Calithera Biosciences, Inc. Form 10-O August 10, 2015

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 10-Q

XQUARTERLY 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: 001-36644

CALITHERA BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction

27-2366329 (I.R.S. Employer

of incorporation or organization) Identification No.) 343 Oyster Point Blvd., Suite 200

South San Francisco, CA 94080

(Address of principal executive offices including zip code)

Registrant's telephone number, including area code: (650) 870-1000

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 $\ddot{}$

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 x No "

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.

Large accelerated filer "

Accelerated filer

Non-accelerated filer x (do not check if a smaller reporting company) 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 "No x

As of July 31, 2015, the registrant had 18,113,448 shares of common stock, \$0.0001 par value per share, outstanding.

Quarterly Report on Form 10-Q

For the Quarter Ended June 30, 2015

INDEX

<u>PART I.</u>	FINANCIAL INFORMATION	Page 3
Item 1.	Financial Statements (Unaudited)	3
	Condensed Balance Sheets at June 30, 2015 and December 31, 2014 Condensed Statements of Operations for the Three and Six Months Ended June 30, 2015 and 2014 Condensed Statements of Comprehensive Loss for the Three and Six Months Ended June 30, 2015 and 2014 Condensed Statements of Cash Flows for the Six Months Ended June 30, 2015 and 2014 Notes to Condensed Financial Statements	3 4 5 6 7
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	12
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	17
Item 4.	Controls and Procedures	17
<u>PART II</u>	OTHER INFORMATION	19
Item 1.	Legal Proceedings	19
Item 1A.	Risk Factors	19
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	40
Item 3.	Defaults Upon Senior Securities	40
Item 4.	Mine Safety Disclosures	40
Item 5.	Other Information	40
Item 6.	Exhibits	40
<u>SIGNAT</u>	URES	41
<u>EXHIBI</u>	<u>T INDEX</u>	42

PART I. - FINANCIAL INFORMATION

Item 1. Financial Statements

Calithera Biosciences, Inc.

Condensed Balance Sheets

(Unaudited)

(In thousands, except per share amounts)

	June 30, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	\$11,319	101,969
Short-term investments	66,382	-
Prepaid expenses and other current assets	1,700	1,894
Total current assets	79,401	103,863
Long-term investments	10,486	-
Restricted cash	46	46
Property and equipment, net	816	861
Total assets	\$90,749	\$104,770
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable	\$923	\$693
Accrued liabilities	3,298	3,428
Total current liabilities	4,221	4,121
Deferred rent	200	270
Other non-current liabilities	13	13
Total liabilities	4,434	4,404
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Common stock, \$0.0001 par value, 200,000 shares authorized as of		
June 30, 2015 (unaudited) and December 31, 2014; 17,980 and 17,943 shares		
issued and outstanding as of June 30, 2015 (unaudited) and December 31, 2014,		

respectively	2	2
Additional paid-in capital	153,884	152,218
Accumulated deficit	(67,530)) (51,854)
Accumulated other comprehensive loss	(41) -
Total stockholders' equity	86,315	100,366
Total liabilities and stockholders' equity	\$90,749	\$104,770

Condensed Statements of Operations

(Unaudited)

(In thousands, except per share amounts)

	Three Months Ended June 30,		Six Month June 30,	is Ended
	2015	2014	2015	2014
Operating expenses:				
Research and development	\$5,533	\$4,183	\$11,163	\$7,501
General and administrative	2,341	1,309	4,578	2,141
Total operating expenses	7,874	5,492	15,741	9,642
Loss from operations	(7,874)	(5,492)	(15,741)	(9,642)
Other income, net	56	1	65	2
Net loss	\$(7,818)	\$(5,491)	\$(15,676)	\$(9,640)
Net loss per share attributable to common stockholders,				
basic and diluted	\$(0.44)	\$(24.22)	\$(0.87)	\$(47.14)
Weighted average common shares used to compute net loss per				
share attributable to common stockholders, basic and diluted	17,963	227	17,955	204

Condensed Statements of Comprehensive Loss

(Unaudited)

(In thousands)

	Three Months		Six Month	s Ended
	Ended Ju	ne 30,	June 30,	
	2015	2014	2015	2014
Net loss	\$(7,818)	\$(5,491)	\$(15,676)	\$(9,640)
Other comprehensive loss:				
Net unrealized losses on available-for-sale securities	(35)	-	(41)	-
Total comprehensive loss	\$(7,853)	\$(5,491)	(15,717)	(9,640)

Condensed Statements of Cash Flows

(Unaudited)

(In thousands)

	Six Mor 2015	nths Ended Jui	ne 30,	2014		
Cash Flows From						
Operating Activities						
Net loss	\$	(15,676)	\$	(9,640)
Adjustments to						
reconcile net loss to						
net cash used in						
operating activities:						
Depreciation and						
amortization		228			155	
Amortization of						
premium on						
investments		112			-	
Stock-based						
compensation		1,384			211	
(Gain) loss on disposa	1					
of property and						
equipment		(8)		-	
Changes in operating						
assets and liabilities:						
Prepaid expenses and						
other current assets		194			(1,148)
Other assets		-			(609)
Accounts payable		230			736	
Accrued liabilities		(21)		848	
Deferred rent,						
non-current		(70)		344	
Net cash used in						
operating activities		(13,627)		(9,103)
Cash Flows From						
Investing Activities						
Purchases of						
investments		(81,557)		-	
Proceeds from the sale	e					
or maturity of						
investments		4,536			-	
Purchase of property						
and equipment		(285)		(182)
		-			70	

Change in restricted cash						
Net cash used in investing activities		(77,306)		(112)
Cash Flows From Financing Activities						
Funds received in advance for the Series						
D convertible preferred stock						
financing Proceeds from stock		-			3,000	
option exercises and employee stock plan						
purchases		283			145	
Net cash provided by financing activities		283			3,145	
Net decrease in cash and cash equivalents		(90,650)		(6,070)
Cash and cash			,			
equivalents at beginning of period		101,969			33,820	
Cash and cash equivalents at end of						
period	\$	11,319		\$	27,750	
Supplemental Disclosure of						
Non-Cash Investing						
and Financing						
Information: Non-cash issuance of						
common stock	\$	_		\$	55	
Unpaid amounts						
related to property and equipment purchases	\$	(110)	\$	168	
equipment purchases	Ψ	(110	,	Ψ	100	

Notes to Condensed Financial Statements

1. Organization and Basis of Presentation

Calithera Biosciences, Inc. (the "Company") was incorporated in the State of Delaware on March 9, 2010. The Company is a clinical-stage biopharmaceutical company focused on discovering and developing novel small molecule drugs directed against tumor metabolism and tumor immunology targets for the treatment of cancer. The Company's principal operations are based in South San Francisco, California, and it operates in one segment.

Initial Public Offering

In October 2014, the Company completed an initial public offering ("IPO") of its common stock. In connection with its IPO, the Company issued and sold 8,000,000 shares of its common stock, at a price to the public of \$10.00 per share. As a result of the IPO, the Company received \$71.6 million in net proceeds, after deducting underwriting discounts and commissions of \$5.6 million and offering expenses of \$2.8 million paid by the Company. At the closing of the IPO, 9,592,042 shares of outstanding convertible preferred stock were automatically converted into 9,592,042 shares of common stock. Following the IPO, there were no shares of preferred stock outstanding. In connection with the IPO, the Company amended and restated its Amended and Restated Certificate of Incorporation to change the authorized capital stock to 200,000,000 shares designated as common stock and 10,000,000 shares designated as preferred stock, all with a par value of \$0.0001 per share.

2. Summary of Significant Accounting Policies

Unaudited Interim Financial Information

The interim condensed balance sheet as of June 30, 2015, and the statements of operations, comprehensive loss, and cash flows for the six months ended June 30, 2015 and 2014 are unaudited. The unaudited interim financial statements have been prepared on the same basis as the annual financial statements and reflect, in the opinion of management, all adjustments of a normal and recurring nature that are necessary for the fair presentation of the Company's condensed financial statements included in this report. The financial data and the other information disclosed in these notes to the financial statements related to the six-month periods are also unaudited. The results of operations for the six months ended June 30, 2015 are not necessarily indicative of the results to be expected for the year ending December 31, 2015 or for any other future annual or interim period. The balance sheet as of December 31, 2014 included herein was derived from the audited financial statements as of that date. These financial statements should be read in conjunction with the Company's audited financial statements included in the Company's Form 10-K as filed with the Securities and Exchange Commission ("SEC").

Use of Estimates

The accompanying financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities as of the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. On an ongoing basis, management evaluates its estimates, including those related to clinical trial accrued liabilities, fair value of common stock, income taxes, and stock-based compensation. Management bases its

estimates on historical experience and on various other market-specific and relevant assumptions that management believes to be reasonable under the circumstances. Actual results could differ from those estimates.

Cash and Cash Equivalents

The Company considers all highly liquid investments with original maturities of three months or less at the date of purchase to be cash equivalents.

Investments

All investments have been classified as "available-for-sale" and are carried at estimated fair value as determined based upon quoted market prices or pricing models for similar securities. Management determines the appropriate classification of its investments at the time of purchase and reevaluates such designation as of each balance sheet date. Unrealized gains and losses are excluded from earnings and are reported as a component of comprehensive loss. Realized gains and losses and declines in fair value judged to be other than temporary, if any, on available-for-sale securities are included in other income, net. The cost of securities sold is based on the specific-identification method. Interest on marketable securities is included in other income, net.

7

Concentration of Credit Risk

Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash, cash equivalents, investments and restricted cash. The Company invests in a variety of financial instruments and, by its policy, limits these financial instruments to high credit quality securities issued by the U.S. government, U.S. government-sponsored agencies and highly rated banks and corporations, subject to certain concentration limits. The Company's cash, cash equivalents, investments and restricted cash are held by financial institutions in the United States that management believes are of high credit quality. Amounts on deposit may at times exceed federally insured limits.

Accrued Research and Development Costs

The Company records accrued liabilities for estimated costs of research and development activities conducted by third-party service providers, which include the conduct of preclinical and clinical studies, and contract manufacturing activities. The Company records the estimated costs of research and development activities based upon the estimated amount of services provided but not yet invoiced, and include these costs in accrued liabilities in the balance sheets and within research and development expense in the statements of operations. These costs are a significant component of the Company's research and development expenses. The Company accrues for these costs based on factors such as estimates of the work completed and in accordance with agreements established with its third-party service providers under the service agreements. The Company makes significant judgments and estimates in determining the accrued liabilities balance in each reporting period. As actual costs become known, the Company adjusts its accrued liabilities. The Company has not experienced any material differences between accrued costs and actual costs incurred. However, the status and timing of actual services performed, number of patients enrolled, and the rate of patient enrollments may vary from the Company's estimates, resulting in adjustments to expense in future periods. Changes in these estimates that result in material changes to the Company's accruals could materially affect the Company's results of operations.

Net Loss per Share Attributable to Common Stockholders

Basic net loss per share attributable to common stockholders is calculated by dividing the net loss attributable to common stockholders by the weighted average number of shares of common stock outstanding during the period without consideration of common stock equivalents. Since the Company was in a loss position for all periods presented, basic net loss per share attributable to common stockholders is the same as diluted net loss per share attributable to common stockholders of all potential common shares outstanding would have been anti-dilutive.

Recent Accounting Pronouncements

In August 2014, the FASB issued ASU No. 2014-15, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern. ASU 2014-15 requires management to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related footnote disclosures. In doing so, companies will have reduced diversity in the timing and content of footnote disclosures than under today's guidance. ASU 2014-15 is effective for the annual period ending after December 15, 2016, and for annual and interim periods thereafter. Management is currently assessing the impact the adoption of ASU 2014-15 will have on the financial statements.

3. Fair Value Measurements

Fair value accounting is applied for all financial assets and liabilities that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually). Financial instruments include cash and cash equivalents, short-term investments, accounts payable and accrued liabilities that approximate fair value due to their relatively short maturities.

Assets and liabilities recorded at fair value on a recurring basis in the balance sheets are categorized based upon the level of judgment associated with the inputs used to measure their fair values. Fair value is defined as the exchange price that would be received for an asset or an exit price that would be paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The authoritative guidance on fair value measurements establishes a three tier fair value hierarchy for disclosure of fair value measurements as follows:

Level 1—Inputs are unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date;

Level 2—Inputs are observable, unadjusted quoted prices in active markets for similar assets or liabilities, unadjusted quoted prices for identical or similar assets or liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the related assets or liabilities; and

Level 3—Unobservable inputs that are significant to the measurement of the fair value of the assets or liabilities that are supported by little or no market data.

A financial instrument's categorization within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement. Where quoted prices are available in an active market, securities are classified as Level 1. The Company classifies money market funds as Level 1. When quoted market prices are not available for the specific security, then the Company estimates fair value by using quoted prices for identical or similar instruments in markets that are not active and model-based valuation techniques for which all significant inputs are observable in the market or can be corroborated by observable market data for substantially the full term of the assets. Where applicable, these models project future cash flows and discount the future amounts to a present value using market-based observable inputs obtained from various third party data providers, including but not limited to, benchmark yields, interest rate curves, reported trades, broker/dealer quotes and market reference data. The Company classifies its corporate notes and U.S. government agency securities as Level 2. Level 2 inputs for the valuations are limited to quoted prices for similar assets or liabilities in active markets and inputs other than quoted prices that are observable for the asset or liability. There were no transfers between Level 1 and Level 2 during the periods presented.

The following table sets forth the fair value of our financial assets and liabilities, allocated into Level 1, Level 2 and Level 3, that was measured on a recurring basis (in thousands):

	June 30, 2015				
	Level 1	Level 2	Level 3	Total	
Financial Assets:					
Money market funds	\$7,041	\$-	\$ -	\$7,041	
Corporate notes and commercial paper	-	44,124	-	44,124	
U.S. government agency securities	-	37,068	-	37,068	
Total financial assets	\$7,041	\$81,192	\$-	\$88,233	
	December	31, 2014			
	Level 1	Level 2	Level 3	Total	
Financial Assets:					
Money market funds	\$102,015	\$-	\$ -	\$102,015	
Total financial assets	\$102,015	\$ -	\$ -	\$102,015	

As of June 30, 2015 and December 31, 2014, the Company had \$46,000 in money market funds that are included in restricted cash on the balance sheets.

4. Financial Instruments

Cash equivalents and short-term and long-term investments, all of which are classified as available-for-sale securities, consisted of the following (in thousands):

	June 30, 2	June 30, 2015					December 31, 2014						
	Cost	Un Ga	nrealize in	edUr (L	nreali oss)	zed	Estimated Fair Value	Cost	Ur Ga	nrealize ain	e d Uni (Lo	realiz (ss)	Estimated Fair Value
Money market funds	\$7,041	\$	-	\$	-		7,041	\$102,015	\$	-	\$	-	102,015
Corporate notes and commercial paper	44,163		-		(39)	44,124	-		-		-	-
U.S. government agency securities	37,070		2		(4)	37,068	-		-		-	-
	\$88,274	\$	2	\$	(43)	\$88,233	\$102,015	\$	-	\$	-	\$102,015
Classified as:													

Cash equivalents	\$11,365	\$102,015
Short-term investments	66,382	-
Long-term investments	10,486	-
Total cash equivalents and investments	\$88,233	\$102,015

At June 30, 2015, the remaining contractual maturities of available-for-sale securities were less than two years. There have been no significant realized gains or losses on available-for-sale securities for the periods presented.

9

5. Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	June	
	30,	December
	2015	31, 2014
Accrued bonus and payroll expenses	\$1,208	\$ 1,476
Accrued professional and consulting services	89	