CATABASIS PHARMACEUTICALS INC
Form 10-Q
August 10, 2017
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 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, 2017

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: 001-37467

Catabasis Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**26-3687168**
(State or Other Jurisdiction of Incorporation or Organization)	(IRS Employer Identification No.)
One Kendall Square **Bldg. 1400E, Suite B14202** **Cambridge, Massachusetts**	**02139**
(Address of Principal Executive Offices)	(Zip Code)

(617) 349-1971

(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** 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 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, 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 (Do not check if a smaller reporting company)	Smaller reporting company	o
		Emerging growth company	x

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 accounting standards provided pursuant to Section 13(a) of the Exchange Act. x

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 31, 2017, there were 22,481,735 shares of the registrant s Common Stock, par value $0.001 per share, outstanding.

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CAUTIONARY NOTE CONCERNING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this Quarterly Report on Form 10-Q, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans and objectives of management and expected market growth are forward-looking statements. The words anticipate, believe, continue, could, estimate, expect, intend, may, plan, potential, should, target, would and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

These forward-looking statements include, among other things, statements about:

- our plans to identify, develop and commercialize novel therapeutics based on our SMART Linkers℠ drug discovery platform;
- our plans to continue to evaluate data from the open label extension of our MoveDMD® clinical trial of edasalonexent for the treatment of Duchenne muscular dystrophy and to announce a Phase 3 clinical trial plan for edasalonexent in Duchenne muscular dystrophy;
- ongoing and planned clinical trials for edasalonexent and other product candidates, whether conducted by us or by any future collaborators, including the timing of initiation of these trials and of the anticipated results;
- our plans to enter into collaborations for the development and commercialization of product candidates;
- the potential benefits of any future collaboration;
- our ability to receive research and development funding and achieve anticipated milestones under any future collaborations;
- the timing of and our ability to obtain and maintain regulatory approvals for our product candidates;
- the rate and degree of market acceptance and clinical utility of any products for which we receive marketing approval;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our intellectual property position and strategy;
- our ability to identify additional products or product candidates with significant commercial potential;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- developments relating to our competitors and our industry; and

- the impact of government laws and regulations.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this Quarterly Report on Form 10-Q, particularly in the Risk Factors section, that could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, collaborations, joint ventures or investments that we may make or enter into.

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PART I FINANCIAL INFORMATION

Item 1. Financial Statements

Catabasis Pharmaceuticals, Inc.

Condensed Consolidated Balance Sheets

(In thousands, except share and per share data)

(Unaudited)

	June, 30 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$ 29,369	$ 23,596
Available-for-sale securities		14,931
Prepaid expenses and other current assets	892	1,001
Total current assets	30,261	39,528
Property and equipment, net	442	568
Restricted cash	113	113
Total assets	$ 30,816	$ 40,209
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	$ 2,055	$ 1,405
Accrued expenses	2,796	3,677
Current portion of notes payable, net of discount	3,278	3,243
Total current liabilities	8,129	8,325
Deferred rent, net of current portion		53
Notes payable, net of current portion and discount	831	2,479
Other liability	306	266
Total liabilities	9,266	11,123
Commitments (Note 7)		
Stockholders equity:		
Preferred stock, $0.001 par value per share, 5,000,000 shares authorized and no shares issued and outstanding		
Common stock, $0.001 par value per share, 150,000,000 shares authorized; 22,481,735 and 18,817,572 shares issued and outstanding at June 30, 2017 and December 31, 2016, respectively	22	19
Additional paid-in capital	180,448	173,141
Accumulated other comprehensive loss		(4)
Accumulated deficit	(158,920)	(144,070)
Total stockholders equity	21,550	29,086
Total liabilities and stockholders equity	$ 30,816	$ 40,209

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

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Catabasis Pharmaceuticals, Inc.

Condensed Consolidated Statements of Operations

(In thousands, except share and per share data)

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	**2016**	**2017**	**2016**
Operating expenses:				
Research and development	$ 4,519	$ 6,818	$ 9,917	$ 13,254
General and administrative	2,400	2,578	4,763	5,348
Total operating expenses	6,919	9,396	14,680	18,602
Loss from operations	(6,919)	(9,396)	(14,680)	(18,602)
Other (expense) income:				
Interest expense	(127)	(220)	(276)	(463)
Interest and investment income	44	80	83	133
Other income, net	28	91	23	69
Total other expense, net	(55)	(49)	(170)	(261)
Net loss	$ (6,974)	$ (9,445)	$ (14,850)	$ (18,863)
Net loss per share - basic and diluted	$ (0.32)	$ (0.61)	$ (0.73)	$ (1.23)
Weighted-average common shares outstanding used in net loss per share - basic and diluted	21,796,194	15,373,964	20,452,200	15,354,740

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

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Catabasis Pharmaceuticals, Inc.

Condensed Consolidated Statements of Comprehensive Loss

(In thousands)

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Net loss	$ (6,974)	$ (9,445)	$ (14,850)	$ (18,863)
Other comprehensive (loss) income:				
Unrealized (loss) gains on available-for-sale securities		(6)	4	8
Total other comprehensive (loss) income:		(6)	4	8
Comprehensive loss	$ (6,974)	$ (9,451)	$ (14,846)	$ (18,855)

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

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Catabasis Pharmaceuticals, Inc.

Condensed Consolidated Statements of Cash Flows

(In thousands)

(Unaudited)

	Six Months Ended June 30,	
	2017	**2016**
Operating activities		
Net loss	$ (14,850)	$ (18,863)
Reconciliation of net loss to net cash used in operating activities:		
Depreciation and amortization	165	195
Stock-based compensation expense	986	1,065
Accretion of discount/premium on investment securities	25	77
Non-cash interest expense	94	153
Gain on sale of fixed assets	(30)	(25)
Changes in assets and liabilities:		
Prepaid expenses and other current assets	109	(140)
Accounts payable	650	210
Accrued expenses	(952)	(622)
Deferred rent	18	(26)
Net cash used in operating activities	(13,785)	(17,976)
Investing activities		
Purchases of available-for-sale securities		(32,111)
Sales and maturities of available-for-sale securities	14,910	13,503
Purchases of property and equipment	(39)	(388)
Sale of property and equipment	30	25
Net cash provided by (used in) investing activities	14,901	(18,971)
Financing activities		
Proceeds from at-the-market offering, net of issuance costs	6,301	
Proceeds from exercise of common stock options and warrants	23	111
Payments on borrowing	(1,667)	(1,666)
Net cash provided by (used in) financing activities	4,657	(1,555)
Net increase (decrease) in cash and cash equivalents	5,773	(38,502)
Cash and cash equivalents, beginning of period	23,596	62,780
Cash and cash equivalents, end of period	$ 29,369	$ 24,278
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 195	$ 463
Non-cash financing activities		
Fixed asset purchases included in accounts payable	$	$ 21

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

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Catabasis Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements

(Unaudited)

1. Organization and Operations

The Company

Catabasis Pharmaceuticals, Inc. (the Company) is a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of novel therapeutics based on the Company s proprietary Safely Metabolized And Rationally Targeted, or SMART, linker drug discovery platform. The Company s SMART LinkerSM technology platform enables the Company to engineer product candidates that can simultaneously modulate multiple targets in a disease. The Company s proprietary product candidates impact pathways that are central to diseases where efficacy may be optimized by a multiple target approach. The Company s primary focus is on treatments for rare diseases. The Company has applied its SMART Linker drug discovery platform to build an internal pipeline of product candidates for rare diseases and plans to pursue partnerships to develop additional product candidates. The Company was incorporated in the State of Delaware on June 26, 2008.

Liquidity

In August 2016, the Company entered into a sales agreement with Cowen and Company LLC (Cowen) pursuant to which the Company may issue and sell shares of its Common Stock for an aggregate maximum offering amount of $10.0 million under an at-the-market (ATM) offering program. Cowen is not required to sell any specific amount, but acts as the Company s sales agent using commercially reasonable efforts consistent with its normal trading and sales practices. Shares sold pursuant to the sales agreement have been sold pursuant to a shelf registration statement, which became effective on July 19, 2016. The Company pays Cowen 3% of the gross proceeds from any Common Stock sold through the sales agreement.

During the six months ended June 30, 2017, the Company sold an aggregate of 3,641,284 shares of Common Stock pursuant to the ATM program, at an average price of $1.80 per share, for gross proceeds of $6.5 million, resulting in net proceeds of $6.3 million after deducting sales commissions and offering expenses. On March 16, 2017, the Company reduced the aggregate maximum amount of the offering under the ATM program, and as of June 30, 2017, $0.6 million of Common Stock remained available for sale under the ATM program.

As of June 30, 2017, the Company had an accumulated deficit of $158.9 million. The Company has been primarily involved with research and development activities and has incurred operating losses and negative cash flows from operations since its inception. The Company is subject to a number of risks similar to other life science companies, including, but not limited to, successful discovery and development of its drug

candidates, raising additional capital, development by its competitors of new technological innovations, protection of proprietary technology and regulatory approval and market acceptance of the Company s products. The Company anticipates that it will continue to incur significant operating losses for the next several years as it continues to develop its product candidates. The Company adopted Accounting Standards Update (ASU) No. 2014-15, *Presentation of Financial Statements Going Concern: Disclosure of Uncertainties about an Entity s Ability to Continue as a Going Concern* (ASU 2014-15) in connection with the issuance of its consolidated financial statements for the year ended December 31, 2016. The Company s current operating plan provides for cash to fund operations through August, 2018. Changes in the estimates and assumptions underlying the Company s operating plan could impact the Company s ability to continue as a going concern for a period of one year from the date of issuance of these financial statements, but the Company believes that the impact of these changes would be mitigated by management s ability to adjust the Company s operating plan, including the ability to reduce or delay expenditures including expenditures for employee incentive compensation and direct program expenses.

The Company will require substantial additional capital to fund operations. The Company has not generated any product revenues and has financed its operations primarily through public offerings and private placements of its equity securities. There can be no assurance that the Company will be able to obtain additional debt or equity financing or generate product revenue or revenues from collaborative partners, on terms acceptable to the Company, on a timely basis or at all. The failure of the Company to obtain sufficient

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funds on acceptable terms when needed could have a material adverse effect on the Company s business, results of operations, and financial condition.

2. Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

The accompanying financial statements and the related disclosures are unaudited and have been prepared in accordance with United States generally accepted accounting principles (U.S. GAAP). Additionally, certain information and footnote disclosures normally included in the Company s annual financial statements have been condensed or omitted from this report. Accordingly, these condensed financial statements should be read in conjunction with the financial statements as of and for the year ended December 31, 2016 and notes thereto, included in the Company s annual report on Form 10-K filed with the Securities and Exchange Commission on March 16, 2017 (the 2016 Annual Report on Form 10-K).

The unaudited interim condensed consolidated financial statements have been prepared on the same basis as the audited financial statements. In the opinion of the Company s management, the accompanying unaudited interim condensed consolidated financial statements contain all adjustments which are necessary to fairly present the Company s financial position as of June 30, 2017, the results of its operations for the three and six months ended June 30, 2017 and 2016 and its cash flows for the six months ended June 30, 2017 and 2016. Such adjustments are of a normal and recurring nature. The results for the three and six months ended June 30, 2017 are not necessarily indicative of the results for the year ending December 31, 2017, or for any future period.

The accompanying condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary, Catabasis Securities Corporation. All intercompany balances and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of the Company s condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the condensed consolidated financial statements and accompanying notes. Actual results could differ from such estimates.

The Company utilizes certain estimates to record expenses relating to research and development contracts. These contract estimates, which are primarily related to the length of service of each contract, are determined by the Company based on input from internal project management, as well as from third-party service providers.

Stock-Based Compensation

The Company accounts for its stock-based compensation awards in accordance with Accounting Standards Codification (ASC) Topic 718, *Compensation Stock Compensation (* ASC 718). ASC 718 requires all share-based payments to employees, including grants of employee stock options, to be recognized in the statements of operations based on their grant date fair values. For stock options granted to employees and to members of the board of directors for their services on the board of directors, the Company estimates the grant date fair value of each option award using the Black-Scholes option-pricing model. The use of the Black-Scholes option-pricing model requires management to make assumptions with respect to the expected term of the option, the expected volatility of the Common Stock consistent with the expected life of the option, risk-free interest rates and expected dividend yields of the Common Stock.

For awards subject to service-based vesting conditions, the Company recognizes stock-based compensation expense equal to the grant date fair value of stock options on a straight-line basis over the requisite service period.

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Share-based payments issued to non-employees are recorded at their fair values, and are periodically revalued as the equity instruments vest and are recognized as expense over the related service period in accordance with the provisions of ASC Topic 505, *Equity*. For equity instruments granted to non-employees, the Company recognizes stock-based compensation expense on a straight-line basis.

During the three and six months ended June 30, 2017 and 2016, the Company recorded stock-based compensation expense for employee and non-employee stock options, which was allocated as follows in the condensed consolidated statements of operations (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Research and development	$ 197	$ 179	$ 397	$ 351
General and administrative	284	338	589	714
Total	$ 481	$ 517	$ 986	$ 1,065

Net Loss Per Share

Basic net loss per share is calculated by dividing net loss by the weighted average shares outstanding during the period, without consideration for Common Stock equivalents. Diluted net loss per share is calculated by adjusting weighted average shares outstanding for the dilutive effect of Common Stock equivalents outstanding for the period, determined using the treasury-stock method. For purposes of the Company s dilutive net loss per share calculation, stock options and warrants to purchase Common Stock were considered to be Common Stock equivalents but were excluded from the calculation of diluted net loss per share, as their effect would be anti-dilutive; therefore, basic and diluted net loss per share were the same for all periods presented.

The following Common Stock equivalents were excluded from the calculation of diluted net loss per share for the periods indicated because including them would have had an anti-dilutive effect:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Sto				