UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2023

OR

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

FOR THE TRANSITION PERIOD FROM TO

Commission File Number 001-38096

G1 THERAPEUTICS, INC.

(Exact name of Registrant as specified in its Charter)

Delaware	**26-3648180**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

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:

Title of each class	**Trading Symbol**	**Name of each exchange on which registered**
Common Stock $.0001 par value	**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 x No o

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 x No o

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

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

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

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

As of July 28, 2023 the registrant had 51,745,578 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)

	June 30, 2023	December 31, 2022
Assets		
Current assets		
Cash and cash equivalents	$ 55,914	$ 94,594
Restricted cash	63	63
Marketable securities	48,317	50,476
Accounts receivable and unbilled receivables, net	13,171	11,094
Inventories	15,600	16,179
Prepaid expenses and other current assets	7,371	7,094
Total current assets	140,436	179,500
Property and equipment, net	1,727	1,989
Restricted cash	250	250
Operating lease assets	5,446	5,962
Other assets	32	264
Total assets	$ 147,891	$ 187,965
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 5,762	$ 7,431
Accrued expenses	24,681	25,557
Deferred revenue	143	7
Other current liabilities	3,326	2,593
Total current liabilities	33,912	35,588
Loan payable	50,936	77,015
Deferred revenue	500	1,000
Operating lease liabilities	4,995	5,615
Total liabilities	90,343	119,218
Stockholders' equity		
Common stock, $0.0001 par value, 120,000,000 shares authorized as of June 30, 2023, and December 31, 2022; 51,735,113 and 51,526,100 shares issued as of June 30, 2023, and December 31, 2022, respectively; 51,708,447 and 51,499,434 shares outstanding as of June 30, 2023, and December 31, 2022, respectively	5	5
Treasury stock, 26,666 shares as of June 30, 2023, and December 31, 2022	(8)	(8)
Additional paid-in capital	808,454	800,768
Accumulated deficit	(750,903)	(732,018)
Total stockholders' equity	57,548	68,747
Total liabilities and stockholders' equity	$ 147,891	$ 187,965

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)

	Three Months Ended June 30,		Six Months Ended June 30, 2023	
	2023	**2022**	**2023**	**2022**
Revenues				
Product sales, net	$ 11,091	$ 8,718	$ 21,583	$ 14,198
License revenue	31,301	1,855	33,755	3,277
Total revenues	42,392	10,573	55,338	17,475
Operating expenses				
Cost of goods sold	1,404	976	2,863	1,645
Research and development	12,040	20,843	27,520	47,148
Selling, general and administrative	17,432	25,716	39,185	52,425
Total operating expenses	30,876	47,535	69,568	101,218
Income (loss) from operations	11,516	(36,962)	(14,230)	(83,743)
Other income (expense)				
Interest income	643	50	1,359	59
Interest expense	(2,710)	(2,407)	(5,799)	(4,672)
Other income (expense)	569	(127)	1,093	(282)
Total other income (expense), net	(1,498)	(2,484)	(3,347)	(4,895)
Income (loss) before income taxes	10,018	(39,446)	(17,577)	(88,638)
Income tax expense	1,308	—	1,308	—
Net income (loss)	$ 8,710	$ (39,446)	$ (18,885)	$ (88,638)
Earnings per share attributable to common stockholders:				
Basic	$ 0.17	$ (0.92)	$ (0.37)	$ (2.08)
Diluted	$ 0.14	$ (0.92)	$ (0.37)	$ (2.08)
Weighted average common shares outstanding:				
Basic	51,667,099	42,707,703	51,657,456	42,697,508
Diluted	61,040,507	42,707,703	51,657,456	42,697,508

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 stock-holders' equity
	Shares	Amount	Shares	Amount			
Balance at December 31, 2022	**51,526,100**	**$ 5**	**(26,666)**	**$ (8)**	**$ 800,768**	**$ (732,018)**	**$ 68,747**
Public offering	—	—	—	—	(1)	—	(1)
Exercise of common stock options	3,008	—	—	—	1	—	1
Restricted stock units vested	156,855	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	3,836	—	3,836
Net income (loss) during quarter	—	—	—	—	—	(27,595)	(27,595)
Balance at March 31, 2023	**51,685,963**	**$ 5**	**(26,666)**	**$ (8)**	**$ 804,604**	**$ (759,613)**	**$ 44,988**
Public Offering	—	—	—	—	40	—	40
Exercise of common stock options	—	—	—	—	—	—	—
Restricted stock units vested	49,150	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	3,810	—	3,810
Net income (loss) during quarter	—	—	—	—	—	8,710	8,710
Balance at June 30, 2023	**51,735,113**	**$ 5**	**(26,666)**	**$ (8)**	**$ 808,454**	**$ (750,903)**	**$ 57,548**

	Common stock		Treasury stock		Additional paid-in capital	Accumulated deficit	Total stock-holders' equity
	Shares	Amount	Shares	Amount			
Balance at December 31, 2021	**42,588,814**	**$ 4**	**(26,666)**	**$ (8)**	**$ 728,004**	**$ (584,459)**	**$ 143,541**
Exercise of common stock options	27,333	—	—	—	18	—	18
Restricted stock units vested	116,051	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	5,765	—	5,765
Net income (loss) during quarter	—	—	—	—	—	(49,192)	(49,192)
Balance at March 31, 2022	**42,732,198**	**$ 4**	**(26,666)**	**$ (8)**	**$ 733,787**	**$ (633,651)**	**$ 100,132**
Exercise of common stock options	—	—	—	—	—	—	—
Restricted stock units vested	21,945	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	5,639	—	5,639
Net income (loss) during quarter	—	—	—	—	—	(39,446)	(39,446)
Balance at June 30, 2022	**42,754,143**	**$ 4**	**(26,666)**	**$ (8)**	**$ 739,426**	**$ (673,097)**	**$ 66,325**

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

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

	Six Months Ended June 30, 2023	
	2023	**2022**
Cash flows from operating activities		
Net loss	$ (18,885)	$ (88,638)
Adjustments to reconcile net loss to net cash used in operating activities		
Stock-based compensation	7,646	11,404
Accretion of discount on available for sale securities	(1,097)	—
Depreciation and amortization	262	254
Amortization of debt issuance costs	840	1,084
Non-cash interest expense	630	642
Non-cash equity interest, net	—	303
Change in operating assets and liabilities		
Accounts receivable	(2,077)	(5,099)
Inventories	579	(10,543)
Prepaid expenses and other assets	657	5,759
Accounts payable	(2,020)	6,098
Accrued expenses and other liabilities	(1,139)	2,016
Deferred revenue	(364)	(21)
Net cash used in operating activities	(14,968)	(76,741)
Cash flows from investing activities		
Purchases of marketable securities	(65,244)	—
Maturities of marketable securities	68,500	—
Purchases of property and equipment	—	(506)
Net cash provided by/(used in) investing activities	3,256	(506)
Cash flows from financing activities		
Proceeds from stock options exercised	1	18
Repayment of debt	(26,688)	—
Payment of public offering costs	(281)	—
Net cash (used in)/provided by financing activities	(26,968)	18
Net change in cash, cash equivalents and restricted cash	(38,680)	(77,229)
Cash, cash equivalents and restricted cash		
Beginning of period	94,907	221,561
End of period	$ 56,227	$ 144,332
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 5,179	$ 3,537
Non-cash operating, investing and financing activities		
Upfront project costs and other current assets in accounts payable and accrued expenses	$ 418	$ 354

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

G1 Therapeutics, Inc.
Notes to Financial Statements
(unaudited)

1. Description of Business

G1 Therapeutics, Inc. (the “Company”) is a commercial-stage biopharmaceutical company focused on the development and commercialization of novel small molecule therapeutics for the treatment of patients with cancer. The Company's first product approved by the U.S. Food and Drug Administration (“FDA”), COSELA® (trilaciclib), is the first and only therapy indicated to proactively help protect bone marrow from the damage of chemotherapy (myeloprotection) and is the first innovation in managing myeloprotection in decades. In July 2022, COSELA (trilaciclib hydrochloride for injection) was conditionally approved by the China National Medical Products Administration (NMPA) for marketing in mainland China. The Company is also exploring the potential use of trilaciclib in certain cancers, including trials designed to inform the design of future additional pivotal studies and treatment combinations with targeted chemotherapy medicines called antibody-drug conjugates ("ADCs") including other indications.

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 June 30, 2023, and for the three and six months ended June 30, 2023, and 2022, is unaudited. The results for the three and six months ended June 30, 2023, 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, 2022 filed with the SEC on March 1, 2023, (the “2022 Form 10-K”). The December 31, 2022 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.

The Company has experienced net losses since its inception and has an accumulated deficit of $750.9 million and $732.0 million as of June 30, 2023 and December 31, 2022, respectively. The Company expects to incur losses and have negative net cash flows from operating activities as it executes on its strategy including engaging in further research and development activities, particularly conducting non-clinical studies and clinical trials. The success of the Company depends on the ability to successfully commercialize its technologies to support its operations and strategic plan. Management has evaluated actions already taken, the significance of anticipated continued losses, future cash flow projections, and the ability of the Company to remain in compliance with the financial covenants and requirements as defined within the Loan Agreement (as defined below). Based on the foregoing, as of the date of issuance of these condensed financial statements, the Company expects that its cash and cash equivalents and marketable securities as of June 30, 2023 will be sufficient to fund the Company’s planned operations and remain in compliance with its objective financial covenants for at least the next 12 months from the date of issuance of these condensed financial statements. Until such time, if ever, as the Company can generate substantial revenues, the Company expects to finance its 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. There can be no assurances that the Company will be able to secure such additional financing if at all, or on terms that are satisfactory to the Company, and that it will be sufficient to meet its needs. In the event the Company is not successful in obtaining sufficient funding, this could force it to delay, limit, or reduce its product development, commercialization efforts or other operations. The Company’s condensed financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The condensed financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of the uncertainties described above.

In connection with the Loan Payable described in Note 7, the Company is required to be in compliance with a minimum cash covenant and is subject to a conditional borrowing base measured on a trailing three-month net revenue basis, which begins with the financial reporting for the period ending June 30, 2023. The lender also has the ability to call debt based on a material adverse change clause, which is subjectively defined. If the Company is not in compliance with the minimum cash covenant, conditional borrowing base requirements, or the subjective acceleration clauses are triggered under the agreement, then the lender may call the debt resulting in the Company immediately needing additional funds. As of June 30, 2023, the Company is in compliance with the minimum cash covenant and the conditional borrowing base requirements as set forth in the Loan Agreement.

On February 22, 2023, the Company approved a reduction in its workforce to streamline operations and reduce operating expenses. The Company recognized $1.4 million in severance and termination-related costs in the first quarter of 2023 and all remaining costs were paid out as of June 30, 2023. See Note 14 for further discussion on this restructuring activity.

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, net product sales, common stock valuation, stock-based compensation expense and deferred tax asset valuation allowance. Actual results could differ from those estimates.

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with an original maturity of three months or less at the date of purchase to be cash equivalents. Cash and cash equivalents at June 30, 2023 consist of amounts on deposit in banks, including checking accounts and money market accounts. Cash deposits are all in financial institutions in the United States. As part of the lease for the office space which commenced on September 2, 2019, 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 lease until the end of the lease term. As of June 30, 2023, restricted cash totaled $0.3 million.

Marketable Securities

The Company determines the appropriate classification of marketable securities at the time of purchase and reevaluates such designation at each balance sheet date. The Company classified all of its marketable securities at June 30, 2023 as "available-for-sale" pursuant to ASC Topic 320, Investments – Debt and Equity Securities. Investments not classified as cash equivalents are presented as either short-term or long-term investments based on both their maturities as well as the time period the Company intends to hold such securities. Available-for-sale securities are maintained by an investment manager and primarily consist of fixed income securities. Available-for-sale securities are carried at fair value. Any premium or discount arising at purchase is amortized or accreted to interest income over the life of the instrument. Realized gains and losses are determined using the specific identification method and are included in other (income) expense, net. As of June 30, 2023 the unrealized gains and losses are not considered to be material.

Accounts Receivable

The Company's accounts receivable consists of amounts due from specialty distributors in the U.S. (collectively, its "customers") related to sales of COSELA and have standard payment terms. Trade receivables are recorded net of the estimated variable consideration for chargebacks based on contractual terms and the Company's expectation regarding the utilization and earnings of the chargebacks and discounts as well as the net amount expected to be collected from the Company's customers. Estimates of the Company's credit losses are determined based on existing contractual payment terms, individual customer circumstances, and any changes to the economic environment.

In addition, the Company's accounts receivable consists of open invoices issued to its license partners for services rendered by the Company or receivables with its license partners for invoices related to milestones that were completed and recognized as revenue. The Company also has unbilled accounts receivable related to clinical trial reimbursements where the Company has the right to invoice the license partner and accordingly has recognized revenue. Invoicing to the license partner will occur once the Company has been invoiced by the service provider. As of June 30, 2023, unbilled accounts receivable totaled $1.3 million.

Inventories

Inventories are stated at the lower of cost or net realizable value and recognized on a weighted-average cost method. The Company uses actual cost to determine the cost basis for inventory. Inventory is capitalized based on when future economic benefit is expected to be realized. Due to the nature of the Company's supply chain process, inventory that is owned by the Company, is physically stored at third-party warehouses, logistics providers, and contract manufacturers.

Inventory valuation is established based on a number of factors including, but not limited to, finished goods not meeting product specifications, product excess and obsolescence, or application of the lower of cost or net realizable value concepts. The determination of events requiring the establishment of inventory valuation, together with the calculation of the amount of such adjustments may require judgment. The Company analyzes its inventory levels on a periodic basis to determine if any inventory is at risk for expiration prior to sale or has a cost basis that is greater than its estimated future net realizable value. Any adjustments are recognized through cost of sales in the period in which they are incurred. No inventory valuation adjustments have been recorded for any periods presented.

Debt

The Company classifies its loan payable in current or long-term liabilities based on the timing of scheduled principal payments. The loan and security agreement with Hercules Capital, Inc. (as amended, the "Loan Agreement") contains events of default, including a material adverse change, which is subjectively defined, in the Company's business, payment defaults, and breaches of covenants following any applicable cure period. In the event of default by the Company under the Loan Agreement, the Company may be required to repay all amounts then outstanding under the Loan Agreement. The Company has determined that subjective acceleration under the material adverse events clause included in the Loan Agreement is not probable and, therefore, has classified the outstanding principal amount in long-term liabilities based on the timing of scheduled principal payments.

Revenue Recognition

For elements of those arrangements that the Company determines should be accounted for under ASC 606, *Revenue from Contracts with Customers* ("ASC 606"), the Company assesses which activities in its license or collaboration agreements are performance obligations that should be accounted for separately and determines the transaction price of the arrangement, which includes the assessment of the probability of achievement of future milestones and other potential consideration. For arrangements that include multiple performance obligations, such as granting a license or performing manufacturing or research and development activities, the Company allocates the transaction price based on the relative standalone selling price and recognizes revenue that is allocated to the respective performance obligation when (or as) control is transferred to the customer and the performance obligation is satisfied. Accordingly, the Company develops assumptions that require judgment to determine the standalone selling price for each performance obligation identified in the contract. These key assumptions may include revenue forecasts, clinical development timelines and costs, discount rates and probabilities of clinical and regulatory success.

License Revenue

Licenses of Intellectual Property

If a license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenue allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue associated with the bundled performance obligation. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of progress and related revenue recognition.

Milestone Payments

At the inception of each arrangement that includes developmental and regulatory milestone payments, the Company evaluates whether the achievement of each milestone specifically relates to the Company's efforts to satisfy a performance obligation or transfer a distinct good or service within a performance obligation. The Company evaluates each milestone to determine when and how much of the milestone to include in the transaction price. The Company first estimates the amount of the milestone payment that the Company could receive using either the expected value or the most likely amount approach. The Company primarily uses the most likely amount approach as that approach is generally most predictive for milestone payments with a binary outcome. Then, the Company considers whether any portion of that estimated amount is subject to the variable consideration constraint (that is, whether it is probable that a significant reversal of cumulative revenue would not occur upon resolution of the uncertainty). The Company updates the estimate of variable consideration included in the transaction price at each reporting date which includes updating the assessment of the likely amount of consideration and the application of the constraint to reflect current facts and circumstances. For regulatory milestones, the Company recognizes revenue at a point in time upon approval, as that is when achievement of the milestone is considered probable. The Company assesses milestones as they are achieved to determine whether they are tied to any other performance obligations in the respective license agreements.

Royalties

For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company will recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). During the six months ended June 30, 2023, the Company recognized $0.6 million in revenue related to sales-based royalties.

Product Sales, Net

The Company sells COSELA to specialty distributors in the U.S. and, in accordance with ASC 606, recognizes revenue at the point in time when the customer is deemed to have obtained control of the product. The customer is deemed to have obtained control of the product at the time of physical receipt of the product at the customers' distribution facilities, or Free on Board ("FOB") destination, the terms of which are designated in the contract.

Product sales are recorded at the net selling price, which includes estimates of variable consideration for which reserves are established for (a) rebates and chargebacks, (b) co-pay assistance programs, (c) distribution fees, (d) product returns, and (e) other discounts. Where appropriate, these estimates take into consideration a range of possible outcomes which are probability-weighted for relevant factors such as current contractual and statutory requirements, and forecasted customer buying and payment patterns. Overall, these reserves reflect the Company's best estimates of the amount of consideration to which it is entitled based on the terms of the applicable contract. The amount of variable consideration may be constrained and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts of consideration ultimately received may differ from the Company's estimates. If actual results in the future vary from estimates, the Company adjusts these estimates, which would affect net product revenue and earnings in the period such variances become known.

Liabilities related to co-pay assistance, rebates, returns, and GPO fees are classified as "Accrued Expenses" in the Condensed Balance Sheets. Discounts such as chargebacks and specialty distributor fees are recorded as a reduction to trade accounts receivable, which is included in "Accounts Receivable" in the Condensed Balance Sheets.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to credit risk consist of cash and cash equivalents. Deposits with financial institutions are insured, up to certain limits, by the Federal Deposit Insurance Corporation ("FDIC"). The Company's cash deposits often exceed the FDIC insurance limit; however, all deposits are maintained with high credit quality institutions and the Company has not experienced any losses in such accounts. The financial condition of financial institutions is periodically reassessed, and the Company believes the risk of any loss is minimal. The Company believes the risk of any loss on cash due to credit risk is minimal.

Cost of Goods Sold

Cost of goods sold includes direct and indirect costs related to the manufacturing and distribution of COSELA, including third-party manufacturing costs, packaging services, freight-in, third-party logistics costs associated with COSELA, and Company personnel costs. Cost of goods sold may also include period costs related to certain inventory manufacturing services and inventory adjustment charges.

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 associated with clinical trial activities. The process of estimating and accruing expenses involved 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 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 external clinical study costs as of each balance sheet date are based on the facts and circumstances known at the time.

Income Taxes

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

In accordance with Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) 740, *Accounting for Income Taxes*, the Company reflects in the financial statements the benefit of positions taken in a previously filed tax return or expected to be taken in a future tax return only when it is considered 'more-likely-than-not' that the position taken will be sustained by a taxing authority. As of June 30, 2023 and December 31, 2022, the Company had no unrecognized income tax benefits and correspondingly there is no impact on the Company's effective income tax rate associated with these items. The Company's policy for recording interest and penalties relating to uncertain income tax positions is to record them as a component of income tax expense in the accompanying statements of operations. As of June 30, 2023 and December 31, 2022, the Company had no such accruals.

Stock-Based Compensation

The primary type of stock-based payments utilized by the Company are stock options. The Company accounts for stock-based employee compensation arrangements by measuring the cost of employee services received in exchange for all equity awards granted based on the fair value of the award on the grant date. The fair value of each employee stock option is estimated on the date of grant using an options pricing model. The Company currently uses the Black-Scholes valuation model to estimate the fair value of its share-based payments. The model requires management to make a number of assumptions including expected volatility, expected life, risk-free interest rate and expected dividends.

The Company also incurs stock-based compensation expense related to restricted stock units ("RSUs"), performance based restricted stock units ("PSUs"), and deferred share units ("DSUs"). The fair value of RSUs, PSUs, and DSUs is determined by the closing market price of the Company's common stock on the date of grant and then recognized over the requisite service period of the award. As the PSUs have non-market performance and service conditions, compensation expense will be recognized over the requisite service periods if and when the achievement of such performance condition(s) is determined to be probable by the Company. If a performance condition is not determined to be probable or is not met, no stock-based compensation expense is recognized. The Company reassesses the probability of achieving the performance condition(s) at each reporting period. As of June 30, 2023, the Company did not deem the achievement of any performance condition(s) to be probable and no compensation expense related to PSUs was recognized.

Debt Issuance Costs

Debt issuance costs are amortized to interest expense over the estimated life of the related debt based on the effective interest method. In accordance with ASC 835, Interest, the Company presents debt issuance costs on the balance sheet as a direct deduction from the associated debt.

3. Fair Value of Financial Instruments

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

Level 1	Inputs are unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date.
Level 2	Inputs include quoted prices for similar assets and liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active, inputs other than quoted prices that are observable for the asset or liability and inputs that are derived principally from or corroborated by observable market data by correlation or other means.
Level 3	Unobservable inputs that reflect the Company's estimates of the assumptions that market participants would use in pricing the asset or liability. The Company develops these inputs based on the best information available, including its own data.

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

At June 30, 2023 and December 31, 2022, 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 June 30, 2023
Assets:				
Money market funds	$ 53,753	$ —	$ —	$ 53,753
Marketable securities:				
U.S. Treasury Bills	48,317	—	—	48,317
Total assets at fair value	$ 102,070	$ —	$ —	$ 102,070

	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, 2022
Assets:				
Money market funds	$ 84,167	$ —	$ —	$ 84,167
Marketable securities:				
U.S. Treasury Bills	50,476	—	—	50,476
Total assets at fair value	$ 134,643	$ —	$ —	$ 134,643

During the three and six months ended June 30, 2023, and the year ended December 31, 2022, there were no changes in valuation methodology.

The Loan Payable (discussed in Note 7) has a variable interest rate and is carried at amortized cost, which approximates its fair value that is determined using Level 3 inputs. As of June 30, 2023, the carrying value was $50.9 million.

4. Inventories

Inventories as of June 30, 2023 and December 31, 2022 consist of the following (in thousands):

	June 30, 2023	December 31, 2022
Raw materials	$ 2,715	$ 2,790
Work in process	9,714	10,153
Finished goods	3,171	3,236
Inventories	$ 15,600	$ 16,179

The Company uses third party contract manufacturing organizations for the production of its raw materials, active pharmaceutical ingredients, and finished drug product which the Company owns.

5. Property and Equipment

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

	June 30, 2023	December 31, 2022
Computer equipment	$ 327	$ 327
Laboratory equipment	334	334
Furniture and fixtures	866	866
Leasehold improvements	1,782	1,782
Manufacturing equipment	506	506
Accumulated depreciation	(2,088)	(1,826)
Property and equipment, net	$ 1,727	$ 1,989

Depreciation expenses relating to property and equipment were $130 thousand and $262 thousand for the three and six months ended June 30, 2023, respectively, and $139 thousand and $254 thousand for the three and six months ended June 30, 2022, respectively.

6. Accrued Expenses

Accrued expenses are comprised as follows (in thousands):

	June 30, 2023	December 31, 2022
Accrued external research	$ 190	$ 268
Accrued professional fees and other	4,659	4,304
Accrued external clinical study costs	17,086	15,566
Accrued compensation expense	2,746	5,419
Accrued expenses	$ 24,681	$ 25,557

7. Loan Payable

On May 29, 2020, the Company entered into a loan and security agreement (the “Loan Agreement”) with Hercules Capital, Inc. (“Hercules”), under which Hercules agreed to lend the Company up to $100.0 million, to be made available in a series of tranches, subject to certain terms and conditions. The first tranche totals $30.0 million, of which the Company received $20.0 million at closing. Upon initiation of the Phase 3 trial of COSELA for metastatic colorectal cancer and receiving FDA approval for COSELA for small cell lung cancer (the "Performance Milestone”), the second tranche of $20.0 million became available to the Company for drawdown through December 15, 2021. The third tranche of $30.0 million was available through December 31, 2022. The fourth tranche of $20.0 million was available at Hercules’ approval through December 31, 2022. On March 31, 2021, the Company entered into the First Amendment to Loan and Security Agreement (the “First Amendment”) with Hercules whereby the Company drew the remaining $10.0 million of the first tranche and the interest rate and financial covenants were amended. Unless loan advances exceeded $40.0 million, no financial covenants were required.

Amounts initially borrowed under the original terms of the Loan Agreement bore an interest rate equal to the greater of either (i) (a) the prime rate as reported in The Wall Street Journal, plus (b) 6.40%, and (ii) 9.65%. Based on original terms of the Loan Agreement, the Company agreed to make interest only payments through June 1, 2022 and following the interest only period, the Company agreed to repay the principal balance and interest of the advances in equal monthly installments through June 1, 2024. Based on the original terms of the Loan Agreement, upon satisfaction of the Performance Milestone, the interest only period was extended through January 1, 2023 and the maturity date was extended to June 1, 2025. Upon entering into the First Amendment on March 31, 2021, the interest rate was amended to the greater of either (i) (a) the prime rate as reported in The Wall Street Journal, plus (b) 6.20%, and (ii) 9.45%.

The Company may prepay advances under the Loan Agreement, in whole or in part, at any time subject to a prepayment charge equal to (a) 3.0% of the prepayment amount in the first year; (b) 2.0% of the prepayment amount in the second year; and (c) 1.0% of the prepayment amount in the third year.

Upon prepayment or repayment of all or any of the advances under the Loan Agreement, the Company agreed to pay (in addition to the prepayment charge) an end of term charge of 6.95% of the aggregate funded amount. With respect to the first tranche, the end of term charge of $2.1 million would be payable upon any prepayment or repayment. To the extent that the Company was provided additional advances under the Loan Agreement, the 6.95% end of term charge would be applied to such additional amounts. These amounts have been accrued over the term of the loan using effective-interest method.

On November 1, 2021, the Company entered into a Second Amendment to Loan and Security Agreement (the “Second Amendment”) under which Hercules agreed to lend the Company up to $150.0 million, to be made available in a series of tranches, subject to certain terms and conditions. The first tranche was increased to $100.0 million. At close of the Second Amendment, the Company borrowed an additional $45.0 million from the first tranche. The Company had the right to request that Hercules make the remaining $25.0 million term loan advances under the first tranche to the Company by September 15, 2022, which the Company did not exercise. The second tranche of $20.0 million will become available to the Company upon achievement of $50.0 million trailing six-month net product revenue of COSELA no later than June 30, 2023 and will be available through December 15, 2023. The third tranche of $15.0 million will become available upon achievement of certain development performance milestones and available through December 15, 2023. The fourth tranche of $15.0 million will be available at Hercules’ approval through June 30, 2024.

Amounts borrowed under the Second Amendment bore an interest rate equal to the greater of either (i) (a) the prime rate as reported in The Wall Street Journal, plus (b) 5.90%, and (ii) 9.15%. The Company will make interest only payments through December 1, 2024 and may be extended through December 1, 2025, in quarterly increments, subject to compliance with covenants of the Second Amendment. Following the interest only period, the Company will repay the principal balance and interest of the advances in equal monthly installments through November 1, 2026.

The Company may prepay advances under the Second Amendment, in whole or in part, at any time subject to a prepayment charge equal to (a) 3.0% of the prepayment amount in the first year from the closing of the Second Amendment; (b) 2.0% of the prepayment amount in the second year from the closing of the Second Amendment; and (c) 1.0% of the prepayment amount in the third year from the closing of the Second Amendment.

Upon prepayment or repayment of all or any of the advances under the Second Amendment, the Company will pay (in addition to the prepayment charge) an end of term charge of 6.75% of the aggregate amount funded. The Company will be required to make a final payment to Hercules in the amount of 6.75% of the amounts funded, less any amount previously paid. In addition, the Company will be required to make a payment to Hercules for $2.1 million on the earliest occurrence of (i) June 1, 2025, (ii) the date the Company repays the outstanding principal amount in full, or (iii) the date that the principal amount becomes due and payable in full.

The Second Amendment is secured by substantially all of the Company's assets, including intellectual property, subject to certain exemptions. The Company out-licensed lerociclib as permitted in the Loan Agreement.

The Second Amendment contains a minimum revenue covenant. Beginning August 15, 2022, with the reporting of the financial results for the second fiscal quarter ended June 30, 2022, and tested monthly, the Company must have achieved net product revenue of COSELA of at least 65% of the amounts projected in the Company's forecast. Testing of the minimum revenue covenant shall be waived at any time in which either (a) the Company's market capitalization exceeds $750.0 million and the Company maintains unrestricted cash equal to at least 50% of the total amounts funded, or (b) the Company maintains unrestricted cash equal to at least 100% of the total amounts funded.

The Company evaluated the Second Amendment under the guidance found in ASC 470-50 *Modification and* Extinguishment. The Company concluded that the previous debt under the Loan Agreement was extinguished based on the difference in present value of the cash flows of the Loan Agreement and the Second Amendment. Accordingly, the difference between the carrying value of the Loan Agreement as of November 1, 2021, including the unamortized debt issuance costs, and the fair value of the Second Amendment was recorded as a $0.2 million loss on extinguishment of debt for the twelve months ended December 31, 2021. Fees paid to third parties directly related to the funded portion of the Second Amendment have been capitalized as debt issuance costs and will be amortized to interest expense over the life of the Second Amendment using the effective interest method. Fees paid that were directly related to the unfunded portion is accounted for as a deferred financing charge and amortized to interest expense over the period the unfunded portions are available. The end of term charges associated with the Second Amendment are being accreted through interest expense using the effective interest method over the related term of the debt.

On June 24, 2022, the Company entered into a Third Amendment to Loan and Security Agreement (the "Third Amendment") with Hercules, which extended the time for drawing the remainder of the first tranche advance of up to $25.0 million from September 15, 2022 to December 31, 2022, which the Company did not exercise. The Third Amendment also added a minimum cash covenant whereby the Company must maintain unrestricted cash equal to at least 50% of the outstanding debt, and such percentage shall decrease upon the Company achieving specified net product revenue of COSELA. It further provided for a minimum revenue covenant that, beginning August 15, 2022 with the reporting of the financial results for the second fiscal quarter ended June 30, 2022, and tested monthly, the Company must have achieved net product revenue of COSELA of at least 80% of the amounts projected in the Company's forecast. Testing of the minimum revenue covenant shall be waived at any time in which either (a) the Company's market capitalization exceeds $750.0 million and the Company maintains unrestricted cash equal to at least 50% of the total amounts funded, or (b) the Company maintains unrestricted cash equal to at least 100% of the total amounts funded. The Company evaluated the Third Amendment under the guidance found in ASC 470-50 *Modification and Extinguishment.* The Company concluded that the Third Amendment was a modification and there was no impact to the financial statements.

On November 1, 2022, the Company entered into a Fourth Amendment to Loan and Security Agreement (the “Fourth Amendment”) with Hercules, which extended the time for drawing the remainder of the first tranche advance of up to $25.0 million from December 31, 2022 to June 30, 2023. The Fourth Amendment continued to provide for a minimum revenue covenant, tested monthly, where the Company must achieve net product revenue of COSELA of at least 80% of the amounts projected in the Company's forecast. The Fourth Amendment also amended the minimum cash covenant such that if the outstanding debt is less than or equal to $75.0 million, the Company must maintain unrestricted cash equal to at least 65% of the outstanding debt in addition to meeting the required revenue covenant. In addition, if the outstanding debt is greater than $75.0 million, the Company must maintain unrestricted cash equal to at least 70% of the outstanding debt while meeting the revenue covenant. If the Company achieves the specified net revenue of COSELA, the cash percentage will decrease to 45% of the outstanding debt. Testing of the minimum revenue covenant shall be waived at any time in which either (a) the Company's market capitalization exceeds $750.0 million and the Company maintains unrestricted cash equal to at least 50% of the total amounts funded, or (b) the Company maintains unrestricted cash equal to at least 100% of the total amounts funded. The Fourth Amendment also re-set the prepayment premiums associated with any prepayment of the loans under the Loan Agreement. The Company evaluated the Fourth Amendment under the guidance found in ASC 470-50 *Modification and Extinguishment*. The Company concluded that the Fourth Amendment was a modification and there was no impact to the financial statements.

On June 6, 2023, the Company entered into a Fifth Amendment to Loan and Security Agreement (the “Fifth Amendment”) with Hercules, under which Hercules agreed to lend the Company up to $75.0 million, subject to specified conditions. In conjunction with the closing of the Fifth Amendment, the Company repaid $25.0 million of the outstanding debt such that the total loan amount outstanding upon closing of the Fifth Amendment is $50.0 million. In addition to the $25.0 million principal prepayment, upon closing of the Fifth Amendment, the Company made a $1.7 million pro-rata payment of the end-of-term charge. The Company continues to be required to make a payment to Hercules for $2.1 million on the earliest occurrence of (i) June 1, 2025, (ii) the date the Company repays the outstanding principal amount in full, or (iii) the date that the principal amount becomes due and payable in full.

The Fifth Amendment eliminated advances under Tranches 2 and 3 and increased the advance available under Tranche 4 from $15.0 million to $25.0 million and extended the time for drawing the Tranche 4 Advance (as defined in the Loan and Security Agreement) from June 30, 2024 to December 15, 2024.

Amounts borrowed under the Fifth Amendment will bear an interest rate equal to the greater of either (i) (a) the prime rate as reported in The Wall Street Journal, plus (b) 5.65%, and (ii) 9.15% The Company will make interest only payments through December 1, 2024 and may be extended through December 1, 2025, in quarterly increments, subject to conditional borrowing base compliance. Following the interest only period, the Company will repay the principal balance and interest of the advances in equal monthly installments through November 1, 2026.

The Company may prepay advances under the Fifth Amendment, in whole or in part, at any time subject to a prepayment charge equal to (a) 3.0% of the prepayment amount in the first year from the effective date of the Fourth Amendment; (b) 2.0% of the prepayment amount in the second year from the effective date of the Fourth Amendment; and (c) 1.0% of the prepayment amount in the third year from the effective date of the Fourth Amendment. For the avoidance of doubt, no prepayment charge shall be applicable when repayments are required to maintain compliance with the conditional borrowing base limit as discussed below.

The Fifth Amendment amended the minimum cash covenant such that the Company must maintain unrestricted cash equal to at least 35% of the outstanding debt at all times. The minimum cash covenant shall be eliminated upon the Company's achievement of quarterly net product revenue of $45.0 million or trailing six months net product revenue of $85.0 million.

The Fifth Amendment removed the existing minimum revenue covenant and provided for a conditional borrowing base limit, beginning with the financial reporting for the period ending June 30, 2023, and tested monthly thereafter. The Fifth Amendment also provides that the Company’s debt outstanding shall not exceed certain thresholds of trailing three month net product revenue of COSELA.

The Company evaluated the Fifth Amendment under the guidance found in ASC 470-50 *Modification and Extinguishment*. The Company concluded that the Fifth Amendment was a modification; accordingly, no gain or loss was recorded. A new effective interest rate was established based on the carrying value of the debt and the revised cash flows. The remaining end of term charges will be accreted through interest expense through the maturity date using the updated effective interest rate. The borrowing capacity of the new arrangement is less than the old arrangement. As such, the existing unamortized deferred financing costs of the new arrangement were written off in proportion to the decrease in the borrowing capacity of the unfunded portion of the arrangement. The remaining unamortized deferred financing costs will be amortized to interest expense and deferred over the commitment term of the new arrangement.

The Loan Agreement contains events of default, including a material adverse change, which is subjectively defined, in the Company's business, payment defaults, and breaches of covenants following any applicable cure period. In the event of default by the Company under the Loan Agreement, the Company may be required to repay all amounts then outstanding under the Loan Agreement. The Company has determined that subjective acceleration under the material adverse events clause included in the Loan Agreement is not probable and, therefore, has classified the outstanding principal amount in long-term liabilities based on the timing of scheduled principal payments.

As of June 30, 2023 the outstanding debt of $50.0 million does not exceed the required threshold of trailing three month revenue for the period ended June 30, 2023. Additionally, as of June 30, 2023 the Company maintained unrestricted cash equal to more than 35% of the total outstanding debt and has not been notified of an event of default by the lender under the Loan Agreement.

The Company recognized $2.7 million and $5.8 million of interest expense related to the debt for the three and six months ended June 30, 2023, respectively, and $2.4 million and $4.7 million for the three and six months ended June 30, 2022, respectively. Interest expense is reflected in other income (expense), net on the statement of operations.

As of June 30, 2023, the future principal payments due under the Loan Agreement, excluding interest, are as follows (in thousands):

	Amount
2023	$ —
2024	1,819
2025	23,469
2026	24,712
Total principal outstanding	50,000
End of term charge	1,508
Unamortized debt issuance costs	(572)
Total	$ 50,936

8. Stockholders' Equity

Common stock

The Company is authorized to issue 120,000,000 shares of common stock. Holders of common stock are entitled to one vote per share and are entitled to receive dividends, as if and when declared by the Company's Board of Directors.

On July 2, 2021, the Company filed an automatic shelf registration statement on Form S-3ASR with the Securities and Exchange Commission (the "SEC"), which became effective upon filing, pursuant to which the Company registered for sale an unlimited amount of any combination of its common stock, preferred stock, debt securities, warrants, rights and/or units from time to time and at prices and on terms that the Company may determine, so long as the Company continued to satisfy the requirements of a "well-known seasoned issuer" under SEC rules (the "2021 Form S-3"). The 2021 Form S-3 also included a prospectus covering up to an aggregate of $150.0 million in shares of common stock that the Company may issue and sell from time to time through Cowen and Company, LLC ("Cowen"), acting as its agent, pursuant to a sales agreement for "at the market offerings" the Company entered into with Cowen in July 2021 (the "2021 Sales Agreement"). The Company did not sell any shares of common stock under the 2021 Sales Agreement.

At the time of the filing of the Company's Annual Report on Form 10-K for the year ended December 31, 2021 filed with the SEC on February 23, 2022, the Company no longer qualified as a “well-known seasoned issuer” as such term is defined in Rule 405 under the Securities Act of 1933, as amended. As a result, in February 2022, the Company amended the 2021 Form S-3 to register for sale up to $300.0 million of any combination of its common stock, preferred stock, debt securities, warrants, rights and/or units from time to time and at prices and on terms that the Company may determine. The 2021 Form S-3, as amended, will remain in effect for up to three years from the date it originally became effective, which was July 2, 2021. The amended 2021 Form S-3 also includes a prospectus covering up to an aggregate of $100.0 million in common stock that the Company may issue and sell from time to time, through Cowen acting as its sales agent, pursuant to that certain sales agreement that the Company entered into with Cowen on February 23, 2022 (the “2022 Sales Agreement”). In connection with the Company entering into the 2022 Sales Agreement with Cowen, the Company terminated the 2021 Sales Agreement. As of the date hereof, the Company has not sold any shares of common stock or other securities under the 2022 Sales Agreement for “at the market offerings.”

On November 17, 2022, the Company entered into an underwriting agreement related to a public offering of 7,700,000 shares of common stock at a public offering price of $6.50 per share less the underwriting discounts and commissions, pursuant to the shelf registration statement on Form S-3. The Company received approximately $50.1 million in gross proceeds from this offering, before deducting underwriting discounts and commissions and offering expenses. The offering closed on November 22, 2022. In addition, 873,353 shares of common stock were issued upon exercise by the underwriters of their option to purchase additional shares at the same offering price, which closed on December 20, 2022. The gross proceeds from the offering of the aggregate of 8,573,353 shares of the Company's common stock were $55.7 million and net proceeds of $52.0 million, after deducting underwriting discounts and commissions and other offering expenses payable by the Company.

Preferred stock

The Company is authorized to issue 5,000,000 shares of undesignated preferred stock in one or more series. As of June 30, 2023, no shares of preferred stock were issued or outstanding.

Shares Reserved for Future Issuance

The Company has reserved authorized shares of common stock for future issuance at June 30, 2023 and December 31, 2022 as follows:

	June 30, 2023	December 31, 2022
Common stock options outstanding	7,533,653	7,372,028
RSUs outstanding [(1)]	1,818,053	675,406
PSUs outstanding [(1)]	218,450	—
DSUs outstanding [(1)]	50,000	—
Options, RSUs, PSUs and DSUs available for grant under Equity Incentive Plans [(1)]	1,638,357	2,323,539
	11,258,513	10,370,973

[(1)] RSUs, PSUs, and DSUs are further defined in Note 9.

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, 2023, 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.

In January 2021, the Company began granting RSUs under the 2017 Plan. RSUs are granted at the fair market value of a share of common stock on the date of grant.

In January 2023, the Company began granting PSUs, which are subject to non-market performance and service conditions, to Company executives under the 2017 Plan. PSUs are granted at the fair market value of a share of common stock on the date of grant.

2023 Deferred Compensation Plan (a sub-plan to the 2017 Plan)

In May 2023, the Company adopted the G1 Therapeutics, Inc. Deferred Compensation Plan for Non-Employee Directors to enable non-employee directors of the Company (each a "Non-Employee Director") to elect to defer annually the receipt of shares that vest in accordance with the terms of RSUs granted under the 2017 Plan (the "Vested RSUs") for service as a Non-Employee Director (the "Deferred Compensation Plan"). The Deferred Compensation Plan is intended to comply with the requirements of Section 409A of the Internal Revenue Code of 1986, as amended. Under the Deferred Compensation Plan, the Non-Employee Directors shall be entitled to file with the Compensation Committee of the Board prior to December 31 of each Plan Year (as defined therein) an election form so as to make an election under the Deferred Compensation Plan effective for the following Plan Year, pursuant to which a Non-Employee Director may elect to defer receipt of shares underlying Vested RSUs with respect to RSUs granted in the following Plan Year. The Deferred Compensation Plan is unfunded and unsecured.

As of June 30, 2023, there were a total of 838,693 shares of common stock available for future issuance under the 2017 Plan.

Amended and Restated 2021 Inducement Equity Incentive Plan

In February 2021, the Company adopted the 2021 Inducement Equity Incentive Plan (the “2021 Inducement Plan”). The 2021 Inducement Plan provides for the grant of up to 500,000 non-qualified options, stock grants, and stock-based awards to employees and directors of the Company. The 2021 Inducement Plan does not include an evergreen provision.

In September 2021, the Company adopted the 2021 Sales Force Inducement Equity Incentive Plan (the “2021 Sales Force Inducement Plan”). The 2021 Sales Force Inducement Plan provides for the grant of up to 500,000 non-qualified options, stock grants, and stock-based awards to sales force individuals and support staff that were not previously employees or directors of the Company. The 2021 Sales Force Inducement Plan does not include an evergreen provision.

In March 2022, the Company merged the 2021 Sales Force Inducement Plan into the 2021 Inducement Plan and amended and restated the 2021 Inducement Plan to create the Amended and Restated 2021 Inducement Equity Incentive Plan (the “Amended and Restated 2021 Plan”). In addition, the number of shares reserved for issuance under the Amended and Restated 2021 Plan was increased by 750,000 shares of the Company’s common stock, for an aggregate of 1,750,000 shares of the Company’s common stock authorized to issue under the Amended and Restated 2021 Plan. The Amended and Restated 2021 Plan does not include an evergreen provision.

As of June 30, 2023, there was a total of 799,664 shares of common stock available for future issuance under the Amended and Restated 2021 Plan.

Stock-based Compensation

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.

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.

The Company also incurs stock-based compensation expense related to RSUs, PSUs, and DSUs. The fair value of RSUs, PSUs, and DSUs is determined by the closing market price of the Company's common stock on the date of grant and then recognized over the requisite service period of the award. As the PSUs have non-market performance and service conditions, compensation expense will be recognized over the requisite service periods if and when the achievement of such performance condition(s) is determined to be probable by the Company. If a performance condition is not determined to be probable or is not met, no stock-based compensation expense is recognized. The Company reassesses the probability of achieving the performance condition(s) at each reporting period. As of June 30, 2023, the Company did not deem the achievement of any performance condition(s) to be probable and no compensation expense related to PSUs was recognized.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Cost of goods sold	$ 123	$ 52	$ 158	$ 103
Research and development	514	1,020	1,188	2,169
Selling, general and administrative	3,173	4,567	6,300	9,132
Total stock-based compensation expense	$ 3,810	$ 5,639	$ 7,646	$ 11,404

Stock options – Black-Scholes inputs

The fair value of each option grant is estimated on the grant date using the Black-Scholes option-pricing model, using the following weighted average assumptions for the three and six months ended June 30, 2023 and June 30, 2022:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Expected volatility	86.2% - 88.4%	77.4% - 79.3%	81.4% - 88.4%	76.7% - 79.3%
Weighted-average risk free rate	3.6% - 3.9%	2.5% - 3.2%	3.4% - 3.9%	1.4% - 3.2%
Dividend yield	—%	—%	—%	—%
Expected term (in years)	5.77	5.72	6.00	6.00

Stock Option Activity

The following table is a summary of stock option activity for the six months ended June 30, 2023:

	Options outstanding	Weighted average exercise price	Weighted average Remaining contractual for life (Years)	Weighted average Aggregate intrinsic value
				(in thousands)
Balance as of December 31, 2022	7,372,028	$ 16.15	6.9	$ 3,281
Granted	1,352,230	4.83		
Cancelled	(1,187,597)	16.46		
Exercised	(3,008)	0.30		
Balance as of June 30, 2023	7,533,653	$ 14.08	6.8	$ 1,032
Exercisable at December 31, 2022	4,562,674	$ 17.85	5.8	$ 3,248
Vested at December 31, 2022 and expected to vest	7,372,028	$ 16.15	6.9	$ 3,281
Exercisable at June 30, 2023	4,969,779	$ 16.37	5.7	$ 1,032
Vested at June 30, 2023 and expected to vest	7,533,653	$ 14.08	6.8	$ 1,032

As of June 30, 2023, unrecognized compensation expense related to unvested stock options totaled $15.6 million, which is expected to be recognized over a weighted-average period of approximately 2.1 years.

Restricted Stock Units

The Company’s restricted stock units (“RSUs”) are considered nonvested share awards and require no payment from the employee. For each RSU, employees receive one common share at the end of the vesting period. Compensation cost is recorded based on the market price of the Company’s common stock on the grant date and is recognized on a straight-line basis over the requisite service period.

The following table is a summary of the RSU activity for the six months ended June 30, 2023:

	Number of RSUs	Weighted – Average Fair Value per Share
Balance as of December 31, 2022	675,406	$ 12.31
Granted	1,608,650	3.77
Cancelled	(259,998)	7.61
Vested	(206,005)	12.56
Balance as of June 30, 2023	1,818,053	$ 5.39

As of June 30, 2023, there was $8.1 million of total unrecognized compensation cost related to the Company's RSUs that are expected to vest. These costs are expected to be recognized over a weighted-average period of approximately 2.4 years.

Performance Based Restricted Stock Units

The Company's performance based restricted stock units ("PSUs") are considered nonvested share awards and require no payment from the employee. For each PSU, employees receive one common share at the end of the vesting period, subject to non-market performance and service conditions. Compensation cost is recorded based on the market price of the Company's common stock on the grant date and is recognized over the requisite service if and when the achievement of such performance condition(s) is determined to be probable by the Company. The Company reassesses the probability of achieving the performance condition(s) at each reporting period. As of June 30, 2023, the Company did not deem the achievement of any performance condition(s) to be probable and compensation expense related to PSUs was not recognized.

The following table is a summary of the PSU activity for the six months ended June 30, 2023:

	Number of PSUs	Weighted – Average Fair Value per Share
Balance as of December 31, 2022	—	$ —
Granted	218,450	5.73
Cancelled	—	—
Vested	—	—
Balance as of June 30, 2023	218,450	$ 5.73

As of June 30, 2023, there was $1.3 million of total unrecognized compensation cost related to the Company's PSUs that are expected to vest. These costs are expected to be recognized over a weighted-average period of approximately 2.5 years.

Deferred Share Units

The Company's DSUs are considered nonvested share awards and require no payment from the holders. For each DSU, holders receive one common share on a future date, generally upon "Separation from Service" (within the meaning of Section 409A of the Code) as a Non-Employee Director of the Company for any reason. Upon settlement, holders will receive one fully paid and non-assessable common share in respect of each vested DSU. Compensation cost is recorded based on the market price of the Company’s common stock on the grant date and is recognized on a straight-line basis over the requisite service period.

The following table is a summary of the DSU activity for the six months ended June 30, 2023:

	Number of DSUs	Weighted – Average Fair Value per Share
Balance as of December 31, 2022	—	$ —
Granted	50,000	2.83
Cancelled	—	—
Vested	—	—
Balance as of June 30, 2023	50,000	$ 2.83

As of June 30, 2023, there was $0.1 million of total unrecognized compensation cost related to the Company's DSUs that are expected to vest. These costs are expected to be recognized over a weighted-average period of approximately one year.

10. License Revenue

Incyclix License Agreement

On May 22, 2020, the Company entered into an exclusive license agreement with Incyclix Bio, LLC (“Incyclix”), formerly ARC Therapeutics, LLC, a company primarily owned by a former board member, whereby the Company granted to Incyclix an exclusive, worldwide, royalty-bearing license, with the right to sublicense, solely to make, have made, use, sell, offer for sale, import, export, and commercialize products related to its cyclin dependent kinase 2 (“CDK2”) inhibitor compounds. At close, the Company received consideration in the form of an upfront payment of $1.0 million and an equity interest in Incyclix equal to 10% of its issued and outstanding units valued at $1.1 million. In addition, the Company may receive a future development milestone payment totaling $2.0 million and royalty payments in the mid-single digits based on net sales of the licensed compound after commercialization. The Company has right of first negotiation to re-acquire these assets. In the first quarter of 2022, Incyclix announced a new round of financing which the Company did not participate. Following the financing, the Company's equity interest is now approximately 6.5%.

The Company assessed the license agreement in accordance with ASC 606 and identified one performance obligation in the contract, which is the transfer of the license, as Incyclix can benefit from the license using its own resources. The Company recognized $2.1 million in license revenue consisting of the upfront payment and the 10% equity interest in Incyclix upon the effective date as the Company determined the license was a right to use the intellectual property and the Company had provided all necessary information to Incyclix to benefit from the license.

The Company considers the future potential development milestone and sales-based royalties to be variable consideration. The development milestone is excluded from the transaction price because it determined the payment to be fully constrained under ASC 606 due to the inherent uncertainty in the achievement of such milestone due to factors outside of the Company’s control. As sales-based royalties are all related to the license of the intellectual property, the Company will recognize revenue in the period when subsequent sales are made pursuant to the sales-based royalty exception. The Company will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

There was no revenue recognized during the six months ended June 30, 2023.

Genor License Agreement

On June 15, 2020, the Company entered into an exclusive license agreement with Genor Biopharma Co. Inc. (“Genor”) for the development and commercialization of lerociclib in the Asia-Pacific region, excluding Japan (the “Genor Territory”). Under the license agreement, the Company granted to Genor an exclusive, royalty-bearing, non-transferable license, with the right to grant sublicenses, to develop, obtain, hold and maintain regulatory approvals for, and commercialize lerociclib, in the Genor Territory.

Under the license agreement, Genor agreed to pay the Company a non-refundable, upfront cash payment of $6.0 million with the potential to pay an additional $40.0 million upon reaching certain development and commercial milestones. In addition, Genor will pay the Company tiered royalties ranging from high single to low double-digits based on annual net sales of lerociclib in the Genor Territory. In September 2020, the Company transferred to Genor the related technology and know-how that is necessary to develop, seek regulatory approval for, and commercialize lerociclib in the Genor Territory, which resulted in the recognition of $6.0 million in revenue in accordance with ASC 606. Since then, through December 31, 2022, the Company had recognized an additional $3.0 million in revenue for the achievement of development and commercial milestones as defined by the license agreement.

There was no milestone revenue recognized during the six months ended June 30, 2023.

EQRx License Agreement

On July 22, 2020, the Company entered into an exclusive license agreement with EQRx, Inc. (“EQRx”) for the development and commercialization of lerociclib in the U.S., Europe, Japan and all other global markets, excluding the Asia-Pacific region (except Japan) (the “EQRx Territory”). Under the license agreement, the Company granted to EQRx an exclusive, royalty-bearing, non-transferable license, with the right to grant sublicenses, to develop, obtain, hold and maintain regulatory approvals for, and commercialize lerociclib in the EQRx Territory.

Under the license agreement, EQRx had agreed to pay the Company a non-refundable, upfront cash payment of $20.0 million with the potential to pay an additional $290.0 million upon reaching certain development and commercial milestones. In addition, EQRx would pay the Company tiered royalties ranging from mid-single digits to mid-teens based on annual net sales of lerociclib in the EQRx Territory. In September 2020, the Company transferred to EQRx the related technology and know-how that was necessary to develop, seek regulatory approval for, and commercialize lerociclib in the EQRx Territory which resulted in the recognition of $20.0 million in revenue in accordance with ASC 606. EQRx agreed to be responsible for the development of the product in the EQRx Territory. The Company agreed to continue until completion, as the clinical trial sponsor, its two primary clinical trials at EQRx's sole cost and expense. EQRx agreed to reimburse the Company for all of its out-of-pocket costs incurred after the effective date of the license agreement in connection with these clinical trials. The Company agreed to invoice EQRx within 30 days following the end of the quarter, and EQRx agreed to pay within 30 days after its receipt of such invoice. On August 1, 2023, the Company received formal notice from EQRx of their intent to terminate, as part of their proposed acquisition by Revolution Medicines, Inc., the lerociclib license agreement and to revert the lerociclib product rights back to the Company. The Company is currently assessing next steps, but does not expect to receive any further milestone payments or future royalties from EQRx as a result of the termination.

During the six months ended June 30, 2023, the Company recognized revenue of $0.8 million for the reimbursement of patent and clinical trial costs. No development and commercial milestones, as defined by the license agreement, have been achieved through June 30, 2023.

Simcere License Agreement

On August 3, 2020, the Company entered into an exclusive license agreement with Simcere for the development and commercialization of trilaciclib in all indications in Greater China (mainland China, Hong Kong, Macau, and Taiwan) (the "Simcere Territory"). Under the license agreement, the Company granted to Simcere an exclusive, royalty-bearing, non-transferable license, with the right to grant sublicenses, to develop, obtain, hold and maintain regulatory approvals for, and commercialize trilaciclib in the Simcere Territory. Since entering into the license agreement, the Company had received an upfront payment of $14.0 million and an additional $22.0 million for the achievement of development milestones through December 31, 2022.

On April 28, 2023, the Company amended the license agreement with Simcere, whereby the Company received a one-time, non-refundable payment of $30.0 million in exchange for the relief of future royalty payments from the sale of COSELA in Greater China. In addition, the milestone payments under the license agreement were adjusted such that the Company will be eligible to receive a $5.0 million payment upon Simcere's filing an NDA of TNBC in mainland China and a $13.0 million payment upon Simcere receiving regulatory approval of TNBC in mainland China. Under the amended license agreement, Simcere is not responsible for any sales milestone payments or any royalties accrued after April 28, 2023. Following the amendment, the Company continues to own all the global development and commercial rights to trilaciclib, excluding Greater China.

During the six months ended June 30, 2023, the Company recognized $30.0 million in revenue from the one-time payment for the relief of future royalty payments, $2.0 million in supply and manufacturing services, $0.6 million in royalty revenue, and $0.2 million in patent and clinical trial reimbursable costs.

11. 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. The following potentially dilutive securities have been excluded from the computations of diluted weighted-average shares outstanding for the periods presented below, except for the three months ended June 30, 2023, because the effect would be anti-dilutive:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Stock options issued and outstanding	7,696,646	7,760,860	7,888,449	7,748,660
Unvested RSUs	1,450,070	623,932	1,202,495	615,201
Unvested PSUs	218,450	—	214,829	—
Unvested DSUs	8,242	—	4,144	—
Total potential dilutive shares	9,373,408	8,384,792	9,309,917	8,363,861

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

12. Income Taxes

The Company’s effective income tax rate was 13.1% and 0.0% for the three months ended June 30, 2023 and 2022, respectively, and (7.4)% and 0.0% for the six months ended June 30, 2023 and 2022, respectively.

13. Related Party Transactions

The Company entered into a senior advisor agreement on September 29, 2020 with Mark A. Velleca, M.D., Ph.D., a member of the Board of Directors, with an effective date of January 1, 2021. Pursuant to the terms of the agreement, Dr. Velleca will receive $200,000 annually, paid in equal quarterly installments, for his services. The senior advisor agreement will expire on December 31, 2023.

14. Restructuring Charges

On February 13, 2023, the Company made the decision to discontinue the PRESERVE 1 trial following the announcement of top-line results. In connection with the announcement, on February 22, 2023, the Company approved changes to the Company's organization as well as a broader operational cost reduction plan. As part of this plan, the Company approved a reduction in the Company's workforce by approximately 30% across different areas and functions in the Company effective on March 1, 2023. Affected employees were offered separation benefits, including severance payments. The costs incurred in connection with the reduction in workforce of $1.4 million were fully paid as of June 30, 2023. There are no remaining liabilities as of June 30, 2023.

15. Subsequent Event

On August 1, 2023, the Company received formal notice from EQRx of their intent to terminate, as part of their proposed acquisition by Revolution Medicines, Inc., the lerociclib license agreement and to revert the lerociclib product rights back to the Company. The termination does not have any impact on the condensed financial statements for the period ended June 30, 2023. The Company is currently assessing next steps, but does not expect to receive any further milestone payments or future royalties from EQRx as a result of the termination.

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 2022 Form 10-K, and in our subsequently filed Quarterly Reports on Form 10-Q, 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.

In this Quarterly Report on Form 10-Q, the terms "we," "us," "our," the "Company" and "G1" mean G1 Therapeutics, Inc.

Overview

We are a commercial-stage biopharmaceutical company focused on the development and commercialization of novel small molecule therapeutics for the treatment of patients with cancer. Our first product approved by the U.S. FDA, COSELA® (trilaciclib), is the first and only therapy indicated to proactively help protect bone marrow from the damage of chemotherapy ("myeloprotection") and is the first innovation in managing myeloprotection in decades. In July 2022, COSELA (trilaciclib hydrochloride for injection) was conditionally approved by the China NMPA for marketing in mainland China.

Trilaciclib was developed from a technology platform that targets key cellular pathways including transient arrest of the cell cycle at the G1 phase, prior to the beginning of DNA replication. Controlled administration and clean G1 arrest from transient CDK4/6 inhibition can protect bone marrow and reduce hematologic adverse events ("AEs") caused by cytotoxic therapy and may increase the ability to receive longer treatment durations. Transient CDK4/6 inhibition also may improve survival in combination with leading and emerging treatments through myeloprotection, protecting the immune system from damage caused by cytotoxic therapy, and/or through long-term immune surveillance by increasing T cell function and generation of certain memory T cells. We are exploring the use of trilaciclib in a variety of trials to optimize these potential benefits in combination with leading and emerging treatments for patients globally. Based on trilaciclib data generated to date and to optimize the opportunity ahead, we plan to focus primarily on two core development paths for trilaciclib: (1) in metastatic TNBC settings, where we have already shown a survival advantage in the trilaciclib arms in a Phase 2 trial, and (2) in ADC combinations including additional tumor types.

We use "COSELA" when referring to our FDA approved drug and "trilaciclib" when referring to our development of COSELA for additional indications.

COSELA is a prescription medicine used to help reduce the occurrence of low blood cell counts caused by damage to bone marrow from chemotherapy. COSELA is used to treat adults taking certain chemotherapies (platinum/etoposide or topotecan) for extensive stage small cell lung cancer ("ES-SCLC").

Commercial Product

On February 12, 2021, COSELA was approved by the FDA to decrease the incidence of chemotherapy-induced myelosuppression in adult patients treated with a platinum/etoposide-containing regimen or topotecan-containing regimen for ES-SCLC. COSELA became commercially available through our specialty distributor network on March 2, 2021.

COSELA is an injection for intravenous use given within four hours before chemotherapy.

In March 2021, COSELA was included in two updated National Comprehensive Cancer Network® (“NCCN”) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): The Treatment Guidelines for Small Cell Lung Cancer and the Supportive Care Guidelines for Hematopoietic Growth Factors. These guidelines document evidence-based, consensus-driven management to ensure that all patients receive preventive, diagnostic, treatment, and supportive services that are most likely to lead to optimal outcomes. On October 1, 2021, the permanent J-code for COSELA that was issued in July 2021 by the Centers for Medicare & Medicaid Services (CMS) became effective for provider billing for all sites of care. All hospital outpatient departments, ambulatory surgery centers and physician offices in the United States have one consistent Healthcare Common Procedure Coding System ("HCPCS") code to standardize the submission and payment of COSELA insurance claims across Medicare, Medicare Advantage, Medicaid and commercial plans. Our new technology add-on payment ("NTAP") for COSELA which provides additional payment to inpatient hospitals above the standard Medicare Severity Diagnosis-Related Group ("MS-DRG") payment amount also became effective for provider billing on October 1, 2021.

On August 3, 2020, we entered into an exclusive license agreement with Nanjing Simcere Dongyuan Pharmaceutical Co., Ltd (“Simcere”) for the development and commercialization of trilaciclib in all indications in Greater China (mainland China, Hong Kong, Macau and Taiwan). On July 13, 2022, the NMPA conditionally approved COSELA (trilaciclib hydrochloride for injection) for marketing in mainland China. COSELA is indicated in mainland China to decrease the incidence of chemotherapy-induced myelosuppression in adult patients when administered prior to a platinum/etoposide-containing regimen for ES-SCLC. Since entering into the license agreement, through April 28, 2023, we received an upfront payment of $14.0 million and an additional $22.0 million for the achievement of development milestones.

On April 28, 2023, we amended the license agreement with Simcere, whereby we received a one-time, non-refundable payment of $30.0 million in exchange for the relief of future royalty payments from the sale of COSELA in Greater China. In addition, the milestone payments under the license agreement have been adjusted such that we will be eligible to receive a $5.0 million payment upon Simcere’s filing an NDA of TNBC in mainland China and a $13.0 million payment upon Simcere receiving regulatory approval of TNBC in mainland China. Under the amended license agreement, Simcere is not responsible for any sales milestone payments or any royalties accrued after April 28, 2023. Following the amendment, we continue to own all the global development and commercial rights to trilaciclib, excluding Greater China.

Product Pipeline

We are also exploring potential use of trilaciclib in certain cancers, including trials designed to inform the design of future additional pivotal studies and in treatment combinations including targeted chemotherapy medicines called ADCs. Based on trilaciclib data generated to date and to optimize the opportunity ahead, we plan to focus primarily on two core development paths for trilaciclib: (1) in metastatic TNBC settings, where a survival advantage has been observed in the trilaciclib arms of an ongoing Phase 2 trial, and (2) in ADC combinations including additional tumor types.

Trilaciclib is a first-in-class therapy designed to help protect against chemotherapy-induced myelosuppression. Trilaciclib, a novel transient IV CDK4/6 inhibitor has unique attributes including rapid onset from IV administration, potent and selective CDK4 and CDK6 inhibition and a short half-life. Controlled administration and clean G1-phase arrest reduce hematologic AEs caused by cytotoxic therapy and may increase patients’ abilities to receive longer treatment durations. Transient CDK4/6 inhibition also modulates multiple immune functions ("immunomodulation") while allowing beneficial T cell proliferation which may improve patients’ anti-tumor immune responses.

Trilaciclib transiently blocks progression through the cell cycle. This provides benefits which manifest depending on the tumor type and therapeutic backbone, including: (1) proactive multi-lineage myeloprotection to protect the bone marrow from cytotoxic damage, and (2) potentially improved survival in combination with leading and emerging treatments.

We are pursuing trilaciclib across key growth platforms. Trilaciclib provides proactive multi-lineage myeloprotection by transiently arresting hematopoietic stem and progenitor cells (“HSPCs”), helping to protect them from damage caused by cytotoxic therapy thereby minimizing cytopenias across neutrophils, erythrocytes, and platelets. These proactive multi-lineage myeloprotection benefits were seen in our three double-blind, placebo-controlled clinical trials in ES-SCLC, where highly myelosuppressive chemotherapy regimens are administered multiple days in a row. In addition, these multilineage myeloprotection benefits have been observed in the Phase 2 trial of trilaciclib in combination with the ADC, sacituzumab govitecan-hziy in patients with unresectable locally advanced or metastatic triple-negative breast cancer ("TNBC"). Preliminary results presented at the European Society for Medical Oncology ("ESMO") Breast Cancer 2023 Annual Congress showed a clinically meaningful on-target effect of trilaciclib to reduce (>50%) the rates of multiple adverse events compared to the previously published sacituzumab govitecan-hziy single agent safety profile from the ASCENT trial, including myelosuppression (neutropenia, anemia) and diarrhea.

Trilaciclib has the potential to improve survival in combination with leading and emerging treatments, as a result of (1) protecting the immune system from damage caused by cytotoxic therapy, and/or (2) enhancing long term immune surveillance via increased generation of certain memory T cells. This mechanism lends itself to longer term endpoints, such as OS. We are exploring this potential survival benefit in a variety of ongoing Phase 2 and Phase 3 clinical trials, including the recently completed Phase 2 trial in neoadjuvant TNBC designed to validate trilaciclib's immune-based mechanism of action ("MOA"), results of which were recently presented at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting. These findings highlighted the potential for trilaciclib to enhance long term immune surveillance by increasing T cell function and generation of certain memory T cells and demonstrate gene expression profiles that may be associated with improved clinical outcome.

We currently have three ongoing clinical trials: a pivotal Phase 3 trial in 1L mTNBC (PRESERVE 2), a Phase 2 trial in combination with an ADC in 2L/3L mTNBC, and a Phase 2 trial in 1L bladder cancer with chemotherapy induction and a checkpoint inhibitor maintenance. These studies will evaluate trilaciclib’s benefits of proactive multi-lineage myeloprotection and survival in combination with leading and emerging treatments and inform the design of future additional pivotal studies. We have also conducted significant preclinical work to assess the additive/synergistic potential of trilaciclib with a variety of novel and emerging therapeutic agents to identify synergies to evaluate in future clinical trials. Our overall development approach includes monitoring and anticipating the evolving future standards of care across tumor types in order to design or support studies that generate important data for trilaciclib across relevant future treatment settings and maximize future usage.

Prior studies including the Phase 2 TNBC trial have shown that the greatest effect of trilaciclib is on longer term endpoints like OS rather than earlier efficacy measures such as overall response rate ("ORR") and progression free survival ("PFS"). This is consistent with other immunotherapies like checkpoint inhibitors, which have the greatest effect at survival timepoints. Our data to date suggest that this could be due to trilaciclib enhancing long term immune surveillance by increased generation of certain memory T cells. Additionally, Programmed Cell Death-Ligand 1 ("PD-L1") status of the tumors is likely to affect how trilaciclib works across these different measures of efficacy, including how long it may take to see any potential benefit. For example, in our previous TNBC Phase 2 trial, patients with PD-L1(+) tumors, which have an immune inflamed tumor microenvironment, experienced a numerical improvement in earlier efficacy metrics including ORR and PFS. The Kaplan Meier curves for OS separated early and continued to improve over time, leading to a median OS of 32.7 months for patients receiving trilaciclib compared to 10.5 months for patients receiving chemotherapy alone, with a hazard ratio of 0.34. By comparison, patients with PD-L1(-) tumors, which have immune excluded or immune desert tumor microenvironments, did not experience a meaningful improvement in ORR or PFS. However, we did observe a median OS of 17.8 months for patients receiving trilaciclib compared to 13.9 months for patients receiving chemotherapy alone, with a hazard ratio of 0.48. The Kaplan Meier curves for OS did not separate until ~15 months, but this separation then continued to accelerate over time leading to a hazard ratio of 0.48. We expect that the OS results will be the most meaningful to evaluate trilaciclib in this and future studies.

PRESERVE 2 is an ongoing pivotal Phase 3 trial in 1L mTNBC. A meaningful anti-tumor efficacy benefit was observed in our previous Phase 2 mTNBC study in which trilaciclib led to a significant improvement in OS when administered in combination with gemcitabine/carboplatin chemotherapy ("GC") compared to chemotherapy alone; these are the foundational data for the Phase 3 PRESERVE 2 trial. An interim OS analysis is currently anticipated for PRESERVE 2 in the first quarter of 2024 to evaluate the effect of trilaciclib on OS in patients with TNBC when administered prior to treatment with GC. If the interim OS analysis achieves the threshold of statistical significance required for the interim assessment showing that trilaciclib has superior efficacy in OS, the trial will be unblinded, and the data will be reported. In addition, we will discuss the data with regulatory health authorities regarding filing for potential approval of this indication. If the interim OS analysis does not meet the interim stopping criteria, the trial will continue to the final analysis.

Recent Phase 2 Results

In May 2023, we provided additional results at the ESMO Breast Cancer 2023 Annual Congress from our ongoing Phase 2 trial of trilaciclib in combination with the ADC, sacituzumab govitecan-hziy. Initial data demonstrate the potential for an on-target effect of trilaciclib to reduce (>50%) the rates of adverse events associated with sacituzumab, including myelosuppression (neutropenia, anemia) and diarrhea, compared to the previously published sacituzumab single agent safety profile. These results highlight the potential for trilaciclib to meaningfully reduce adverse events related to use of sacituzumab. As expected, patients with PD-L1(+) tumors appear to respond earlier than patients with PD-L1(-) tumors. We expect to reach the OS endpoints in the first quarter of 2024.

In June 2023, we reported results at the 2023 ASCO Annual Meeting from our Phase 2, single arm mechanism of action study of trilaciclib administered as a single agent to patients with early-stage triple-negative breast cancer (TNBC) prior to receiving trilaciclib and neoadjuvant therapy. These results highlight the potential for trilaciclib to enhance long term immune surveillance by increasing T cell function and generation of certain memory T cells and demonstrate gene expression profiles that may be associated with improved clinical outcome. As expected, high rates of pathologic complete response ("pCR") were observed in patients with PD-L1(+) tumors and in patients with inflamed tumor immune microenvironments. These results help confirm the role of trilaciclib in increasing the pool of functional memory T cells that could contribute to long-term immune surveillance and efficacy, as measured by longer term endpoints like OS.

In August 2023, we provided an update on PRESERVE 3, the ongoing, randomized, open-label Phase 2 study of first-line platinum-based chemotherapy and maintenance therapy with the immune checkpoint inhibitor, avelumab, administered alone, or in combination with trilaciclib, in patients with untreated, locally advanced or metastatic urothelial carcinoma (“mUC”). As of the data cutoff on July 5, 2023, PFS is similar between patients receiving trilaciclib prior to gemcitabine/platinum + avelumab and patients receiving gemcitabine/platinum + avelumab alone (median PFS=6.0 months and 6.1 months, respectively; hazard ratio=1.07). Median PFS was also similar across arms in both PD-L1 subsets. Median duration of response ("DOR") favored participants that received trilaciclib (7.0 months) compared to those that did not (6.0 months); median DOR also favored the trilaciclib arms in both PD-L1 subsets. We expect that the OS results will be the most meaningful to evaluate trilaciclib in this setting; we expect to reach the OS endpoints in the first quarter of 2024.

Trilaciclib Development Pipeline

Candidate	Indication	Current Status	Initial Results	Additional Results	Endpoints	Development & Commercialization Rights (all indications)
trilaciclib	1L metastatic Triple negative breast cancer (mTNBC)	Registrational Phase 3 trial (enrollment complete)	Interim OS analysis expected in 1Q 2024*		Primary: OS Secondary: PRO, myeloprotection, PFS/ORR	G1 Therapeutics owns all global development and commercial rights across all indications, with the exception of Greater China (Simcere)
	Antibody-drug conjugate (ADC) combination trial in mTNBC	Phase 2 trial (enrollment complete)	Initial results announced in 4Q 2022	Additional results presented at ESMO Breast Cancer 2023; OS endpoint expected in 1Q 2024	Primary: PFS Secondary: ORR, OS, safety, myeloprotection, others	
	Mechanism of action (MOA) trial in early-stage neoadjuvant TNBC	Phase 2 trial (trial complete)	Initial MOA data presented in 4Q 2022	Results presented at ASCO 2023	Primary: Immune-based MOA Secondary: pCR, immune response, others	
	1L Bladder cancer (mUC)	Phase 2 trial (enrollment complete)	Initial results announced in 1Q 2023	Results expected in 3Q2023; OS endpoint expected in 1Q 2024	Primary: PFS Secondary: ORR, OS, safety and efficacy, others	

PFS=progression-free survival; OS=overall survival; PRO=patient reported outcome; ORR=overall response rate; pCR=pathological complete response; MOA=mechanism of action; ESMO = European Society for Medical Oncology; ASCO = American Society of Clinical Oncology

*Initial results expected in 1Q2024 from the ongoing Phase 3 1L mTNBC trial: Interim OS analysis; if the trial meets the interim analysis stopping rule, it will be unblinded and we will report the topline results. If it does not, the trial will continue to the final analysis.

Lerociclib

Lerociclib is a differentiated clinical-stage oral CDK4/6 inhibitor being developed for use in combination with other targeted therapies in multiple oncology indications. In 2020, we entered into separate, exclusive agreements with EQRx, Inc. (rights for U.S., Europe, Japan and all markets outside Asia-Pacific) and Genor Biopharma Co. Inc. (rights for Asia-Pacific, excluding Japan) for the development and commercialization of lerociclib in all indications. Combined, these agreements provided $26.0 million in upfront payments. On August 1, 2023, we received formal notice from EQRx of their intent to terminate, as part of their proposed acquisition by Revolution Medicines, Inc., the lerociclib license agreement and to revert the lerociclib product rights back to us.

The Genor agreement provides sales-based royalties, and the opportunity for up to $40.0 million in potential milestone payments. Genor Biopharma Co. Inc. is responsible for all costs related to the development and commercialization of lerociclib in its territory.

CDK2 Inhibitor

In 2020, we entered into a global license agreement with Incyclix Bio, LLC (“Incyclix”), formerly ARC Therapeutics, LLC, for the development and commercialization of an internally discovered cyclin-dependent kinase 2 (“CDK2”) inhibitor for all human and veterinary uses. Incyclix is currently granted an exclusive, royalty-bearing, license with the right to grant sublicenses to one of our solely owned patent families.

Coronavirus (COVID-19) on Operations

We implemented business continuity plans to address the COVID-19 pandemic and minimize disruptions to ongoing operations. While its most severe effects appear to have subsided, the virus could re-emerge, or new public health threats could appear. If the COVID-19 pandemic re-emerges as a serious public health threat in the United States and elsewhere, or if another serious pathogen appears, we could experience disruptions to our clinical development timelines. The future impact of the COVID-19 pandemic or a similar health disruption is highly uncertain and subject to change. We will continue to monitor the impact of COVID-19 on our operations, including how it may impact our employees, clinical trials, development programs, supply chain, and other aspects of our operations, and report to our Board of Directors as necessary.

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 selling, general and administrative support for these operations as well as securing intellectual property protection for our products. Currently, COSELA is our only product approved for sale. We began generating revenue for the net product sales from COSELA in March of 2021. We recorded $21.6 million and $31.3 million of net product sales from COSELA for the six months ended June 30, 2023, and the year ended December 31, 2022, respectively. We recorded $33.8 million and $20.0 million of license revenue for the six months ended June 30, 2023, and the year ended December 31, 2022, respectively. To date, we have financed our operations primarily through the sale of equity securities, our loan agreement with Hercules Capital, Inc., and licensing arrangements. Under our licensing arrangements, we are eligible to receive certain development and sales-based milestones. Our ability to earn these milestones and the timing of achieving these milestones is primarily dependent upon the outcome of the licensee’s activities and is uncertain at this time.

As of June 30, 2023, we had cash and cash equivalents of $55.9 million and marketable securities of $48.3 million. Since inception we have incurred net losses. As of June 30, 2023, we had an accumulated deficit of $750.9 million. Substantially all of our net losses have resulted from costs incurred in connection with our research and development programs, our commercial launch of COSELA, and from selling, general and administrative expenses associated with our operations. We expect to continue to incur significant expenses and increasing operating losses. On February 22, 2023, in connection with the decision to discontinue the PRESERVE 1 trial following the announcement of top-line results on February 13, 2023, we approved a reduction in our workforce by approximately 30% across different areas and functions in the Company, effective March 1, 2023. Affected employees were offered separation benefits, including severance payments. The costs incurred in connection with the workforce reduction was $1.4 million, which was fully paid off as of June 30, 2023. See Note 14 for further discussion on this restructuring activity. As disclosed in the Liquidity and Capital Resources section, as of the date of issuance of these condensed financial statements, we expect that our cash and cash equivalents and marketable securities as of June 30, 2023 will be sufficient to fund our planned operations and remain in compliance with our objective financial covenants for at least the next 12 months from the date of issuance of these condensed financial statements. To date, inflation has not had a material impact on our business, but if the global inflationary trends continue, we expect appreciable increases in clinical trial, selling, labor, and other operating costs. If our costs were to become subject to significant inflationary pressures, we may not be able to fully offset such higher costs through price increases of our product. Our inability or failure to do so could adversely affect our business, financial condition and results of operations.

In addition, currently there is a conflict involving Russia and Ukraine, and this may impact our contract research organizations, clinical data management organizations, and clinical investigators' ability to conduct future trials in Eastern European countries, which may increase our product development costs and materially harm our business.

We also expect our research and development, commercial activities, and selling, general and administrative expenses will continue to increase in connection with our ongoing and future activities as we:

- continue development of trilaciclib, including initiation of additional clinical trials;
- identify and develop new product candidates;
- seek additional marketing approvals for trilaciclib upon successful completion of clinical trials;
- grow our sales, marketing and distribution infrastructure to commercialize COSELA and any future products for which we may obtain marketing approval;
- achieve market acceptance of our product in the medical community and with third-party payors;
- maintain, expand and protect our intellectual property portfolio;
- enter into collaboration arrangements, if any, for the development of our product or in-license other products and technologies;
- add operational, financial and management information systems and personnel, as needed, 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.

Components of our Results of Operations

Revenues

On February 12, 2021, COSELA was approved by the FDA and we began generating revenue for the product sales of COSELA in March 2021. Prior to the approval of COSELA, our revenues have been derived from our license agreements.

We entered into an exclusive license agreement with Simcere in August 2020 and granted them the rights to develop and commercialize trilaciclib in Greater China (mainland China, Hong Kong, Macau, and Taiwan) (the "Simcere Territory"). Since then, through December 31, 2022, we recognized a total of $36.0 million in milestone revenue as defined by the license agreement. On April 28, 2023, we amended the license agreement with Simcere, whereby we received a one-time, non-refundable payment of $30.0 million in exchange for the relief of future royalty payments from the sale of COSELA in Greater China. In addition, the milestone payments under the license agreement have been adjusted such that we will be eligible to receive a $5.0 million payment upon Simcere's filing an NDA of TNBC in mainland China and a $13.0 million payment upon Simcere receiving regulatory approval of TNBC in mainland China. Under the amended license agreement, Simcere is not responsible for any sales milestone payments or any royalties accrued after April 28, 2023. Following the amendment, we continue to own all the global development and commercial rights to trilaciclib, excluding Greater China. During the six months ended June 30, 2023, we recognized $30.0 million in revenue from the one-time payment for the relief of future royalty payments, $2.0 million in supply and manufacturing services, $0.6 million in royalty revenue, and $0.2 million in patent and clinical trial reimbursable costs. We did not receive any development milestones during the six months ended June 30, 2023.

We entered into an exclusive license agreement with EQRx, Inc. ("EQRx") in July 2020 and granted them the rights to develop and commercialize lerociclib in the U.S, Europe, Japan and all other global markets, excluding the Asia-Pacific region (except Japan) (the "EQRx Territory"). We received an upfront payment of $20.0 million in August 2020. This was recognized as revenue in September 2020 when we transferred the license and related technology and know-how. During the six months ended June 30, 2023, we recognized revenue of $0.8 million for the reimbursement of patent and clinical trial costs. We did not receive any development milestones during the six months ended June 30, 2023.

We entered into an exclusive license agreement with Genor Biopharma Co. Inc. ("Genor") in June 2020 and granted them the rights to develop and commercialize lerociclib in the Asia-Pacific Region, excluding Japan (the "Genor Territory"). We received an upfront payment of $6.0 million in July 2020. This was recognized as revenue in September 2020 when we transferred the license and related technology and know-how. We have the potential to receive $40.0 million upon reaching development and commercial milestones, and receive tiered royalties ranging from high single to low double-digits based on annual net sales of lerociclib in the Genor Territory. We did not receive any development milestones during the six months ended June 30, 2023.

We entered into an exclusive license agreement with Incyclix Bio, LLC ("Incyclix"), formerly ARC Therapeutics, LLC, a company primarily owned by a former board member, in May 2020. We granted Incyclix an exclusive, worldwide, royalty-bearing license of its CDK2 inhibitor compounds in exchange for an upfront payment and equity in Incyclix with a total value of approximately $2.1 million, which resulted in the recognition of related party revenue. We are entitled to receive an additional milestone payment and sales-based royalties, and have right of first negotiation to re-acquire these assets. We did not receive the development milestone payment during the six months ended June 30, 2023.

Operating expenses

We classify our operating expenses into three categories: cost of goods sold, research and development and selling, general and administrative expenses. Personnel costs, including salaries, benefits, bonuses, and stock-based compensation expense, comprise a significant component of each of these expense categories. We allocate expenses associated with personnel costs based on the nature of work associated with these resources. In addition, costs to sell and market COSELA are included within selling, general and administrative expense categories.

Cost of goods sold

Cost of goods sold includes direct and indirect costs related to the manufacturing and distribution of COSELA, including third-party manufacturing costs, packaging services, freight-in, third-party logistics costs associated with COSELA, and personnel costs. Cost of goods sold may also include period costs related to certain inventory manufacturing services and inventory adjustment charges.

Research and Development Expenses

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

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

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

The successful development of our products is highly uncertain. Products 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 as we conduct later stage clinical trials. However, we do not believe that it is possible at this time to accurately project total program-specific 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 products 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;
- uncertainties in clinical trial enrollment rates or drop-out or discontinuation rates of patients;
- potential additional studies requested by regulatory agencies;
- significant and changing government regulation; and
- the timing and receipt of any regulatory approvals.

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

Selling, general and administrative expenses

Selling, 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 selling, general and administrative expenses include facility-related costs not otherwise allocated to research and development expense, professional fees, commercialization costs, expenses associated with obtaining and maintaining patents and costs of our information systems. We anticipate that our selling, general and administrative expenses will continue to increase in the future as we continue to expand our research and development and commercialization of COSELA.

Total other income (expense), net

Total other income (expense), net consists of interest income earned on cash and cash equivalents and interest expenses incurred under our loan and security agreement with Hercules.

Income taxes

To date, we have not been required to pay U.S. federal or state income taxes because we have not generated taxable income. Income tax recognized for the three and six months ended June 30, 2023 related to the foreign withholding taxes incurred as a result of the milestone payment received from the Simcere license agreement during the quarter. We did not recognize any income tax expense for the three and six months ended June 30, 2022.

Results of operations

Comparison of the three months ended June 30, 2023 and June 30, 2022

	Three Months Ended June 30,		Change
	2023	2022	$
	(in thousands)		
Revenues			
Product sales, net	$ 11,091	$ 8,718	$ 2,373
License revenue	31,301	1,855	29,446
Total revenues	42,392	10,573	31,819
Operating expenses			
Cost of goods sold	1,404	976	428
Research and development	12,040	20,843	(8,803)
Selling, general and administrative	17,432	25,716	(8,284)
Total operating expenses	30,876	47,535	(16,659)
Loss from operations	11,516	(36,962)	48,478
Other income (expense)			
Interest income	643	50	593
Interest expense	(2,710)	(2,407)	(303)
Other income (expense)	569	(127)	696
Total other income (expense), net	(1,498)	(2,484)	986
Income (loss) before income taxes	10,018	(39,446)	49,464
Income tax expense	1,308	—	1,308
Net income (loss)	$ 8,710	$ (39,446)	$ 48,156

Product sales, net

Product sales, net was $11.1 million and $8.7 million for the three months ended June 30, 2023 and 2022, respectively. The increase of $2.4 million, or 28%, was primarily due to increased sales volume as we continued our commercialization efforts. We received FDA approval of COSELA on February 12, 2021 and the product has been commercially available since March 2, 2021.

License revenue

License revenue was $31.3 million and $1.9 million for the three months ended June 30, 2023 and 2022, respectively. License revenue increased $29.4 million, or 1547%. License revenue recognized in the current period was primarily related to $30.0 million in revenue from the one-time payment for the relief of future royalty payments and $0.8 million in supply and manufacturing services and royalty revenue from Simcere. Additionally, in the current period we recognized $0.5 million in license revenue related to patent and clinical trial costs reimbursed by EQRx and Simcere.

Cost of goods sold

Cost of goods sold was $1.4 million and $1.0 million for the three months ended June 30, 2023 and 2022, respectively. The increase of $0.4 million, or 40%, was primarily due to an increase in units sold.

Research and development

Research and development expenses were $12.0 million for the three months ended June 30, 2023 as compared to $20.8 million for the three months ended June 30, 2022. The decrease of $8.8 million, or 42%, was primarily due to a decrease of $8.2 million in our clinical program costs, and a decrease of $0.6 million in personnel costs related to manufacturing active pharmaceutical ingredients and drug products to support our clinical trials. The following table summarizes our research and development expenses allocated to trilaciclib, rintodestrant (discontinued), lerociclib, and unallocated research and development expenses for the periods indicated:

	Three Months Ended June 30,	
	2023	2022
	(in thousands)	
Clinical Program Expenses—trilaciclib	$ 10,964	$ 18,054
Clinical Program Expenses—rintodestrant	87	581
Clinical Program Expenses—lerociclib	363	862
Chemical Manufacturing and Development	93	721
Discovery, Pre-Clinical and Other Expenses	533	625
Total Research and Development Expenses	$ 12,040	20,843

Selling, general and administrative

Selling, general and administrative expenses were $17.4 million for the three months ended June 30, 2023 as compared to $25.7 million for the three months ended June 30, 2022. The decrease of $8.3 million, or 32%, was due to decreases of $4.0 million in commercialization activities, $3.6 million in personnel costs, $0.5 million in medical affairs costs related to trilaciclib, and $0.2 million in IT costs.

Total other income (expense), net

Total other income (expense), net was $(1.5) million for the three months ended June 30, 2023 as compared to $(2.5) million for three months ended June 30, 2022. The change of $1.0 million, or 40%, was primarily driven by an increase of $0.6 million in interest income and an increase of $0.7 million in other income, offset by an increase of $0.3 million in interest expense on the loan payable due to higher interest rates.

Income tax expense

Income tax expense was $1.3 million for the three months ended June 30, 2023. There was no income tax expense recognized during the three months ended June 30, 2022. The increase was related to the foreign withholding taxes incurred as a result of the royalty buyback payment received from Simcere during the quarter.

Results of operations

Comparison of the six months ended June 30, 2023 and June 30, 2022

	Six Months Ended June 30,		Change
	2023	2022	$
	(in thousands)		
Revenues			
Product sales, net	$ 21,583	$ 14,198	$ 7,385
License revenue	33,755	3,277	30,478
Total revenues	55,338	17,475	37,863
Operating expenses			
Cost of goods sold	2,863	1,645	1,218
Research and development	27,520	47,148	(19,628)
Selling, general and administrative	39,185	52,425	(13,240)
Total operating expenses	69,568	101,218	(31,650)
Loss from operations	(14,230)	(83,743)	69,513
Other income (expense)			
Interest income	1,359	59	1,300
Interest expense	(5,799)	(4,672)	(1,127)
Other income (expense)	1,093	(282)	1,375
Total other income (expense), net	(3,347)	(4,895)	1,548
Loss before income taxes	(17,577)	(88,638)	71,061
Income tax expense	1,308	—	1,308
Net loss	$ (18,885)	$ (88,638)	$ 69,753

Product sales, net

Product sales, net was $21.6 million and $14.2 million for the six months ended June 30, 2023 and 2022, respectively. The increase of $7.4 million, or 52%, was primarily due to increased sales volume as we continued our commercialization efforts. We received FDA approval of COSELA on February 12, 2021 and the product has been commercially available since March 2, 2021.

License revenue

License revenue was $33.8 million and $3.3 million for the six months ended June 30, 2023 and 2022, respectively. License revenue increased $30.5 million, or 924%. License revenue recognized in the current year was primarily related to $30.0 million in revenue from the one-time payment for the relief of future royalty payments, $2.0 million in supply and manufacturing services, and $0.6 million in royalty revenue from Simcere. Additionally, we recognized $1.2 million in license revenue related to patent and clinical trial costs reimbursed by EQRx and Simcere.

Cost of goods sold

Cost of goods sold was $2.9 million and $1.6 million for the six months ended June 30, 2023 and 2022, respectively. The increase of $1.3 million, or 81%, was primarily due to an increase in units sold and an increase in overhead.

Research and development

Research and development expenses were $27.5 million for the six months ended June 30, 2023 as compared to $47.1 million for the six months ended June 30, 2022. The decrease of $19.6 million, or 42%, was primarily due to a decrease of $18.7 million in our clinical program costs, and a decrease of $0.9 million for manufacturing of active pharmaceutical ingredients and drug product to support our clinical trials. The following table summarizes our research and development expenses allocated to trilaciclib, rintodestrant (discontinued), lerociclib, and unallocated research and development expenses for the periods indicated:

	Six Months Ended June 30,	
	2023	2022
	(in thousands)	
Clinical Program Expenses—trilaciclib	$ 24,952	$ 41,705
Clinical Program Expenses—rintodestrant	7	1,206
Clinical Program Expenses—lerociclib	736	1,466
Chemical Manufacturing and Development	746	1,573
Discovery, Pre-Clinical and Other Expenses	1,079	1,198
Total Research and Development Expenses	$ 27,520	$ 47,148

Selling, general and administrative

Selling, general and administrative expenses were $39.2 million for the six months ended June 30, 2023 as compared to $52.4 million for the six months ended June 30, 2022. The decrease of $13.2 million, or 25%, was due to decreases of $7.0 million in commercialization activities, $4.6 million in personnel costs due to a reduction in force, $1.0 million in professional fees, $0.4 million in audit, IT, legal, office and other administrative expenses, and $0.2 million in medical affairs costs related to trilaciclib.

Total other income (expense), net

Total other income (expense), net was $(3.3) million for the six months ended June 30, 2023 as compared to $(4.9) million for six months ended June 30, 2022. The change of $1.6 million, or 33%, was primarily driven by an increase of $1.3 million in interest income and an increase of $1.4 million in other income, offset by an increase of $1.1 million in interest expense on the loan payable due to higher interest rates.

Income tax expense

Income tax expense was $1.3 million for the six months ended June 30, 2023. There was no income tax expense recognized during the six months ended June 30, 2022. The increase was related to the foreign withholding taxes incurred as a result of the royalty buyback payment received from Simcere during the current period.

Liquidity and Capital Resources

We have experienced net losses since our inception, and have an accumulated deficit of $750.9 million and $732.0 million as of June 30, 2023 and December 31, 2022, respectively. We expect to incur losses and have negative net cash flows from operating activities as we execute on our strategy including engaging in further research and development activities, particularly conducting non-clinical studies and clinical trials. Our success depends on the ability to successfully commercialize our technologies to support our operations and strategic plan. As of the date of issuance of these condensed financial statements, we expect that our cash and cash equivalents and marketable securities as of June 30, 2023 will be sufficient to fund our planned operations and remain in compliance with our objective financial covenants for at least the next 12 months from the date of issuance of these condensed financial statements. 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. There can be no assurances that we will be able to secure such additional financing if at all, or on terms that are satisfactory to us, and that it will be sufficient to meet our needs. In the event we are not successful in obtaining sufficient funding, this could force us to delay, limit, or reduce our product development, commercialization efforts or other operations. Our condensed financial statements have been prepared assuming that we will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The condensed financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of the uncertainties described above. In connection with the Loan Payable described in Note 7, we are required to remain in compliance with a minimum cash covenant and are subject to a conditional borrowing base measured on a trailing three-month net revenue basis, which begins with the financial reporting for the period ending June 30, 2023. The lender also has the ability to call debt based on a material adverse change clause, which is subjectively defined. As of June 30, 2023, we are in compliance with the minimum cash covenant and the conditional borrowing base requirements. If we do not maintain unrestricted cash equal to at least 35% of the outstanding or do not comply with the conditional borrowing base requirements or the subjective acceleration clauses are triggered under the agreement, then the lender may call the debt, resulting in us immediately needing additional funds.

To date, we have funded our operations primarily through proceeds from our initial public offering, our follow-on stock offerings, our Loan Agreement with Hercules, and proceeds from our license agreements. Under our licensing arrangements, we are eligible to receive certain development and sales-based milestones. Our ability to earn these milestones and the timing of achieving these milestones is primarily dependent upon the outcome of the licensee’s activities and are uncertain at this time.

Shelf registration statement

On July 2, 2021, we filed an automatically effective shelf registration statement (the “2021 Form S-3”) with the Securities and Exchange Commission (the “SEC”). Each issuance under the shelf registration statement would have required the filing of a prospectus supplement identifying the amount and terms of securities to be issued. The 2021 Form S-3 did not limit the amount of securities that could have been issued thereunder.

At the time of the filing of our Annual Report on Form 10-K for the year ended December 31, 2021 filed with the SEC on February 23, 2022, we no longer qualified as a “well-known seasoned issuer” as such term is defined in Rule 405 under the Securities Act of 1933, as amended. As a result, in February 2022, we amended the 2021 Form S-3 to register for sale up to $300.0 million of any combination of our common stock, preferred stock, debt securities, warrants, rights and/or units from time to time and at prices and on terms that we may determine. The 2021 Form S-3, as amended, will remain in effect for up to three years from the date it originally became effective, which was July 2, 2021.

At-the-market offerings

In connection with the 2021 Form S-3, as amended, we entered into a sales agreement for “at the market offerings” with Cowen and Company, LLC ("Cowen") acting as our agent (the "2022 Sales Agreement"), which allows us to issue and sell shares of common stock pursuant to the amended 2021 Form S-3 for total gross sales proceeds of up to $100.0 million from time to time through Cowen.

As of the date hereof, we have not sold any shares of common stock or other securities under the 2022 Sales Agreement.

Equity Offering

On November 17, 2022, we entered into an underwriting agreement related to a public offering of 7,700,000 shares of our common stock at a public offering price of $6.50 per share less the underwriting discounts and commissions, pursuant to the 2021 Form S-3, as amended. We received approximately $50.1 million in gross proceeds from this offering, before deducting underwriting discounts and commissions and offering expenses. The offering closed on November 22, 2022. In addition, 873,353 shares of common stock were issued upon exercise by the underwriters at their option to purchase additional shares at the same offering price, which closed on December 20, 2022. The gross proceeds from the offering of the aggregate of 8,573,353 shares of our common stock were $55.7 million and net proceeds of $52.0 million, after deducting underwriting discounts and commissions and other offering expenses payable by us.

Loan and Security Agreement

On May 29, 2020, we entered into a loan and security agreement with Hercules (the "Loan Agreement") under which they agreed to lend us up to $100.0 million, to be made available in a series of tranches, subject to specified conditions. We borrowed $20.0 million at loan closing. The term of the loan is approximately 48 months, with a maturity date of June 1, 2024. No principal payments were due during an interest-only period, commencing on the initial borrowing date and continuing through June 1, 2022. The interest only period could be extended through January 1, 2023 upon satisfaction of certain milestones. Following the interest only period, we agreed to repay the principal balance and interest of the advances in equal monthly installments through June 1, 2024.

On March 31, 2021, we entered into a First Amendment to Loan and Security Agreement (the “First Amendment”) with Hercules whereby we drew the remaining $10.0 million of the first tranche and the interest rate and financial covenants were amended. Unless loan advances exceeded $40.0 million, no financial covenants were required.

On November 1, 2021, we entered into a Second Amendment to the Loan and Security Agreement (the "Second Amendment") with Hercules under which Hercules agreed to lend us up to $150.0 million, to be made available in a series of tranches, subject to certain terms and conditions. The first tranche was increased to $100.0 million. At close of the Second Amendment, we borrowed an additional $45.0 million from the first tranche. We had the right to request that Hercules make the remaining $25.0 million term loan advances under the first tranche to us by September 15, 2022, which we did not exercise. No principal payments are due during an interest-only period, commencing on the close of the Second Amendment and continuing through December 1, 2024. The interest only period may be extended through December 1, 2025, in quarterly increments, subject to compliance with covenants of the Second Amendment. Following the interest only period, we agreed to repay the principal balance and interest of the advances in equal monthly installments through the maturity date of November 1, 2026.

On June 24, 2022, we entered into a Third Amendment to Loan and Security Agreement (the “Third Amendment”) with Hercules which extended the time for drawing the remainder of the first tranche advance of up to $25.0 million from September 15, 2022 to December 31, 2022, which we did not exercise. The Third Amendment also added a minimum cash covenant whereby we must maintain unrestricted cash equal to at least 50% of the outstanding debt, and such percentage shall decrease upon us achieving specified net product revenue of COSELA. It further provides for a minimum revenue covenant that, beginning August 15, 2022, with the reporting of the financial results for the second fiscal quarter ended June 30, 2022, and tested monthly, we must have achieved net product revenue of COSELA of at least 80% of the amounts projected in our forecast. Testing of the minimum revenue covenant shall be waived at any time in which either (a) our market capitalization exceeds $750.0 million and we maintain unrestricted cash equal to at least 50% of the total amounts funded, or (b) we maintain unrestricted cash equal to at least 100% of the total amounts funded.

On November 1, 2022, we entered into a Fourth Amendment to Loan and Security Agreement (the “Fourth Amendment”) with Hercules. The Fourth Amendment extended the time for drawing the Tranche 1D Advance (as defined in the Loan Agreement) of up to $25.0 million from December 31, 2022 to June 30, 2023. The Fourth Amendment continues to provide for a minimum revenue covenant, tested monthly, where we must achieve net product revenue of COSELA of at least 80% of the amounts projected in our forecast. The Fourth Amendment also amended the minimum cash covenant such that if the outstanding debt is less than or equal to $75.0 million, we must maintain unrestricted cash equal to at least 65% of the outstanding debt in addition to meeting the required revenue covenant. In addition, if the outstanding debt is greater than $75.0 million, we must maintain unrestricted cash equal to at least 70% of the outstanding debt while meeting the revenue covenant. If we achieve the specified net revenue of COSELA, the cash percentage will decrease to 45% of the outstanding debt. Testing of the minimum revenue covenant shall be waived at any time in which either (a) our market capitalization exceeds $750.0 million and we maintain unrestricted cash equal to at least 50% of the total amounts funded, or (b) we maintain unrestricted cash equal to at least 100% of the total amounts funded. The Fourth Amendment also re-set the prepayment premiums associated with any prepayment of the loans under the Loan Agreement.

On June 6, 2023, we entered into a Fifth Amendment to Loan and Security Agreement (the "Fifth Amendment") with Hercules, under which Hercules agreed to lend us up to $75.0 million, subject to specified conditions. In conjunction with the closing of the Fifth Amendment, we repaid $25.0 million of the outstanding debt such that the total loan amount outstanding upon closing of the Fifth Amendment is $50.0 million. The Fifth Amendment eliminated advances under Tranches 2 and 3 and increased the advance available under Tranche 4 from $15.0 million to $25.0 million and extended the time for drawing the Tranche 4 Advance (as defined in the Loan and Security Agreement) from June 30, 2024 to December 15, 2024. The Fifth Amendment adjusted the minimum cash covenant such that we must maintain unrestricted cash equal to at least 35% of the outstanding debt at all times. The Fifth Amendment removed the existing minimum revenue covenant and provided for a conditional borrowing base limit such that, beginning with the financial reporting for the period ending June 30, 2023, and tested monthly, our debt outstanding shall not exceed certain thresholds of trailing three months net product revenue of COSELA.

Hercules also has the ability to call debt based on a material adverse change clause, which is subjectively defined. If we are not in compliance with the minimum cash covenant, conditional borrowing base requirements, or the subjective acceleration clauses are triggered under the agreement, then Hercules may call the debt resulting in us immediately needing additional funds. We have determined that subjective acceleration under the material adverse events clause included in the Loan Agreement is not probable and, therefore, have classified the outstanding principal amount in long-term liabilities based on the timing of scheduled principal payments. As of June 30, 2023, and as of the date of the issuance of these financial statements, we were not in default under the Loan Agreement as we remained in compliance with the minimum cash covenant, the conditional borrowing base requirements, and have not been notified of an event of default by the lender under the Loan Agreement.

Genor License Agreement

On June 15, 2020, we entered into an exclusive license agreement with Genor for the development and commercialization of lerociclib in the Genor Territory. Under the license agreement, we granted to Genor an exclusive, royalty-bearing, non-transferable license, with the right to grant sublicenses, to develop, obtain, hold and maintain regulatory approvals for, and commercialize lerociclib, in the Genor Territory.

Under the license agreement, Genor agreed to pay us a non-refundable, upfront cash payment of $6.0 million with the potential to pay an additional $40.0 million upon reaching certain development and commercial milestones. In addition, Genor will pay us tiered royalties ranging from high single to low double-digits based on annual net sales of lerociclib in the Genor Territory. The upfront cash payment was received in July 2020. In September 2020, we transferred to Genor the related technology and know-how that is necessary to develop, seek regulatory approval for, and commercialize lerociclib in the Genor Territory. Genor will be responsible for the development of the product in the Genor Territory and will be responsible, at its sole cost, for obtaining supply of lerociclib to meet its development, regulatory approval, and commercialization obligations under the agreement. We did not recognize any revenue related to development milestones during the six months ended June 30, 2023.

EQRx License Agreement

On July 22, 2020, we entered into an exclusive license agreement with EQRx for the development and commercialization of lerociclib in the EQRx Territory. Under the license agreement, we granted to EQRx an exclusive, royalty-bearing, non-transferable license, with the right to grant sublicenses, to develop, obtain, hold and maintain regulatory approvals for, and commercialize lerociclib in the EQRx Territory.

Under the license agreement, EQRx agreed to pay us a non-refundable, upfront cash payment of $20.0 million with the potential to pay an additional $290.0 million upon reaching certain development and commercial milestones. In addition, EQRx agreed to pay us tiered royalties ranging from mid-single digits to mid-teens based on annual net sales of lerociclib in the EQRx Territory. EQRx agreed to be responsible for the development of the product in the EQRx Territory. We agreed to continue until completion, as the clinical trial sponsor, our two primary clinical trials at EQRx's sole cost and expense. EQRx agreed to reimburse us for all of its out-of-pocket costs incurred after the effective date of the license agreement in connection with these clinical trials. We agreed to invoice EQRx within 30 days following the end of each quarter, and EQRx agreed to pay within 30 days after its receipt of such invoice. On August 1, 2023, we received formal notice from EQRx of their intent to terminate, as part of their proposed acquisition by Revolution Medicines, Inc., the lerociclib license agreement and to revert the lerociclib product rights back to us. We are currently assessing next steps, but do not expect to receive any further milestone payments or future royalties from EQRx as a result of the termination.

During the six months ended June 30, 2023, we recognized revenue of $0.8 million for the reimbursement of patent and clinical trial costs. We did not recognize any revenue related to development milestones during the six months ended June 30, 2023.

Simcere License Agreement

On August 3, 2020, we entered into an exclusive license agreement with Simcere for the development and commercialization of trilaciclib in all indications in the Simcere Territory. Under the license agreement, we granted to Simcere an exclusive, royalty-bearing, non-transferable license, with the right to grant sublicenses, to develop, obtain, hold and maintain regulatory approvals for, and commercialize trilaciclib in the Simcere Territory.

Under the license agreement, Simcere made a non-refundable, upfront cash payment of $14.0 million in September 2020. In return, we furnished to Simcere the related technology and know-how that is necessary to develop, seek regulatory approval for, and commercialize trilaciclib in the Simcere Territory. Simcere agreed to be responsible for all development and commercialization costs in its territory and may be able to participate in global clinical trials as agreed upon by the companies. In addition to the upfront payment, through December 31, 2022, we received $22.0 million in milestone payments.

On April 28, 2023, we amended the license agreement with Simcere, whereby we received a one-time, non-refundable payment of $30.0 million in exchange for the relief of future royalty payments from the sale of COSELA in Greater China. In addition, the milestone payments under the license agreement have been adjusted such that we will be eligible to receive a $5.0 million payment upon Simcere's filing an NDA of TNBC in mainland China and a $13.0 million payment upon Simcere receiving regulatory approval of TNBC in mainland China. Under the amended license agreement, Simcere is not responsible for any sales milestone payments or any royalties accrued after April 28, 2023. Following the amendment, we continue to own all the global development and commercial rights to trilaciclib, excluding Greater China.

During the six months ended June 30, 2023, we recognized $30.0 million in revenue from the one-time payment for the relief of future royalty payments, $2.0 million in supply and manufacturing services, $0.6 million in royalty revenue, and $0.2 million in patent and clinical trial reimbursable costs.

Cash flows

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

	Six Months Ended June 30,		Change
	2023	2022	$
	(in thousands)		
Net cash used in operating activities	$ (14,968)	$ (76,741)	$ 61,773
Net cash provided by/(used in) investing activities	3,256	(506)	3,762
Net cash (used in)/provided by financing activities	(26,968)	18	(26,986)
Net change in cash, cash equivalents, and restricted cash	$ (38,680)	$ (77,229)	$ 38,549

Net cash used in operating activities

During the six months ended June 30, 2023, net cash used in operating activities was $15.0 million, which consisted of a net loss of $18.9 million, accretion of discount on available for sale securities of $1.0 million, and a decrease in net operating assets and liabilities of $4.4 million, partially offset by non-cash stock compensation expense of $7.6 million, $0.3 million of depreciation expense, $0.8 million in amortization of debt issuance costs, and $0.6 million of non-cash interest expense.

During the six months ended June 30, 2022, net cash used in operating activities was $76.7 million which consisted primarily of a net loss of $88.6 million and a decrease in net operating assets and liabilities of $1.8 million, offset by non-cash stock compensation expense of $11.4 million, $0.3 million of depreciation expense, $1.1 million in amortization of debt issuance costs, $0.6 million of non-cash interest expense, $0.3 million in non-cash equity interest.

Net cash provided by/(used in) investing activities

During the six months ended June 30, 2023, net cash provided by investing activities was $3.3 million, due to marketable securities maturities of $68.5 million, offset by purchases of $65.2 million.

During the six months ended June 30, 2022, net cash used in investing activities was $0.5 million due to the purchase of manufacturing equipment placed in service during the quarter ended June 30, 2022.

Net cash (used in)/provided by financing activities

During the six months ended June 30, 2023, net cash used in financing activities was $27.0 million, which consisted of $26.7 million for repayment of debt and proportionate amount of the end of term fee, and $0.3 million in payment of public offering costs.

During the six months ended June 30, 2022, net cash provided by financing activities was $18.0 thousand, which consisted of proceeds from the exercise of stock options.

Operating capital requirements and plan of operations

To date, we have generated limited revenue from product sales. We expect our expenses to increase as we continue the development of and seek additional regulatory approvals for trilaciclib, and continue to commercialize COSELA. As described in the risk factors included in the 2022 Form 10-K, we are subject to all of the risks inherent in the development of new products, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business.

We believe that our existing cash and cash equivalents and marketable securities will be sufficient to fund our projected cash needs for at least the next 12 months from the date of issuance of the financial statements.

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 agreements 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 and the terms of such in-licenses;
- the costs of commercialization activities, including product sales, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval;
- the potential benefit of the NMPA's conditional approval for our products and product candidates and our ability to provide comprehensive clinical data from post-approval clinical research;
- revenue received from commercial sales of our product candidates;

- our ability to meet the required financial covenants under our loan agreement;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims; and
- global economic uncertainty, rising inflation, rising interest rates, market disruptions and volatility in commodity prices.

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. Other than amounts included under the terms of our licensing arrangements and the Loan Agreement with Hercules, which are subject to certain conditions, we do not have any committed external source of funds. We may be bound by ongoing compliance with financial covenants under the Loan Agreement with Hercules. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders' ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through additional collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Contractual Obligations, Commitments and Contingencies

There have been no material changes to our contractual obligations during the current period from those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2022.

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 2022 Form 10-K. We have updated Note 2 to the condensed financial statements to include disclosure related to our critical accounting policy and significant judgment related to the classification of debt.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies and adopted by the Company as of the specified effective date. Unless otherwise discussed in Note 2, we believe the impact of recently issued standards that are not yet effective will not have a material impact on our financial position or results of operations upon adoption.

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 $55.9 million and marketable securities of $48.3 million as of June 30, 2023. Cash and cash equivalents consist of deposits in banks, including checking accounts and money market accounts. Marketable securities consist of U.S. Treasury bills. 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 also have exposure to market risk on our loan agreement with Hercules. Our loan agreement (as such is amended from time to time) accrues interest from its date of issue at a variable interest rate equal to the greater of either (i) (a) the prime rate as reported in The Wall Street Journal, plus (b) 5.65%, and (ii) 9.15%. As of June 30, 2023, $50.0 million of principal was outstanding under the Loan Agreement with Hercules.

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 six months ended June 30, 2023.

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 June 30, 2023. 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 of 1934 is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial 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 judgement in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of June 30, 2023, our principal executive officer and our principal financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Controls Over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the three months ended June 30, 2023 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 "Item 1A. Risk Factors" of our 2022 Form 10-K, which could materially affect our business, financial condition or future results before investing in our common stock. The information presented below updates, and should be read in conjunction with, the risk factors and information disclosed in our Form 10-K, as updated in our quarterly reports. Except as presented below, there have been no material changes in the risk factors set forth in Part II, Item 1A of our 2022 Form 10-K.

Any significant cost increases or shortages in the supply of chemotherapy products containing platinum/etoposide or topotecan could have an adverse impact on our customers' abilities to order and administer COSELA, our lead product approved by the FDA to decrease the incidence of chemotherapy-induced myelosuppression in adult patients treated with a platinum/etoposide-containing regimen or topotecan-containing regimen for ES-SCLC, and as a result, could impact the sales of COSELA.

As COSELA's efficacy relies on its administration in conjunction with specific chemotherapy regimens containing platinum/etoposide or topotecan, any significant cost increases or shortages in the supply of these chemotherapy products could have an adverse impact on our customers' abilities to order and administer COSELA, and as a result, could impact the sales of COSELA.

If the manufacturers encounter difficulties in the production of these chemotherapy products resulting from any events affecting supply chain disruptions or manufacturing capabilities, including the factors mentioned above, or if our customers encounter difficulties in obtaining an adequate supply of these necessary chemotherapy products due to significant price fluctuations or shortages, our customers may reduce orders of COSELA. Such disruptions could result in potential delays or disruptions in the treatment of ES-SCLC, impacting patient outcomes and treatment timelines.

As of the date of this report, the FDA has reported shortages in the supply of certain platinum-based chemotherapy products, including Cisplatin (since February 2023) and Carboplatin (since April 2023). We are actively monitoring any issues related to the availability of these chemotherapy products and their potential impact on the use of COSELA. However, there can be no assurance that we will be able to mitigate the impact of the drug shortages. Any significant disruption in the supply chain or demand for these chemotherapy products could adversely impact our sales of COSELA and therefore adversely affect our business, results of operations, and financial conditions.

Item 6. Exhibits

Exhibit Number	Description
10.1**+	Fifth Amendment to Loan and Security Agreement by and between G1 Therapeutics, Inc. and Hercules Capital, Inc., dated June 6, 2023, filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on June 9, 2023 (File No. 001-38096), and incorporated herein by reference.
10.2*†	G1 Therapeutics, Inc. Deferred Compensation Plan for Non-Employee Directors
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. § 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. § 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance 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)XBRL Taxonomy Extension Presentation Linkbase Document

* Management contract or compensatory plan or arrangement.

† Filed herewith.

** Certain confidential portions of this Exhibit were omitted by means of marking such portions with brackets ("[***]") because the identified confidential portions (i) are not material and (ii) would be competitively harmful if publicly disclosed.

+ Certain of the exhibits and schedules to this Exhibit have been omitted in accordance with Regulation S-K Item 601(a)(5). The Registrant agrees to furnish a copy of all omitted exhibits and schedules to the SEC upon its request

SIGNATURES

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

G1 THERAPEUTICS, INC.

Date: August 2, 2023

By: */s/ John W. Umstead V*

John W. Umstead V

Chief Financial Officer (On behalf of the Registrant and as Principal Financial and Accounting Officer)

G1 THERAPEUTICS, INC.
DEFERRED COMPENSATION PLAN
FOR NON-EMPLOYEE DIRECTORS
Effective as of May 17, 2023

1. Plan

The Board of Directors (the "Board") of G1 Therapeutics, Inc. (the "Company") hereby adopts this G1 Therapeutics, Inc. Deferred Compensation Plan for Non-Employee Directors (the "Plan").

2. Effective Date and Plan Year

The Plan is effective May 17, 2023 (the "Effective Date"). The Plan Year shall be from January 1 through December 31 each year. The Initial Plan Year shall be from the Effective Date through December 31, 2023.

3. Purpose of the Plan

The Plan's purpose is to enable non-employee directors of the Company (each a "Non-Employee Director") to elect to defer the receipt of shares that vest in accordance with the terms of Restricted Stock Units ("RSUs") granted under the G1 Therapeutics, Inc. Amended and Restated 2017 Employee, Director and Consultant Equity Incentive Plan (the "Equity Plan") for service as a Non-Employee Director (the "Vested RSUs").

4. Participants

Any Non-Employee Director may elect to become a participant (each a "Participant") under the Plan by filing an election in the form prescribed by the Board.

5. Compensation Eligible for Deferral

Any Non-Employee Director may elect, in accordance with Section 6 of this Plan, to defer annually the receipt of shares underlying Vested RSUs with respect to RSUs granted in any calendar year for services to the Company as a Non-Employee Director ("Deferred Compensation"). Compensation paid to a member of the Board for business or professional services rendered to the Company in any capacity other than as a Non-Employee Director shall not be treated as Deferred Compensation.

6. Election Form

Each Non-Employee Director shall be entitled to file with the Plan Administrator (defined below) prior to December 31 of each Plan Year a form prescribed by the Board so as to make an election under the Plan effective for the following Plan Year. Pursuant to such election, a Non-Employee Director may elect to defer receipt of shares underlying Vested RSUs with respect to RSUs granted in the following Plan Year.

Notwithstanding the foregoing, elections with respect to RSUs granted in the Initial Plan Year may be filed by a Non-Employee Director within 30 days of the Effective Date.

A Participant's election regarding Deferred Compensation shall be irrevocable with respect to Deferred Compensation deferred in any one year. A Non-Employee Director must make a new election with respect to Deferred Compensation prior to the start of each Plan Year. An election with respect to Deferred Compensation in effect for a prior Plan Year will not remain in effect for any subsequent Plan Year.

7. Participant Deferral Accounts

Participant Deferral Accounts (the "Accounts") will be established by the Company for each Non-Employee Director electing to defer Vested RSUs as Deferred Compensation. The Accounts shall be credited as of the last day of the calendar month with Deferred Compensation in the amount of Company's common stock ("Shares") resulting from the vesting of a granted RSU subject to a properly executed deferral election. The Shares for purposes of the Plan shall be treasury shares of the Company otherwise reserved for issuance under the Equity Plan.

In the event of any change in the outstanding shares of common stock of the Company by reason of any stock dividend or split, recapitalization, merger, consolidation, spin-off, reorganization, combination or exchange of shares or other similar corporate change, then if the Plan Administrator shall determine, in its sole discretion, that such change equitably requires an adjustment in the number of Shares then held in Accounts, such adjustments shall be made by the Plan Administrator and shall be conclusive and binding for all purposes of the Plan.

8. Settlement of Participant Deferral Accounts

A Participant shall receive distribution of their Accounts within thirty (30) days of "Separation from Service" (within the meaning of Section 409A of the Internal Revenue Code (the "Code")) as a Non-Employee Director for any reason.

Notwithstanding the above, the Deferred Compensation will be settled through distribution of Shares in a lump sum on the earlier to occur of (i) a date within sixty (60) days following a Participant's death or disability (defined in accordance with Section 409A of the Code) and (ii) immediately prior to a "Change of Control." For purposes of this Plan, a Change of Control means (i) the Company's merger or consolidation with or into another entity such that the stockholders of the Company prior to such transaction do not or are not expected to own a majority of the voting stock of the surviving entity (or the ultimate parent of such entity), (ii) the sale or other disposition of all or substantially all of the assets of the Company, or (iii) the sale or other disposition of greater than fifty percent (50%) of the then-outstanding voting stock of the Company by the holders thereof to one or more persons or entities who are not then stockholders of the Company, provided, that such Change of Control constitutes a change in ownership or control of the Company, or a change in ownership of the Company's assets in accordance with Section 409A of the Code.

All shares of Company stock distributed pursuant to this Plan which are not registered with the Securities and Exchange Commission shall bear an appropriate restrictive legend as shall be determined by the Company's securities counsel.

9. Distributions to a Specified Employee

If the Plan Administrator (defined below) considers a Participant to be one of the Company's Specified Employees, distribution of the Shares shall not be made until the earlier of (i) six months following the Participant's Separation from Service, as defined under Code section 409A, or (ii) the date of the Participant's death. "Specified Employee" shall mean a key employee (as defined in Code Section 416(i) without regard to paragraph (5) thereof) of a corporation any stock in which is publicly traded on an established securities market or otherwise.

10. Beneficiary

The Participant shall have the right, at any time, to designate any person or persons as beneficiary (both primary and contingent) to whom payment under the Plan shall be made in the event of the Participant's death. The beneficiary designation shall be effective when it is submitted to and acknowledged by the Plan Administrator during the Participant's lifetime in the format prescribed by the Plan Administrator. If the Participant fails to designate a beneficiary as provided above, or if every person designated as beneficiary predeceases the Participant or dies prior to complete distribution of the Participant's benefits, then the Plan Administrator shall direct the distribution of such benefits to the Participant's estate.

11. Participant's Rights Unsecured

The Plan is intended to constitute an unfunded obligation of the Company, and the Participant shall rely solely on the unsecured promise of the Company for payment hereunder. Nothing contained in the Plan shall give the Participant any rights that are greater than those of a general unsecured creditor of the Company. The Company may authorize the creation of a trust or other arrangements to meet the Company's obligations under the Plan, which trusts or other arrangements shall be consistent with the unfunded status of the Plan. The Deferred Compensation may not be assigned, transferred, encumbered, or otherwise disposed of by the Participant until the same shall be distributed to such Participant.

12. Plan Administrator

The Plan Administrator shall be the Compensation Committee of the Board. The Plan Administrator shall have the sole power and discretion to interpret the Plan (including ambiguous provisions thereof), determine benefits which are payable to Participants, make all final decisions with respect to the rights of Participants hereunder and, to the extent necessary to perform the foregoing powers, make determinations of fact. The Plan Administrator shall at least annually provide each Participant with a statement of his or her account.

13. Amendments to the Plan

The Board may amend the Plan at any time, without the consent of the Participants or their beneficiaries, provided, however, that no amendment shall divest any Participant or beneficiary of rights to which they would have been entitled if the Plan had been terminated on the effective date of such amendment.

14. Termination of Plan

The Board may terminate the Plan at any time. If not so terminated, the Plan will automatically terminate on June 30, 2033. Upon termination of the Plan, distributions in respect of units in Accounts as of the date of termination shall be made in the manner and at the time heretofore prescribed or, alternatively, the Board may provide the Participant or beneficiaries with benefits under a substitute plan which shall not be less than the benefits which would have been distributed in a full and complete distribution of all credits in Accounts as of the date of Plan termination; provided, however, that the terms of such substitute plan are in compliance with Section 409A of the Code and the substitution of benefits does not result in an acceleration of the inclusion in income of any benefits under the Plan.

15. Expenses

All costs of administration of the Plan will be paid by the Company.

Exhibit 31.1

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

I, John E. Bailey, Jr., 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: August 2, 2023

By: /s/ *John E. Bailey, Jr.*

John E. Bailey, Jr.
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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

I, John W. Umstead V, 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: August 2, 2023

By: /s/ *John W. Umstead V*

John W. Umstead V
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 June 30, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned certifies, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: August 2, 2023

/s/ *John E. Bailey, Jr.*

John E. Bailey, Jr.
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 June 30, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned certifies, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: August 2, 2023

/s/ *John W. Umstead V*

John W. Umstead V
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.