Seres Therapeutics, Inc. Form 10-Q August 11, 2016

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, 2016

OR

o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 For the transition period from to

For the transition period from

Commission file number: 001-37465

Seres Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of 27-4326290 (I.R.S. Employer

incorporation or organization)

Identification Number)

200 Sidney Street - 4th Floor

Cambridge, MA 02139 (Address of principal executive offices) (Zip Code)

(617) 945-9626

(Registrant's telephone number, including area code)

N/A

(Former name, former address and former fiscal year, if changed since last report)

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 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 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.

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 o No x

As of August 5, 2016 there were 40,274,503 shares of Common Stock, \$0.001 par value per share, outstanding.

Seres Therapeutics, Inc.

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<u>PART I – FINANCIAL INFORMATION</u>

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FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. All statements other than statements of historical facts contained in this Quarterly Report, including statements regarding our future results of operations and financial position, business strategy, prospective products, product approvals, research and development costs, timing and likelihood of success, plans and objectives of management for future operations and future results of anticipated products, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" or "continue" of these terms or other similar expressions. The forward-looking statements in this Quarterly Report are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this Quarterly Report and are subject to a number of important factors that could cause actual results to differ materially from those in the forward-looking statements, including the factors described under the sections in this Quarterly Report titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" as well as the following:

- •our status as a clinical-stage company and our expectation to incur losses in the future;
- •our future capital needs and our need to raise additional funds;
- •our ability to build a pipeline of product candidates and develop and commercialize drugs;
- •our unproven approach to therapeutic intervention;
- our ability to enroll patients in clinical trials, timely and successfully complete those trials and receive necessary regulatory approvals;
- our ability to establish our own manufacturing facilities and to receive or manufacture sufficient quantities of our product candidates;
- •our ability to protect and enforce our intellectual property rights;
- ·federal, state, and foreign regulatory requirements, including FDA regulation of our product candidates;
- ·our ability to obtain and retain key executives and attract and retain qualified personnel; and
- •our ability to successfully manage our growth.

Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties.

You should read this Quarterly Report and the documents that we reference in this Quarterly Report completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

Part I – Financial Information

SERES THERAPEUTICS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(unaudited, in thousands, except share and per share data)

		December
	June 30,	31,
	2016	2015
Assets		
Current assets:		
Cash and cash equivalents	\$59,824	\$73,933
Investments	152,032	131,149
Prepaid expenses and other current assets	5,247	2,528
Total current assets	217,103	207,610
Property and equipment, net	26,985	7,751
Long-term investments	60,589	-
Restricted cash	1,540	1,539
Total assets	\$306,217	\$216,900
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$4,454	\$5,397
Accrued expenses and other current liabilities	10,865	5,523
Deferred revenue - related party	12,012	
Total current liabilities	27,331	10,920
Lease incentive obligation	9,119	586
Deferred revenue, net of current portion - related party	102,371	
Total liabilities	138,821	11,506
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value;		

10,000,000 shares authorized at June 30, 2016 and December 31, 2015; no shares

issued and outstanding at June 30, 2016 and December 31, 2015 — Common stock, \$0.001 par value; 200,000,000 shares authorized at June 30, 2016

and December 31, 2015; 39,859,155 and 39,082,017 shares issued and outstanding

at June 30, 2016 and December 31, 2015, respectively	40	39
Additional paid-in capital	297,502	287,937
Accumulated other comprehensive income	83	30
Accumulated deficit	(130,229)	(82,612)
Total stockholders' equity	167,396	205,394
Total liabilities and stockholders' equity	\$306,217	\$216,900

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

SERES THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(unaudited, in thousands, except share and per share data)

	Three Mor 30,	nths Ended June	Six Months Ended June 30,	
	2016	2015	2016	2015
Revenue:				
Collaboration revenue - related party	\$3,004	\$—	\$5,714	\$—
Total revenue	3,004		5,714	
Operating expenses:				
Research and development expenses	22,174	8,784	37,590	14,345
General and administrative expenses	8,970	3,556	16,180	6,162
Total operating expenses	31,144	12,340	53,770	20,507
Loss from operations	(28,140) (12,340)) (48,056) (20,507)
Other income (expense):				
Interest income	495	151	763	199
Interest expense	(268) (146)) (324) (211)
Revaluation of preferred stock warrant liability	—	(220)) —	(7)
Total other income (expense), net	227	(215)) 439	(19)
Net loss	\$(27,913) \$(12,555)	\$(47,617) \$(20,526)
Net loss per share attributable to common stockholders, basic	;			
and diluted	\$(0.70) \$(1.45)) \$(1.21) \$(2.64)
Weighted average common shares outstanding, basic and				
diluted	39,600,34	44 8,640,218	39,393,23	38 7,777,679
Other comprehensive income:				
Unrealized gain/(loss) on investments, net of tax of \$0	\$(25) \$(8	\$53	\$23
Total other comprehensive income	(25) (8)) 53	23
Comprehensive loss	\$(27,938) \$(12,563)	\$(47,564)) \$(20,503)

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

SERES THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited, in thousands)

	Six Month	s Ended
	June 30, 2016	2015
Cash flows from operating activities:		
Net loss	\$(47,617) \$(20,526)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	8,621	4,400
Depreciation and amortization expense	1,260	212
Gain from revaluation of preferred stock warrant liability	—	7
Non-cash interest expense	1	141
Accretion of discount on investments	(222) -
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(2,719) (2,230)
Deferred revenue	114,383	
Accounts payable	395	(141)
Accrued expenses and other current liabilities	1,991	141
Net cash provided by (used in) operating activities	76,093	(17,996)
Cash flows from investing activities:		
Purchases of property and equipment	(9,946) (1,649)
Purchases of investments	(206,534) (64,250)
Sales and maturities of investments	125,335	8,725
Changes in restricted cash	(1) —
Net cash used in investing activities	(91,146) (57,174)
Cash flows from financing activities:		
Proceeds from issuance of convertible preferred stock, net of issuance costs	_	(24)
Proceeds from exercise of stock options and common stock warrants	944	95
Repayment of notes payable	_	(600)
Payments of initial public offering costs		(2,148)
Net cash provided by (used in) financing activities	944	(2,677)
Net decrease in cash and cash equivalents	(14,109) (77,847)
Cash and cash equivalents at beginning of period	73,933	114,185
Cash and cash equivalents at end of period	\$59,824	\$36,338
Supplemental disclosure of cash flow information:		
Cash paid for interest	\$108	\$75
Supplemental disclosure of non-cash investing and financing activities:		
Conversion of convertible preferred stock into common stock upon listing of the Company's		
common stock on the NASDAQ	\$—	\$136,053
Deferred offering costs included in accounts payable and accrued expenses	\$—	\$780
Property and equipment purchases included in accounts payable and accrued expenses	\$4,899	\$718

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

SERES THERAPEUTICS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Amounts in thousands, except share and per share data)

(Unaudited)

1. Nature of the Business and Basis of Presentation

Seres Therapeutics, Inc. (the "Company") was incorporated under the laws of the State of Delaware in October 2010 under the name Newco LS21, Inc. In October 2011, the Company changed its name to Seres Health, Inc., and in May 2015, the company changed its name to Seres Therapeutics, Inc. The Company is a microbiome therapeutics platform company developing a novel class of biological drugs, which are designed to restore health by repairing the function of a dysbiotic microbiome. The Company's lead product candidate, SER-109, is intended to prevent further recurrences of Clostridium difficile infection ("CDI"), a debilitating infection of the colon, and, if approved by the FDA, could be a first-in-field drug. Using its microbiome therapeutics platform, the Company is developing additional product candidates to treat diseases where the microbiome is implicated, including SER-262, a synthetic microbiome therapeutic, to prevent an initial recurrence of primary CDI, SER-287 to treat inflammatory bowel disease, including ulcerative colitis, SER-301, a synthetic ulcerative colitis product candidate, and SER-155, a synthetic product candidate, to prevent mortality following allogeneic hematopoietic stem cell transplantation (allo-HSCT) due to infections and graft-versus-host disease. The Company is also using its microbiome therapeutics platform to conduct research on metabolic diseases, such as non-alcoholic steatohepatitis (NASH); inflammatory diseases, such as Crohn's disease; rare liver disorders such as primary sclerosing cholangitis (PSC); and immuno-oncology treatments using checkpoint inhibitors.

The Company is subject to risks common to companies in the biotechnology industry including, but not limited to, new technological innovations, protection of proprietary technology, dependence on key personnel, compliance with government regulations and the need to obtain additional financing. Product candidates currently under development will require significant additional research and development efforts, including extensive pre-clinical and clinical testing and regulatory approval, prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel infrastructure and extensive compliance-reporting capabilities.

The Company's product candidates are in development. There can be no assurance that the Company's research and development will be successfully completed, that adequate protection for the Company's intellectual property will be obtained, that any products developed will obtain necessary government regulatory approval or that any approved products will be commercially viable. Even if the Company's product development efforts are successful, it is uncertain when, if ever, the Company will generate significant revenue from product sales. The Company operates in an environment of rapid change in technology and substantial competition from pharmaceutical and biotechnology companies. In addition, the Company is dependent upon the services of its employees and consultants.

Unaudited Interim Financial Information

The accompanying unaudited consolidated financial statements as of June 30, 2016 and for the three and six months ended June 30, 2016 and 2015 have been prepared by the Company, pursuant to the rules and regulations of the Securities and Exchange Commission (the "SEC") for interim financial statements. Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") have been condensed or omitted pursuant to such rules and

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regulations. However, the Company believes that the disclosures are adequate to make the information presented not misleading. These consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements and the notes thereto for the year ended December 31, 2015 included in the Company's annual report on Form 10-K for the fiscal year ended December 31, 2015, which was filed with the U.S. Securities and Exchange Commission on March 14, 2016.

The unaudited interim financial statements have been prepared on the same basis as the audited consolidated financial statements. The condensed consolidated balance sheet at December 31, 2015 was derived from audited annual financial statements, but does not contain all of the footnote disclosures from the annual financial statements. In the opinion of management, the accompanying unaudited interim consolidated financial statements contain all adjustments which are necessary for a fair statement of the Company's financial position as of June 30, 2016 and consolidated results of operations for the three and six months ended June 30, 2016 and its cash flows for the six months ended June 30, 2016 and 2015. Such adjustments are of a normal and recurring nature. The results of operations for the three and six months ended June 30, 2016 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2016.

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2.Summary of Significant Accounting Policies

The significant accounting policies and estimates used in preparation of the condensed consolidated financial statements are described in the Company's audited financial statements as of and for the year ended December 31, 2015, and the notes thereto, which are included in the Company's Annual Report on Form 10-K. During the three and six months ended June 30, 2016, the Company recorded revenue in connection with its collaboration agreement. See Note 9, "Collaboration Revenue," for additional information.

Use of Estimates

The preparation of the consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, equity, revenue and expenses, and related disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting periods. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, revenue recognition, the accrual of research and development expenses and the valuation of stock-based awards. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Actual results could differ from the Company's estimates.

Fair Value Measurements

Certain assets and liabilities are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- ·Level 1—Quoted prices in active markets for identical assets or liabilities.
- ·Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- ·Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The Company's cash equivalents and investments are carried at fair value, determined according to the fair value hierarchy described above. The Company's investments in certificates of deposit are carried at amortized cost, which approximates fair value. Certain cash equivalents or investments that are measured at fair value using the net asset value per share (or its equivalent) practical expedient have not been classified in the fair value hierarchy. The carrying values of the Company's accounts payable and accrued expenses approximate their fair value due to the short-term nature of these liabilities.

The following table presents information about the Company's assets as of June 30, 2016 and December 31, 2015 that are measured at fair value on a recurring basis and indicate the level of the fair value hierarchy utilized to determine such fair values (note there were no liabilities measured at fair value on a recurring basis in either of the periods presented):

Fair Value Measurements as of June 30, 2016 Using:

	Level 1 Level 2	Level 3	Not Subject to Leveling	Total
Assets:				
Cash Equivalents	\$—\$9,971	\$ —	\$ 7,359	\$17,330
Repurchase Agreements	— 5,500		_	5,500
Investments:				
Commercial Paper	\$—\$45,471	\$ —	\$ —	\$45,471
Certificates of Deposit	— 13,271		_	13,271
Corporate Bonds	— 84,728		_	84,728
Government Securities	— 51,101		—	51,101
Treasury Bonds	— 18,050		_	18,050
	\$-\$228,092	\$ —	\$ 7,359	\$235,451

⁽¹⁾ Certain cash equivalents and investments that are valued using the net asset value per share (or its equivalent) practical expedient have not been classified in the fair value hierarchy.

51, 2015 Using:						
					Not	
					Subject	
					to	
	Le	vel	Le	vel	Leveling	
	1	Level 2	3		(1)	Total
Assets:						
Cash Equivalents	\$-	-\$11,952	\$		\$11,173	\$23,125
Repurchase Agreements	_	- 20,000				20,000
Investments:						
Commercial Paper	\$-	-\$64,820	\$		\$ <i>—</i>	\$64,820
Corporate Bonds	_	- 46,490				46,490
Government Securities	_	- 15,819				15,819
Treasury Bonds	_	- 4,020				4,020
	\$-	-\$163,101	\$		\$11,173	\$174,274

Fair Value Measurements as of December 31, 2015 Using:

⁽¹⁾ Certain cash equivalents and investments that are valued using the net asset value per share (or its equivalent) practical expedient have not been classified in the fair value hierarchy.

As of June 30, 2016, the Company's cash equivalents, which were invested in money market funds, corporate bonds, and repurchase agreements with original maturities of less than 90 days from the date of purchase, were valued based on Level 2 inputs. Repurchase agreements are agreements with banks to repurchase notes that are collateralized by U.S. government securities.

As of December 31, 2015, the Company's cash equivalents consisted of money market funds, corporate bonds, commercial paper, government securities and repurchase agreements with original maturities of less than 90