New Drug application (IND) with the FDA in the fourth quarter of 2017. In 2018, the Company initiated a Phase 1/2a clinical trial in ER+, HER2- breast cancer. Data from the Phase 1 portion of this trial were presented at the ESMO 2019 Congress, showing that G1T48 was well tolerated and demonstrated evidence of anti-tumor activity in heavily pre-treated patients. Based on these data, G1 is planning to initiate a pivotal trial of G1T48 in combination with an oral CDK4/6 inhibitor in 2020.

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 of revenue for the three and nine months ended September 30, 2019 and the year ended December 31, 2018. To date, we have financed our operations primarily through the sale of equity securities.

As of September 30, 2019, we had cash and cash equivalents of \$299.9 million. Since inception we have incurred net losses. As of September 30, 2019 we had an accumulated deficit of \$301.4 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, lerociclib and 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
- continue to incur increased costs as a result of operating as a public company.

License agreement with the University of Illinois

In November 2016, and as amended in March 2017, we entered into a license agreement with the Board of Trustees of the University of Illinois, (“the University”). Pursuant to the license agreement, as amended, the University licensed patent rights to the Company, with rights to sublicense, to make, have made, use, import, sell and offer for sale SERDs, including G1T48, covered by certain patent rights owned by the University. The rights licensed to us are exclusive, worldwide, non-transferable rights, 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 the University 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. In addition, the Company may also be required to pay the University milestone payments of up to an aggregate of \$2.6 million related to the initiation and execution of clinical trials and the first commercial sale of a product and the first commercial sale of a product in another country. To date, the Company has made milestone payments totaling \$0.6 million, of which \$0.5 million was incurred during the current quarter. We will also be responsible for any future patent prosecution costs that may arise.

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 outsourced 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 report 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 three clinical-stage product candidates, trilaciclib, lerociclib and G1T48.

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, pre-commercialization costs, 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 expect to continue to incur additional expenses as we support continued research and development activities and support our operations in a public company environment, including expenses related to compliance with the rules and regulations of the SEC and the Nasdaq Stock Market, additional insurance expenses, and expenses related to investor relations activities and other administrative and professional services.

Total other income, net

Total other income, net consists of interest income earned on cash and cash equivalents.

Results of operations

Comparison of the three months ended September 30, 2019 and September 30, 2018

	<u>Three Months Ended September 30,</u>		<u>Change</u>
	<u>2019</u>	<u>2018</u>	<u>\$</u>
	<i>(in thousands)</i>		
Revenue	\$ —	\$ —	\$ —
Operating Expenses:			
Research and Development	22,941	15,873	7,068
General and Administrative	11,083	4,949	6,134
Total Operating Expenses	34,024	20,822	13,202
Loss from Operations	(34,024)	(20,822)	(13,202)
Other Income	1,660	904	756
Net Loss	<u>\$ (32,364)</u>	<u>\$ (19,918)</u>	<u>\$ (12,446)</u>

Revenue

Revenue was \$0 for the three months ended September 30, 2019 and September 30, 2018.

Research and development

Research and development expenses were \$22.9 million for the three months ended September 30, 2019 compared to \$15.9 million for the three months ended September 30, 2018. The increase of \$7.1 million, or 45%, was primarily due to an increase of \$5.0 million in costs for manufacturing of pharmaceutical active ingredients and drug products, an increase of \$1.6 million in our clinical program costs, which reflects increased costs in our ongoing clinical trials and an increase in headcount related expense to support these trials, as well as an increase of \$0.5 million in discovery and pre-clinical costs. The following table summarizes our research and development expenses allocated to trilaciclib, lerociclib and G1T48, and unallocated research and development expenses for the periods indicated:

	Three Months Ended September 30,	
	2019	2018
	(in thousands)	
Clinical Expenses—trilaciclib	\$ 7,664	\$ 8,619
Clinical Expenses—lerociclib	2,486	1,898
Clinical Expenses—G1T48	2,384	464
Chemical Manufacturing and Development	8,030	3,070
Discovery and Pre-Clinical Expenses	2,377	1,822
Total Research and Development Expenses	<u>\$ 22,941</u>	<u>\$ 15,873</u>

General and administrative

General and administrative expenses were \$11.1 million for the three months ended September 30, 2019 compared to \$4.9 million for the three months ended September 30, 2018. The increase of \$6.1 million, or 124% was due to an increase of \$2.0 million in compensation due to increased headcount, of which \$1.0 million related to non-cash stock compensation expense, an increase of \$1.6 million in medical affairs costs related to trilaciclib, an increase of \$1.2 million in pre-commercialization activities, and an increase of \$1.3 million in professional services, insurance and other administrative costs.

Total other income, net

Total other income, net was \$1.7 million for the three months ended September 30, 2019 as compared to \$0.9 million for the three months ended September 30, 2018. The increase of \$0.8 million was due to additional interest income earned on a higher balance of money market funds during the three months ended September 30, 2019 as compared to the three months ended September 30, 2018.

Results of operations

Comparison of the nine months ended September 30, 2019 and 2018

	Nine Months Ended September 30,		Change
	2019	2018	\$
	(in thousands)		
Revenue	\$ —	\$ —	\$ —
Operating Expenses:			
Research and Development	64,510	51,605	12,905
General and Administrative	27,979	11,595	16,384
Total Operating Expenses	92,489	63,200	29,289
Loss from Operations	(92,489)	(63,200)	(29,289)
Other Income	5,483	2,003	3,480
Net Loss	<u>\$ (87,006)</u>	<u>\$ (61,197)</u>	<u>\$ (25,809)</u>

Revenue

Revenue was \$0 for the nine months ended September 30, 2019 and 2018.

Research and development

Research and development expenses were \$64.5 million for the nine months ended September 30, 2019 compared to \$51.6 million for the nine months ended September 30, 2018. The increase of \$12.9 million, or 25%, was primarily due to an increase of \$6.3 million in our clinical program costs, which reflects increased costs in our ongoing clinical trials and an increase in headcount related expenses to support these trials, an increase of \$5.9 million in costs for manufacturing of pharmaceutical active ingredients and drug products, and an increase of \$0.7 million in discovery and pre-clinical cost. The following table summarizes our research and development expenses allocated to trilaciclib, lerociclib and G1T48, and unallocated research and development expenses for the periods indicated:

	Nine Months Ended September 30,	
	2019	2018
	(in thousands)	
Clinical Expenses—trilaciclib	\$ 25,922	\$ 25,990
Clinical Expenses—lerociclib	8,003	6,013
Clinical Expenses—G1T48	6,012	1,655
Chemical Manufacturing and Development	18,469	12,529
Discovery and Pre-clinical Expenses	6,104	5,418
Total Research and Development Expenses	<u>\$ 64,510</u>	<u>\$ 51,605</u>

General and administrative

General and administrative expenses were \$28.0 million for the nine months ended September 30, 2019 compared to \$11.6 million for the nine months ended September 30, 2018. The increase of \$16.4 million, or 141% was due to an increase of \$6.8 million in compensation due to increased headcount, of which \$4.3 million related to non-cash stock compensation expense, an increase of \$4.0 million in pre-commercialization activities, an increase of \$1.6 million in medical affairs costs related to trilaciclib, an increase of \$1.2 million in information technology systems and related expenses, and an increase of \$2.8 million in professional services, insurance and other administrative costs.

Total other income, net

Total other income, net was \$5.5 million for the nine months ended September 30, 2019 as compared to \$2.0 million for the nine months ended September 30, 2018. The increase of \$3.5 million was primarily due to additional interest income earned on a higher balance of money market funds during the nine months ended September 30, 2019 as compared to the nine months ended September 30, 2018.

Liquidity and capital resources

We have incurred cumulative losses and negative cash flows from operations since our inception in 2008. As of September 30, 2019, we had an accumulated deficit of \$301.4 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.

To date, we have funded our operations primarily through proceeds from our private placements of preferred stock and public offerings of our common stock. As of September 30, 2019, we had cash and cash equivalents of \$299.9 million.

Follow-on offering

On March 12, 2018, we closed an underwritten public offering of 3,910,000 shares of common stock at a public offering price of \$29.50 per share, including 510,000 shares of common stock issued upon exercise by the underwriters of their option to purchase additional shares. The gross proceeds from the offering were \$115.3 million and net proceeds were \$107.9 million, after deducting underwriting discounts and commissions and other offering expenses payable by us.

Shelf registration statement

As of June 15, 2018, we had an effective shelf registration statement on file with the Securities and Exchange Commission. Each issuance under the shelf registration statement will require the filing of a prospectus supplement identifying the amount and terms of securities to be issued. The registration statement does not limit the amount of securities that may be issued thereunder. Our ability to issue securities is subject to market conditions and other factors.

At-the-market offering

On June 15, 2018, we entered into a Sales Agreement for an “at the market offering” arrangement with Cowen and Company, LLC (“Cowen”), which allows us to issue and sell shares of common stock pursuant to a shelf registration statement for total gross sales proceeds of up to \$125.0 million from time to time through Cowen, acting as our agent. Between June 18, 2018 and August 2, 2018, we sold 752,008 shares of common stock pursuant to this agreement resulting in \$36.1 million in net proceeds, realizing \$12.1 million in the second quarter of 2018 and the remaining \$24.0 million by August 2, 2018. As of September 30, 2019, we have remaining authorization to sell up to \$88.2 million under this sales agreement with Cowen.

Follow-on offering

On September 21, 2018, we closed on an underwritten public offering of 3,450,000 shares of our common stock at a public offering price of \$60.00 per share, including 450,000 shares of common stock issued upon exercise by the underwriters of their option to purchase additional shares, pursuant to our shelf registration statement. The gross proceeds from the offering were \$207.0 million and net proceeds were \$194.9 million, after deducting underwriting discounts and commissions and other offering expenses payable by us.

Cash flows

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

	Nine Months Ended September 30,		Change
	2019	2018	\$
	(in thousands)		
Net cash used in operating activities	\$ (69,560)	\$ (53,079)	\$ (16,481)
Net cash used in investing activities	(2,116)	(598)	(1,518)
Net cash provided by financing activities	2,319	340,389	(338,070)
Net change in cash, cash equivalents, and restricted cash	<u>\$ (69,357)</u>	<u>\$ 286,712</u>	<u>\$ (356,069)</u>

Net cash used in operating activities

During the nine months ended September 30, 2019, net cash used in operating activities was \$69.6 million which consisted primarily of a net loss of \$87.0 million, partially offset by non-cash stock compensation expense of \$12.0 million, working capital adjustments of \$5.2 million and \$0.2 million of depreciation expense.

During the nine months ended September 30, 2018, net cash used in operating activities was \$53.1 million, which consisted primarily of a net loss of \$61.2 million, partially offset by non-cash stock compensation expense of \$7.0 million, working capital adjustments of \$1.0 million and \$0.1 million of depreciation expense.

Net cash used in operating activities increased by \$16.5 million as compared to the nine months ended September 30, 2018 due to an increase in research and development activity during the period and increased administrative costs associated with operating as a public entity.

Net cash used in investing activities

Net cash used in investing activities was \$2.1 million for the nine months ended September 30, 2019 and \$0.6 million for the nine months ended September 30, 2018. The increase in cash used was due to increased purchases of property and equipment and the investment in restricted cash.

Net cash provided by financing activities

During the nine months ended September 30, 2019, net cash provided by financing activities was \$2.3 million, in net proceeds from the exercise of stock options.

During the nine months ended September 30, 2018, net cash provided by financing activities was \$340.4 million, consisting of \$339.0 million in net proceeds from our public offerings after deducting cash paid in the quarter for underwriting discounts and commissions and other expenses, and \$1.4 million in proceeds from the exercise of stock options.

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 pharmaceutical products, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. We expect to continue 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 our existing cash and cash equivalents will be sufficient to fund our projected cash needs for at least the next 12 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 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 GIT48, and the terms of such in-licenses;
- the costs of future commercialization activities 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

In November 2018, we signed a new lease to secure 60,000 square feet of laboratory and office space at 700 Park Offices Drive in Research Triangle Park, NC ("700 Lease"). The 700 Lease commenced on September 2, 2019 and has an expiration date of September 30, 2027 for the initial term with the Company having the option to renew for an additional 5 years.

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.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America, or U.S. GAAP. The preparation of our financial statements requires us to make estimates, judgments, and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities as of the dates of the balance sheet, and the reported amount of expenses incurred during the reporting period. In accordance with U.S. GAAP, we evaluate our estimates and judgments on an ongoing basis. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We believe that our accounting policies are critical to the process of making significant judgments and estimates in the preparation of our financial statements and understanding and evaluating our reported financial results. We discussed our accounting policies and significant assumptions used in our estimates in Note 2 of our audited financial statements included in our 2018 Form 10-K. There have been no material changes during the nine months ended September 30, 2019 to our critical accounting policies, significant judgments and estimates disclosed in our 2018 Form 10-K.

Recent Accounting Pronouncements

See Note 2 to our unaudited condensed financial statements included in Item 1 of this Quarterly Report on Form 10-Q for recently issued accounting pronouncements, including respective adoption dates and the potential impact on our financial statements.

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 are affected by changes in the general level of U.S. interest rates. We had cash and cash equivalents of \$299.9 million as of September 30, 2019, 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 a material effect on our business, financial condition or results of operations. We had no outstanding debt as of September 30, 2019.

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 and nine months ended September 30, 2019.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2019. 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 September 30, 2019, 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.

Change in Internal Controls

There were no changes in our internal control over financial reporting that occurred during our most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. In addition to the other information contained elsewhere in this report, you should carefully consider the risks and uncertainties described in our 2018 Form 10-K, which could materially affect our business, financial condition or future results before investing in our common stock. 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 these 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. There have been no material changes in the risk factors set forth in Part II, Item 1A of our 2018 Form 10-K.

Item 6. Exhibits.

Exhibit Number	Description
10.4†	Employment Agreement by and between the Registrant and Mark Avagliano, dated as of July 29, 2019, filed as Exhibit 10.4 to the Registrant's Form 10-Q filed on August 7, 2019 (File No. 001-38096) incorporated herein by reference.
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	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

* Filed herewith.

† Indicates management contract or compensatory plan or arrangement.

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.

G1 THERAPEUTICS, INC.

Date: November 5, 2019

By:

/s/ Jennifer K. Moses
Jennifer K. Moses
Chief Financial Officer (Principal Financial and
Accounting Officer)

**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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles
 - (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
 5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.
-

Date: November 5, 2019

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

**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, Jennifer K. Moses, 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
 5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.
-

Date: November 5, 2019

By: /s/ Jennifer K. Moses
Jennifer K. Moses
Chief Financial Officer
(Principal Financial and Accounting Officer)

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

In connection with the Quarterly Report of G1 Therapeutics, Inc. (the "Company") on Form 10-Q for the period ending September 30, 2019 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: November 5, 2019

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.

**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 September 30, 2019 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: November 5, 2019

By: /s/ Jennifer K. Moses
Jennifer K. Moses
Chief Financial Officer
(Principal Financial and Accounting Officer)

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of 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.