CHIMERIX INC Form 10-Q August 06, 2015

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

FORM 10-Q (Mark One)

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

For the quarterly period ended June 30, 2015

OR

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

For the transition period from to

Commission file number: 001-35867

CHIMERIX, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware 33-0903395

(State or Other Jurisdiction of Incorporation or (I.R.S. Employer Identification No.)

Organization)

2505 Meridian Parkway, Suite 340

Durham, North Carolina 27713 (Address of Principal Executive Offices) (Zip Code)

(919) 806-1074

(Registrant's Telephone Number, Including Area Code)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ý No o

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

Large accelerated filer o

Accelerated filer x

Non-accelerated filer o

Smaller reporting company o

(Do not check if a smaller reporting company)

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

As of July 30, 2015, the number of outstanding shares of the registrant's common stock, par value \$0.001 per share, was 46,068,592.

CHIMERIX, INC.

FORM 10-Q FOR THE QUARTER ENDED JUNE 30, 2015

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PART I - FINANCIAL INFORMATION

ITEM 1. CONSOLIDATED FINANCIAL STATEMENTS

CHIMERIX, INC.
CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share data)
(unaudited)

(unaudited)	June 30, 2015	December 31, 2014
ASSETS		
Current assets:		
Cash and cash equivalents	\$127,776	\$128,462
Short-term investments, available-for-sale	130,555	106,114
Accounts receivable	2,311	106
Prepaid expenses and other current assets	8,651	2,775
Total current assets	269,293	237,457
Long-term investments	150,139	52,973
Property and equipment, net of accumulated depreciation	1,996	1,310
Other long-term assets	80	138
Total assets	\$421,508	\$291,878
LIABILITIES AND STOCKHOLDERS' EQUITY Current liabilities:		
Accounts payable	\$9,819	\$5,938
Accrued liabilities	10,758	6,833
Loan payable, net	1,484	4,296
Total current liabilities	22,061	17,067
Long-term liabilities	134	175
Total liabilities	22,195	17,242
Commitments and contingencies	_	_
Stockholders' equity:		
Preferred stock, \$0.001 par value, 10,000,000 shares authorized at June 30, 2015 and		
December 31, 2014; no shares issued and outstanding as of June 30, 2015 and		_
December 31, 2014		
Common stock, \$0.001 par value, 200,000,000 shares authorized at June 30, 2015 and		
December 31, 2014; 45,847,032 and 41,031,770 shares issued and outstanding as of	46	41
June 30, 2015 and December 31, 2014, respectively		
Additional paid-in capital	666,586	496,602
Accumulated other comprehensive gain, net	1,803	35
Accumulated deficit		(222,042)
Total stockholders' equity	399,313	274,636
Total liabilities and stockholders' equity	\$421,508	\$291,878

The accompanying notes are an integral part of the consolidated financial statements.

CHIMERIX, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS (in thousands, except share and per share data) (unaudited)

	Three Months Ended June 30,		,	Six Months Ended June 30,		led June 30,		
	2015		2014		2015		2014	
Revenues:								
Contract revenue	\$2,598		\$919		\$3,833		\$1,699	
Collaboration and licensing revenue	1,545				1,548			
Total revenues	4,143		919		5,381		1,699	
Operating expenses:								
Research and development	21,762		8,092		39,205		16,384	
General and administrative	7,332		4,423		13,455		7,095	
Total operating expenses	29,094		12,515		52,660		23,479	
Loss from operations	(24,951)	(11,596)	(47,279)	(21,780)
Other income (expense):								
Interest income (expense), net	136		(138)	199		(334)
Net loss	(24,815)	(11,734)	(47,080)	(22,114)
Other comprehensive loss:								
Unrealized gain (loss) on investments, net	1,144		12		1,769		(20)
Comprehensive loss	\$(23,671)	\$(11,722)	\$(45,311)	\$(22,134)
Per share information:								
Net loss, basic and diluted	\$(0.59)	\$(0.39)	\$(1.13)	\$(0.78)
Weighted-average shares outstanding, basic and diluted	42,079,716		30,111,380		41,614,494		28,446,074	

The accompanying notes are an integral part of the consolidated financial statements.

CHIMERIX, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands) (unaudited)

(unaudited)			
	Six Months Ended June 30,		
	2015	2014	
Cash flows from operating activities:			
Net loss	\$(47,080) \$(22,114)
Adjustments to reconcile net loss to net cash used in operating activities:		0.7	
Depreciation of property and equipment	264	95	
Amortization of debt costs	49	83	
Amortization of premium/discount on investments	783	385	
Share-based compensation	5,203	1,415	
Amortization of deferred lease obligation	(15) —	
Changes in operating assets and liabilities:			
Accounts receivable	(2,205) (40)
Prepaid expenses and other assets	(5,828) (489)
Accounts payable and accrued liabilities	6,972	1,912	
Net cash used in operating activities	(41,857) (18,753)
Cash flows from investing activities:			
Purchase of property and equipment	(950) (226)
Purchase of short-term investments	(33,669) (88,641)
Purchase of long-term investments	(147,086) —	
Sales of short-term investments	1,003	_	
Maturities of short-term investments	60,005	7,240	
Net cash used in investing activities	(120,697) (81,627)
Cash flows from financing activities:			
Proceeds from exercise of stock options	1,445	781	
Proceeds from employee stock purchase plan stock purchases	461	229	
Proceeds from exercise of warrants	1,000	_	
Proceeds from public offering, net of offering costs	161,880	111,845	
Repayment of debt	(2,850) (2,850)
Payments for deferred financing costs	(68) —	
Net cash provided by financing activities	161,868	110,005	
Net (decrease) increase in cash and cash equivalents	(686) 9,625	
Cash and cash equivalents:	`		
Beginning of period	128,462	109,976	
End of period	\$127,776	\$119,601	
•	,	,	
Supplemental disclosure cash flow information:			
Cash paid for interest	\$132	\$370	
1	• -	•	

The accompanying notes are an integral part of the consolidated financial statements.

CHIMERIX, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (unaudited)

Note 1. The Business and Summary of Significant Accounting Policies

Description of Business

Chimerix, Inc. (the Company) is a biopharmaceutical company dedicated to discovering, developing and commercializing novel, oral antivirals to address unmet medical needs. The Company was founded in 2000 based on the promise of its proprietary lipid conjugate technology to unlock the potential of some of the most potent broad-spectrum antivirals by enhancing their antiviral activity and safety profiles in convenient, orally administered dosing regimens. Based on the Company's proprietary lipid conjugate technology, its lead compound, brincidofovir (BCV or CMX001), is in Phase 3 clinical development; in addition, the Company has an active discovery program focusing on viral targets for which limited or no therapies are currently available or where current therapies have significant liabilities.

Basis of Presentation

The accompanying unaudited consolidated financial statements include the accounts of the Company and its wholly owned subsidiary and have been prepared in accordance with U.S. generally accepted accounting principles (GAAP), for interim financial information, the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements and should be read in conjunction with the Company's audited financial statements and notes thereto included in its Annual Report on Form 10-K for the year ended December 31, 2014. In the opinion of the Company's management, all adjustments, consisting of normal recurring adjustments, necessary for a fair presentation of its financial position, operating results and cash flows for the periods presented have been included. Operating results for the three and six months ended June 30, 2015 are not necessarily indicative of the results that may be expected for the full year, for any other interim period or for any future year.

Fair Value of Financial Instruments

The carrying amounts of certain financial instruments, including accounts receivable, accounts payable and accrued expenses approximate their fair values due to the short-term nature of such instruments. The carrying amount of borrowings under loans payable approximates its fair value based on the determination that the stated rate on such loans payable is consistent with current interest rates for similar borrowing arrangements available to the Company.

For assets and liabilities recorded at fair value, it is the Company's policy to maximize the use of observable inputs and minimize the use of unobservable inputs when developing fair value measurements, in accordance with the fair value hierarchy. Fair value measurements for assets and liabilities where there exists limited or no observable market data are based primarily upon estimates and are often calculated based on the economic and competitive environment, the characteristics of the asset or liability and other factors. Therefore, fair value measurements cannot be determined with precision and may not be realized in an actual sale or immediate settlement of the asset or liability. Additionally, there may be inherent weaknesses in any calculation technique and changes in the underlying assumptions used, including discount rates and estimates of future cash flows, could significantly affect the calculated current or future fair values. The Company utilizes fair value measurements to record fair value adjustments to certain assets and liabilities and to determine fair value disclosures.

The Company groups assets and liabilities at fair value in three levels, based on the markets in which the assets and liabilities are traded and the reliability of the assumptions used to determine fair value. An adjustment to the pricing method used within either Level 1 or Level 2 inputs could generate a fair value measurement that effectively falls in a lower level in the hierarchy. These levels are:

Level 1 — Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access.

Level 2 — Valuations based on quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active, and models for which all significant inputs are observable, either directly or indirectly.

Level 3 — Valuations based on inputs that are unobservable and significant to the overall fair value measurement.

The determination of where an asset or liability falls in the hierarchy requires significant judgment. The Company evaluates hierarchy disclosures and, based on various factors, it is possible that an asset or liability may be classified differently from period to period. However, the Company expects that changes in classification between levels will be rare.

At June 30, 2015 and December 31, 2014, the Company had cash equivalents, consisting of money market accounts, and short-term and long-term investments consisting of U.S. Treasury securities, whose value is based on using quoted market prices. Accordingly, these securities are classified as Level 1.

At June 30, 2015 and December 31, 2014, the Company had cash equivalents, short-term investments and long-term investments comprised of corporate bonds, commercial paper and brokered certificates of deposit for which quoted prices are not available that are valued using independent pricing models or other model-based valuation techniques such as the present value of future cash flows, adjusted for the security's credit rating, prepayment assumptions and other factors such as credit loss assumptions. Accordingly, these securities are classified as Level 2.

The Company's preferred stock investment in ContraVir Pharmaceuticals (NASDAQ: CTRV) (ContraVir) is categorized as Level 3 as there are significant unobservable inputs. The valuation of the investment at June 30, 2015 and December 31, 2014 was calculated on an as if converted to common share basis with a discount for lack of marketability applied due to the 18 month restriction from the date of the investment on selling the converted common shares. An option pricing model was used to determine the discount for lack of marketability of 23% and 25% at June 30, 2015 and December 31, 2014, respectively. The key unobservable inputs used in the option pricing model at June 30, 2015 were (i) exercise price - \$5.08, (ii) dividend yield - 0%, (iii) expected holding period - 0.97 years, (iv) risk-free rate - 0.28%, and (v) volatility - 65%. The key unobservable inputs used in the option pricing model at December 31, 2014 were (i) exercise price - \$2.22, (ii) dividend yield - 0%, (iii) expected holding period - 1.5 years, (iv) risk-free rate - 0.44%, and (v) volatility - 65%. The increase in valuation of the preferred stock for the three and six months ended June 30, 2015 was recorded as an unrealized gain in investment, net of tax in the Consolidated Statements of Operations and Comprehensive Loss.

There was no material re-measurement to fair value of financial assets and liabilities that are not measured at fair value on a recurring basis.

Below is a table that presents information about certain assets and liabilities measured at fair value on a recurring basis (in thousands):

	Fair Value Measu June 30, 2015	rements		
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash equivalents				
Money market funds	\$117,537	\$117,537	\$ —	\$ —
Certificates of deposit	240	_	240	_
Commercial paper	9,999		9,999	
Total cash equivalents	127,776	117,537	10,239	
Short-term investments				
Certificates of deposit	25,646	_	25,646	_
Corporate bonds	23,409	_	23,409	_
Commercial paper	3,999		3,999	
U.S. Treasury securities	73,310	73,310	_	_
Preferred stock of U.S.		,		4.404
corporation	4,191	_	_	4,191
Total short-term investments	130.555	73,310	53,054	4,191
Long-term investments	100,000	, , , , , ,	22,02.	.,
Certificates of deposit	18,261		18,261	
U.S. Treasury securities	131,878	131,878		
Total long-term investments	150,139	131,878	18,261	_
Total long-term investments Total assets	\$408,470	\$322,725	\$81,554	\$ 4,191
Total assets	\$400,470	\$322,123	\$01,334	\$ 4,191
	Fair Value Measu December 31, 201			
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash equivalents		,		
Money market funds	\$125,606	\$125,606	\$ —	\$ —
Certificates of deposit	480		480	_
Total cash equivalents	126,086	125,606	480	_
Short-term investments	,	,		
Certificates of deposit	16,981		16,981	_
Corporate bonds	69,892	_	69,892	
Commercial paper	11,240		11,240	
U.S. Treasury securities	8,000	8,000		
Total short-term investments	106,114	8,000	98,114	
Long-term investments	100,114	0,000	70,114	
Certificates of deposit	10,996		10,996	
U.S. Treasury securities	40,197	40,197		
Preferred stock of U.S.	•	70,177	-	-
corporation	1,781	_	_	1,781
corporation				

Total long-term investments	52,973	40,197	10,996	1,781
Total assets	\$285.173	\$173.803	\$109.590	\$ 1.781

Below is a table that presents a reconciliation of the beginning and ending balances of assets and liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) (in thousands):

	Fair Value
	Measurements
	(Level 3)
Preferred stock of U.S. corporation:	
Fair value at December 31, 2014	\$1,781
Fair value increase recorded in other comprehensive gain	2,410
Fair value at June 30, 2015	\$4,191

Revenue Recognition

The Company's revenues generally consist of (i) contract and grant revenue – revenue generated under federal contracts and other awarded grants, and (ii) collaboration and licensing revenue – revenue related to non-refundable upfront fees, royalties and milestone payments earned under license agreements. Revenues are recognized when the following criteria are met: (1) persuasive evidence that an arrangement exists; (2) delivery of the products and/or services has occurred; (3) the selling price is fixed or determinable; and (4) collectability is reasonably assured.

For arrangements that involve the delivery of more than one element, each product, service and/or right to use assets is evaluated to determine whether it qualifies as a separate unit of accounting. This determination is based on whether the deliverable has "stand-alone value" to the customer. The consideration that is fixed or determinable is then allocated to each separate unit of accounting based on the relative selling prices of each deliverable. The consideration allocated to each unit of accounting is recognized as the related goods and services are delivered, limited to the consideration that is not contingent upon future deliverables. If the arrangement constitutes a single unit of accounting, the revenue recognition policy must be determined for the entire arrangement and the consideration received is recognized over the period of inception through the date the last deliverable within the single unit of accounting is expected to be delivered. Revisions to the estimated period of recognition are reflected in revenue prospectively.

Non-refundable upfront fees are recorded as deferred revenue and recognized into revenue as license fees from collaborations on a straight-line basis over the estimated period of the Company's substantive performance obligations. If the Company does not have substantive performance obligations, the Company recognizes non-refundable upfront fees into revenue through the date the deliverable is satisfied. Analyzing the arrangement to identify deliverables requires the use of judgment and each deliverable may be an obligation to deliver services, a right or license to use an asset, or another performance obligation.

Milestone payments are recognized when earned, provided that (i) the milestone event is substantive; (ii) there is no ongoing performance obligation related to the achievement of the milestone earned; and (iii) it would result in additional payments. Milestone payments are considered substantive if all of the following conditions are met: the milestone payment is non-refundable; achievement of the milestone was not reasonably assured at the inception of the arrangement; substantive effort is involved to achieve the milestone; and the amount of the milestone appears reasonable in relation to the effort expended, the other milestones in the arrangement, and the related risk associated with the achievement of the milestone. Contingent based event payments the Company may receive under a license or collaboration agreement will be recognized when received.

Research and Development Prepaids and Accruals

As part of the process of preparing financial statements, the Company is required to estimate its expenses resulting from its obligation under contracts with vendors and consultants and clinical site agreements in connection with conducting clinical trials. The financial terms of these contracts are subject to negotiations which vary contract to

contract and may result in payment flows that do not match the periods over which materials or services are provided to the Company under such contracts. The Company's objective is to reflect the appropriate clinical trial expenses in its financial statements by matching those expenses with the period in which services and efforts are expended. The Company accounts for these expenses according to the progress of the trial as measured by patient progression and the timing of various aspects of the trial. Depending on amounts paid to the contract research organization and other third-party vendors as compared to actual expenses incurred, there might be a prepaid balance recorded as a prepaid asset. The Company determines accrual estimates through discussion with applicable personnel and outside service providers as to the progress or state of completion of trials, or the services completed. During the course of a clinical trial, the Company adjusts its rate of clinical trial expense recognition if actual results differ from its estimates. The Company makes estimates of its accrued expenses as of each balance sheet date in its financial statements based on facts and circumstances known at that time. Although the Company does not expect its estimates to be materially different from amounts actually incurred, its

understanding of status and timing of services performed relative to the actual status and timing of services performed may vary and may result in the Company reporting amounts that are too high or too low for any particular period. Through June 30, 2015, there had been no material adjustments to the Company's prior period estimates of accrued expenses for clinical trials. The Company's clinical trial accrual is dependent upon the timely and accurate reporting of contract research organizations and other third-party vendors.

Basic and Diluted Net Loss Per Common Share

Basic net loss per share of common stock is computed by dividing net loss by the weighted-average number of shares of common stock outstanding during the period, excluding the dilutive effects of warrants and options to purchase common stock and employee stock purchase plan rights. Diluted net loss per common share is computed by dividing net loss by the sum of the weighted-average number of shares of common stock outstanding during the period plus the potential dilutive effects of warrants and options to purchase common stock outstanding during the period calculated in accordance with the treasury stock method, but are excluded if their effect is anti-dilutive. Because the impact of these items is anti-dilutive during the periods of net loss, there was no difference between basic and diluted net loss per share of common stock for the three and six months ended June 30, 2015 and 2014.

The calculation of weighted-average diluted shares outstanding excludes the dilutive effect of warrants and options to purchase common stock and employee stock purchase plan rights, as the impact of such items are anti-dilutive during periods of net loss. Potential common shares excluded from the calculations were 1.2 million and 2.4 million for the three months ended June 30, 2015 and 2014, respectively, and 1.3 million and 2.5 million for the six months ended June 30, 2015 and 2014, respectively.

Impact of Recently Issued Accounting Standards

In June 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2014-12, "Compensation — Stock Compensation (Topic 718): Accounting for Share-Based Payments When the Terms of an Award Provide That a Performance Target Could Be Achieved after the Requisite Service Period." The amendments in this update require that a performance target that affects vesting and that could be achieved after the requisite service period should be treated as a performance condition. A reporting entity should apply existing guidance in Topic 718 as it relates to awards with performance conditions that affect vesting to account for such awards. As such, the performance target should not be reflected in estimating the grant-date fair value of the award. ASU 2014-12 is effective for annual periods and interim periods within those annual periods beginning after December 15, 2015. Earlier adoption is permitted. The Company does not expect the adoption of ASU 2014-12 to have a material impact on its consolidated financial statements.

In May 2014, the FASB issued ASU No. 2014-09, "Revenue from Contracts with Customers (Topic 606)." The ASU establishes a principles-based approach for accounting for revenue arising from contracts with customers and supersedes existing revenue recognition guidance. The ASU provides that an entity should apply a five-step approach for recognizing revenue, including (1) identify the contract with a customer; (2) identify the performance obligations in the contract; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations in the contract; and (5) recognize revenue when, or as, the entity satisfies a performance obligation. Also, the entity must provide various disclosures concerning the nature, amount and timing of revenue and cash flows arising from contracts with customers. ASU 2014-09 is effective for annual periods and interim periods within those annual periods beginning after December 15, 2016. Earlier adoption is not permitted. The Company is currently analyzing the impact of this new accounting guidance.

In April 2015, the FASB issued ASU No. 2015-03, "Interest-Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs," which requires debt issuance costs be presented in the balance sheet as a direct

deduction from the carrying amount of the associated debt liability, and amortization of those costs should be reported as interest expense. This ASU is effective for financial statements issued for annual and interim periods beginning after December 15, 2015, and early adoption is permitted for financial statements that have not been previously issued. The new guidance should be applied on a retrospective basis for each period presented in the balance sheet. The Company does not expect the adoption of ASU 2015-03 to have a material impact on its consolidated financial statements.

In June 2015, the FASB issued ASU 2015-10, "Technical Corrections and Improvements." The amendments in ASU 2015-10 will clarify and correct some of the difference that arose between original guidance from FASB, EITF and other sources, and the translation into the new Codification. ASU 2015-10 is effective for annual periods and interim periods within those annual periods beginning after December 15, 2015. The Company does not expect the adoption of ASU 2015-10 to have a material impact on its consolidated financial statements.

Note 2. Investments

The following table summarizes the Company's short-term and long-term investments (in thousands):

	June 30, 20)15			
	Amortized	Gross Cost Unrealized Ga	Gross insUnrealized	Los	Estimated Fair Value
Corporate bonds	\$23,415	\$ —	\$ (6)	\$ 23,409
Certificates of deposit	43,884	29	(6)	43,907
U.S. Treasury securities	205,173	38	(23)	205,188
Commercial paper	3,999				3,999
Preferred stock of U.S. corporation	1,545	2,646			4,191
Total investments	\$278,016	\$ 2,713	\$ (35)	\$ 280,694
	December	31, 2014			
	Amortized	Cost Unrealized Ga	Gross insUnrealized	l Los	Estimated Fair Value
Corporate bonds	\$69,947	\$ —	\$ (56)	\$ 69,891
Certificates of deposit	28,039	1	(62)	27,978
U.S. Treasury securities	48,279		(82)	48,197
Commercial paper	11,242	_	(2)	11,240
Preferred stock of U.S. corporation	1,545				